64B16-27.1001 Practice of Pharmacy.

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:

(a) Supervise and be responsible for the controlled substance inventory.

(b) Receive verbal prescriptions from a practitioner.

(c) Interpret and identify prescription contents.

(d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.

(e) Engage in professional communication with practitioners, nurses or other health professionals.

(f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:

(a) Interpret and identify all incoming orders.

(b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.

(c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.

(d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 11-18-07, Amended 1-1-10.

Effective: July 1, 2012

West's Florida Statutes Annotated Currentness
Title XXXII. Regulation of Professions and Occupations (Chapters 454-493) (Refs & Annos)
Chapter 465. Pharmacy (Refs & Annos)
465.003. Definitions

As used in this chapter, the term:

(1) "Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.

(2) "Board" means the Board of Pharmacy.

(3) "Consultant pharmacist" means a pharmacist licensed by the department and certified as a consultant pharmacist pursuant to s. 465.0125.

(4) "Data communication device" means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.

(5) "Department" means the Department of Health.

(6) "Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

(7) "Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy.

(8) "Medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.

(9) "Patent or proprietary preparation" means a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act.

(10) "Pharmacist" means any person licensed pursuant to this chapter to practice the profession of pharmacy.

(11)(a) "Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1. The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2. The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3. The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4. The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5. The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

(b) The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(12) "Pharmacy intern" means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.

(13) "Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189.

(14) "Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

(15) "Nuclear pharmacist" means a pharmacist licensed by the department and certified as a nuclear pharmacist pursuant to s. 465.0126.

(16) "Centralized prescription filling" means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17) "Automated pharmacy system" means a mechanical system that delivers prescription drugs received from a

Florida licensed pharmacy and maintains related transaction information.

CREDIT(S)

Laws 1979, c. 79-226, § 1; Laws 1981, c. 81-259, § 322; Laws 1981, c. 81-302, § 14; Laws 1982, c. 82-179, § 1; Laws 1983, c. 83-101, § 1; Laws 1983, c. 83-216, § 36; Laws 1983, c. 83-329, § 29; Laws 1985, c. 85-35, § 1; Laws 1986, c. 86-256, § 2; Laws 1988, c. 88-172, § 1; Laws 1989, c. 89-77, § 1. Amended by Laws 1994, c. 94-218, § 123, eff. May 20, 1994; Laws 1997, c. 97-103, § 239, eff. July 1, 1997; Laws 1997, c. 97-264, § 87, eff. July 1, 1997; Laws 1999, c. 99-397, § 118, eff. July 1, 1999; Laws 2002, c. 2002-182, § 1, eff. July 1, 2002; Laws 2004, c. 2004-25, § 1, eff. May 11, 2004; Laws 2004, c. 2004-387, § 1, eff. July 1, 2004; Laws 2007, c. 2007-152, § 2, eff. July 1, 2007; Laws 2012, c. 2012-60, § 2, eff. July 1, 2012.

HISTORICAL AND STATUTORY NOTES

Prior Provisions for Legislative Review of Regulatory Statutes:

Laws 1982, c. 82-179, § 2, provided that provisions of that law amending Florida Statutes Chapter 465 were to be repealed on October 1, 1986, and to be reviewed by the legislature pursuant to s. 11.61, the Regulatory Sunset Act. Laws 1983, c. 83-265, § 3, repealed Laws 1982, c. 82-179, § 2.

CROSS REFERENCES

Complimentary drugs, distribution, see § 499.028.
Medicinal drugs, making, altering and forging prescriptions, see F.S.A. § 831.30.
Prescription drugs,
Pedigree papers, see § 499.01212.
Storage and handling, recordkeeping, see § 499.0121.

LIBRARY REFERENCES

Health 198.
Westlaw Topic No. 198H.

RESEARCH REFERENCES

ALR Library

79 ALR 5th 409, Civil Liability of Pharmacists or Druggists for Failure to Warn of Potential Drug Interactions in Use of Prescription Drug.

44 ALR 5th 393, Liability of Pharmacist Who Accurately Fills Prescription for Harm Resulting to User.

Encyclopedias

Physician's Failure to Protect Third Party from Harm by Nonpsychiatric Patient, 43 Am. Jur. Proof of Facts 2d 657.

Injuries from Drugs, 7 Am. Jur. Proof of Facts 3d 1.

Failure to Warn as Proximate Cause of Injury, 8 Am. Jur. Proof of Facts 3d 547.

Proof of Physical Disability of Driver of Motor Vehicle, 53 Am. Jur. Proof of Facts 3d 67.

Medical Necessity Defense, Fla. Jur. 2d Criminal Law Substantive Principles and Offenses § 1371.

Drug; Dispense; Distribute, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 63.

Pharmacy, Pharmacist, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 66.

Prescription, Proprietary Drug, Administration, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 67.

Pharmacy Technicians, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 75.

Centralized Prescription Filling, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 89.

Prescription Drugs; Pedigree Papers, Fla. Jur. 2d Foods, Drugs, and Cosmetics § 105.

Forms

Florida Pleading and Practice Forms § 34:104, Complaint--Failure to Meet Minimum Requirements for Safe Practice Under the Florida Pharmacy Act.

NOTES OF DECISIONS

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1. Construction and application

Drugs not properly "dispensed" are, per se, "misbranded" for purposes of offense of adulterating or misbranding prescription drugs. Rodriguez v. State, App. 3 Dist., 67 So.3d 326 (2011). Health 982

No private cause of action was created by amendment of Pharmacy Act's definition of "dispense"--as element of dispensing, pharmacist shall, prior to actual physical transfer, interpret and assess prescription order for potential adverse reactions, interactions, and dosage regimen he deems appropriate, shall certify that medicinal drug called for by prescription is ready for transfer, and shall provide counseling on proper drug usage, either orally or in writing, if deemed necessary. Johnson v. Walgreen Co., App. 1 Dist., 675 So.2d 1036 (1996). Action 3; Health 198; Products Liability 225; Products Liability 303

Definitions enacted under § 465.031 (repealed, see, now this section) in 1961 had no bearing on question of whether acts allegedly committed prior to effective date of such definitions constituted violations of law relating to pharmacists. Hall v. Florida Bd. of Pharmacy, 177 So.2d 833 (1965). Health 106

2. Practice of pharmacy

Hydrocodone shipped to consumers from defendants' Internet pharmacy without being reviewed by a pharmacist was not properly "dispensed," thus supporting convictions for adulterating or misbranding prescription drugs. Rodriguez v. State, App. 3 Dist., 67 So.3d 326 (2011). Health 982

Pharmacy is a "profession" in the general sense of the word. Lee v. Gaddy, 133 Fla. 749, 183 So. 4 (1938). Health 110

Practice of pharmacy was the art of practice of preparing and preserving drugs and of compounding and dispensing medicines according to prescriptions of physicians; the occupation of apothecary or pharmaceutical chemist. Ex parte Sarros, 116 Fla. 86, 156 So. 396 (1934).

3. Criminal prosecutions

Prescription defense is available to an innocent possessor of a controlled substance who has a legally recognized reason for the possession of controlled substance prescribed to another individual. McCoy v. State, App. 1 Dist., 56 So.3d 37 (2010). Controlled Substances 51

In prosecution for sale of prescription drug without prescription in which State's drug chemist was unable to say whether substance sold by defendant was prescription drug, and trial court improperly took judicial notice that such substance required prescription, State failed to prove substance which defendant sold was within definition of "medicinal drugs" or "drugs." Block v. State, App. 2 Dist., 437 So.2d 792 (1983). Health 989

To convict defendant for violating § 465.015 proscribing sale of prescription drug without prescription, State had to prove drug which defendant sold was among those defined by statute as "medicinal drugs" or "drugs."

Block v. State, App. 2 Dist., 437 So.2d 792 (1983). Health 982

4. Civil actions

Pharmacists who are licensed under Florida Pharmacy Act are not "health care providers" who are entitled to presuit notice under statutes governing medical malpractice actions. GalenCare, Inc. v. Mosley, App. 2 Dist., 59 So.3d 138 (2011), rehearing denied. Health 807

Complaint that alleged that pharmacies filled numerous lawful prescriptions for customer for narcotic medications too closely in time, within days of having filled previous prescriptions, and that customer subsequently died as result of combined drug overdose, stated cause of action for negligence; strong public policy supported imposition of duty on pharmacies to warn customers of risks inherent in filling repeated and unreasonable prescriptions with potentially fatal consequences. Powers v. Thobhani, App. 4 Dist., 903 So.2d 275 (2005), review granted 924 So.2d 812, review denied 934 So.2d 1182. Products Liability 114; Products Liability 133; Products Liability 225

5. Pharmacies

Requirement of supervision of retail drug establishment by licensed pharmacist could not be extended so as to cover all operations of drugstore including those which were unrelated by their nature to the preparation and sale of controlled drugs and medicines. State v. Leone, 118 So.2d 781 (1960). Health 198

A drug room situated in a hospital operated by a practicing physician is not a "drug store" and regulated by the statutes respecting pharmacists, where the drug room was used for the exclusive accommodations of hospital patients and prescriptions of other physicians were not filled, and orders on the drug room for medicine for patients were in the nature of memoranda rather than prescriptions which were filled either by physicians or some one in their constant presence and direction. Parr v. Spires, 41 So.2d 336 (1949). Health 198

5.5. Prescription

Trial court's failure to instruct jury on a prescription defense to the charge of trafficking in hydrocodone, to which defendant did not object, was fundamental error at trial on the trafficking charge and a charge of possession of cocaine with intent to sell; prescription defense was defendant's primary defense to the trafficking charge, and properly instructed jury could have found that defendant had implied authority from his mother, who had a valid prescription for the pills that were found at defendant's bedside, to safeguard the pills until he could return them to her. Ramirez v. State, App. 4 Dist., 2013 WL 163461 (2013). Controlled Substances 98

The prescription defense to a charge of trafficking in a controlled substance is not limited to the person holding a valid prescription, but may also be asserted by any individual authorized by the prescription holder to hold the medications on his or her behalf; this extension derives from statutes which allow pharmacists to dispense prescription drugs to a patient's agent. Ramirez v. State, App. 4 Dist., 2013 WL 163461 (2013). Controlled Substances 51

6. Voluntary duty

Pharmacy did not undertake voluntary duty by giving warning to pharmacy patron not to drive while using medication and placing a "use caution while driving" label on prescription bottle, and therefore its actions did not broaden the zone of foreseeable risk to unidentified third parties including motorist who was injured in collision with pharmacy patron who fell asleep at the wheel while under the influence of medication, where pharmacy was required to give warnings under state administrative code and state statute. Dent v. Dennis Pharmacy, Inc., App. 3 Dist., 924 So.2d 927 (2006), review dismissed 939 So.2d 1058, rehearing denied. Health 752; Products Liability 133; Products Liability 225

7. Duty, generally

The administratively mandated inherent benefit of additional drug regimen review did not, by itself, create a legal duty to nursing home resident nor did it expand the consultant pharmacist's role beyond that of an administrative advisor, and the Pharmacy Act specifically restricted pharmacist from altering a prescriber's directions, diagnosing or treating any disease, initiating any drug therapy, or practicing medicine. Estate of Johnson ex rel. Johnson v. Badger Acquisition Of Tampa LLC, App. 2 Dist., 983 So.2d 1175 (2008), rehearing denied. Health 198; Health 706

8. Pharmacist review

Evidence supported finding that defendants knowingly packaged and delivered misbranded drugs, thus supporting convictions for adulterating or misbranding prescription drugs; defendants were the sons of a pharmacist who had worked alongside their father for years and had working knowledge of the operations of the pharmacy, rendering them well aware that it was not legally permissible to ship hydrocodone to consumers from Internet pharmacy without pharmacist review. Rodriguez v. State, App. 3 Dist., 67 So.3d 326 (2011). Health 989

West's F. S. A. § 465.003, FL ST § 465.003

Current through Ch. 272 (End) of the 2013 1st Reg. Sess. of the 23rd Legislature

END OF DOCUMENT

Cumbie, James A

From: Cumbie, James A
Sent: Friday, March 14, 2014 2:59 PM
To: 'TJones@akingump.com'
Subject: Request for Declaratory Statement

Good Afternoon,

This email is to inform you that your request for a declaratory statement to the Board of Pharmacy will be heard Tuesday, April 1, 2014 in Tampa, FL. The attached document contains all required information regarding location and time. If you have any questions or concerns, please feel free to contact me via email or by phone at the number provided below. Thank you for your time and have a great day.

Declaratory Statement - Gra...

Sincerely,

Jay Cumbie
Regulatory Specialist II
Florida Board of Pharmacy
Phone: 850-245-4444 ext: 3367
James.Cumbie@flhealth.gov

March 14, 2014

Daniel David Graver

RE: Request for Declaratory Statement

Dear Mr. Graver:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, April 1, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 1:00 p.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

Akin Gump
STRAUSS HAUER & FELD LLP

Daniel David Graver
+1 202.887.4562/fax: +1 202.887.4288
dgraver@akingump.com

January 22, 2014

BY U.S. MAIL

Florida Board of Pharmacy
4052 Bald Cypress Way, BIN C04
Tallahassee, FL 32399-3254

Re: Request for Declaratory Statement

Dear Florida Board of Pharmacy:

We represent a pharmaceutical manufacturer considering an arrangement with retail pharmacies through which the manufacturer would pay the pharmacies to perform certain "adherence services" for patients who have been prescribed the manufacturer's drugs, either through their pharmacists or through a contracted third party business associate. We are writing to inquire whether this program would implicate the provisions of **Fla. Stat. §§ 465.185; 456.054; 817.505; 465.017;** and/or **Fla. Admin. Code Ann. r. 64B16-27.104.**

As you know, a physician's prescription for a patient indicates both the medication and how often it should be taken. Sometimes, patients do not adhere to the doctor's instructions because they forget to refill their prescription, or they take the medication inconsistently due to adverse side effects.

Under the proposed program, a pharmacy, via its pharmacists or a third-party contractor (collectively "the pharmacy"), would provide "adherence services," designed to improve patients' adherence to their prescription drug regimens. Patients will be reminded to refill prescriptions and counseled to address any problems, concerns, or barriers they may experience with continuing with their medication regimens as prescribed by their physicians. This may include refill reminder letters, texts, emails, phone calls, face-to-face counseling of patients, coaching, or other adherence support tools (e.g., pharmacist-initiated point-of-sale tools). Patients will be free to opt out of the program at any time.

In exchange for performing these adherence services for certain patients who have been prescribed the manufacture's drugs, the pharmacy could be compensated under one of two models. First, in the vast majority of these arrangements, the manufacturer would pay the pharmacy for these services on a fee-for-service or hourly basis. Alternatively, in certain limited circumstances, the pharmacy could be compensated based on a percentage of the increased revenue earned by the pharmaceutical manufacturer resulting from the proper utilization of the specific drugs for which the pharmacy has been performing these adherence services.

An example of how the revenue-sharing compensation structure would work:

> The Manufacturer produces Drug X. A certain group of patients at the Pharmacy with prescriptions for Drug X will be enrolled in the Pharmacy's adherence services program. In exchange for these services, the Pharmacy will receive 15% of the Manufacturer's increased profits resulting from the increase in purchases of Drug X by the participating patients, as compared to the amount of Drug X purchased by a group of non-participating patients who do not receive adherence services, and do not properly adhere to the regime prescribed by their doctor.

Before our client implements this program, we would like to confirm that neither the program nor either payment model violates Florida law. Specifically, we would like to know whether this arrangement implicates **Fla. Stat. §§ 465.185; 456.054; 465.017; 817.505;** and/or **Fla. Admin. Code Ann. r. 64B16-27.104.** Fla. Stat. §§ 465.185, 456.054, and 817.505 govern kickbacks, rebates, commissions, and fee-splitting. Fla. Admin. Code Ann. r. 64B16-27.104 prohibits pharmacists from entering rebate agreements limiting a patient's free choice of pharmacist or pharmacy. Fla. Stat. § 465.017 governs disclosures of pharmacy records.

Based upon our analysis of the language of these provisions, we do not believe that they apply to the facts presented. The manufacturer's payments to the pharmacy would not constitute kickbacks, division of fees, or rebates, but rather are legitimate payments for bona fide services rendered. The adherence services program would not limit a patient's free choice of pharmacist or pharmacy. The arrangement would provide services only to patients to encourage them to stay on the regimen already prescribed by their physicians and thus presumably in their best interest. Finally, under the adherence services program the pharmacy will not disclose pharmacy records to the manufacturer.

Because this issue is extremely important and time-sensitive for our client, we would be grateful if the Board could review our inquiry at its earliest convenience. Should the Board need additional information for its analysis, please do not hesitate to contact me at (202) 887-4578 or TJones@akingump.com.

Sincerely,

Daniel David Graver

Division of
Medical Quality Assurance

MQA

Processed: 3/12/2014 10:40:56PM

COMPAS DataMart Reporting System
New License Report for 2201 : Pharmacist
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51465	01/02/2014	Jagasia, Kunal K	02/26/1988	Appalachian College Of Pharmacy		124 Duval Street	Key West, FL 33040
PS	51466	01/06/2014	Paar, Frank Charles	05/16/1955	Oklahoma State University, Oklahoma City		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51467	01/06/2014	Sully, Michael	08/23/1974	Nova Southeastern University		7618 Kismet Street	Miramar, FL 33023
PS	51468	01/07/2014	Bhatt, Jwalant Rajendra	03/24/1987	Massachusetts College Of Phar & Allied H		110 Laurens Ln.	Colonial Heights, VA 23834
PS	51469	01/08/2014	Walters, Adam Lee	10/14/1987	Nova Southeastern University		6250 Palm Trace Landings Dr Apt 301	Davie, FL 33314
PS	51470	01/10/2014	Vaddi, Haranath Kumar	07/13/1968	Foreign Schools		1944 Aspen Ln	Weston, FL 33327
PS	51471	01/10/2014	Enos, Merin Elsa	04/11/1982	Nova Southeastern University		1724 Olive Tree Circle	Greenacres, FL 33413
PS	51472	01/10/2014	Ragoonathsingh, Faria Anika	08/13/1983	Nova Southeastern University		12001 Nw 2Nd Street	Plantation, FL 33325
PS	51473	01/10/2014	Delgado, Samantha Anne	02/12/1987	Florida A & M University		2400 Avenue 1	Huntsville, TX 77340
PS	51474	01/10/2014	Cardenas, Kristine Rose Ignacio	12/02/1980	Foreign Schools		2200 4Th St North	Saint Petersburg, FL 33704
PS	51475	01/10/2014	Dietrich, Scott Kenneth	11/29/1985	University Of Colorado Health Sciences C		3000 N Bern Ave	Raleigh, NC 27610
PS	51476	01/10/2014	Patel, Rupal	06/22/1988	Midwestern State University		8706 B. Gregory Lane	Des Plaines, IL 60016
PS	51477	01/10/2014	Spears, Eric Stephen		Florida A & M University		21217 Bassett Ave	Port Charlotte, FL 33952
PS	51478	01/10/2014	John, Jaimy Mary	05/23/1986	Nova Southeastern University		7990 Sw 24Th Pl Apt #204	Davie, FL 33324
PS	51479	01/15/2014	Arndt, Sheri Lynette Hoyler	01/24/1967	University Of Texas At Austin		901 S Flagler Dr Box 24708	West Palm Beach, FL 33416
PS	51480	01/15/2014	Do, Mai Thi	01/19/1976	Xavier University		4605 N. Narcissus Ave	Broken Arrow, OK 74012
PS	51481	01/15/2014	Lee, Medina	09/13/1968	Ohio State University Main Campus		9353 Isla Bella Circle	Bonita Springs, FL 34135
PS	51482	01/15/2014	Patel, Jigneshkumar R	07/02/1976	Foreign Schools		102 N. Centerville Rd	Sturgis, MI 49091
PS	51483	01/15/2014	Malsom, Richard David	09/26/1984	Jefferson School Of Pharmacys		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51484	01/15/2014	Ontko, Samuel	07/19/1963	University Of Toledo		4702 Milan Rd	Sandusky, OH 44870
PS	51485	01/15/2014	Tsai, Meng Sien	09/20/1981	Xavier University		1524 Polk St	San Francisco, CA 94109

COMPAS DataMart Reporting System
New License Report for 2201 : Pharmacist
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51486	01/15/2014	Oh, Jin Seung	01/11/1974	Shenandoah University		Box 430374	Miami, FL 33243
PS	51487	01/21/2014	Vickers, Lee Tramell	04/16/1988	Florida A & M University		2457 Ave A Sw	Winter Haven, FL 33880
PS	51488	01/22/2014	Muggli, John Wesley	05/01/1980	Nova Southeastern University		3 South 4Th Avenue	Marshalltown, IA 50158
PS	51489	01/23/2014	Smith, Claire	08/08/1963	Foreign Schools		5009 Turnpike Feeder Rd	Fort Pierce, FL 34951
PS	51490	01/23/2014	Moore, Rebecca Diane	03/30/1986	Southwestern Oklahoma State University		8220 Navarre Parkway	Navarre, FL 32566
PS	51491	01/24/2014	Sardelli, Alyssa Iva	06/17/1987	Albany College Of Pharmacy		614 Columbia Turnpike	East Greenbush, NY 12061
PS	51492	01/24/2014	Ezepue, Julius Chukwugekwu	02/13/1956	University Of Florida		2600 Sw 19Th Ave Road	Ocala, FL 34474
PS	51493	01/24/2014	Manawelian, Herayer Kevork	02/08/1946	Temple University		2530 West Chester Pike	Broomall, PA 19008
PS	51494	01/27/2014	Seward, Jennifer Lynn	07/06/1972	Midwestern State University		4000 Dekalb Technology Parkway Ste 250	Doraville, GA 30342
PS	51495	01/31/2014	Lordan, Kady Lynn	10/29/1987	Ohio Northern University		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51496	01/31/2014	O'Donnell, Karen Lynn	01/09/1956	University Of Minnesota Twin Cities		301 2Nd St. N.E.	New Prague, MN 56071
PS	51497	01/31/2014	Rivers, Gayle Latisha	07/09/1986	Florida A & M University		4470 Columbia Rd	Martinez, GA 30907
PS	51498	01/31/2014	Varieur, Melissa Ann	02/24/1985	Midwestern State University		2785 N Pinal Ave	Casa Grande, AZ 85122
PS	51499	02/03/2014	Correa, Stefan	09/11/1981	Nova Southeastern University		Box 3100	Miami, FL 33154
PS	51500	02/04/2014	Allen, Travis Lawrence	09/27/1987	University Of Florida		8269 Commercial Way	Weeki Wachee, FL 34613
PS	51501	02/04/2014	Khamissizadeh, Farhad	12/01/1954	Howard University		337 Maple Ave E	Vienna, VA 22180
PS	51502	02/04/2014	Manacheril, Annie Alphonsa	08/12/1986	St Louis College Of Pharmacy		12450 E. Arapahoe Rd Suite A 1	Centennial, CO 80112
PS	51503	02/04/2014	Nickleski, Victoria Michelle	03/26/1980	Midwestern State University		680 S Weber Rd	Romeoville, IL 60446
PS	51504	02/06/2014	Able, Frances Katherine Taylor	05/08/1983	University Of South Carolina - Columbia		2001 Nw 180Th Way	Pembroke Pines, FL 33029
PS	51505	02/06/2014	Hilton, Julie Wright	04/05/1953	Virginia Commonwealth University		2315 W. Mercury Blvd	Hampton, VA 23666

COMPAS DataMart Reporting System
New License Report for 2201 : Pharmacist
1/ 1/2014 - 2/28/2014

Processed: 3/12/2014 10:40:56PM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51506	02/06/2014	Patel, Natasha	06/01/1988	Florida A & M University		15639 Indian Queen Dr.	Odessa, FL 33556
PS	51507	02/06/2014	Taylor, Anya Chimere	09/15/1987	Hampton University School Of Pharmacy		718 East Blvd	Williamston, NC 27892
PS	51508	02/06/2014	Gust, Michael Alan	02/01/1988	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		1926 Fruitridge St.	Brandon, FL 33510
PS	51509	02/06/2014	Treadway, Sarah Angel		University Of Tennessee-Central Office		650 Clinic Dr Suite 2100	Mobile, AL 36688
PS	51510	02/11/2014	Shatz, Michael David	10/27/1950	University Of Arizona		2100 Preston Street	Richmond, TX 77469
PS	51511	02/11/2014	Le, Trang Bao Huynh	05/10/1983	Samford University		230 Tucker Hollow Rd	Calhoun, GA 30701
PS	51512	02/12/2014	Klar, Terence F	05/12/1961	Northeastern University		69 Emerald Ridge Drive	Bear, DE 19701
PS	51513	02/12/2014	Mcgowan, Veronica Lynn	01/20/1967	University Of Arizona		3200 E Speedway Blvd	Tucson, AZ 85716
PS	51514	02/12/2014	Patel, Ketal	07/26/1984	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		4640 Royal Birkdale Way	Wesley Chapel, FL 33543
PS	51515	02/12/2014	Schwartz, Kimberly Marie	02/25/1981	University Of Minnesota Twin Cities		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51516	02/12/2014	Dittus, Krystal Star	03/04/1972	University Of Kentucky		3606 Gulfstream St	Big Pine Key, FL 33043
PS	51517	02/12/2014	Miller, Michael Shane	10/12/1968	Virginia Commonwealth University Medical		1710 Cleveland Hwy	Dalton, GA 30721
PS	51518	02/12/2014	French, Christopher Benjamin	11/08/1983	University Of Florida		101 Sivley Rd	Huntsville, AL 35801
PS	51519	02/12/2014	Henderson, James E	05/31/1951	University Of Cincinnati Main Campus		1425 Columbus Ave	Lebanon, OH 45036
PS	51520	02/12/2014	Matlock, Jessica Anne	07/05/1984	Belmont University		5215 Linbar Dr Suite 210	Nashville, TN 37211
PS	51521	02/12/2014	Mccluskey, Patti Lynn	06/12/1975	Philadelphia College Of Pharmacy And Sci		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51522	02/12/2014	Zayas-Aiken, Carmen Yazmin	06/26/1978	Ohio State University Main Campus		4377 Atlanta Highway	Loganville, GA 30052
PS	51523	02/12/2014	Haas, Adam Justin Sandler	09/19/1982	Auburn University Main Campus		4042 Jacaranda Trace	Milton, FL 32583
PS	51524	02/13/2014	Emmanuelli, Giselle	02/16/1981	Nova Southeastern University		Box 7861	Ponce, PR 00732
PS	51525	02/14/2014	Nayak, Ankur Mahesh	11/15/1986	Foreign Schools		5909 Se Abshier Blvd	Belleview, FL 34420
PS	51526	02/17/2014	Nairn, Shawn R	06/04/1969	Duquesne University		2103 Noblestown Rd	Pittsburgh, PA 15205

COMPAS DataMart Reporting System
New License Report for 2201 : Pharmacist
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Sort Order: Original License Date

Processed: 3/12/2014 10:40:56PM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PS	51527	02/18/2014	Jenkins, Precious Miceala	09/08/1985	Florida A & M University		2791 David H. Mcleod Blvd	Florence, SC 29501
PS	51528	02/19/2014	Musick, Stacy Hope	03/17/1979	Mercer University		7A Seaspring Cove	Santa Rosa Beach, FL 32459
PS	51529	02/21/2014	Ecker, Ashley Nell	10/07/1985	Lake Erie Coll. Of Osteo Med. Sch. Of Pharm.		3825 East Bay Drive	Largo, FL 33771
PS	51530	02/24/2014	Ray, David William	06/07/1985	Saint John'S University		30 Prospect Avenue	Hackensack, NJ 07601
PS	51531	02/25/2014	Tawadrous, Shady Mahrous John	02/20/1983	Foreign Schools		31818 Us Hwy 19 N	Palm Harbor, FL 34684
PS	51532	02/25/2014	Schultz, Michael Gregory	07/09/1989	Ohio Northern University		11806 Rive Isle Run	Parrish, FL 34219
PS	51533	02/25/2014	Harris, Toya Rena	02/16/1970	Xavier University		4000 Dekalb Technology Pkwy Suite 250	Doraville, GA 30342
PS	51534	02/26/2014	Rogers, Walter Joel	03/08/1958	University Of Georgia		123 Dolphin Point Rd.	Niceville, FL 32578
PS	51535	02/26/2014	Patel, Hiren Indravadan	10/30/1983	Temple University		1 Yorktown Plaza	Elkins Park, PA 19027
PS	51536	02/26/2014	Temples, John Frederick	12/18/1986	Nova Southeastern University		605 Highland Circle	Nashville, GA 31639
PS	51537	02/26/2014	Thomas, Jeeva	08/15/1971	Rutgers The State University Central Off		139 Cobb Road	Brewster, NY 10509
PS	51538	02/27/2014	Lipo, David Richard	03/12/1961	Philadelphia College Of Pharmacy And Sci		Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
PS	51539	02/27/2014	Rudyshyn, Natalie Mayor	08/06/1987	Samford University		3023K Massey Rd	Birmingham, AL 35216
PS	51540	02/27/2014	Khanlian, Shant Ardashes	02/24/1979	Lebanon American University		6605 Berkshire Dr	Alexandria, VA 22310
PS	51541	02/27/2014	Halim, Sherif Nabil	09/11/1961	Ohio Northern University		8201 Chancellor Drive	Orlando, FL 32809

Total Records: **77**

Division of
Medical Quality Assurance

MQA

COMPAS DataMart Reporting System
Exam Eligibility Report For Board of 2201 : Pharmacist
Eligible Between 1/ 1/2014 - 2/28/2014

Sort Order: Eligibility Date

Processed: 3/13/2014 6:40:05AM

Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	42962	Palmer, Darren James	01/07/2014	
2201	43968	Sosa, Kris Elaine	01/07/2014	
2201	43623	Asprer, Maria Luisa Dela Rosa	01/08/2014	
2201	44277	Sippel, George Edward	01/10/2014	
2201	33723	Onwuanaibe, Louis	01/13/2014	
2201	39769	Louie, Raymond	01/13/2014	
2201	44301	Kemper, Jonna Vick	01/13/2014	
2201	44323	Semple, Kayhende Viola	01/13/2014	
2201	39376	Patel, Hinaben Hetalkumar	01/14/2014	
2201	44158	Ashley, Ronald Dennis	01/14/2014	
2201	44293	Quinones, Ines	01/14/2014	
2201	44305	Mandal, Kunal	01/14/2014	
2201	42974	Dimoff, Christopher George	01/15/2014	
2201	44135	Allen, Mollie Lynn	01/15/2014	
2201	44330	Che, Jianhong	01/15/2014	
2201	44336	Sapienza, Stephen Paul	01/16/2014	
2201	40871	Lee, Jammy	01/17/2014	
2201	44276	Ukoha, Uchenna Nwokedi	01/21/2014	
2201	44319	Brahmbhatt, Akshar Ashok	01/21/2014	
2201	41171	Certo, Stephen Paul	01/22/2014	
2201	42478	Vo, Thuy-Linh Thi	01/22/2014	
2201	44268	Herring, Wendy Louise	01/22/2014	
2201	44298	Pongvitayapanu, Pudit	01/22/2014	
2201	44308	Hellinger, Hillel	01/22/2014	
2201	44337	Olsufka, William Anthony	01/22/2014	
2201	42748	Tenis, Vedia	01/23/2014	
2201	44333	Guevara, Diego	01/23/2014	
2201	44334	Ivezic, Suzanna	01/23/2014	
2201	44315	Hoang, Peter Dinh	01/24/2014	
2201	44357	Dorough, Benjamin J	01/24/2014	
2201	44092	Ybarra, Alyson Marie	01/28/2014	
2201	44338	Carolan, Andrea Jean	01/28/2014	
2201	36299	Stanley, Robert L	01/30/2014	
2201	39313	Roberts, Yolanda April	01/30/2014	
2201	42863	Jariwala, Sameer M	01/30/2014	
2201	43827	Fohtung, Leticia Mbongo	01/30/2014	
2201	44324	Lopez Figueroa, Diana E	01/30/2014	
2201	44367	Ezihe, Patrick N	01/30/2014	
2201	44294	Luk, Tan-Yi	01/31/2014	
2201	44126	Johnston, Pamela Sue	02/03/2014	
2201	44358	Lewis, Sarah Butler	02/03/2014	
2201	44374	Sauls, Mark Andrew	02/03/2014	
2201	44382	Rivera Gonzalez, Hector Francisco	02/03/2014	
2201	44352	Allen, Megan Kristina	02/04/2014	
2201	44355	Stetzler, Alison Lindsey	02/04/2014	

COMPAS DataMart Reporting System
Exam Eligibility Report For Board of 2201 : Pharmacist
Eligible Between 1/ 1/2014 - 2/28/2014

Sort Order: Eligibility Date

Processed: 3/13/2014 6:40:05AM

Profession	File Nbr	Licensee Name	Eligible Date	Exam Modifiers
2201	44356	Schwinghammer, Saundra Marie	02/04/2014	
2201	44342	Gandhi, Ripal Amratlal	02/05/2014	
2201	44384	Henen, Merit G	02/05/2014	
2201	44360	Bishop, Margaret Brooke	02/10/2014	
2201	44394	Nguyen, Jennifer L	02/10/2014	
2201	44340	Stinner, Nicole Diane	02/12/2014	
2201	44354	Ornella, Elizabeth Anne	02/12/2014	
2201	44359	Mcmillin, Jason Grant	02/12/2014	
2201	44378	Schwinghammer, Paul Joseph	02/12/2014	
2201	43715	Lynn, Chad R	02/17/2014	
2201	44410	Dean, Karim Rocio	02/17/2014	
2201	44250	Landers, Amy Elizabeth	02/18/2014	
2201	44313	Shah, Sonal Radha	02/18/2014	
2201	44377	Paulson, Gregory John	02/18/2014	
2201	44380	Thummuru, Seetha Ramireddy	02/18/2014	
2201	44412	Mcgehee, Adam Winston	02/18/2014	
2201	44339	Malish, Katherine Jane	02/20/2014	
2201	44416	Melika, Shereen Tharwat Kostandy	02/20/2014	
2201	44175	Sproul, Craig A	02/21/2014	
2201	44327	Frost, Amy Ann	02/21/2014	
2201	44426	Resposo, Claudine Jo	02/21/2014	
2201	42808	Nihalani, Parag Doulat	02/25/2014	
2201	44343	Donaldson, John Dee	02/25/2014	
2201	44438	Vazquez Torres, Zilka	02/25/2014	
2201	44370	Lehmann, Robert Thomas	02/26/2014	
2201	44397	Putrus, Mays	02/26/2014	
2201	44402	Truong, Judy Ou	02/26/2014	
2201	44408	Miranda, Naray	02/26/2014	
2201	44159	Sreshta, Michael Simon	02/27/2014	
2201	44242	Gutoski, Richard	02/27/2014	
2201	44404	Azzawi, Ali Ghalib Jaafar	02/27/2014	
2201	42928	Mercier, Pierre Richard	02/28/2014	
2201	44295	Schutzenhofer, Richard Michael	02/28/2014	
2201	44391	Stephenson, Deja Marie	02/28/2014	
2201	44427	Richard, Jennifer Len	02/28/2014	

Total Number of Eligible Applications: 80

COMPAS DataMart Reporting System
New License Report for 2202 : Pharmacist Intern
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Processed: 3/13/2014 6:28:19AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32215	01/02/2014	Yoon, Heejeong	01/06/1975	Foreign Schools	Ewha Womans University And Seoul National University In Korea	6002 Grand Palm Drive Apt #410	Tampa, FL 33647
PSI	32216	01/02/2014	Mitchell, William Scales	01/22/1991			558 N Lake Pleasant Rd	Apopka, FL 32712
PSI	32217	01/02/2014	Mabey, Stephanie Jeanette	02/03/1982			505 Mall Blvd Apt 319	Savannah, GA 31406
PSI	32218	01/02/2014	Morgan, Terese Yoland	07/17/1990			3501 Johnson Street	Hollywood, FL 33021
PSI	32219	01/02/2014	Mcnair, Joseph Dwight	12/30/1986			1201 Redbud Ct.	Mcdonough, GA 30253
PSI	32220	01/06/2014	Polk, Alexas Olivia	07/23/1992	South Carolina College Of Pharmacy		1085 Shop Road Unit 343	Columbia, SC 29201
PSI	32221	01/06/2014	Suzuki, Mari	02/16/1984	Foreign Schools	Tokyo University Of Pharmacy And Life Sciences	55 Merrick Wy Apt752	Coral Gables, FL 33134
PSI	32222	01/07/2014	Pughakoff, Amanda Pearl	09/19/1991			64 Rondelay Drive	Cheektowaga, NY 14227
PSI	32223	01/07/2014	Ibrahim, Samar Adel	03/10/1985			1201 Monument Road Suite 100	Jacksonville, FL 32225
PSI	32224	01/07/2014	Francisconi, Richard Joseph	01/23/1991			2157 Main St	Buffalo, NY 14214
PSI	32225	01/07/2014	Moyer, Sarah Jessica	03/18/1987			University Of Florida 1225 Center Drive	Gainesville, FL 32610
PSI	32226	01/07/2014	Bedoya, Diana Karina	09/21/1983	Foreign Schools	Norbert Wienner University	8840 Nw 153 Terrace	Miami Lakes, FL 33018
PSI	32227	01/08/2014	Obiabo, Edwin	05/06/1974	Other;Other;Other	University Of Jos, Nigeria;University Of Gloucestershire;University Of Sunderland, United Kingdom	1551 1551 Nw 147 Street Drive	Miami, FL 33167
PSI	32228	01/08/2014	Stalas, Theodore Philip	05/05/1991			2940 Bethany Place	Clearwater, FL 33759
PSI	32229	01/10/2014	Able, Holly Austin	04/25/1990			900 Mccormick Hwy	Saluda, SC 29138
PSI	32230	01/10/2014	Lee, Allison Nicole	04/05/1989	South Carolina College Of Pharmacy		10204 Two Notch Road	Columbia, SC 29229
PSI	32231	01/10/2014	Onyeukwu, Nnamdi Anny	04/04/1968	Other	School Of Pharmacy,University Of Benin, Benin-City,Nigeria	7639 Tam O Shanter Blvd North Lauderdale	North Lauderdale, FL 33068
PSI	32232	01/10/2014	Machalick, Christina Lauren	09/18/1987			1900 Taylor Dr Apt 8	Winchester, VA 22601

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New License Report for 2202 : Pharmacist Intern
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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32233	01/10/2014	Sweeney, Jillian Elizabeth	02/13/1989			2070 Honeysuckle Ln.	Winchester, VA 22601
PSI	32234	01/14/2014	Placides, Devon Sebastian	10/09/1989			12901 Bruce B. Downs Blvd	Tampa, FL 33612
PSI	32235	01/14/2014	Abdou, Ibrahem Fares	10/13/1982	Other	College Of Pharmacy,Cairo University	1321 Lisabelle Ln Apartment #8307	Holiday, FL 34961
PSI	32236	01/14/2014	August, Erin Lee	12/23/1989			6059 Portage Rd	De Forest, WI 53532
PSI	32237	01/15/2014	Seakan, Ashley Elizabeth	09/20/1990			7410 W. Boynton Beach Blvd Suite A4	Boynton Beach, FL 33437
PSI	32238	01/16/2014	Exantus, Henry D	05/25/1965			10072 12Th Way North Apt 107	Saint Petersburg, FL 33716
PSI	32239	01/16/2014	Sharp, Amanda Nicole	02/27/1988	Other	Northeast Ohio Medical University	4137 4137 Lynn Road	Ravenna, OH 44266
PSI	32240	01/16/2014	Fowler, Adam Pierce	05/20/1990			6720 Crooked Palm Terrace	Miami Lakes, FL 33014
PSI	32241	01/16/2014	Bonggi, Andrea Maria	08/15/1972			322 Madeira Ave Apt 501	Coral Gables, FL 33134
PSI	32242	01/16/2014	Conte, Allison Caroline	05/03/1990			2 East Street Road	Feasterville, PA 19053
PSI	32243	01/22/2014	Zewdu, Veronica	06/28/1989	Shenandoah University		3 Taft Ave Apt 3	Winchester, VA 22601
PSI	32244	01/22/2014	Thaureaux, Alicia	03/05/1969			7945 Nw 2Nd St	Miami, FL 33126
PSI	32245	01/22/2014	Phillips, Catherine Elizabeth	02/19/1990	University Of Georgia		5 Bailey Reach	Savannah, GA 31411
PSI	32246	01/22/2014	Nguyen, Chau Quy Diem	03/28/1985	University Of Maryland School Of Pharmacy		3503 West Leona St	Tampa, FL 33629
PSI	32247	01/22/2014	Patel, Vidhi Jaymish	10/07/1987	Temple University		2201 Tremont St, Apt # D121	Philadelphia, PA 19115
PSI	32248	01/23/2014	Langlois, Courtney Morgan	05/06/1989			7070 Grelot Rd Apt 1133	Mobile, AL 36695
PSI	32249	01/23/2014	Wieczorek, Malgorzata	07/03/1976	Midwestern State University		7001 Cottie Dr	Joliet, IL 60431
PSI	32250	01/23/2014	Ball, Danielle Jordan	09/17/1990	South Carolina College Of Pharmacy		1100 Bluff Rd. Unit#402	Columbia, SC 29201
PSI	32251	01/27/2014	Trego, Nicholas David	11/22/1987	Ohio State University Main Campus		7653 Old Foxe Ct.	Columbus, OH 43235
PSI	32252	01/28/2014	Mcelveen, Derek Michael	09/14/1989			600 St. James Ave	Goose Creek, SC 29445
PSI	32253	01/28/2014	Kerollous, Nermine Gamal Gabra	09/29/1983	Foreign Schools	Faculty Of Pharmacy Cairo University	2930 Drew Street Apt 1436	Clearwater, FL 33759
PSI	32254	01/28/2014	Muirhead, Elaine Li	12/06/1966	Husson University		47 Haskell Rd	Bangor, ME 04401

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32255	01/28/2014	Francies, Jobin Jose	05/26/1993			3831 N Monroe St	Tallahassee, FL 32303
PSI	32256	01/28/2014	Chizmadia, Katie Ann	01/24/1989			337 Wenger Road N	Dalton, OH 44618
PSI	32257	01/28/2014	Tarroza, Karenina Jaucian	02/15/1970	Foreign Schools	University Of Santo Tomas	705 Milwaukee Avenue Deer Lodge	Deer Lodge, MT 59722
PSI	32258	01/28/2014	Chen, Xiaolan	01/10/1977	Foreign Schools;Foreign Schools	Chinese Academy Of Sciences,Shanghai Institute Of Materia Medica;Fudan University, School Of Pharmacy	155 Great Harbor Way Apt 1903	Ponte Vedra, FL 32082
PSI	32259	01/28/2014	Whitman, Phillip Ryan	04/20/1991			3091 Palm Trace Landings Dr Apt 1415	Davie, FL 33314
PSI	32260	01/28/2014	Salatic, Jovana	02/20/1983			1508 Bay Road Apt 871	Miami Beach, FL 33139
PSI	32261	01/30/2014	Elia, Mariana M	08/16/1988	Other	Faculty Of Pharmacy Alexandria University Egypt	3521 Thomasville Rd	Tallahassee, FL 32309
PSI	32262	01/30/2014	Baid, Rinku	08/04/1974	University Of Colorado Health Sciences C		2088 Hawthorne Street	Sarasota, FL 34239
PSI	32263	02/03/2014	Tran, Nhi Thi	08/17/1990	South University		101 Chippewa Dr.	Savannah, GA 31406
PSI	32264	02/03/2014	Smith, Terence Kelvin Jr	08/30/1980	Howard University		291 Wood Avenue	Oak Hill, FL 32759
PSI	32265	02/04/2014	Plana, Jorge Luis	07/15/1991			2735 Sw 35Th Place	Gainesville, FL 32608
PSI	32266	02/04/2014	Allewaert, Frederik	08/29/1985	Foreign Schools	Ghent University	6012 Lakes Divide Rd	Temple Terrace, FL 33637
PSI	32267	02/05/2014	Smith, Michelle Renee	11/17/1988			2403 Northlake Heights Cir Ne	Atlanta, GA 30345
PSI	32268	02/05/2014	Tierman, Amy Marie	04/07/1987			110 Mcbride Trl	Fayetteville, GA 30215
PSI	32269	02/06/2014	Tran, Francis Anh	11/19/1985	Massachusetts College Of Phar & Allied H		18 Walnut St Apt 10	Worcester, MA 01608
PSI	32270	02/06/2014	Bastawrous, Yasser George Sadik	02/20/1971			2050 Polo Gardens Dr Apt. 101	Wellington, FL 33414
PSI	32271	02/06/2014	Arnold, Aleah Michelle	04/28/1984	Creighton University		15550 San Carlos Blvd	Fort Myers, FL 33908
PSI	32272	02/06/2014	Elsbernd, Jake Phillip	06/12/1982	Shenandoah University		2909 Charing Cross Road Apt #15	Falls Church, VA 22042
PSI	32273	02/07/2014	Barin, Irene Ramos	07/05/1983	Other	University Of Immaculate Conception, Philippines	1059 Jones Creek Dr	Jacksonville, FL 32225
PSI	32274	02/07/2014	Dillenbeck, Heather Leigh	12/26/1990	Suny At Buffalo		61 Stuart Rd	Churchville, NY 14428
PSI	32275	02/07/2014	Huynh, Benson Q	02/13/1974			35 Terrace Villas	Fairport, NY 14450

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New License Report for 2202 : Pharmacist Intern
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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32276	02/10/2014	Polk, James Patrick	01/28/1986			7070 Grelot Rd Apt 611	Mobile, AL 36695
PSI	32277	02/10/2014	Marian, Christopher	04/20/1990	Duquesne University		3501 East Frontage Rd Concourse Center 1	Tampa, FL 33607
PSI	32278	02/11/2014	Lampasone, Laura Katherine	03/08/1990	South University		8000 Waters Ave Apt 175	Savannah, GA 31406
PSI	32279	02/11/2014	Droopad, Alyssa Devi	09/01/1991			187 Whaley Street	Freeport, NY 11520
PSI	32280	02/12/2014	Hassoun, Farah H	07/31/1989	Ohio Northern University		552 N Main St.	Ada, OH 45810
PSI	32281	02/18/2014	Tadros, Lydia Alber	11/27/1986	Foreign Schools	Faculty Of Pharmacy, Cairo University	3045 Zaharias Dr	Orlando, FL 32837
PSI	32282	02/18/2014	Huynh, Jennifer	01/03/1991			92 Travertine Circle	Savannah, GA 31419
PSI	32283	02/18/2014	Harvell, Brittney Leigh	08/22/1990			15 Brasseler Blvd. Apt K14	Savannah, GA 31419
PSI	32284	02/18/2014	Hayes, Sheena Lynn	10/31/1987			912 Van Ave Apt 1025	Daphne, AL 36526
PSI	32285	02/18/2014	Hana, Bishoy Amirhom	04/11/1982	Other	Faculty Of Pharmacy, Helwan University, Cairo Egypt	646 County Road 415	New Smyrna Beach, FL 32186
PSI	32286	02/19/2014	Nemecek, Kaitlyn Rachel	03/17/1991			5650 Graduate Circle Apt 2302A	Tampa, FL 33617
PSI	32287	02/19/2014	Khundkar, Rafa Zaman	07/10/1992			14654 Sw 140 Ct	Miami, FL 33186
PSI	32288	02/19/2014	Jacobson, Eric Ryan	04/19/1990	North Dakota State University Main Campu		2202 35Th Ave. S.	Fargo, ND 58104
PSI	32289	02/19/2014	Bianco, Suzy Drumond	09/14/1961	Foreign Schools	Federal University Of Minas Gerais	University Of Miami 1580 Nw 10Th Avenue	Miami, FL 33136
PSI	32290	02/19/2014	Alozie, Jimmara Anyino	06/18/1960			1706 W. Dr. Martin Luther King Jr. Blvd	Tampa, FL 33607
PSI	32291	02/20/2014	Kurdy, Deema	10/13/1982			4400 Lindell Blvd Apt 3F	Saint Louis, MO 63108
PSI	32292	02/20/2014	Mendez, Jessica M	02/09/1988			11241 Sw 180Th St	Miami, FL 33157
PSI	32293	02/20/2014	Summerson, Thomas Anthony	09/15/1985			6450 Us Hwy 1	Rockledge, FL 32955
PSI	32294	02/20/2014	Mrzygut, Steven Alan Ii	02/14/1988	Suny At Buffalo		1066 Payne Avenue	North Tonawanda, NY 14120
PSI	32295	02/20/2014	Chowdhury, Faria	02/15/1980	Other	University Of Dhaka, Bangladesh	5382 Rishley Run Way	Mount Dora, FL 32757
PSI	32296	02/26/2014	Liu, Yangang	11/01/1967	Foreign Schools	Pharmacy School, Second Military Medical University, China	3741 Country Grove Dr	Madison, WI 53719

COMPAS DataMart Reporting System
New License Report for 2202 : Pharmacist Intern
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PSI	32297	02/27/2014	Distefano, Daniel Scott	02/27/1991	Philadelphia College Of Pharmacy And Sci		3007 Ocean Heights Ave	Egg Harbor Township, NJ 08234
PSI	32298	02/27/2014	Yen, Vann Joe	02/17/1988			329 Crichton St.	Ruskin, FL 33570
PSI	32299	02/27/2014	Riad, Fiby	11/12/1986	Other	Faculty Of Pharmacy - Alexandria University	705 Mermaid Dr Apt 111	Deerfield Beach, FL 33441
PSI	32300	02/28/2014	Girgis, Mina Melad Basha	11/10/1980			190 Avenue B Apt 3	Bayonne, NJ 07002

Total Records: **86**

COMPAS DataMart Reporting System
New License Report for 2208 : Registered Pharmacy Technician
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Processed: 3/13/2014 6:41:57AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51863	01/02/2014	Patel, Binauta R	04/24/1985			717 W Lancaster Rd.	Orlando, FL 32809
RPT	51864	01/02/2014	Munoz, Maydoris	07/18/1988			6227 S W 16Th Street	Miami, FL 33155
RPT	51865	01/02/2014	Subrun, Vexan			Florida Keys Comm College	7637 N E 1 Avenue	Miami, FL 33138
RPT	51866	01/02/2014	Willis, Harry Joseph	08/25/1962	Kash N' Karry Food Stores, Inc		5258 Beach Dr	Saint Petersburg, FL 33705
RPT	51867	01/02/2014	Vassell, Talisa R	07/22/1969	Other	Medical Instuite Of Palm Beach	5213 Blueberry Hill	Lake Worth, FL 33460
RPT	51868	01/02/2014	Ricardo, Yadileidis	02/22/1986	Medical Institute Of Palm Beach,Inc		6164 Forest Hill Blvd Apt 102	West Palm Beach, FL 33415
RPT	51869	01/02/2014	Rameau, Gemina	11/20/1985	Walgreens		8001 Miramar Parkway	Miramar, FL 33025
RPT	51870	01/02/2014	Hazellief, Michelle Ranae	04/08/1973	Publix Super Market, Inc.		13031 Walshingham Road	Largo, FL 33774
RPT	51871	01/02/2014	Elliott, John M				2499 Sw 101 Ave	Miramar, FL 33025
RPT	51872	01/02/2014	Hellebusch, Rick Lee	02/28/1965			3465 Genevieve Park Dr	Tallahassee, FL 32308
RPT	51873	01/02/2014	Houston, Roosevelt	08/17/1962			128 Lake Jackson Blvd	Kingsland, GA 31548
RPT	51874	01/02/2014	Christ, Garrett Nathaniel	11/13/1993			2040 Sheperd Rd	Mulberry, FL 33860
RPT	51875	01/02/2014	Morales Garcia, Yaisel	02/23/1988			3195 Nw 18 Street	Miami, FL 33125
RPT	51876	01/02/2014	Seaman, Hannah M	12/10/1993	Cvs Caremark		2529 Brimhollow Dr.	Valrico, FL 33596
RPT	51877	01/02/2014	Raiyani, Avani Nilesh	09/14/1984	Cvs Caremark		4302 Cortez Road West	Bradenton, FL 34210
RPT	51878	01/02/2014	Desir, Rebecca	02/01/1990	Cvs Caremark		11221 Sw 152Nd Street	Miami, FL 33157
RPT	51879	01/02/2014	Saiyed, Huma	10/07/1992	Cvs Caremark		1800 North Wickham Road	Melbourne, FL 32935
RPT	51880	01/03/2014	Cardona, Ana Marie	03/12/1990	Other	Winter Park Tech- Avalon Campus	4732 Sutton Terrace Unit 125	Orlando, FL 32811
RPT	51881	01/03/2014	Rivera, Rebecca	02/28/1989	Other	Everest University Tampa	1716 E. 143Rd Ave Apt 5	Tampa, FL 33613
RPT	51882	01/03/2014	Servantes, Tracy Jo	05/27/1985	Walgreens		4700 4340 South Florida Ave	Lakeland, FL 33813
RPT	51883	01/03/2014	Cowart, Joseph Britt	08/04/1975	Walgreens		800 S Hwy A 1A	New Smyrna Beach, FL 32169
RPT	51884	01/03/2014	Smith, Tiffiny Leshon	10/22/1986	Walgreens		1903 1903 State Rd 60 E	Lake Wales, FL 33853
RPT	51885	01/03/2014	Wilkinson, Brenden Lee	09/20/1988	Other;Walgreens	Rite Aid Corporation	401 Channelside Walk Way Apt 1385	Tampa, FL 33602
RPT	51886	01/03/2014	Brown, Julian Matthew	09/22/1985	Florida Discount Drug Dba Taylors Pharmacy		1021 W. Fairbanks Ave.	Winter Park, FL 32789

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51887	01/03/2014	Britt, Katisha Sholonia	07/08/1989	Cvs Caremark		800 Hillcrest Ave	Titusville, FL 32796
RPT	51888	01/06/2014	Lopezdiaz, Evelyn	01/17/1979	Other	Everest University	326 Pecan Grove Dr	Orange Park, FL 32073
RPT	51889	01/06/2014	Ingannamorte, April	04/05/1977	Publix Super Market, Inc.		951 North State Road 434	Altamonte Springs, FL 32714
RPT	51890	01/06/2014	Pham, Christine	04/09/1970	Other	Everest University	7512 Dr. Phillips Blvd., #50 - 216	Orlando, FL 32819
RPT	51891	01/06/2014	Phogat, Jasmine	05/20/1989	Walgreens		6179 Mandalay Circle	Naples, FL 34112
RPT	51892	01/06/2014	Miller, Jerilyn Marie	07/04/1979	Kash N' Karry Food Stores, Inc		4203 Larkin St	Sarasota, FL 34232
RPT	51893	01/06/2014	Pascual, Lidiana	06/05/1985	Cvs Caremark		301 S 6Th Ave	Wauchula, FL 33873
RPT	51894	01/06/2014	King, Nafisa	10/06/1995	Other	Atlantic Technical High School	7Th 4971 Sw 7Th Ct	Margate, FL 33068
RPT	51895	01/06/2014	Keshner, Ryan Louis	09/11/1992	Walgreens		8987 Cherry Oaks Tr. Unit 102	Naples, FL 34114
RPT	51896	01/06/2014	Paradiso, Danielle Marie	03/11/1984	Cvs Caremark		2911 Fowler Avenue	Tampa, FL 33612
RPT	51897	01/06/2014	Petit-Bien, Marcco Elessort	01/26/1988	Cvs Caremark		818 Southern Boulevard	West Palm Beach, FL 33405
RPT	51898	01/06/2014	Mecum, Lois Eileen	03/18/1963	Cvs Caremark		12806 Yarn Place	Riverview, FL 33569
RPT	51899	01/06/2014	Mccullough, Nicolle Marie	12/30/1986	Target Pharmacy		10500 Ulmerton Rd	Largo, FL 33771
RPT	51900	01/06/2014	Matos, Khrystyna Siobhan	11/19/1991	Walgreens		3518 Henderson Blvd.	Tampa, FL 33609
RPT	51901	01/06/2014	Rojas, Zulema Mercedes	10/18/1982	Other	Everest University	1016 Ne 33Rd St	Oakland Park, FL 33334
RPT	51902	01/06/2014	Luchkiw, Jessica Elizabeth	02/06/1993	Cvs Caremark		301 3Rd Street South	St. Petersburg, FL 33701
RPT	51903	01/06/2014	Patel, Nilaben	02/02/1989	Cvs Caremark		12703 Peloria Ct	Seminole, FL 33778
RPT	51904	01/06/2014	Pitre, Marius Joseph	11/01/1991	Cvs Caremark		101 Keating Drive	Largo, FL 33770-2816
RPT	51905	01/06/2014	Ortiz, Zuleika Marie	08/16/1981	Pharmerica Drug Systems, Llc		301 Belcher Road North Apt 1752	Largo, FL 33771
RPT	51906	01/06/2014	Ogitani Mccreary, Francesca Sumiko	02/23/1995	Walgreens		11880 28Th Street North	St. Petersburg, FL 33716
RPT	51907	01/06/2014	Torres, Isabella	06/02/1992	Cvs Caremark		7016 Bera Casa Way	Boca Raton, FL 33433
RPT	51908	01/06/2014	Perino, Mary Katherine	05/30/1991			301 Memorial Medical Pkwy	Daytona Beach, FL 32117
RPT	51909	01/06/2014	Lastinger, Samuel Thomas	02/15/1989	Other	Cvs Pharmacy Learnrx	10074 Jog Rd	Boynton Beach, FL 33437

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51910	01/06/2014	Iglesias, Mireya M	07/22/1963	Hialeah Adult Education Center		339 East 42 Street	Hialeah, FL 33013
RPT	51911	01/06/2014	Padron, Mariela	06/16/1970	Hialeah Adult Education Center		853 E 32 St	Hialeah, FL 33013
RPT	51912	01/06/2014	Olivera, Madalys	09/26/1967	Hialeah Adult Education Center		7105 W 13 Ave Apt 101	Hialeah, FL 33014
RPT	51913	01/06/2014	Omarrah, Amy Frances	04/20/1975	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	51914	01/06/2014	Santana Gonzalez, Maydelys	06/29/1974		Florida Education Institute	780 E 21St Street	Hialeah, FL 33013
RPT	51915	01/06/2014	Walker, Jasmine Elexus	03/01/1993	Cvs Caremark		10Th 700 Nw 10Th Ave	Pompano Beach, FL 33060
RPT	51916	01/06/2014	Balbi Puentes, Sherlien	01/01/1991	Other	Professional Training Centers	11480 Sw 193 St.	Miami, FL 33157
RPT	51917	01/06/2014	Ahsan, Sydney Sara	09/07/1994	Publix Super Market, Inc.		16674 122Nd Dr N	Jupiter, FL 33478
RPT	51918	01/06/2014	Dahnke, Carla Josephine	12/18/1978	Target Pharmacy		5800 20Th Street	Vero Beach, FL 32966
RPT	51919	01/06/2014	Cacio Cruz, Emmanuel	12/24/1986	Concorde Career Institute		4571 Cove Dr Apt 203	Orlando, FL 32812
RPT	51920	01/06/2014	Wilson-Edwards, Shauna Gaye	04/30/1982	Cvs Caremark		16310 Bayberry View Drive	Lithia, FL 33547
RPT	51921	01/06/2014	Qualis, Angela	02/09/1990	Cvs Caremark		8504 Southampton Dr	Miramar, FL 33025
RPT	51922	01/06/2014	Foust, Shannon Marie	12/28/1982	Concorde Career Institute		4405 W. Wyoming Ave	Tampa, FL 33616
RPT	51923	01/07/2014	Smith, Mitchell Aaron	08/22/1989	Cvs Caremark		302 East James Lee Blvd	Crestview, FL 32539
RPT	51924	01/07/2014	Cabrera, Rosali	02/11/1991		Florida Education Institute	6861 Sw 129 Ave	Miami, FL 33183
RPT	51925	01/07/2014	Harget, Kristina Aleta	07/21/1981	Walgreens		930 Providence Rd	Brandon, FL 33511
RPT	51926	01/07/2014	Demian, Bishoy Asaad	04/05/1979			31818 Us 19 N	Palm Harbor, FL 34684
RPT	51927	01/07/2014	Amarquaye, Audrey	06/03/1991	Cvs Caremark		7030 Jog Road	Lake Worth, FL 33467
RPT	51928	01/07/2014	Heath, Andrea Kasaundra	09/13/1983	Other	Everest University Orange Park	1111 West 7Th St Apt 1	Jacksonville, FL 32209
RPT	51929	01/07/2014	Cruz, Amy Marie	08/02/1981	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51930	01/07/2014	Babu, Binsey Chrisey	12/25/1982	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51931	01/07/2014	Abdu, Yasmin	03/05/1993	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	51932	01/07/2014	Bailey, Mark Edward	06/13/1975	Other	Everest University	725 14 Street North	Saint Petersburg, FL 33705

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51933	01/07/2014	Dawdy, Andrew William	12/27/1985	Other	Passassured Pharmacy Technician Training Program	5710 Anazaohealth Hoover Blvd	Tampa, FL 33634
RPT	51934	01/07/2014	Diaz-Brito, Christina Marie	01/03/1991	Other	Sanford Brown Institute Tampa	15101 Lynx Dr.	Tampa, FL 33624
RPT	51935	01/07/2014	Floyd, Amanda Leigh	08/19/1977	Other	Sanford Brown Institute Tampa	1020 Cowart Road	Plant City, FL 33567
RPT	51936	01/07/2014	Clippard, Stephanie Amber	05/26/1989	Other	Sanford Brown Institute Tampa	6919 Greenhill Pl	Tampa, FL 33617
RPT	51937	01/07/2014	Giglifiore, Julio Alberto	10/10/1989	Aguilas International Medical Institute		10017 Oasis Palm Dr	Tampa, FL 33615
RPT	51938	01/07/2014	Auxila, Valerie Jean	03/25/1993	Cvs Caremark		1601 Celleny Ct.	Kissimmee, FL 34744
RPT	51939	01/07/2014	Bellante, Ann	09/03/1961	Walgreens		13613 Us Hwy 1	Sebastian, FL 32958
RPT	51940	01/07/2014	Gordon, Dwayne Mcdonald	12/12/1983	Cvs Caremark		5208 E County Rd 466	The Villages, FL 32162
RPT	51941	01/07/2014	Bowles, Carrie Jeanne	01/08/1986	Walgreens		7318 Sky Drive	Wesley Chapel, FL 33545
RPT	51942	01/07/2014	Evans, Kyle Anthony	09/14/1988	Other	Pass Assured	7595 Baymeadows Cir W Apt 2203	Jacksonville, FL 32256
RPT	51943	01/07/2014	Hampton, Mitchell Denton	03/22/1992	Other	United States Navy	3523 27Th Ave Ne	Naples, FL 34120
RPT	51944	01/07/2014	Geffrard, Carline	06/05/1991			1895 N. Congress Ave	Boynton Beach, FL 33426
RPT	51945	01/07/2014	Crosten, Jason Edward	12/05/1987	Walgreens		20Th 5950 Sw 20Th Ave Apt 37	Gainesville, FL 32607
RPT	51946	01/07/2014	Holmes, Nicole Ashley	12/28/1990	Other	Rasmussen	418 Sw 19Th St	Cape Coral, FL 33991
RPT	51947	01/07/2014	Dowling, Deborah Ann	06/15/1961			9251 University Pkwy	Pensacola, FL 32514
RPT	51948	01/07/2014	Hammett, Rebecca Lynn	08/07/1984			4718 9Th Pl	Vero Beach, FL 32966
RPT	51949	01/07/2014	Hughes, Kristen Michelle	08/05/1991	Other	2419	13949 Sound Overlook Dr N	Jacksonville, FL 32224
RPT	51950	01/07/2014	Hebert, Amber Nicole	09/07/1986			17623 Meadowbridge Dr	Lutz, FL 33549
RPT	51951	01/07/2014	Sierra, Anthony	07/21/1991	Other	Everest University	103 Burgos Road	Winter Springs, FL 32708
RPT	51952	01/07/2014	Grady, Thomas Charles	10/02/1963	Other	2419 University Of Florida - College Of Pharmacy	5596 W Conestoga St	Beverly Hills, FL 34465
RPT	51953	01/07/2014	Strong, Carlos	01/14/1960			2803 Arlington St Apt 301	Orlando, FL 32805
RPT	51954	01/07/2014	Garcell Herrera, Yadira	08/05/1989	Hialeah Adult Education Center		5300 Nw 180 Ter	Miami Gardens, FL 33055

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51955	01/08/2014	Williams, Vanessa Renee	09/23/1966		Virginia College - Jax	2020 Wells Road #29 E	Orange Park, FL 32073
RPT	51956	01/08/2014	Petit, Emmanuel Sr	04/15/1976	Other	Other	206 Ne 173 Street	North Miami Beach, FL 33162
RPT	51957	01/08/2014	Lopez, Arely	07/18/1969	Hialeah Adult Education Center		4187 E 9 Ln	Hialeah, FL 33013
RPT	51958	01/08/2014	Jenkins, Victoria Lee	05/15/1992	Other	Sanford Brown Institute	508 Highview Terrace N	Brandon, FL 33510
RPT	51959	01/08/2014	Downs, Carissa Kiriay	07/16/1993			16825 E. Colonial Dr.	Orlando, FL 32820
RPT	51960	01/08/2014	Diaz-Capdevila, Susana T	10/26/1989			13680 Sw 88 St	Miami, FL 33186
RPT	51961	01/08/2014	Mullikin, Andrew Tyler	11/04/1986	Other	Sanford Brown Institute Tampa	10667 Cedar Pine Dr.	Tampa, FL 33647
RPT	51962	01/08/2014	Garcell Herrera, Olga Yaritza	02/03/1993	Hialeah Adult Education Center		5300 Nw 180 Ter	Miami Gardens, FL 33055
RPT	51963	01/08/2014	Toussaint, Cherlin	09/10/1982		Sanford-Brown, Ft Lauderdale	930 South West 30Th Avenue	Fort Lauderdale, FL 33312
RPT	51964	01/08/2014	Stanley, Crystal L	05/06/1991	Medical Institute Of Palm Beach,Inc		1325 Southwest Ave C	Belle Glade, FL 33430
RPT	51965	01/08/2014	Vanderderheydem, Melissa Ann	03/27/1994	Cvs Caremark		1010 Ne 14Th Ave	Trenton, FL 32693
RPT	51966	01/08/2014	Hoston, Ukweli Amber Amani	05/18/1988			3187 Nw 118Th Drive	Coral Springs, FL 33065
RPT	51967	01/08/2014	Lara Acosta, Dania	02/19/1970	Other	Professional Training Centers	7946 East Drive Apt 202	North Bay Village, FL 33141
RPT	51968	01/08/2014	Cangas, Yamirka Ines	12/15/1976	Hialeah Adult Education Center		7510 W 29 Ave	Hialeah, FL 33018
RPT	51969	01/08/2014	Baird, Elissa Carmen	08/18/1988	Other	Everest University	1863 Wells Road R268	Orange Park, FL 32073
RPT	51970	01/09/2014	Capone, Justin R	03/13/1981	Other	Ultimate Medical Academy	1515 Scranton Avenue	Clearwater, FL 33756
RPT	51971	01/09/2014	Brown, Nicolette Leigh	10/07/1992	Other	University Of Florida-College Of Pharmacy	1170 81St St S	Saint Petersburg, FL 33707
RPT	51972	01/09/2014	Fuentes, Leany	11/20/1993	Walgreens		6800 W 28 Ave	Hialeah, FL 33018
RPT	51973	01/09/2014	Fernandez, Miriam	07/12/1955	Hialeah Adult Education Center		551 West 35Th Place	Hialeah, FL 33012
RPT	51974	01/09/2014	Alajeeli, Mohanad	08/01/1980	Other	Rasmussen College - New Port Richey Campus	7024 Castanea Dr.	Port Richey, FL 34668
RPT	51975	01/09/2014	Carrara, Elisabeth	03/04/1953	Other	Brewster Technical Center	3103 Clover Blossom Circle	Land O Lakes, FL 34638

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51976	01/09/2014	Rosales, Erica Marie	12/15/1983	Publix Super Market, Inc.		1510 Nw 21St. Street	Boynton Beach, FL 33436
RPT	51977	01/09/2014	Smith, Riley Ann	03/04/1995	Publix Super Market, Inc.		3475 Wedgewood Lane	The Villages, FL 32162
RPT	51978	01/09/2014	Simmons, Chelsi	03/30/1992	Cvs Caremark		1625 Pinewood Drive	Clearwater, FL 33756
RPT	51979	01/09/2014	Davidson, John Edward	05/03/1941			4651 Cortez Rd	Bradenton, FL 34210
RPT	51980	01/09/2014	Dimarco, Nicole Donna	10/31/1994			1801 East Broadway St.	Oviedo, FL 32765
RPT	51981	01/09/2014	Tisdale, Shantara Monique	02/02/1993	Wal-Mart		1601 W Kennedy Blvd	Tampa, FL 33606
RPT	51982	01/09/2014	Sherman, Kevin Scott	09/03/1991	Walgreens		2614 Willie Lane	Dover, FL 33527
RPT	51983	01/09/2014	Alarcon, Mailyn	07/29/1981	Walgreens		7400 Collins Ave	Miami Beach, FL 33141
RPT	51984	01/09/2014	Gutierrez, Sahilyn	06/13/1974	Hialeah Adult Education Center		12350 Sw 188Th Terrace	Miami, FL 33177
RPT	51985	01/09/2014	Abreu, Yudith	11/24/1985	Hialeah Adult Education Center		1060 West 74 St Apt 204	Hialeah, FL 33014
RPT	51986	01/10/2014	Mclean, Angelica Cordelia	05/16/1986	Cvs Caremark		3500 University Blvd N Apt 2005	Jacksonville, FL 32277
RPT	51987	01/10/2014	Vieux, Jilber A	04/06/1987	Other	Medvance Medical Institute	2301 Sw 42Nd Terrace	Fort Lauderdale, FL 33317
RPT	51988	01/10/2014	Somwaru, Melissa Ali	03/04/1992	Other	West Side Tech	1294 Vickers Lake Drive	Ocoee, FL 34761
RPT	51989	01/10/2014	Martin, Pablo	08/14/1995			4050 N W 135Th St Apt 11-4	Opa Locka, FL 33054
RPT	51990	01/10/2014	Perdomo, Leslie Iris	06/03/1991			2616 Commerce Park Dr	Orlando, FL 32819
RPT	51991	01/10/2014	Morgan, Britany	06/26/1989	Cvs Caremark		5299 Nw South Delwood Dr	Port Saint Lucie, FL 34986
RPT	51992	01/10/2014	Mcdonald, Hunter Scott	06/16/1990	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	51993	01/10/2014	Mcgill, Luciana Beatrice	10/27/1976			3848 Lyons Road #205	Coconut Creek, FL 33073
RPT	51994	01/10/2014	Aparcedo, Lisber R	08/22/1971			8881 B Fountainbleau Blvd #201 B	Miami, FL 33172
RPT	51995	01/10/2014	Kaur, Kamaljot	07/23/1994			575 West Indiantown Road	Jupiter, FL 33458
RPT	51996	01/10/2014	Works, Tashara Tiera	03/07/1991	Other	Walgreens	1903 St Rd 60 E	Lake Wales, FL 33853
RPT	51997	01/10/2014	Seibert, Julieanna Lynne	12/28/1982	Wal-Mart		300 N Cattleman Rd	Sarasota, FL 34232

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	51998	01/10/2014	Ramsaran, Sharlene Sherida	10/31/1980		Dr. G'S Pharmacy Inc	234 Commercial Blvd	Lauderdale By The Se, FL 33308
RPT	51999	01/13/2014	Resina, Danielle Marie	01/06/1994	Other	Sanford-Brown Tampa	16111 Copperfield Dr.	Tampa, FL 33618
RPT	52000	01/13/2014	Sterbens, Jacqueline Ann	06/16/1972	Publix Super Market, Inc.		9850 Little Road	New Port Richey, FL 34654
RPT	52001	01/13/2014	Reyes, Ludmila	09/29/1976	Other	Professional Training Centers	7668 Sw 152 Avenue Apt 108	Miami, FL 33193
RPT	52002	01/13/2014	Turner, Cheyenne Autumn Tabitha	05/23/1989		Sweet Bay Pharmacy	7491 4Th St N	Saint Petersburg, FL 33702
RPT	52003	01/13/2014	Shah, Jigna M	06/15/1987	Walgreens		7801 Sw 70Th St.	Miami, FL 33143
RPT	52004	01/13/2014	Perez, Damaris	05/24/1975	Hialeah Adult Education Center		1425 West 28 St Apt #1	Hialeah, FL 33010
RPT	52005	01/13/2014	Sosa, Suley	01/11/1975	Hialeah Adult Education Center		8390 Nw 103 St Apt 201	Hialeah Gardens, FL 33016
RPT	52006	01/13/2014	Rice, Dawn M	10/21/1974	Other	Pharmacy Technician Certification Board	1298 Sw Jericho Ave	Port Saint Lucie, FL 34953
RPT	52007	01/13/2014	Samson, Dane Ellison	07/13/1990	Walgreens		110 Oconee Street	Lakeland, FL 33805
RPT	52008	01/13/2014	Vargas, Christine	03/20/1991	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52009	01/13/2014	Rodriguez, Vivian Maria	06/28/1974		South Dade Educational Center	23201 Sw 112Th Ave	Miami, FL 33032
RPT	52010	01/13/2014	Rivera, Nubia	10/02/1992	Other	Jacksonville Jobcorps	8716 Cambourne Way	Orlando, FL 32817
RPT	52011	01/13/2014	Ynoa, Eliana Luisa	09/19/1989	Walgreens		944 Sw 68Th Ave	Miami, FL 33144
RPT	52012	01/13/2014	Tate, Tiffany Jasmine	09/14/1986	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52013	01/13/2014	Townsend, Jessica	04/15/1981	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52014	01/13/2014	Reitz, Katarina Marie	09/23/1994	Publix Super Market, Inc.		7117 Merrill Rd.	Jacksonville, FL 32277
RPT	52015	01/13/2014	Youmans, William Iii	10/12/1993	Walgreens		11131 Battery Park Pl	Bradenton, FL 34211
RPT	52016	01/13/2014	Strickland, Jennifer Lynne	01/18/1992	Publix Super Market, Inc.		1700 N Monroe St	Tallahassee, FL 32303
RPT	52017	01/13/2014	Silva, Berangely	05/27/1966	Other	Everest Institute	210 174 Street Apt. 2416	North Miami Beach, FL 33160
RPT	52018	01/13/2014	Wallace-Joseph, Brenda Gail	02/12/1962	Wal-Mart		4444 West Vine St	Kissimmee, FL 34746
RPT	52019	01/13/2014	Ware, Jerry Lamar Jr	11/10/1988	Cvs Caremark		7534 Sun Tree Circle #142	Orlando, FL 32807
RPT	52020	01/13/2014	Soth, Pouv Vessna	01/07/1995	Other	Everest University Largo Campus	3232 32Nd Ave N	Saint Petersburg, FL 33713

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RPT	52021	01/13/2014	Walden, Mykal Anthony	12/15/1990	Cvs Caremark		2602 Nancy St	Sarasota, FL 34237
RPT	52022	01/13/2014	Solis, Jose Angel	07/18/1992	Other	Adult And Community Education Center Of Indian River County	5320 5320 U.S. 1	Vero Beach, FL 32967
RPT	52023	01/13/2014	Tate, Tristin Levar	12/12/1987	Walgreens		42 4228 13Th Ave North	Saint Petersburg, FL 33713
RPT	52024	01/14/2014	Maragh, Chantalle Tiffany	08/11/1991	Cvs Caremark		2643 Graduate Ct	Orlando, FL 32826
RPT	52025	01/14/2014	Melekalathil, Sathyanarayanan	05/18/1968	Other	Everest University	13999 Darchance Road	Windermere, FL 34786
RPT	52026	01/14/2014	Perez, Carolyn Sue	03/07/1951	Other	Education To Go Pharmacy Techniciaon V 3	4222 Arborwood Lane	Tampa, FL 33618
RPT	52027	01/14/2014	Austin, Omega Francisca	12/31/1987	Cvs Caremark		1836 Racquet Ct	North Lauderdale, FL 33068
RPT	52028	01/14/2014	Edouard, Belinda Caroline	07/01/1989	Publix Super Market, Inc.		7640 Sand Lake Rd	Orlando, FL 32819
RPT	52029	01/14/2014	Deppner, Ellen Jo Anne	06/19/1981	Cvs Caremark		7071 Mitchell Blvd	New Port Richey, FL 34655
RPT	52030	01/14/2014	Duarte, Dudley Jose	03/13/1989	Walgreens		1114 Sw 12Th Ave	Miami, FL 33129
RPT	52031	01/14/2014	Gomez, Celia	02/14/1990	Other	Fortis College	19340 Nw 8Th Street	Pembroke Pines, FL 33029
RPT	52032	01/14/2014	Gross, Mary Kathryn	10/24/1983	Cvs Caremark		811 S. Fairfield Drive	Pensacola, FL 32506
RPT	52033	01/14/2014	Carrillo, Sarah Lizabeth	11/12/1985	Cvs Caremark		1116 28Th St W	Bradenton, FL 34205
RPT	52034	01/14/2014	Carter, Takiana Reshae'	11/09/1991	Walmart And Sam'S Club Pharmacies		5700 Nw 23Rd Street	Gainesville, FL 32653
RPT	52035	01/14/2014	Applegate, Malinda Eileen	07/08/1986	Publix Super Market, Inc.		17Th S 303 Se 17Th St	Ocala, FL 34471
RPT	52036	01/14/2014	Castillo, Christina Gina	10/15/1993	Publix Super Market, Inc.		2345 Robin Drive	Naples, FL 34117
RPT	52037	01/14/2014	Davis, Deontavia Shaylice	07/27/1990			5010 N Lane Apt 17	Orlando, FL 32808
RPT	52038	01/14/2014	Ashcroft, Zoe Alexandra	02/17/1992	Cvs Caremark		910 Sandpiper Lane	Vero Beach, FL 32963
RPT	52039	01/15/2014	Atlas, Cherish Domuniqe	09/11/1993	Other	Everest University	3800 Double Eagle Dr	Orlando, FL 32839
RPT	52040	01/15/2014	Joseph, Laura	04/24/1993			553 Ne 133Rd St	Miami, FL 33161

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RPT	52041	01/15/2014	Gaines, April Nicole	11/22/1989	Other	Everest University Tampa	2608 Rustic Ridge Loop Apt. 201	Lutz, FL 33559
RPT	52042	01/15/2014	Leon, Destiney Monique	11/09/1986			508 Sw 11 St	Hallandale, FL 33009
RPT	52043	01/15/2014	Hernandez, Cindy Diane	03/20/1993	Everest University-Pompano Beach		6719 6719 N. Clearview Ave.	Tampa, FL 33614
RPT	52044	01/15/2014	Khan, Farzaana Salma	07/12/1990			10300 Nw 8Th Street #101	Pembroke Pines, FL 33026
RPT	52045	01/15/2014	Bens, Latoria L	11/06/1986	Other	Everest University Of Tampa	14546 Seaford.Cir #204	Tampa, FL 33613
RPT	52046	01/15/2014	Perez, Melba L	07/31/1985	Other	Everest University	473 473 Jordan Stuart Cir Apt 115	Apopka, FL 32703
RPT	52047	01/15/2014	Acosta Perez, Ray	08/16/1983	South Dade Adult Education Center		14873 Sw 35Th Lane	Miami, FL 33185
RPT	52048	01/15/2014	Pugh, Megan Rose	02/02/1992	Winn Dixie		1021 Lockwood Blvd	Oviedo, FL 32765
RPT	52049	01/15/2014	Ramilo, Bambie Nicole	03/08/1982			3 Padgett Court	Pensacola, FL 32505
RPT	52050	01/15/2014	Mathew, Johnson	11/24/1977			1400 Nw 10Th Ave Apt 1706	Miami, FL 33136
RPT	52051	01/15/2014	Ruinato, Amanda Marie	05/17/1989	Virginia College		6605 Warren Road	Milton, FL 32583
RPT	52052	01/15/2014	Nonyelum, Kenneth Chijioke	09/13/1980	Cvs Caremark		8612 Villa Point Apt 421	Orlando, FL 32810
RPT	52053	01/15/2014	Medina, Mya Lucero	03/28/1995	Other	Cvs Pharmacy	99 Magnolia Avenue	Auburndale, FL 33823
RPT	52054	01/15/2014	Jackson, Nakita	09/12/1990	Other	Everest Institute	21300 Nw 9Th Place Apt. 302	Miami, FL 33169
RPT	52055	01/15/2014	Ryan, Heather Nicole	01/27/1986	Other	Duffs Business Institute	8024 Southside Blvd #155	Jacksonville, FL 32256
RPT	52056	01/15/2014	De La Fuente, Maria Fiorella	03/23/1988	Other	University Of Florida College Of Pharmacy	2610 Boat Cove Circle	Kissimmee, FL 34746
RPT	52057	01/15/2014	Beaumont, Krystin	06/07/1992	Other	Southeastern College	6014 Us Highway 19 North,Suite 250	New Port Richey, FL 34652
RPT	52058	01/15/2014	Gomez-Ramirez, Myra	01/05/1990	Cvs Caremark		611 Madison Ave W	Immokalee, FL 34142
RPT	52059	01/15/2014	Dejesus, Ariel Marie	09/13/1993	Walgreens		390 State Road 13	St Johns, FL 32259
RPT	52060	01/15/2014	Gordon, Jynecia Quinay	02/14/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52061	01/15/2014	Turner, Sherrie Marie	07/15/1976	Cvs Caremark		13430 Innerarity Point Road	Pensacola, FL 32507

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RPT	52062	01/15/2014	Abraham, Shawn Kalloor	12/27/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52063	01/15/2014	Faria, Valeria	10/01/1992	Cvs Caremark		4150 Nw 90Th Ave Apt 207	Coral Springs, FL 33067
RPT	52064	01/15/2014	Alava, Jeanette Armada	05/30/1994			8703 Sw 161St Ct	Miami, FL 33193
RPT	52065	01/15/2014	Cason, Brandi Nicole	12/09/1987	Other	University Of Florida-College Of Pharmacy	106 Sw Future Court	Fort White, FL 32038
RPT	52066	01/16/2014	Canales-Carmona, Widnelly	04/20/1995	Other	Technical Education Center Osceola	2623 Quarterdeck Court	Kissimmee, FL 34743
RPT	52067	01/16/2014	Hanley, Christopher	09/09/1989	Walgreens		16900 E Colonial Drive	Orlando, FL 32820
RPT	52068	01/16/2014	Carey, Shanique Maxann	10/28/1922	Other	Heritage Institute	1St 1514 Ne 1St Terr	Cape Coral, FL 33909
RPT	52069	01/16/2014	Butcher, Shane Teddy	02/13/1983	Other	University Of Florida - College Of Pharmacy	1220 Nw 12Th Street	Gainesville, FL 32601
RPT	52070	01/16/2014	Mcgarey, Daniel Sean	09/14/1980	Other	Everest University	265 Sawyerwood Place	Oviedo, FL 32765
RPT	52071	01/16/2014	Johnson, Margaret Lynn	08/09/1967	Other	Everest Institute	14603 Sw 125 Place	Miami, FL 33186
RPT	52072	01/16/2014	Murray, Anthony L	06/04/1980			4749 Barley Street	Orlando, FL 32811
RPT	52073	01/16/2014	Burke, Jessica Hea Ran	06/27/1982	Pinellas County Job Corps Center		3661 Kings Road Apt. 106	Palm Harbor, FL 34685
RPT	52074	01/16/2014	Germain, Tamara Lee	01/19/1978	Other	Passassurd, Llc	34911 Us Highway 19 North	Palm Harbor, FL 34684
RPT	52075	01/16/2014	Bras, Glenmilya L	11/25/1994	Other	Jacksonville Job Corp	12752 New Field Drive	Orlando, FL 32837
RPT	52076	01/16/2014	Hazard, Amanda Marie	01/05/1984	Publix Super Market, Inc.		1545 Rock Springs Road	Apopka, FL 32712
RPT	52077	01/16/2014	Williams, Tiana Shareece	01/16/1990	Other	Florida State College At Jacksonville	7850 Summer Star Ct	Jacksonville, FL 32221
RPT	52078	01/16/2014	Harwood, Mary Doreen	12/22/1968	Cvs Caremark		2789 Ne Pine Ridge Ave	Arcadia, FL 34266
RPT	52079	01/16/2014	Ramirez, Yanetsy	08/29/1979	Hialeah Adult Education Center		17211 Nw 42Nd Pl	Miami Gardens, FL 33055
RPT	52080	01/16/2014	Bellido De Luna, Dasiel	08/23/1989	Cvs Caremark		818 Southern Boulevard	West Palm Beach, FL 33405
RPT	52081	01/16/2014	Spencer, Coretta J	02/24/1969	Walgreens	Medco;	8435 Sandstone Lake Drive Apt. 201	Tampa, FL 33615
RPT	52082	01/16/2014	Harris, Kaneisha Genee'	07/20/1991			8802 Rocky Creek Drive	Tampa, FL 33615

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RPT	52083	01/16/2014	Powelson, Ashlee Lynn	10/20/1990	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52084	01/16/2014	Deatherage, Ashley	10/09/1992	Cvs Caremark		4117 Sw 20Th Ave. Apt 274	Gainesville, FL 32607
RPT	52085	01/16/2014	Thompson, Shakesha Lashawn	04/12/1975	Concorde Career Institute		Box 471381	Miami, FL 33247
RPT	52086	01/16/2014	Hoosain, Imran Alli				10300 Nw 8Th St #101	Pembroke Pines, FL 33026
RPT	52087	01/16/2014	Sweeting, Shakeem Cardel	10/25/1993	Concorde Career Institute		2750 Pierce St	Hollywood, FL 33020
RPT	52088	01/16/2014	Azizi, Abdul Tahir	12/09/1991	Walmart And Sam'S Club Pharmacies		12398 Tropic Dr	Jacksonville, FL 32225
RPT	52089	01/16/2014	Rivera, Annette	04/29/1994	Walmart And Sam'S Club Pharmacies		5608 Curry Ford Rd. Apt. J-14	Olrando, FL 32822
RPT	52090	01/16/2014	Robertson, Michelle A	11/18/1966	Other	Ultimate Medical Academy	701 8Th Avenue Nw #60	Largo, FL 33770
RPT	52091	01/16/2014	Ramos, Vilma Leilani	02/10/1989	Other	Everest University	690 Buford Ave	Orange City, FL 32763
RPT	52092	01/16/2014	Rivero, Elisa	07/05/1971	Hialeah Adult Education Center		5375 West 27 Ave	Hialeah, FL 33016
RPT	52093	01/16/2014	Rodriguez, Jose Miguel	07/09/1990	Cvs Caremark		4267 South Semoran Blvd Apt 16	Orlando, FL 32822
RPT	52094	01/16/2014	Soltero, Cinthia Consuelo	09/23/1992		Homstead Job Corps	17468 Sw 20Th Ct	Miramar, FL 33029
RPT	52095	01/16/2014	Heimbach, Crystal Renee	09/08/1991	Other	Ptce	8874 Pisces Circle South	Jacksonville, FL 32222
RPT	52096	01/16/2014	Buongiorne, Valerie Lynn	01/27/1992	Cvs Caremark		731 Tara Farms Dr	Middleburg, FL 32068
RPT	52097	01/16/2014	Hare, Teddy Leigh	05/16/1991	Cvs Caremark		1 E 9 Mile	Pensacola, FL 32514
RPT	52098	01/16/2014	Delgado, Darissa	08/02/1979	Cvs Caremark		1618 Kendrick Drive Apt. E	Kissimmee, FL 34741
RPT	52099	01/16/2014	Gordon, Lamont C	04/15/1993	Other	Ultimate Medical Academy	1001 N. Mlk Jr Avenue #704	Clearwater, FL 33755
RPT	52100	01/16/2014	Alvarez, Miriam	08/09/1978	Other	Southeastern College St. Petersburg	1081 55Th Terrace S	St. Petersburg, FL 33705
RPT	52101	01/16/2014	Chacon, Masiel A	09/09/1988	Other	Miami Dade College	5033 Nw 7Th St Apt 211	Miami, FL 33126
RPT	52102	01/16/2014	Ayano, Paul Olalere	02/11/1966	Other	Everest University Jacksonville	8859 Old Kings Road South # 902	Jacksonville, FL 32257
RPT	52103	01/16/2014	Crabb, Wendell Scott	12/01/1962	Other	Everest University Jacksonville	4428 Genna Trace Court	Jacksonville, FL 32257

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RPT	52104	01/16/2014	De La Cruz, Maria Ms	07/22/1992	Other	Cvs Pharmacy	2773 Chaddsford Circle Apt#203	Oviedo, FL 32765
RPT	52105	01/16/2014	Gerena, Anthony	06/09/1992	Cvs Caremark		4400 Branbleton Ave	Roanoke, VA 24018
RPT	52106	01/16/2014	Crespo, Wilenith	08/26/1990	Other	University Of West Florida Continuing Education Division	522 Chinquapin Dr	Eglin Afb, FL 32542
RPT	52107	01/17/2014	Munoz, Paula Marie	10/19/1992	Other	Everest University Tampa	4602 N Armenia Ave Suite A-2	Tampa, FL 33603
RPT	52108	01/17/2014	Saunders, Suzanne Renee	01/13/1966	Cvs Caremark		175 Sr 312	St Augustine, FL 32086
RPT	52109	01/17/2014	Lambert, Eric Daniel	05/25/1986	Cvs Caremark		637 Ne 2Nd St 637 Ne 2Nd St	Wiliston, FL 32696
RPT	52110	01/17/2014	Manning, Victoria Lee	12/08/1992	Other	Rite Aid Pharmacy Technician Training Program	12376 Blue Stream Dr. 4651 Salisbury Rd.S., Ste. 449	Jacksonville, FL 32256
RPT	52111	01/17/2014	Patterson, Brittney E	02/18/1986	Other	Ultimate Medical Academy	2409 Winter Park Ct	Fort Walton Beach, FL 32547
RPT	52112	01/17/2014	Jacques, Jackson	04/19/1991	Pharmerica Drug Systems Inc, Pharmerica		53Rd 3690 Nw 53Rd Street Suite 104	Fort Lauderdale, FL 33309
RPT	52113	01/17/2014	Ramirez, Cecilia R	11/16/1969	Hialeah Adult Education Center		3215 Nw 91 Terrace	Miami, FL 33147
RPT	52114	01/17/2014	Elsouri, Kawther Naser	12/07/1994			5684 Via De La Plata Cir.	Delray Beach, FL 33484
RPT	52115	01/17/2014	Day, Shantinica Ann	05/02/1990			28710 Sw 143 Ct	Homestead, FL 33033
RPT	52116	01/17/2014	Gonzalez, Lourdes	03/21/1970	Miami Sunset Adult Education Center		191 Nw 97Th Ave Apt 110	Miami, FL 33172
RPT	52117	01/17/2014	Howell, Constance	05/24/1978	Other	Fortis Institute	2901 Nw 46Th Ave Apt 402	Lauderdale Lakes, FL 33313
RPT	52118	01/17/2014	Gordon, Amanda Michelle	07/16/1994	Publix Super Market, Inc.		2100 Winter Springs Blvd	Oviedo, FL 32765
RPT	52119	01/17/2014	Roy, Andrea Lynne	01/05/1993	Cvs Caremark		27407 Imperial Oaks Circle	Bonita Springs, FL 34135
RPT	52120	01/17/2014	Churukian, Brittany Rose	06/13/1991	Publix Super Market, Inc.		857 Westbay Dr	Largo, FL 33770
RPT	52121	01/17/2014	Aguilera, Nancy Caridad	02/21/1962	Other	Professional Training Centers	9591 Sw 9 Terr # 1	Miami, FL 33174
RPT	52122	01/17/2014	Silva, Amanda	05/13/1986	Other	Everest University	1679 Tarrytown Ave	Deltona, FL 32725
RPT	52123	01/17/2014	Cameron, Dorsie Jacquiline	09/04/1964	Wal-Mart		4537 Oak Haven Dr Apt 201	Orlando, FL 32839

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RPT	52124	01/17/2014	Hijaz, Rula Haitham	07/13/1995	Cvs Caremark		3327 Pine Top Dr.	Valrico, FL 33594
RPT	52125	01/17/2014	Cowart, Stephen Ray	04/01/1979	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52126	01/21/2014	Gamino, Patti Lea	10/30/1984	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52127	01/21/2014	Alvarez Jimenez, Jenifer	06/21/1994	Other	Everest Institute	7735 Nw 27 Avenue #205	Miami, FL 33147
RPT	52128	01/21/2014	Puertas, Maria	09/17/1991	Other	Everest Institute	771 Sw 97 Place/Circle	Mami, FL 33174
RPT	52129	01/21/2014	Griffin, Audrey	06/24/1984	Other	Florida State College At Jacksonville	4245 Katanga Dr. S	Jacksonville, FL 32209
RPT	52130	01/21/2014	Michaels, Marian Michelle	02/10/1959	Cvs Caremark		Cvs 2137 N Young Blvd	Chiefland, FL 32626
RPT	52131	01/21/2014	Duemmel, Allyson Nicole	04/26/1992			5909 University Blvd W	Jacksonville, FL 32246
RPT	52132	01/21/2014	Zemola, Stephanie Nichole	03/25/1992	Other	Everest University	80Th 4503 80Th Street N #1	St. Petersburg, FL 33709
RPT	52133	01/21/2014	Tillan, Tania	11/22/1970	Other	Professional Training Centers	7630 Sw 19 St.	Miami, FL 33155
RPT	52134	01/21/2014	Williams, Kareemah Rosetta	10/25/1989	Other	Lively Technical Center	3279 Sugar Berry Way	Tallahassee, FL 32303
RPT	52135	01/21/2014	Bowman-Bostic, Jennifer Lynn	10/27/1986	Walgreens		409 South St	Fern Park, FL 32730
RPT	52136	01/21/2014	Ramoutar, Brian Reaz	02/03/1989	Cvs Caremark		7330 Curry Ford Road	Orlando, FL 32822
RPT	52137	01/21/2014	Rench, Wayne Thomas	05/25/1988	Other	Everest University	2810 Stagecoach Dr.	Orange Park, FL 32065
RPT	52138	01/21/2014	Thomas, Serennah Precious	07/14/1994	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52139	01/21/2014	Shaw, Candace N	11/29/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52140	01/21/2014	Lindsey, Nikita Cheryl	12/27/1973	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52141	01/21/2014	Nash, Darran Maurice Jr	11/01/1992	Cvs Caremark		6206 Emerald Dr	New Port Richey, FL 34653
RPT	52142	01/21/2014	Polwort, Jennifer Marie	11/08/1974			1010 E. Gonzalez St	Pensacola, FL 32503
RPT	52143	01/21/2014	Jackson, Laura Rebecca	07/20/1987			500 E. Fairfield Dr. Apt. A1	Pensacola, FL 32503
RPT	52144	01/21/2014	Gibson, Armani	03/06/1992	Pinellas County Job Corps Center		3030 Edison Ave Apt 5	Ft Myers, FL 33916
RPT	52145	01/21/2014	Henry, Julissa Michelle	02/15/1993	Walgreens		8337 South Park Circle	Orlando, FL 32819

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RPT	52146	01/21/2014	Howell, Christen Marie	02/13/1994	Cvs Caremark		4684 Hwy 90	Marianna, FL 32446
RPT	52147	01/21/2014	Conner, Tina Marie	05/17/1968	Other	Everest University	149 Myrtle Rd	Palatka, FL 32177
RPT	52148	01/21/2014	Dawes, Kasandra Rena	02/08/1991			2701 Stirling Road	Fort Lauderdale, FL 33312
RPT	52149	01/21/2014	Dawson, Simone Melissa	03/04/1980	Cvs Caremark		13546 13546 Fletcher Regency Drive	Tampa, FL 33613
RPT	52150	01/21/2014	Holligan, Ja'Quette Von'Ques	09/24/1991	Hendry Regional Medical Center		917 Arkansas Ave	Clewiston, FL 33440
RPT	52151	01/21/2014	Scott, Courtney Elaine	02/15/1987	Cvs Caremark		32Nd 2631 32Nd Ave E	Bradenton, FL 34208
RPT	52152	01/21/2014	Araya, Mauricio	06/07/1975	Other	Edutek Professional Colleges	13150 Wenonah Ave Se. # 121	Albuquerque, NM 87123
RPT	52153	01/21/2014	Estupinan, Maria E	01/04/1988	Everest University-Pompano Beach		402 Sw 31 Ave	Miami, FL 33135
RPT	52154	01/21/2014	Valdes, Lazaro Barbaro	12/04/1957	Hialeah Adult Education Center		1725 West 76 Street	Hialeah, FL 33014
RPT	52155	01/21/2014	Boozer, Dawn Michele	02/22/1969	Other	Sanford-Brown Institute	1265 Floyd Street	Fleming Island, FL 32003
RPT	52156	01/21/2014	Charles, Jurnide	07/09/1978	Other	Everest Institiute	413 Ne 191 Stret Apt. 201	Miami, FL 33179
RPT	52157	01/21/2014	Comptis, Cecilia	07/08/1973	Other	Everest Institute	7365 W. 4 Avenue Apt. 11	Hialeah, FL 33014
RPT	52158	01/21/2014	Fundora, Krystel	03/09/1984	Other	Everest Insitute , Miami Fl	5761 West 3Rd Avenue	Hialeah, FL 33012
RPT	52159	01/21/2014	Bush, Camille Nicole	06/01/1992	Cvs Caremark		1300 Apalachee Parkway	Tallahassee, FL 32301
RPT	52160	01/21/2014	Blount, Nicholas M	09/06/1989	Other	Ultimate Medical Academy	1016 Leisure Avenue	Tampa, FL 33613
RPT	52161	01/21/2014	Wilcox, Kathy Anne	08/28/1969	Cvs Caremark		7325 State Road 54	New Port Richey, FL 34653
RPT	52162	01/21/2014	Helwig, Jean Marie	04/09/1964			2851 Old Mill Way	Crestview, FL 32539
RPT	52163	01/21/2014	Gregory, Yolanda Marie	06/05/1989			4200 Nw 3Rd Ct. #235	Plantation, FL 33317
RPT	52164	01/21/2014	Carter, Christopher Wayne	09/30/1989			500 Eagles Landing	Lakeland, FL 33810
RPT	52165	01/21/2014	Guerra, Diuby	09/25/1975			9974 N W 127 Terrace	Hialeah Gardens, FL 33018
RPT	52166	01/21/2014	Collins, Jessica Lynn	12/29/1987			5463 Blue Springs Rd	Youngstown, FL 32466
RPT	52167	01/21/2014	Gabelt, Sherry	09/12/1963			Box 552	Christiansted, VI 00821
RPT	52168	01/21/2014	France, Suzanne	11/06/1958			1721 Dibble Circle East	Jacksonville, FL 32246
RPT	52169	01/21/2014	Galeas, Antonia	04/07/1971			10396 Agave Rd	Jacksonville, FL 32246

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RPT	52170	01/22/2014	Martin, Kayla Lynnett	01/17/1991	Cvs Caremark		3535 Roberts Ave Lot#134	Tallahassee, FL 32310
RPT	52171	01/22/2014	Wolf, Alexander Iv	11/21/1988	Walgreens		28115 Wesley Chapel Blvd	Wesley Chapel, FL 33544
RPT	52172	01/22/2014	Southall, Iva Michelle	03/20/1989	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52173	01/22/2014	Vieira, Amanda Marie	06/28/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52174	01/22/2014	Quinn, Stephanie Rene'	12/22/1988	Walgreens		18932 Pebble Links Cir Apt 301	Tampa, FL 33647
RPT	52175	01/22/2014	Guia, Yeliana	06/16/1994			12252 Sw 214 St.	Miami, FL 33177
RPT	52176	01/22/2014	Soto, Abdiel	10/05/1991	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52177	01/22/2014	Tzortzis, Lily	02/25/1966		Sandford Brown Institue - Garden City Ny	1509 Humphrey Blvd	Deltona, FL 32738
RPT	52178	01/22/2014	Mattar, Lama Walid	12/29/1994	Cvs Caremark		6912 Cauesway Blvd	Tampa, FL 33619
RPT	52179	01/22/2014	Hill, Tina Jean	07/22/1985	Other	Everest University	948 Osceola Trail	Casselberry, FL 32707
RPT	52180	01/22/2014	Demarco, Kaylyn	09/09/1992	Cvs Caremark		5027 Cameron Lane	Boynton Beach, FL 33472
RPT	52181	01/22/2014	Marsh, Michael D	12/02/1993	Other	Fortis Institute	5011 Wiles Road	Coconut Creek, FL 33073
RPT	52182	01/22/2014	Rebello, Kenneth James Jr	05/21/1993	Cvs Caremark		6652 Treehaven Dr	Spring Hill, FL 34606
RPT	52183	01/22/2014	Viera, Stephanie	05/18/1991	Other	Winter Park Tech- Avalon Campus	433 Avalon Park S Blvd	Orlando, FL 32828
RPT	52184	01/22/2014	Prihadash, Dana	01/16/1990			2565 Jardin Way	Weston, FL 33327
RPT	52185	01/22/2014	Nguyen, Michelle Thuy-Tien	12/28/1993	Cvs Caremark		1621 Sw 13Th St	Gainesvile, FL 32608
RPT	52186	01/22/2014	Mahon, Antoinette Latoya	02/13/1990	Other	Florida State College At Jacksonvillle	6887 Snow White Drive	Jacksonville, FL 32210
RPT	52187	01/22/2014	Kuhlman, Tiffany	09/01/1990	Publix Super Market, Inc.		11750 Se Federal Hwy	Hobe Sound, FL 33455
RPT	52188	01/22/2014	Martinez, Amanda Marie	09/04/1989	Wal-Mart		5775 Bent Pine Dr.	Orlando, FL 32822
RPT	52189	01/22/2014	Lingan, Steven Luis	11/29/1990			6191 Orange Dr #6177-N	Davie, FL 33314
RPT	52190	01/22/2014	Pazhukayil, Mareena	10/19/1991	Cvs Caremark		4403 Brandon Ridge Dr	Valrico, FL 33594
RPT	52191	01/22/2014	Turner, Jessica Rene	10/02/1986	Walmart And Sam'S Club Pharmacies		601 E Hazzard Ave	Eustis, FL 32726
RPT	52192	01/22/2014	Flammia, Anita Russ	11/17/1955	Other	Pinellas Technical Education Centers	139 Citrus Ave	Dunedin, FL 34698
RPT	52193	01/22/2014	Fuller, Catherine M	11/29/1979	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52194	01/22/2014	Taylor, Na'Tauishia Spentrice	01/01/1996		Jax Jobs Corps	1913 West 44Th Street	Jacksonville, FL 32209

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RPT	52195	01/22/2014	Hawkins, Terence Micah	08/24/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52196	01/22/2014	Hafley, Constantine Dian	09/30/1974	Walgreens		8337 S. Park Circle	Orlando, FL 32819
RPT	52197	01/22/2014	Cruz, Wesley	11/11/1991	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52198	01/22/2014	Anand, Raja	08/29/1992	Cvs Caremark		130 East State Road 434	Longwood, FL 32750
RPT	52199	01/22/2014	Acceus, Sherrene	10/27/1987	Adventist Health System		1473 South Kirkman Road Apt 3074	Orlando, FL 32811
RPT	52200	01/22/2014	El-Hajji, Kasem Darwish	03/27/1993	Cvs Caremark		15499 North Dale Mabry Highway	Tampa, FL 33618
RPT	52201	01/22/2014	Daley, Elisa V	06/14/1954	Cvs Caremark		57 Tuscan Way	Saint Augustine, FL 32092
RPT	52202	01/22/2014	Guzman, Deidre	10/17/1992	Cvs Caremark		37115 37115 Cody Circle Apt M5	Hilliard, FL 32046
RPT	52203	01/22/2014	Drang, Lisa Machelle	08/10/1973	Welldynerx, Inc		1954 Melrose Plantation Drive	Jacksonville, FL 32223
RPT	52204	01/22/2014	Audette, Amanda Ann	01/27/1991	Cvs Caremark		1483 Surrey Park Drive	Port Orange, FL 32128
RPT	52205	01/23/2014	Moran, Casey Allison	02/25/1994	Walgreens		8716 Thornwood Lane	Tampa, FL 33615
RPT	52206	01/23/2014	Malave-Aponte, Noelia	12/19/1991	Other	N/A	4126 Gulfstream Bay Ct	Orlando, FL 32822
RPT	52207	01/23/2014	Parkerson, Lisa Diane	11/26/1968	Cvs Caremark		3090 S Monroe St	Tallahassee, FL 32301
RPT	52208	01/23/2014	Patel, Hardika Dipenkumar	05/15/1986	Cvs Caremark		309 Emerson Drive Northwest	Palm Bay, FL 32907
RPT	52209	01/23/2014	Jusufovic, Muamer	05/25/1992	Cvs Caremark		43 Way 8280 43Rd Way	Pinellas Park, FL 33781
RPT	52210	01/23/2014	Patel, Neil	09/13/1991			2705 Cotton Ct.	Eustis, FL 32726
RPT	52211	01/23/2014	Lightcap, Barbara Anne	04/30/1958			14 W. Lightcap Road	Pottstown, PA 19464
RPT	52212	01/23/2014	Mendez, Milagros Yolliett	09/27/1989			1101 Royal Palm Beach Blvd	Royal Palm Beach, FL 33411
RPT	52213	01/23/2014	Isaac, Nibia	04/11/1969			325 Nw 72 Ave #410	Miami, FL 33126
RPT	52214	01/23/2014	Matarazzo, Stefania Marcia	12/11/1990			1400 E Colonial Dr	Orlando, FL 32803
RPT	52215	01/23/2014	Patel, Shilan	12/05/1995			2705 Cotton Ct.	Eustis, FL 32726
RPT	52216	01/23/2014	Scafa, Nikki	08/09/1977	Cvs Caremark		3375 Yonge Ave	Sarasota, FL 34235
RPT	52217	01/23/2014	Sosa, Karilys	01/23/1995	Cvs Caremark		4500 Pleasant Hill Road	Kissimmee, FL 34746
RPT	52218	01/23/2014	Spooner, Stephanie Renee	08/29/1986	Cvs Caremark		543 One Center Blvd Apt#201	Altamonte Springs, FL 32701

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RPT	52219	01/23/2014	Richardson, Charva Charice	10/03/1986	Other	Ultimate Medical Academy	5831 Bent Pine Dr Apt 308	Orlando, FL 32822
RPT	52220	01/23/2014	Merchant, Brielle Elizabeth	12/01/1992	Cvs Caremark		8090 Dreamcatcher Cir Unit 2903	Naples, FL 34119
RPT	52221	01/23/2014	Warren, Raheem	02/19/1993	Pinellas County Job Corps Center		3030 Edison Ave Apt5	Ft Myers, FL 33916
RPT	52222	01/23/2014	Strilich, Thomas David	07/13/1958	Other	Southeastern College	9805 Hidden Ln Apt 1	Port Richey, FL 34668-3668
RPT	52223	01/23/2014	Dufresne-Stenvil, Elisianne	06/17/1977	Walgreens		12456 Muddy Creek Lane	Fort Myers, FL 33913
RPT	52224	01/23/2014	Tirado, William Christian Iii	04/13/1994	Publix Super Market, Inc.		7117 7117 Merrill Road	Jacksonville, FL 32277
RPT	52225	01/23/2014	Stewart, Sandy Marie	02/22/1990	Other	Everest University	8625 Hillcrest Dr.	Macclenny, FL 32063
RPT	52226	01/23/2014	Aaron, Bianca Olivia Cherie	02/18/1992			1346 Osceola Hollow Rd	Odessa, FL 33556
RPT	52227	01/23/2014	Davis, Danielle Marie	01/19/1975			2600 Green Wood Rd	Shreveport, LA 71103
RPT	52228	01/24/2014	Nembhard, David George	09/20/1977	Wal-Mart		9990 Belvedere Road	Royal Palm Beach, FL 33411
RPT	52229	01/24/2014	Martinez, Zulima	11/25/1986			13948 Sw 52Nd Ave	Miami, FL 33175
RPT	52230	01/24/2014	Puckett, William Kenneth	06/23/1953			10697 Ulmerton Rd	Largo, FL 33771
RPT	52231	01/24/2014	Pierre, Patricia	12/06/1984			10018 Boynton Place Circle Apartment 338	Boynton Beach, FL 33437
RPT	52232	01/24/2014	Phillips, Tangela Jameca	03/14/1990			2580 Crawfordville Hwy	Crawfordville, FL 32327
RPT	52233	01/24/2014	Mange, Bonnie Bella	06/12/1985			225 Se 23Rd Place	Cape Coral, FL 33990
RPT	52234	01/24/2014	Marquez, Lujan	10/18/1993	Walgreens		201 W Hunter St	Lakeland, FL 33803
RPT	52235	01/24/2014	Mckinzie, Kara Ann	03/03/1992	Winn Dixie		16564 Nw 85Th Terace	Fanning Springs, FL 32693
RPT	52236	01/24/2014	Brown, Michael Joseph	09/09/1991	Walgreens		5617 Legacy Crescent Pl #101	Riverview, FL 33578
RPT	52237	01/24/2014	Scott, Brandy Lea	05/11/1985	Wal-Mart		899 Blanding Blvd	Orange Park, FL 32065
RPT	52238	01/24/2014	Tapia, Jennifer Elizabeth	12/27/1983	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52239	01/24/2014	Sotunbo, Khadija Olubusola	12/14/1982	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	52240	01/27/2014	Cutrone, Melissa Lynn	06/03/1984	Other	Rasmussen College, 3326	3322 Old Village Way	Oldsmar, FL 34677
RPT	52241	01/27/2014	Reveland, Lisa Alison	06/27/1990	Walgreens		1896 Calusa Court	Marco Island, FL 34145

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RPT	52242	01/27/2014	Gardner-Scarpello, Suzette Marie	11/28/1959	Publix Super Market, Inc.		7880 113Th Street	Seminole, FL 33772
RPT	52243	01/27/2014	Brito, Lissett	01/07/1977			3085 West 80 Street	Hialeah, FL 33018
RPT	52244	01/27/2014	Quintero, Karen A	08/09/1980	Other	Fortis College	1820 Nw River Dr	Miami, FL 33125
RPT	52245	01/27/2014	Patel, Darshil Yogeshkumar	12/05/1992	Other	University Of Florida - College Of Pharmacy	5226 Cardinal Cove Circle	Sanford, FL 32771
RPT	52246	01/27/2014	Storck, Laurie J	04/30/1958	Cvs Caremark		1341 1341 Little Deer Run	Canton, GA 30114
RPT	52247	01/27/2014	Mccullough, Ryan James	08/15/1990	Walgreens		5110 Magnolia Terrace	Fruitland Park, FL 34731
RPT	52248	01/27/2014	Evett, Lee Jackson	09/29/1988	Publix Super Market, Inc.		318 N. Cove Blvd	Panama City, FL 32401
RPT	52249	01/27/2014	Gonzalez, Isliany	08/15/1988	Cvs Caremark		7210 N Manhattan Ave 813	Tampa, FL 33614
RPT	52250	01/27/2014	Aiad, Mina Helmy	01/27/1994	Publix Super Market, Inc.		3309 Barrow Hill	Tallahassee, FL 32312
RPT	52251	01/27/2014	Fuentes, Crystal	01/27/1988	Cvs Caremark		8765 South Dixie Highway	Miami, FL 33156
RPT	52252	01/27/2014	Raver, Amanda	10/29/1987	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52253	01/27/2014	Butler, Karyn Dionne	03/31/1983	Other	Everest University-Jacksonvillie	887 Franklin St Apt.3102	Jacksonvillie, FL 32206
RPT	52254	01/27/2014	Shack, William Madison	01/14/1988	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	52255	01/27/2014	Faust, Sandra Wetherell	10/01/1955	Other	University Of Florida College Of Pharmacy	201 South Clark Ave	Tampa, FL 33609
RPT	52256	01/27/2014	Greenfield, Jason Wade	02/26/1975	Other	University Of Florida College Of Pharmacy	229 Sw 25Th Avenue	Cape Coral, FL 33991
RPT	52257	01/27/2014	Cline, Robin Marie	09/02/1964	Other	Everest Universary	2308 Morning Glory Dr	Orlando, FL 32809
RPT	52258	01/27/2014	Scott, Sharisse Robin	10/02/1990	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52259	01/27/2014	Duffy, Dawn	12/06/1964	Cvs Caremark		13201 Country Road 200	Oxford, FL 34484
RPT	52260	01/27/2014	Bustillo, Sindy Elizabeth	05/28/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52261	01/27/2014	Wilkinson, Garrett Steven	10/11/1993	Walgreens		3416 3416 S Windingpath	Inverness, FL 34450
RPT	52262	01/27/2014	Dame, Scott J	09/30/1981			95 S. Us Hwy 1	Jupiter, FL 33477
RPT	52263	01/27/2014	Cheek, Neelie Rene	11/02/1993			1780 Ne Jensen Bch Blvd	Jensen Beach, FL 34957
RPT	52264	01/27/2014	Saran, Aman	08/13/1992	Cvs Caremark		5933 Nw 126Th Terrace	Coral Springs, FL 33076
RPT	52265	01/27/2014	Nichols, Lauren	07/20/1993	Walgreens		3727 Austin Range Dr	Land O Lakes, FL 34639

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RPT	52266	01/27/2014	Mendez, Jose Manuel	09/17/1990	Walmart And Sam'S Club Pharmacies		1600 Nw 33Rd St Lot 47	Pompano Beach, FL 33064
RPT	52267	01/27/2014	Ackerman, Ronald	10/03/1976	Cvs Caremark		6176 Coverty Place	Vero Beach, FL 32966
RPT	52268	01/27/2014	Campbell, Leisha Gaye	09/21/1975	Walgreens		1995 Erving Circle	Ocoee, FL 34761
RPT	52269	01/28/2014	Minaya, Rangel Eliezer Jr	08/28/1993	Other	Everest University Brandon Campus	6213 Gondola Drive	Riverview, FL 33578
RPT	52270	01/28/2014	Porteous, Carissa Candace	11/16/1992	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	52271	01/28/2014	Pope, Veija Pavielle	11/23/1984			7400 Powers Ave Apt 455	Jacksonville, FL 32217
RPT	52272	01/28/2014	Killoren, Jayme Lynn	01/01/1986			23026 Pcb Pr Kwy	Panama City Beach, FL 32413
RPT	52273	01/28/2014	Rowe, Matthew R	03/16/1993	Publix Super Market, Inc.		17184 Se 155Th Ave	Weirsdale, FL 32195
RPT	52274	01/28/2014	Morse, Dennis Lee	12/22/1964			283 S.W Bay Dr.	Lake City, FL 32025
RPT	52275	01/28/2014	Mccarthy, Kaitlin Alyssa	02/23/1995	Walgreens		1925 Providence Blvd	Deltona, FL 32725
RPT	52276	01/28/2014	Jackson, Brandy Elenda	09/14/1978	Other	Everest University	3696 Tomlin Drive	Cocoa, FL 32926
RPT	52277	01/28/2014	Mikes, Chantel	09/16/1985	Walgreens		614 Tamarin Lane	Kissimmee, FL 34759
RPT	52278	01/28/2014	Fernandez, Juliet	02/04/1976	Other	Palm Ave Pharmacy Discount	219 Sw 8 Ave	Miami, FL 33130
RPT	52279	01/28/2014	Persad, Shivanand Vijay	02/16/1992	Cvs Caremark		10000 W Commercial Blvd	Sunrise, FL 33351
RPT	52280	01/28/2014	Nalefski, Shannon Kay	09/19/1975	Walgreens		9150 Kings Crossing	Fort Myers, FL 33912
RPT	52281	01/28/2014	Maqueira, Tomasa	08/28/1969	Hialeah Adult Education Center		2435 W 6Th Ct Apt#8 2435 W 6Th Ct #8	Hialeah, FL 33010
RPT	52282	01/28/2014	Raymond, Ashleyy Skyy	06/28/1995	Cvs Caremark		2312 Weston Point Dr Apt. 413	Orlando, FL 32810
RPT	52283	01/28/2014	Spradley, Carolyn Ann	01/22/1964	Cvs Caremark		410 W. Oakdale Ave	Deland, FL 32720
RPT	52284	01/28/2014	Jack-Davis, Murissa T	05/20/1975	Other	Ultimate Medical Academy	4747 West Waters Ave Apt 2915	Tampa, FL 33614
RPT	52285	01/28/2014	Samedi, Lukagea	05/12/1990		Miami Dade College	420 Nw 84Th St Apt E23	Miami, FL 33150
RPT	52286	01/28/2014	Torres, Elizabeth	10/29/1987		Miami Dade College	3655 S. Dixie Hwy	Miami, FL 33133
RPT	52287	01/28/2014	Anderson, Jolan Diandra	09/15/1989	Other	Barry University School Of Adult And Continuing Education	6834 Aliso Avenue	West Palm Beach, FL 33413

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RPT	52288	01/28/2014	Townsend, Emily Michelle	12/26/1994	Publix Super Market, Inc.		19221 North Dale Mabery	Lutz, FL 33548
RPT	52289	01/28/2014	Woolington, Alexander James	12/30/1988	Cvs Caremark		615 Clematis Rd	Venice, FL 34293
RPT	52290	01/28/2014	La Plante, Mary Raquel	11/27/1985	Other	Everest Univeristy	3940 55Th St. N. Apt. 103	St. Petersburg, FL 33709
RPT	52291	01/28/2014	Koerber, Jackie Therese	01/10/1990	Walgreens		45076Th Ave N Apt 210	St.Petersburg, FL 33702
RPT	52292	01/28/2014	Ward, Liz	09/22/1966	Cvs Caremark		3520 East Laurel Road	Venice, FL 34275
RPT	52293	01/28/2014	Didonato, Maridith	06/05/1990	Cvs Caremark		4090 Tamiami Trail	Venice, FL 34293
RPT	52294	01/28/2014	Gonzalez, Vivian	11/29/1970	Other	Fortis College	14612 Sw 38Th St #16	Miami, FL 33175
RPT	52295	01/28/2014	Schoening, Whitney Shianne	03/28/1992	University Of Florida		5235 Cr 125	Lawtey, FL 32058
RPT	52296	01/28/2014	Flood, Brigid	08/10/1977	Other	Everest University	931 Balaye Ridge Cir Apt 202	Tampa, FL 33619
RPT	52297	01/28/2014	Toro, Karelyz	03/09/1964	Miami Sunset Adult Education Center		6276 18Th St. S	West Palm Beach, FL 33415
RPT	52298	01/28/2014	Diaz, Sherilet	12/22/1993	Other	New York Medical Career Center	14020 Biscayne Blvd Apt 204	North Miami Beach, FL 33181
RPT	52299	01/28/2014	Shaffren, Jeffrey Evan	03/15/1991	Publix Super Market, Inc.		5200 Sw 34Th St.	Gainesville, FL 32608
RPT	52300	01/28/2014	Hatmaker, Rachel Nicole	07/17/1994			4219 Ewell Street	Pace, FL 32571
RPT	52301	01/28/2014	Varner, Sandra Lynn	01/09/1969	Other	Osco Pharmacy/National Healthcareer Association	2132 Sw 15Th St	Cape Coral, FL 33991
RPT	52302	01/28/2014	Salas Navarro, Yudania	06/20/1979	Other	Everest Institute	10100 Sw 46 St	Miami, FL 33165
RPT	52303	01/29/2014	Daniels, Victoria Renee	10/31/1967	Cvs Caremark		9541 103Rd St #220	Jacksonville, FL 32210
RPT	52304	01/29/2014	Felo, Ahmed	07/04/1993	Walmart And Sam'S Club Pharmacies		201 South Chickasaw Trail	Orlando, FL 32825
RPT	52305	01/29/2014	Caamano, Bhryana Cathryn	04/13/1994	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	52306	01/30/2014	Kemper, Heather Lynne	07/16/1992	Cvs Caremark		164 22Nd Avenue	Apalachicola, FL 32320
RPT	52307	01/30/2014	Landeta, Philip Alexander	04/11/1989	Cvs Caremark		5357 Ehrlich Road	Tampa, FL 33625
RPT	52308	01/30/2014	Pettrey, Ronalda Jeanne	04/30/1959	Walmart And Sam'S Club Pharmacies		17030 Us Hwy 441	Mount Dora, FL 32757

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RPT	52309	01/30/2014	Monzon, Tania	08/21/1966	Miami Sunset Adult Education Center		2498Sw 17 Ave Apt 4311	Miami, FL 33145
RPT	52310	01/30/2014	Lopez, Mariano Lazaro	02/02/1966	Miami Sunset Adult Education Center		2498 Sw 17 Ave. Apt 4311	Miami, FL 33145
RPT	52311	01/30/2014	Martinez, Aniat	09/30/1969	Miami Sunset Adult Education Center		223 Sidonia Ave Apt.#6	Coral Gables, FL 33134
RPT	52312	01/30/2014	Leal Lopez, Ida Maria	03/29/1968	Miami Sunset Adult Education Center		6851 Sw 129Th Ave Apt 6 6851 Sw 129Th Ave Apt 6	Miami, FL 33183
RPT	52313	01/30/2014	Miller, Saralynne Cecelia	07/08/1987	Walgreens		720 N Dove Pt	Crystal River, FL 34429
RPT	52314	01/30/2014	Gibbons, Icy Katrese	11/28/1977	Other	Everest University	1404 S.Deleon Ave Apt 21	Titusville, FL 32780
RPT	52315	01/30/2014	Thibodeau, Kristy	04/04/1984	Cvs Caremark		2221 Pomeroy Rd	Spring Hill, FL 34609
RPT	52316	01/30/2014	Vukan, Kelly Marie	01/18/1991	Kash N' Karry Food Stores, Inc		1486 Loman Court	Palm Harbor, FL 34683
RPT	52317	01/30/2014	Scotto, Angelica Sarah	09/06/1986	Publix Super Market, Inc.		1809 Hazelwood Dr	Fort Pierce, FL 34982
RPT	52318	01/30/2014	Sanchez, Daymis	04/24/1973		Ta Ta Pharmacy	3810 S W 8Th Street	Coral Gables, FL 33134
RPT	52319	01/30/2014	Saint-Louis, Farley	03/06/1991	Cvs Caremark		8901 Miramar Parkway	Miramar, FL 33025
RPT	52320	01/30/2014	West, Rubina	08/28/1979	Other	Bladen Community College	2833 Roosevelt Blvd, Apt 239	Clearwater, FL 33760
RPT	52321	01/30/2014	Haxton, Brian Matthew	01/04/1980	Other	Eberest University	1620 Sadigo St.	Palm Bay, FL 32909
RPT	52322	01/30/2014	Gamoneda, Fernando E	05/26/1975	Cvs Caremark		4415 East 9Th Ct	Hialeah, FL 33013
RPT	52323	01/30/2014	Puerto, Yuniel	09/29/1981	Miami Sunset Adult Education Center		300-76 Street Apt 12	Miami Beach, FL 33141
RPT	52324	01/30/2014	Escudero, Tatiana	06/22/1989	Cvs Caremark		8809 New Tampa Blvd	Tampa, FL 33647
RPT	52325	01/30/2014	Castillo, Diana J	05/09/1992	Other	Fortis College	10841 Sw 243 Ln	Homeastead, FL 33032
RPT	52326	01/30/2014	Dominguez, Yirermis Aida	12/08/1990	Ominicare, Inc.		38608 Alston Ave	Zephyrhills, FL 33542
RPT	52327	01/30/2014	Hernandez, Tiffany	04/01/1992	Other	Sanford Brown Tampa	8650 Boardwalk Path Drive Apt 1011D	Temple Terrace, FL 33637
RPT	52328	01/30/2014	Chhotalal, Manisha Mahendra	09/30/1986	Other	University Of Florida College Of Pharmacy	12807 Us Highway 301	Dade City, FL 33525
RPT	52329	01/30/2014	Guillen, Mayra Alejandra	11/17/1990			692 Sw Prima Vista Blvd	Port Saint Lucie, FL 34983
RPT	52330	01/30/2014	Borrero, Maria	04/04/1955	Miami Sunset Adult Education Center		6317 Sw 12Th St	West Miami, FL 33144

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	52331	01/30/2014	Aguilar, Lazara C	12/17/1991	Other	Professional Training Center	13271 Nw 8 St	Miami, FL 33182
RPT	52332	01/30/2014	Gordon, Glenroy Anthony Jr	03/15/1992	Other	Barry University	18245 Nw 68Th Ave Apt# 511	Hialeah, FL 33015
RPT	52333	01/30/2014	Vasquez, Heather Ann	03/17/1989	Concorde Career Institute		910 E. 19Th Ave Apt #1	Tampa, FL 33605
RPT	52334	01/30/2014	Sheppard, Rhyana Kaelon	10/17/1989	Cvs Caremark		5945 Us Hw 301 N	Ellenton, FL 34222
RPT	52335	01/30/2014	Castro, Natasha Nicole	09/19/1989	Other	Everest University	5028 Millenia Blvd Apt 207	Orlando, FL 32839
RPT	52336	01/30/2014	Soto, Alexandra Ivette	04/07/1992	Cvs Caremark		10623 Gibsonton	Riverview, FL 33578
RPT	52337	01/30/2014	Ferenczi, Erzsebet Krisztina	08/14/1955	University Of Florida		5250 Smithfield	Melbourne, FL 32934-7868
RPT	52338	01/30/2014	Cotton, Talandra La'Phonda	07/15/1988	Other	Everest University	5704 Wingate Drive	Orlando, FL 32839
RPT	52339	01/30/2014	Gonzalez, Sailin	03/27/1972	Miami Sunset Adult Education Center		19563Nw 62Pl Hialeah	Miami, FL 33015
RPT	52340	01/30/2014	Diaz, Jorge Luis	05/18/1973	Miami Sunset Adult Education Center		590 Sw 7 St #14	Miami, FL 33130
RPT	52341	01/30/2014	Chirinos, Hector Manuel	06/21/1987	Ace Pharmacy, Llc		1480 Nw 79Th Ave	Miami, FL 33126
RPT	52342	01/30/2014	Dukes, Amanda Lee	07/24/1979	Other	Ultimate Medical Academy	7486 Green Acres Road	Donalsonville, GA 39845
RPT	52343	01/30/2014	Herold, Emily Mclean	02/17/1993	Cvs Caremark		139 West Davis Boulevard	Tampa, FL 33606
RPT	52344	01/30/2014	Barbeito, Dayami E	07/27/1973	Miami Sunset Adult Education Center		2560 W 67 Pl Bldg 31 Apt 102	Hialeah, FL 33016
RPT	52345	01/31/2014	Morin Diaz, Enmanuel	09/20/1988	Other	Everest Institute	12870 Sw 14Th St	Miami, FL 33184
RPT	52346	01/31/2014	Mcneil, Trianna Nicole	04/18/1988	Other	Everest Institute	765 Nw 6Th St	Florida City, FL 33034
RPT	52347	01/31/2014	Nunez, Liset	01/08/1987	Miami Sunset Adult Education Center		10639 Sw 182 Street	Miami, FL 33157
RPT	52348	01/31/2014	Kimbrel, Dianna Lynn	01/05/1963	Other	Everest University	116 W. Cypress St.	Davenport, FL 33836
RPT	52349	01/31/2014	Hernandez, Rainoa	06/28/1972	Miami Sunset Adult Education Center		16900 Sw 79 Ct	Miami, FL 33157
RPT	52350	01/31/2014	Chustz, Cheryl	06/17/1977	Cvs Caremark		6800 Collier Blvd	Naples, FL 07899
RPT	52351	01/31/2014	Candido, Sergio	05/03/1964	Miami Sunset Adult Education Center		17100 North Bay Road # 1704	Sunny Isles, FL 33160
RPT	52352	01/31/2014	Fernandez, Jade Do	09/29/1982	Wal-Mart		1675 Nw Saint Luice West Blvd	Port Saint Luice, FL 34986

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RPT	52353	01/31/2014	Frison, Morghan Sharee	04/06/1995			4250 Phillips Highway	Jacksonville, FL 32207
RPT	52354	01/31/2014	Gonzalez, Juan Carlos	12/01/1986	Cvs Caremark		7210 N Manhattan Ave 813	Tampa, FL 33614
RPT	52355	01/31/2014	Dawson, Ashlee Nicole	12/10/1989	Cvs Caremark		9716 W. Mcnab St.	Tamarac, FL 33321
RPT	52356	01/31/2014	Dominguez, Yanisey	05/27/1989	Other	Everest University	10801 Sw 88 St Apt#213	Miami, FL 33176
RPT	52357	01/31/2014	Denton, Mychal Vincent	10/07/1994	Publix Super Market, Inc.		7838 Gall Blvd	Zephyrhills, FL 33541
RPT	52358	01/31/2014	Hoodbhoy, Anum Baledina	09/27/1994	Other	Miami Lakes Technical Educational Center	19990 Nw 65Th Court	Miami, FL 33015
RPT	52359	01/31/2014	Reyes, Nancy Nathaly	04/02/1992		Homestead Jobs Corps	620 North H Street	Lake Worth, FL 33460
RPT	52360	01/31/2014	Ferrer, Cynthia Ivelisse	01/15/1977	Other	Everest University	653 Laurel Lake Cove # 105	Orlando, FL 32825
RPT	52361	01/31/2014	Wheeler, Katelyn Patricia	08/04/1987	Other	Heritage Institute	1437 Se 28Th Ter	Cape Coral, FL 33904
RPT	52362	01/31/2014	Villanueva, Nicole Jean	10/12/1993	Other	Miami Dade College	9661 N.W 46Th Lane	Doral, FL 33178
RPT	52363	01/31/2014	De Jesus Sanchez, Yomayra	06/24/1984	Other	Everest Institute	8240 Sw 149 Ct Apt#101	Miami, FL 33193
RPT	52364	01/31/2014	Eicher, Tawnya S	04/27/1983	Cvs Caremark		715 53Rd Terrace N	St.Petersburg, FL 33703
RPT	52365	01/31/2014	Davis, Devonte Lavon	07/27/1992	Pinellas County Job Corps Center		1810 Homestead St	Sebring, FL 33870
RPT	52366	01/31/2014	Falise, Gianna Rose	10/26/1995			10260 Reflections Blvd Apt #103	Sunrise, FL 33351
RPT	52367	01/31/2014	Doval, Carolina	07/24/1991	Ace Pharmacy, Llc		60 6000 East 2Nd Ave	Hialeah, FL 33013
RPT	52368	01/31/2014	Arguelles, Yuniali	06/11/1982	Other	Fortis College	7935 Sw 10Th Terrace	Miami, FL 33144
RPT	52369	01/31/2014	Scolari, Dustin Mitchell	11/27/1982		Virginia College - Pensacola	8211 Riverside Landing Ln.	Navarre, FL 32566
RPT	52370	01/31/2014	Gant, Brooke L	03/21/1990	Cvs Caremark		65 East Main Street	Apopka, FL 32703
RPT	52371	01/31/2014	Fultz, Patricia Ann	11/06/1993	Other	Everest University-Orange Park	46 Bluebell Avenue	Middleburg, FL 32068
RPT	52372	01/31/2014	Hobbs, Jason Edward	08/29/1983	Other	Everest University	2953 Southbank Circle	Green Cove Springs, FL 32043
RPT	52373	01/31/2014	Griffith, Jennifer Lynn	08/03/1992	Publix Super Market, Inc.		1035 Cove Landing Dr	Atlantic Beach, FL 32233
RPT	52374	01/31/2014	Brice, Yfigenie	01/07/1987	Other	Everest University	2820 W.Hardwood St	Orlando, FL 32805
RPT	52375	01/31/2014	Bhagroo, Jason Tushtanand	04/07/1991	Other	Everest University	5710 Riviera Dr	Orlando, FL 32808

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RPT	52376	01/31/2014	Gallman, Keyanna Marshee	03/12/1991	Other	Everest University	5704 Perrine Road	Orlando, FL 32808
RPT	52377	01/31/2014	Gordon, Alicia R	01/28/1968	Other	Airforce	5464 Club Circle	Haverhill, FL 33415
RPT	52378	01/31/2014	Desormot, Johnathan Eric	02/05/1990	Other	Barry University	14040 Biscayne Blvd Apt 801	North Miami, FL 33181
RPT	52379	01/31/2014	Economos, Joan Marie	10/11/1988			40932 Us Hwy 19 N	Tarpon Springs, FL 34689
RPT	52380	02/03/2014	Ortega, Ada	08/24/1965	University Of Florida		800 East Hallandale Beach Blvd	Hallandale, FL 33009
RPT	52381	02/03/2014	Iglesias, Dorkis	03/02/1994	Vivi Pharmacy, Llc		902 Sw 65 Ave	Miami, FL 33144
RPT	52382	02/03/2014	Michalak, Lindsey Marie	10/26/1990	Trinity Pharmacy Inc		6060 67Th Ave N	Pinellas Park, FL 33781
RPT	52383	02/03/2014	Lakuriqi, Marsel	07/06/1976	Wal-Mart		41232 Us Hwy 19 North	Tarpon Springs, FL 34689
RPT	52384	02/03/2014	Martinez, Manuel	09/14/1992	Walgreens		1050 Nw 44Th Avenue	Miami, FL 33126
RPT	52385	02/03/2014	Ocaranza, Fernando M	07/26/1994	Vivi Pharmacy, Llc		1610 Sw 92 Place 1610 Sw 92 Nd Place	Miami, FL 33165
RPT	52386	02/03/2014	Brown, Kutana Lafaye	12/10/1975	Other	Ultimate Medical Academy	5718 Nw Us Hwy 41	Jasper, FL 32052
RPT	52387	02/03/2014	Thibeaud, Michele R	05/05/1992	Other	Fortis Institute	2042 Nw 55Th Way	Lauderhill, FL 33313
RPT	52388	02/03/2014	Stewart, Katrina Lynn	09/11/1980	Other	Everest University	134 11Th St. W.	Winter Haven, FL 33880
RPT	52389	02/03/2014	Audet, Rachel Ann	05/29/1986	Other	Sanford Brown Institute	4639 Executive Meadows Dr	Plant City, FL 33567
RPT	52390	02/03/2014	Sanfratello, Donna Jean	07/10/1970	Other	Everset University	267 Victory Avenue	Davenport, FL 33837
RPT	52391	02/03/2014	Velasquez, Adrian Edward	03/25/1970	Everest University-Pompano Beach		235 Canis Drive West	Orange Park, FL 32073
RPT	52392	02/03/2014	Suarez, Jennifer	10/05/1980	Walgreens		13921 Sw 122 Ave, Apt 207	Miami, FL 33186
RPT	52393	02/03/2014	Fortner, Crystal	04/16/1987	Other	Everest University	2541 S. Semoran Blvd Apt1732	Orlando, FL 32822
RPT	52394	02/03/2014	Rivera, Chantelle Jenna	08/13/1991	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52395	02/04/2014	Cunningham, Carol	07/15/1958	Cvs Caremark		1020 1020 Partridge Cir. #101	Naples, FL 34104
RPT	52396	02/04/2014	Batson, Demetrius Antoine	07/28/1982	Other	Everest University Largo	4301 28Th Street North Apt 206	Saint Petersburg, FL 33714
RPT	52397	02/04/2014	Gardner, Patrick James	10/01/1991	Publix Super Market, Inc.		2875 University Blvd West	Jacksonville, FL 32217

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RPT	52398	02/04/2014	Hardy, Jannette	09/07/1963	Cvs Caremark		11020 Vanderbilt Drive	Naples, FL 34108
RPT	52399	02/04/2014	Burandt, Kayla Lynn	07/15/1994	Publix Super Market, Inc.		11977 Southern Blvd	Royal Palm Beach, FL 33411
RPT	52400	02/04/2014	Silva, Gisela	03/15/1989	Cvs Caremark		11817 11817 Sw 123 Ave	Miami, FL 33186
RPT	52401	02/04/2014	Roman, Melissa S	10/06/1988	Cvs Caremark		32 Wood Amber Lane Unit #A	Palm Coast, FL 32164
RPT	52402	02/04/2014	Rodriguez, Karla Michelle	10/31/1984	Other	Everest Institute	17004 Sw 119 Pl	Miami, FL 33177
RPT	52403	02/04/2014	Patz, Karen M	10/19/1963	Other	Everest University	298 Tarpon Lane	Oldsmar, FL 34677
RPT	52404	02/04/2014	Washington, Leroy Lamont	02/11/1961	Other	Everest Institute	26463 Sw 135Th Ct	Homestead, FL 33032
RPT	52405	02/04/2014	Padgett, Lindsay Nicole	01/27/1987	Other	Tennessee College Of Applied Technology Livingston	7135 7135 Sw 13Th St	Okeechobee, FL 34974
RPT	52406	02/04/2014	Knowles, Jessica Latrice	03/08/1994	Cvs Caremark		3580 North Federal Highway	Lighthouse Point, FL 33064
RPT	52407	02/04/2014	Larrea, Camila	05/30/1994	Publix Super Market, Inc.		10520 Marsh Street	Wellington, FL 33414
RPT	52408	02/04/2014	Rosero-Romero, Miriam	01/20/1967	Publix Super Market, Inc.		9755 Nw 41 Street	Doral, FL 33178
RPT	52409	02/04/2014	Martinez, Berta Lymarie	10/27/1976	Other	Everest University	7849 Hidden Hollow Drive	Orlando, FL 32822
RPT	52410	02/04/2014	Patel, Birvaben M	10/15/1984	Walgreens		1947 Big Cypress Drive	Saint Cloud, FL 34771
RPT	52411	02/04/2014	Matthews, Jason	02/14/1975	Florida Health Care Plans-Deland		309 Palm Coast Parkway Ne 86 Brockton Lane	Palm Coast, FL 32137
RPT	52412	02/04/2014	Symons, Alexis Nichole	07/17/1995	Publix Super Market, Inc.		695 Sw Stillman Ave	Port Saint Lucie, FL 34953
RPT	52413	02/04/2014	Hunt, Shayna Jalon	09/10/1981	Target Pharmacy		7951 Nolpark Ct	Glen Burnie, MD 21061
RPT	52414	02/04/2014	Harper, Donald Lamont	09/08/1974	Other	Sanford-Brown Institute Jacksonville	10566 Briarcliff Road East	Jacksonville, FL 32218
RPT	52415	02/04/2014	Sahab, Susan	10/05/1989	Cvs Caremark		9202 N Florida Ave	Tampa, FL 33612
RPT	52416	02/04/2014	Stegall, Floyd J	05/07/1963	Other	Sanford Brown Institute	14 Ave 2601 Ne 14Th Avenue #408	Oakland Park, FL 33334
RPT	52417	02/04/2014	Reyes, Jeannie	01/10/1972	Other	Technical Education Center Osceola	1044 La Mirada Court	Kissimmee, FL 34744
RPT	52418	02/05/2014	Monath, William Joel	06/18/1988	Cvs Caremark		109 Clark Ct	Youngsville, NC 27596
RPT	52419	02/05/2014	Jean-Baptiste, Naika	04/11/1992	Other	Fortis Institute	4248 Nw 38Th Ave	Laudredale Lakes, FL 33309

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RPT	52420	02/05/2014	Osorio Sierra, Susan N	04/07/1989	Other	Fortis College	2970 Nw 95Th Street	Miami, FL 33147
RPT	52421	02/05/2014	Raza, Adnan	06/08/1980			6923 Lee Vista Blvd	Orlando, FL 32822
RPT	52422	02/05/2014	Adeogun, Daniel K	08/26/1961	Walgreens		8337 South Park Circle	Orlando, FL 32819-9049
RPT	52423	02/05/2014	Bolte, Vanessa	02/07/1989	Publix Super Market, Inc.		5380 Stadium Parkway	Rockledge, FL 32955
RPT	52424	02/05/2014	Hess, Sonia Leah	02/10/1969	University Of Florida		4915 Oakway Drive	Saint Cloud, FL 34771
RPT	52425	02/05/2014	Haynes, Wendy Shalaya	11/01/1989			10521 Maidstone Cove Dr.	Jacksonville, FL 32218
RPT	52426	02/05/2014	Gonzalez, Ronny Ramon	12/04/1991		Fpa	3810 S W 8Th Street	Coral Gables, FL 33134
RPT	52427	02/05/2014	Abolarin, Zabrina Yetunde	06/17/1996		Broward County School Board	5410 Lyons Rd Apt 206	Coconut Creek, FL 33073
RPT	52428	02/05/2014	Gillispie, Joshua Alexander	05/26/1992	Cvs Caremark		5905 Us Highway 301 South	Riverview, FL 33569
RPT	52429	02/05/2014	Frazier, William Robert	12/03/1953		Concorde Career Inst Tampa	35438 Holmes St	Webster, FL 33597
RPT	52430	02/05/2014	Bale, Jenna Nicole	05/04/1990	Publix Super Market, Inc.		2419 Thomas Drive	Panama City Beach, FL 32408
RPT	52431	02/05/2014	Valle, Chris L	08/22/1984	Other	Technical Education Center Osceola	11640 Blackmoor Drive	Orlando, FL 32837
RPT	52432	02/06/2014	Lovett, Ashley Christina	12/19/1993	Walgreens		3851 4Th St N	St Petersburg, FL 33703
RPT	52433	02/06/2014	Celestin, Brenda	12/05/1993	Cvs Caremark		17270 68Th St N	Loxahatchee, FL 33470
RPT	52434	02/06/2014	Schlipf, Megan Denise	10/04/1991	Other	Everest University	45 Tower Manor Drive	Auburndale, FL 33823
RPT	52435	02/06/2014	Ruiz, Wilfredo	11/20/1964	Miami Sunset Adult Education Center		19801 Sw 110 Ct Apt 622	Miami, FL 33157
RPT	52436	02/06/2014	Ruiz, Priscilla	08/15/1994	Miami Sunset Adult Education Center		19801 Sw 110 Ct Apt 622	Miami, FL 33157
RPT	52437	02/06/2014	Reinoso, Courtney Nicole	06/29/1988		Miami-Dade College	18485 S Dixie Hwy	Cutler Bay, FL 33157
RPT	52438	02/06/2014	Beltran, Adriana M	01/31/1976			3990 Woodside Dr Apt 24	Coral Springs, FL 33065
RPT	52439	02/07/2014	Merritt, Ashlee Marie	12/02/1992	Walgreens		4497 Mobile Hwy	Pensacola, FL 32506
RPT	52440	02/07/2014	Crotte, Jesica	12/08/1973	Vivi Pharmacy, Llc		1610 Sw 92 Place	Miami, FL 33165
RPT	52441	02/07/2014	Cowgill, Taylor Ann	06/30/1993	Other	Indian River Adult And Community Education	112 Liberty Way	Fort Pierce, FL 34951
RPT	52442	02/07/2014	Head, Latasha Renee	03/07/1987	Everest University-Pompano Beach		943 S. Kirkman Road Apt 164	Orlando, FL 32811

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RPT	52443	02/07/2014	Curl, Stacey Amanda	02/04/1987	Cvs Caremark		9962 Baymeadows Rd.	Jacksonville, FL 32256
RPT	52444	02/07/2014	Garcia, Yamilet	09/07/1967	Miami Sunset Adult Education Center		19801 Sw 110 Ct Apt 622	Miami, FL 33157
RPT	52445	02/07/2014	Chamorro, Martha	02/24/1958	Hialeah Adult Education Center		2560 W 64 Place	Hialeah, FL 33016
RPT	52446	02/07/2014	Arias, Ilainner	12/25/1980	Miami Sunset Adult Education Center		677 Ne 26 St Apt 7	Miami, FL 33137
RPT	52447	02/07/2014	Flanagan, Sean Michael	09/29/1989	Walgreens		4706 Cohune Palm Courts	Greenacres, FL 33463
RPT	52448	02/07/2014	Aristazabal, Stephanie Y	10/10/1993	Other	Fortis College	17901 Nw 68Th Ave Apt # Q101	Hialeah, FL 33015
RPT	52449	02/07/2014	Chapman, Molly	07/22/1982	Other	Florida Gulf Coast University	2334B Risher Ct	Pensacola, FL 32507
RPT	52450	02/07/2014	Gardner, Jeffrey Brent	04/08/1964	Other	Florida Institute Of Technology	3960 Raney Road	Titusville, FL 32780
RPT	52451	02/07/2014	Guerra Garcia, Rayniel	07/25/1990	Other	Fortis College	500 Nw 36 Street Apt 107	Miami, FL 33127
RPT	52452	02/07/2014	Azua Belmonte, Gladys	02/27/1964	Other	Everest Institute	3231 Sw 89 Ct	Miami, FL 33165
RPT	52453	02/07/2014	Casanas, Idolidia	10/31/1965	Hialeah Adult Education Center		1871 West 62 St Apt. 223	Hialeah, FL 33012
RPT	52454	02/07/2014	Hernandez, Jennifer	08/14/1991	Other	Everest Institute	585 Se 8 Court	Hialeah, FL 33010
RPT	52455	02/07/2014	Giniebra, Doralis	06/30/1982	Miami Sunset Adult Education Center		10365North Kendalldr.Aptod-3	Miami, FL 33176
RPT	52456	02/07/2014	Atkins, Terrance Jamal	04/25/1990			100 South Ridgewood Ave	Daytona Beach, FL 32114
RPT	52457	02/07/2014	Garcia, Yenisley	08/31/1992	Other	Fortis College	7083 Sw 22Nd Street	Miami, FL 33155
RPT	52458	02/07/2014	Madera, Jessica	08/07/1986	Suddha Pharmacy, Llc		5712 Lime Rd	West Palm Beach, FL 33413
RPT	52459	02/07/2014	Jones, S Nichole	11/02/1986	Other	Rttp241	5580 96Th Terrace N	Pinellas Park, FL 33782
RPT	52460	02/07/2014	Grubb, Phillip Christopher	08/28/1989	Cvs Caremark		11 Pine Track Place	Ocala, FL 34472
RPT	52461	02/07/2014	Baker, Robert Alan	12/12/1955	Other	Cape Coral Institute Of Technology	1311 Clayton Ave	Lehigh Acres, FL 33972
RPT	52462	02/07/2014	Black, Natasha	08/07/1995			3580 N Federal Hwy	Lighthouse Point, FL 33064
RPT	52463	02/07/2014	Bishop, Mackenzie Leigh	11/20/1993			1024 Se 10 Street	Cape Coral, FL 33990

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RPT	52464	02/10/2014	Irving, Fabion	07/02/1992	Other	Heritage Insitute	6835 Santa Fe South Apt. 131	Labelle, FL 33935
RPT	52465	02/10/2014	Lawson, Garcia Petrina	10/11/1979			8738 Tierra Vista Cir #301	Kissimmee, FL 34747
RPT	52466	02/10/2014	Kaelin, Kristine Marie	06/05/1994			11977 Southern Blvd	Royal Palm Beach, FL 33411
RPT	52467	02/10/2014	Perez, Deysi	02/11/1968	Miami Sunset Adult Education Center		2122Sw 58Ave	Miami, FL 33155
RPT	52468	02/10/2014	Kamel, Mekhiel Ibrahim	05/04/1982			1431 Orange Camp Rd Suite #102	Deland, FL 32724
RPT	52469	02/10/2014	Kane, Jonathan Charles	02/24/1994	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52470	02/10/2014	Nelson, Sara	02/28/1966	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52471	02/10/2014	Ortt, Patrick Jay	11/22/1962	Concorde Career Institute		5214 Ne 6Th Ave #F3	Oakland Park, FL 33334
RPT	52472	02/10/2014	Ofori, Courtney Alexandra	04/12/1981	Other	Everest University North Orlando	151 Grand Junction Blvd	Orlando, FL 32835-1254
RPT	52473	02/10/2014	Paul, Brian	01/16/1992	Other	Sanford Brown Institute	7105 W Mcnab Rd	North Lauderdale, FL 33068
RPT	52474	02/10/2014	Jeune, Nadege L	11/03/1980	Everest University-Pompano Beach		116 856 Nw 116 Ter	Miami, FL 33168
RPT	52475	02/10/2014	Morales, Eglys	06/13/1986	Miami Sunset Adult Education Center		13533 Sw 63 Ln	Miami, FL 33183
RPT	52476	02/10/2014	Luebcke, Jeffrey Thomas	05/22/1988			1829 West Hillsboro Blvd	Deerfield Beach, FL 33442
RPT	52477	02/10/2014	Miranda, Alicia Catalina	04/16/1962	Other	Everest Institute	13730 Sw 276 St	Homestead, FL 33032
RPT	52478	02/10/2014	Jenkins, Ashley Nicole	11/29/1994	University Of Florida		3475 Hickory Landing Ct.	Jacksonville, FL 32226
RPT	52479	02/10/2014	Valera Fernandez, Mayra A	11/02/1963	Other	Everest Institute	5434 Nw 192 Lane	Miami Gardens, FL 33055
RPT	52480	02/10/2014	Stanko, Carlene	09/06/1990	Cvs Caremark		2336 Honolulu Ct	Jacksonville, FL 32246
RPT	52481	02/10/2014	Romero, Mitsy	12/01/1985	Cvs Caremark		9962 Baymeadow Drive	Jacksonville, FL 32256
RPT	52482	02/11/2014	Jean-Louis, Goby Widmaier	04/16/1991	Other	Everest University	599 Nw 48Th Ave	Delray Beach, FL 33445
RPT	52483	02/11/2014	Mansour, Sukinah Ghassan	04/04/1996			3007 W. Cypress St.	Tampa, FL 33609
RPT	52484	02/11/2014	Inostroza, Felipe Javier	04/19/1980	Other	Everest Institute	11332 Sw 69 Ln	Miami, FL 33173
RPT	52485	02/11/2014	Kristofik, Jamie	07/29/1979	Walgreens		80 Ponce De Leon Blvd	Brooksville, FL 34601

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RPT	52486	02/11/2014	O'Brien, Heather Lynn	07/04/1974	Walgreens		6506 Caroline St	Milton, FL 32570
RPT	52487	02/11/2014	Mayo, Elizabeth A	03/08/1988	University Of Florida		8816 Riverscape Way	Tampa, FL 33635
RPT	52488	02/11/2014	Schubert, Audra	06/11/1979	University Of Florida		2658 2658 Grande Isle Dr Apt 18110	Orange City, FL 32763
RPT	52489	02/11/2014	Ramos, Eddy A	10/10/1990	Cvs Caremark		7815 Regal Heron Cir Apt 301	Naples, FL 34104
RPT	52490	02/11/2014	Stanton, Tiffany Gail	10/19/1992	Winn Dixie		6600 N Socrum Loop Rd	Lakeland, FL 33809
RPT	52491	02/11/2014	Trumbull, Chelsea Lee	07/10/1992	Other	Sanford Brown-Tampa	10813 Venice Cir.	Tampa, FL 33635
RPT	52492	02/11/2014	Fore, Pamela Faye	01/13/1959			865 Hibernia Rd	Fleming Island, FL 32003
RPT	52493	02/11/2014	Cooper, Tracy Lee	07/26/1992			2709 Amsden Rd	Winter Park, FL 32792
RPT	52494	02/11/2014	Berdellans, Amanda Marie	02/18/1995			8814 Palafox Hwy	Pensacola, FL 32534
RPT	52495	02/11/2014	Fernandez, Lisset	11/30/1990			2013 Harding St	Hollywood, FL 33020
RPT	52496	02/11/2014	Cardona, Jeancarlos Gabriel	03/15/1992			185 Citrus Dr.	Kissimmee, FL 34743
RPT	52497	02/11/2014	Short, Brittney Amanda	09/29/1994	Cvs Caremark		475 15Th St Sw	Naples, FL 34117
RPT	52498	02/11/2014	St Juste, Mirth	05/21/1991	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52499	02/11/2014	Avalos, Monica	10/05/1984	Cvs Caremark		1253 1253 Eclair St	Lehigh Acres, FL 33974
RPT	52500	02/12/2014	Nguyen, Chau	11/11/1987	University Of Florida		429 S Primrose Drive	Orlando, FL 32803
RPT	52501	02/12/2014	Lundy, Aquila De'Nicka	10/09/1991			12387 Yellow Bluff Rd	Jacksonville, FL 32226
RPT	52502	02/12/2014	Penn, Magdalena B	05/30/1956	Other	Rassmussen College	2523 Lee Blvd.	Lehigh Acres, FL 33971
RPT	52503	02/12/2014	Oien, Lisa Renee	12/17/1987	Target Corporation		4305 Norfolk Parkway Suite 102	West Melbourne, FL 32904
RPT	52504	02/12/2014	Garcia, Iris	04/21/1971			93 Sw 80Th Avenue	Miami, FL 33144
RPT	52505	02/12/2014	Bardge, Kurtiss Delano	12/30/1985	Other	Everest University	1825 3Rd St. S.E.	Winter Haven, FL 33880
RPT	52506	02/12/2014	White, Andrew Layton Jr	01/22/1993			2180 W Nine Mile Rd	Pensacola, FL 32534
RPT	52507	02/12/2014	Saile, Dusty	04/10/1983	Other	Cape Coral Institute Of Technology	3316 Nw 6Th Terrace	Cape Coral, FL 33993
RPT	52508	02/12/2014	Hernandez, Sheila	05/04/1993			11400 W Flagler St Ste 109	Miami, FL 33174
RPT	52509	02/12/2014	Algarin, Christopher	04/10/1993			11936 Forest Hill Boulevard	Wellington, FL 33414

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RPT	52510	02/12/2014	Garcia, Natalie Rochelle	11/27/1991	Publix Super Market, Inc.		12231 East Colonial Dr	Orlando, FL 32826
RPT	52511	02/12/2014	Edwards, Gabriel Darius	04/14/1991	Other	Everest University	8022 8022 Sunvalley Drive	Jacksonville Florida, FL 32210
RPT	52512	02/12/2014	Gil, Maria	09/02/1967	Miami Sunset Adult Education Center		10225 Sw 24 Street Apt B 326	Miami, FL 33165
RPT	52513	02/12/2014	Fish, Amber M	11/15/1978	Publix Super Market, Inc.		3309 Ne 22Nd Ct	Ocala, FL 34479
RPT	52514	02/13/2014	Monroe, Doreen Ellice	12/31/1971	Other	Sullivan County Boces Monticello Ny	2476 Hassonite Street	Kissimmee, FL 34744
RPT	52515	02/13/2014	James, Caleb	07/10/1992	Walmart And Sam'S Club Pharmacies		7001 Nw 49Th Ct	Lauderhill, FL 33319
RPT	52516	02/13/2014	Lloyd, Christopher Scott	02/08/1990	Publix Super Market, Inc.		3101 Sw 34Th Ave #500	Ocala, FL 34474
RPT	52517	02/13/2014	Kathka, Christopher Paul	06/12/1978	Other	Everest University	3008 Savannah Way Apt # 206	Melbourne, FL 32935
RPT	52518	02/13/2014	Christensen, Michelle Nicole	10/04/1982	Other	Ultimate Medical Academy- License By The Board Of Independent	2708 2708 Acorn Court 102	Tampa, FL 33613
RPT	52519	02/13/2014	Stagliano, Nicholas James	08/27/1991	Cvs Caremark		4893 Town Center Parkway	Jacksonville, FL 32246
RPT	52520	02/13/2014	Watson, Anexstacia Thailene	09/16/1988	Other	Pharmacy Technicians University	1101 South Goldwyn Ave	Orlando, FL 32805
RPT	52521	02/13/2014	Sushil, Lori Lynn	07/04/1962	Cvs Caremark		5780 Airport Rd	Naples, FL 34105
RPT	52522	02/13/2014	Sumner, Ashlyn Margaret	12/10/1993	Cvs Caremark		25848 Holiday Dr	Astor, FL 32102
RPT	52523	02/14/2014	D'Amico, Nicole Marie	12/12/1990	Other	Everest University	3538 Beau Chene Dr	Kissimmee, FL 34746
RPT	52524	02/14/2014	Polton, Brittany Lee	07/11/1991			7062 41St Ter N	Saint Petersburg, FL 33709
RPT	52525	02/14/2014	Thomas, Chakahana Latrice	11/13/1984	Coopers Drug, Inc		306 Viola Ave	Panama City, FL 32404
RPT	52526	02/14/2014	Regueira, Ezequiel Emanuel	04/12/1993	Publix Super Market, Inc.		9104 Kentucky Day Ct	Gibsonton, FL 33534
RPT	52527	02/14/2014	Sammut, Alexander	11/28/1994	Cvs Caremark		37Ave 701 Nw 37 Ave	Cape Coral, FL 33993
RPT	52528	02/14/2014	Ford, Jasmyne A	06/18/1989	Other	Ultimate Medical Academy	4747 West Waters Avenue #3604	Tampa, FL 33614
RPT	52529	02/14/2014	Savary, Carey Anne	09/06/1988		People'S Pharmacy	4977 Us Hwy 98 N	Lakeland, FL 33809
RPT	52530	02/14/2014	Robbins, Charles Daniel	11/01/1978	Other	Fortis Institute	1109 Nw 30Th Street	Wilton Manors, FL 33311

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RPT	52531	02/14/2014	Redding, Ashley Renee	07/02/1983	Other	Columbus Technical College	305 A Kawamura Street	Fort Benning, GA 31905
RPT	52532	02/14/2014	Villena, Eva Elizabeth	08/22/1980		Global Medical & Technical Training School	2416 Nw 27Th Ave	Miami, FL 33144
RPT	52533	02/14/2014	Brome, Hal Alan	05/23/1958	A-1 Healthcare Academy, Inc.		2900 Idlewood Ave Apt 5	Richmond, VA 23221
RPT	52534	02/17/2014	Milne, Melanie Jean	07/23/1983	Ominicare, Inc.		6334 102Nd Terr N	Pinellas Park, FL 33782
RPT	52535	02/17/2014	Lopez, Conrad Albert	03/27/1960	Cvs Caremark		4747 Waters Ave Apt 211	Tampa, FL 33614
RPT	52536	02/17/2014	Perez, Cynthia	12/08/1992	Cvs Caremark		4914 Hall Rd	Immokalee, FL 34142
RPT	52537	02/17/2014	Mckenzie, Sean Luis	03/11/1992	Other	Pharmacy Technicians University	8761 Huntington Woods Circle North	Jacksonville, FL 32244
RPT	52538	02/17/2014	Westfall, Maria Theresa	07/14/1965	Walgreens		1402 Ohio Avenue	Lynn Haven, FL 32444
RPT	52539	02/17/2014	Nguyen, Thuy Thi	02/08/1994	Cvs Caremark		11670 Countryway Blvd	Tampa, FL 33626
RPT	52540	02/17/2014	Perez Chala, Martha Mayelin	07/06/1974			8145 N W 7Th St #216	Miami, FL 33126
RPT	52541	02/17/2014	Pridgen, Kimberly Dawn	11/16/1992			2300 Griffin Rd	Lakeland, FL 33810
RPT	52542	02/17/2014	Nguyen, Phuong-Anh Ngoc	11/16/1984	University Of Florida		12316 Woodleigh Ave	Tampa, FL 33612
RPT	52543	02/17/2014	Witte, Dennis Alan	03/14/1974	Other	Everest University	315 Lake Eloise Pointe Dr.	Winter Haven, FL 33880
RPT	52544	02/17/2014	Parrish, Nia A	07/24/1994			1937 W 24Th St	Jacksonville, FL 32209
RPT	52545	02/17/2014	Stolzenfeld, Amy Lynn	05/17/1985	Publix Super Market, Inc.		5656 Eagle Lake Dr	Palm Beach Gardens, FL 33418
RPT	52546	02/17/2014	Watson, April Burford	05/12/1976	Express Training Services, Llc		3793 Highway 4	Jay, FL 32565
RPT	52547	02/17/2014	Iturralde Dominguez, Yenisleydis	07/16/1986			4380 Sw 112 Ave	Miami, FL 33165
RPT	52548	02/17/2014	Janz, Tyler Allen	04/13/1991			3280 N. Tamiami Tr.	Port Charlotte, FL 33952
RPT	52549	02/17/2014	Spicer, Emily Alida Mary	03/21/1991	Express Training Services, Llc		58 Juniper Trak	Ocala, FL 34480
RPT	52550	02/17/2014	Kelleher, Brian Francis Jr	09/01/1984	Publix Super Market, Inc.		3604 W. Tyson Ave.	Tampa, FL 33611
RPT	52551	02/17/2014	Phan, Thu-Thuy	07/16/1972	V & T Pharmacy,Inc		4040 W Waters Ave Ste 105	Tampa, FL 33614
RPT	52552	02/17/2014	Manning, Christopher Bryan	08/10/1993	Publix Super Market, Inc.		1921 South Alafaya Trail Publix Supermarket	Orlando, FL 32828
RPT	52553	02/17/2014	Mccool, Barbara Ann	06/19/1954	Cvs Caremark		5561 Se Federal Highway	Stuart, FL 34997

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RPT	52554	02/17/2014	Joseph, Shama Fleurinord	06/24/1987	Cvs Caremark		10Th 2002 South 10Th Street Apt A	Fort Pierce, FL 34950
RPT	52555	02/17/2014	Talley, Keaondra S	07/29/1990	Cvs Caremark		3318 Nw 53 Street	Miami, FL 33142
RPT	52556	02/17/2014	Silveira, Jorge A	11/09/1965	Miami Sunset Adult Education Center		2601 Sw 122 Ave	Miami, FL 33175
RPT	52557	02/18/2014	Jones, Lavisa	06/02/1958	Cvs Caremark		4747 W.Waters Ave Apt 1608	Tampa, FL 33614
RPT	52558	02/18/2014	Leyva, Denisse	11/20/1986	Cvs Caremark		124 35Th Sq Sw	Vero Beach, FL 32968
RPT	52559	02/18/2014	Motley, Maria Lanay	09/15/1989	Cvs Caremark		7380 Davis Blvd	Naples, FL 34104
RPT	52560	02/18/2014	Kidd, Jon Michael	12/07/1987	Cvs Caremark		2909 Gulf To Bay Blvd Apt O204	Clearwater, FL 33759
RPT	52561	02/18/2014	Keys, Treniea Lashunta	05/14/1987			4507 Pageant Way	Orlando, FL 32808
RPT	52562	02/18/2014	Kleckley, Crystal Nicole	04/19/1984	Walgreens		4950 Midway Road	Fort Pierce, FL 34982
RPT	52563	02/18/2014	Key, Kim L	07/29/1973	Other	Ultimate Medical Academy	4903 Moses White Square	Tampa, FL 33610
RPT	52564	02/18/2014	Johnson, Tequila D	08/17/1992	Other	Ultimate Medical Academy	1909 E. Wilder Avenue	Tampa, FL 33610
RPT	52565	02/18/2014	Kemp, Zachary Brandon	10/14/1993			4407 Kissimmee Park Rd	Saint Cloud, FL 34772
RPT	52566	02/18/2014	Sims, Rachel	02/01/1994	Other	Na	912 Roseman Court	Orlando, FL 32811
RPT	52567	02/18/2014	Ramos, Kara Camille	02/17/1993	Walmart And Sam'S Club Pharmacies		3570 Sw Archer Rd	Gainesville, FL 32608
RPT	52568	02/18/2014	Stogdon, Brad Monroe	04/08/1991	Publix Super Market, Inc.		11250-4 Old St. Augustine Rd	Jacksonville, FL 32257
RPT	52569	02/18/2014	Thompson, Summer Fay	10/27/1990	Other	Florida State College At Jacksonville	7921 Normandy Blvd	Jacksonville, FL 32221
RPT	52570	02/18/2014	Whitt, Anjelica Elise	05/24/1993	University Of Florida		6635 Se 221 Street	Hawthorne, FL 32640
RPT	52571	02/18/2014	Shapiro, John Dee	01/31/1991	Cvs Caremark		901 N Main St	Gainesville, FL 32601
RPT	52572	02/18/2014	Giles, Shawnee Patrice	03/30/1962	Other	Everest University	1916 Nw 28Th St #1	Fort Lauderdale, FL 33311
RPT	52573	02/18/2014	Sullivant, Melissa Ann	09/19/1985	Other	Career Step	10808 10808 Creek Ridge Drive	Pensacola, FL 32506
RPT	52574	02/18/2014	Nichols, Kathleen Marie	10/29/1960			944 Bichara Blvd	Lady Lake, FL 32159
RPT	52575	02/18/2014	Cairns, Elaine Encarnacion	05/10/1975			10016 Pines Blvd	Pembroke Pines, FL 33024
RPT	52576	02/18/2014	Gutierrez, Ximena Milagros	11/07/1989			15584 Sw 43 Ter	Miami, FL 33185

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RPT	52577	02/18/2014	Moussa, Maha	06/22/1981	Publix Super Market, Inc.		2195 4Th Lane Sw	Vero Beach, FL 32962
RPT	52578	02/18/2014	Alonso, Midialys Ne'Lida	02/22/1975			11400 W Flagler St Unit 109-110	Miami, FL 33174
RPT	52579	02/18/2014	Lachmansingh, Frank Esmond	04/05/1966	Other	Pharmacy Technician Certification Board	17201 Pines Blvd	Pembroke Pines, FL 33029
RPT	52580	02/18/2014	Strahan, Joshua Leigh	06/03/1991	Other	Everest University	7291 Vassar Ave	Keystone Heights, FL 32656
RPT	52581	02/18/2014	Morehead, Savannah Grace Ann	10/03/1995	Hars Drugs Inc. Dba Family Drug Mart		7135 N Us Highway 1 6200 Allmont Street	Port St. John, FL 32927
RPT	52582	02/18/2014	Cardo, Olivia Brooke	03/13/1991			16560 N. Nebraska Ave	Lutz, FL 33549
RPT	52583	02/18/2014	Rodriguez, Martha Isabel	04/01/1982	Walgreens		2855 Sterling	Fort Lauderdale, FL 33312
RPT	52584	02/18/2014	Velazquez, Milene	10/23/1971	Aguilas International Medical Institute		3212 W. Cordelia St	Tampa, FL 33607
RPT	52585	02/18/2014	Reyes, Lisa Marie	11/24/1989	Usav Pharmaceutical Inc.		4280 Nw 21 Ave Apt 2	Oakland Park, FL 33309
RPT	52586	02/18/2014	Bonanno, Heather Lynn	09/04/1985			2094 W Us Hwy 90	Lake City, FL 32025
RPT	52587	02/18/2014	Stewart, Shakira Branie	06/18/1991	Other	Southeastern College	1349 Fairmont Street	Clearwater, FL 33755
RPT	52588	02/18/2014	Cook, Trent James	02/08/1991			16560 N. Nebraska Avenue	Lutz, FL 33549
RPT	52589	02/18/2014	Shreck, Carly Lynn	08/20/1990	Cvs Caremark		7810 Crosswater Trail Apt 5202	Windermere, FL 34786
RPT	52590	02/18/2014	Da Silva, Carolyne	10/25/1990	Walgreens		6003 14Th St W	Bradenton, FL 34207
RPT	52591	02/18/2014	Echeverri, Carolina	10/22/1984	Winn Dixie		281 Se Port Saint Lucie	Port Saint Lucie, FL 34953
RPT	52592	02/18/2014	Harned, Tiffany Anne	10/06/1980	Cvs Caremark		2873 Sw Port St Lucie Blvd	Port St. Lucie, FL 34953
RPT	52593	02/18/2014	Everett, Jessica Nicole	04/23/1989	Other	D.A. Dorsey Educational Center	1410 Nw 67St	Miami, FL 33147
RPT	52594	02/19/2014	Mcintosh, Rachel Lashaye	06/07/1984	Other	Everest University	4320 Summerlanding Drive Apt. 308	Lakeland, FL 33810
RPT	52595	02/19/2014	Mcalpin, Amanda Sue	05/13/1990	Walmart And Sam'S Club Pharmacies		3038 4Th St	Marianna, FL 32446
RPT	52596	02/19/2014	Lopez, Christian Humberto	04/27/1992	Publix Super Market, Inc.		4195 W. Lake Mary Blvd.	Lake Mary, FL 32746
RPT	52597	02/19/2014	Kaiuyum, Andrew	02/05/1991	Cvs Caremark		11212 Dale Mabry Hwy	Tampa, FL 33618

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RPT	52598	02/19/2014	Maali, Ali	05/08/1986			7932 W Sand Lake Rd Suite 301	Orlando, FL 32819
RPT	52599	02/19/2014	Brun, Rosie	10/26/1987	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52600	02/19/2014	Silva, Alicia Beatriz	01/27/1994	Shands At University Of Florida;Walgreens		9733 Doriath Circle	Orlando, FL 32825
RPT	52601	02/19/2014	Curry, Takina Nicole	06/29/1991	Other	Sanford-Brown Institute-Tampa	4221 E Okara Rd Apt A	Takina, FL 33617
RPT	52602	02/19/2014	Cantu, Brittany	07/17/1994	Wal-Mart		0959 2163 C W 48	Bushnell, FL 33513
RPT	52603	02/19/2014	Conlin, William E	05/29/1953	University Of Florida		4339 Tahitian Gardens Circle Apt H	Holiday, FL 34692
RPT	52604	02/19/2014	Gutierrez, Nasby	08/12/1992	Cvs Caremark		8Th 2780 Campbell Drive Ne	Homestead, FL 33033
RPT	52605	02/19/2014	Hamm-Johnson, Laurie L	07/29/1972			2703 N. Ponce De Leon Blvd	St Augustine, FL 32084
RPT	52606	02/19/2014	Jones, Mitchell Thomas	05/31/1993	Walgreens		1120 E University Ave	Gainesville, FL 32641
RPT	52607	02/19/2014	Phelps, Mallory Jayne	10/10/1987	Walgreens		12041 Palm Beach Blvd	Fort Myers, FL 33905
RPT	52608	02/19/2014	Patel, Kartik	11/13/1984	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52609	02/19/2014	Simmons, Jessica Renay	04/17/1987	Other	Everest University Jacksonville Fl	11501 Harts Rd Unit 1604	Jacksonville, FL 32218
RPT	52610	02/19/2014	Floyd, Kayla Elizabeth	02/23/1991	Kelson Drug, Inc.		3008 Jefferson St Suite B	Marianna, FL 32446
RPT	52611	02/19/2014	Drake, Apryl Lynn	06/20/1983	Other	Everest University	1697 Dockside Drive	Fleming Island, FL 32003
RPT	52612	02/19/2014	Tapia, Elizabeth	02/11/1993	Other	Sanford Brown Institute	1510 South 66Th Street	Tampa, FL 33619
RPT	52613	02/19/2014	Rivera, Brianna Jasmen	03/05/1993	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52614	02/19/2014	Roberts, Alison Lanell	01/21/1995	Cvs Caremark		2850 Ward Rd	Perry, FL 32348
RPT	52615	02/19/2014	Brooks, Tecara Victoria	05/08/1989	Walgreens		5207 Normandy Blvd	Jacksonville, FL 32205
RPT	52616	02/19/2014	Rawls, Sherelle Sade	02/10/1989		Fortis College - Orange Park	1570 Lane Ave S Apt 410	Jacksonville, FL 32210
RPT	52617	02/19/2014	Blas, Diana	04/10/1988	Cvs Caremark		2401 Sw 27Th Ave	Ocala, FL 34474
RPT	52618	02/19/2014	Ramirez, Esequiel Guadalupe	02/04/1992	South Dade Adult Education Center		35501 Sw 214Th Ave	Homestead, FL 33034
RPT	52619	02/19/2014	Hall, Bridgette Yevette	06/26/1972	Other	Pharmacy Technician University	1737 Messina Avenue	Orlando, FL 32811
RPT	52620	02/20/2014	Jean, Esther	02/07/1988			516 Sunset Dr. Apt #7	Orlando, FL 32805

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RPT	52621	02/20/2014	Keys, Zamia Briona	07/23/1993	Cvs Caremark		5801 Central Avenue	Saint Petersburg, FL 33710
RPT	52622	02/20/2014	Lopez, Betzaida	01/09/1972	Cvs Caremark		3005 State Road 504 W	Winter Haven, FL 33880
RPT	52623	02/20/2014	Mai, James Dai-Loc	08/17/1990	Cvs Caremark		435 E. Noble Ave	Williston, FL 32696
RPT	52624	02/20/2014	Nix, Georgia Ann	10/04/1971	Cvs Caremark		2215 Us Hwy 331 N	Defuniak Springs, FL 32433
RPT	52625	02/20/2014	Jimenez Del Pino, Evelyn	12/16/1969			10942 Sw 6Th St #2	Miami, FL 33174
RPT	52626	02/20/2014	Leyva Hardy, Elianne	07/21/1982			626 West 37Th Street	Hialeah, FL 33012
RPT	52627	02/20/2014	Ochoa Narante, Zoila L	08/29/1958			13200 Sw 5Th Street	Miami, FL 33184
RPT	52628	02/20/2014	Lacorte Rodriguez, Mahe	11/12/1975			4803 Nw 7Th St #409	Miami, FL 33126
RPT	52629	02/20/2014	Mantell, William-Joseph Wayne	01/18/1983			34909 Emerald Coast Pkwy	Destin, FL 32541
RPT	52630	02/20/2014	Oni, Damilola	03/11/1990	Walgreens		2201 2201 Columns Circle	Seminole, FL 33772
RPT	52631	02/20/2014	Omar, Stephen Ritchie	06/14/1991			840 Hyacinth Circle	Micco, FL 32976
RPT	52632	02/20/2014	Martinez, Yumisleidy	04/11/1988			1260 W 64 Terrace	Hialeah, FL 33012
RPT	52633	02/20/2014	Nelson, Sherly	10/05/1994	Other	Mci Institute Of Technology	6322 Pinestead Drive Apt 615	Lake Worth, FL 33463
RPT	52634	02/20/2014	Osorio Malave, Stephanie A	06/04/1989	Walmart And Sam'S Club Pharmacies		950 N University Dr	Coral Spring, FL 33071
RPT	52635	02/20/2014	Kaiser, Jordan Melanie-Lynn	07/09/1992			15 N Charles Richard Beall Blvd	Debary, FL 32713
RPT	52636	02/20/2014	Larsen, Cheryl-Lynn	10/29/1960	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52637	02/20/2014	Zalewski, Jade Marie	03/20/1992	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52638	02/20/2014	Reyes, Diana	03/16/1973	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52639	02/20/2014	Onyewu, Chikez	09/23/1965	Other	Kaiser Foundation Health Plan Technician Training Program	6312 Langdon Lane	Lanham, MD 20706
RPT	52640	02/20/2014	Paff, Reina Rachelle	03/31/1969	Other	Rasmussen College	8445 Sw Yellowtail Ct.	Stuart, FL 34997
RPT	52641	02/20/2014	Lobo, Judith	04/08/1990	Vivi Pharmacy, Llc		1610 Sw 92 Nd Place	Miami, FL 33165
RPT	52642	02/20/2014	Perez, Anais	07/11/1987	Other	Fortis College	6745 Sw 132Th Avenue Apt # 203	Miami, FL 33183
RPT	52643	02/20/2014	Pares, Rafael	11/02/1966	Other	Fortis College	21164 Sw 112Th Avenue Building # 3 Apt # 104	Cutler Bay, FL 33189

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	52644	02/20/2014	O'Brien, Kimberly Cox	05/25/1987	Cvs Caremark		2Nd St 3323 Se 2Nd Street	Ocala, FL 34471
RPT	52645	02/20/2014	Lau, Stephanie	07/26/1989	Cvs Caremark		1770 E Las Olas Blvd Apt 201	Fort Lauderdale, FL 33301
RPT	52646	02/20/2014	Resler, Jennifer Lynn	12/23/1992	Publix Super Market, Inc.		10185 Gate Pkwy N Apt. 909	Jacksonville, FL 32246
RPT	52647	02/20/2014	Cortez, Jessica Mae	12/15/1986			700 Sw 7 Terrace	Hallandale, FL 33009
RPT	52648	02/20/2014	Donk, Miguel Irvin	09/24/1982			17961 N W 2 Court	Miami, FL 33169
RPT	52649	02/20/2014	Talavera, Lianys	05/23/1982		Florida Education Institute	610 Nw 59Th Avenue	Miami, FL 33126
RPT	52650	02/20/2014	Dixon, Evelynne Janai	06/12/1989	Other	Florida State College At Jacksonville	Not Practicing In Florida P O Box 6320	Tallahassee, FL 32314-6320
RPT	52651	02/20/2014	Cole, Earl L Iii	05/31/1981	Cvs Caremark		3090 South Monroe St.	Tallahassee, FL 32301
RPT	52652	02/20/2014	Bauta Alfonso, Laura	09/18/1988	Other	Miami Dade College	1155 W 68Th St	Hialeah, FL 33014
RPT	52653	02/20/2014	Allen, Brittani Darlene	03/16/1991	Other	Everest University	2820 Caribbean Isle Boulevard Apt 413	Melbourne, FL 32935
RPT	52654	02/20/2014	Deliard, Edwine	06/07/1977	Ominicare, Inc.		3232 Nw 84Th Ave #328	Sunrise, FL 33351
RPT	52655	02/20/2014	Adelson, Harolde	11/10/1991	Cvs Caremark		4150 Looking Glass Lane Unit #3	Naples, FL 34112
RPT	52656	02/20/2014	Boodhoo, Kamloutie Nina	05/16/1961	Other	Westside Tech, Winter Garden - Orange County Public School	143 Blue Stone Circle	Winter Garden, FL 34787
RPT	52657	02/20/2014	Hart, Julie	11/15/1989	Walmart And Sam'S Club Pharmacies		1925 Jungle Road 1925 Jungle Road	New Smyrna Beach, FL 32168
RPT	52658	02/20/2014	Perez Fraga, Annet	09/03/1989	Other	Everest Institute	8751 Sw 43 Terr	Miami, FL 33165
RPT	52659	02/20/2014	Estoque, Rodrigo	09/13/1962	Publix Super Market, Inc.		4854 Sun City Center Blvd	Sun City Center, FL 33573
RPT	52660	02/20/2014	Barnett, Shalon	06/12/1977	University Of Florida		9313 9313 Mandrake Court	Tampa, FL 33647
RPT	52661	02/20/2014	Harris, Lyriss	08/02/1990	Cvs Caremark		317 Dr. Mlk Jr Memorial Road	Crawfordville, FL 32327
RPT	52662	02/20/2014	Ganesh, Savitri	12/10/1975	Other	Westside Tech	12337 Appomatox Dr	Orlando, FL 32837
RPT	52663	02/20/2014	Hayes, Jessie Ellen	05/25/1992	Wal-Mart		394 Pineview Dr	Venice, FL 34293
RPT	52664	02/21/2014	Bedward, Marcia Yvonne	05/01/1987	Wal-Mart		21 Sw 14Th Ave	Delray Beach, FL 33444
RPT	52665	02/21/2014	Castleberry, Meagan E	01/12/1995	Cvs Caremark		1514 Tradewinds Ave.	Lakeland, FL 33801
RPT	52666	02/21/2014	Blazier, Susan Jorgensen	09/12/1954	University Of Florida		5400 Brabrook Avenue	Grant, FL 32949

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RPT	52667	02/21/2014	Gomez, Roimer	08/03/1980	Miami Sunset Adult Education Center		677 Ne 26 St Apt 7	Miami, FL 33137
RPT	52668	02/21/2014	Bramwell, Nicole	03/16/1994	Cvs Caremark		18811 Annelis Drive	Lutz, FL 33548
RPT	52669	02/21/2014	Gohil, Kishan Subodh	12/07/1987	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52670	02/21/2014	Atwood, Stephen Sheldon Iii	08/18/1993	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52671	02/21/2014	Parker, Parris Alexis	06/20/1992	Shands Jacksonville Medical Center		5429 Shady Pine St S	Jacksonville, FL 32244
RPT	52672	02/21/2014	Capers, Helana Marie	05/19/1988	University Of Florida		6750 Ramona Blvd. Apt.149	Jacksonville, FL 32205
RPT	52673	02/21/2014	Adams, Chelsie Mishaye	01/04/1993	Cvs Caremark		2220 S. Us Hwy 1	Fort Pierce, FL 34950
RPT	52674	02/21/2014	Rosado - Cosme, Brendaliz	10/18/1977	Other	Na	10861 Windsor Walk Drive	Orlando, FL 32837
RPT	52675	02/21/2014	Ferrell, Brittney Nicole	08/03/1989	Other	West Side Tech	6251 Chancellor Drive	Orlando, FL 32809
RPT	52676	02/21/2014	Stoner, Sherry Lynn	09/21/1964	Walgreens		12807 Hwy 301	Dade City, FL 33525
RPT	52677	02/21/2014	Arnett, Jenifer Lynn	07/18/1982	Other	Ultimate Medical Academy	2901 Windsor Heigts St	Deltona, FL 32738
RPT	52678	02/21/2014	Sardina, Kristina Joy	03/02/1994	Other	University Of South Florida	1520 S Ohio Ave	Live Oak, FL 32064
RPT	52679	02/21/2014	Hartje, Frederick J	12/31/1976	Other	Everest University	265 Broyles Drive Se	Palm Bay, FL 32909
RPT	52680	02/21/2014	Best, Ryenn Alease	08/12/1991	Cvs Caremark		5317 Cartier Dr	Pensacola, FL 32507
RPT	52681	02/21/2014	Carbone, Melissa Marie	05/25/1985	Cvs Caremark		7930 Woodland Center Blvd Suite 500	Tampa, FL 33614
RPT	52682	02/21/2014	Garcia, Matthew Joel	02/21/1991	Other	Everest University	708 W Columbia Ave	Kissimmee, FL 34741
RPT	52683	02/21/2014	Garcia, Rosmery	12/22/1991	Other	Fortis College Cutler Bay	15476 Nw. 77Th. Ct. #143	Miami Lakes, FL 33016
RPT	52684	02/21/2014	Cunningham, Shanneka K	10/10/1992	Other	Fortis College	11100 Sw 197Th Street Apt # 220	Miami, FL 33157
RPT	52685	02/21/2014	Bolanos, Frank	08/04/1974	Other	Ultimate Medical Academy	8408 N. Packwood Avenue	Tampa, FL 33604
RPT	52686	02/21/2014	Welsh, Jacob David	04/08/1994		Fortis College - Orange Park	2270 Amarylis Ave	Middleburg, FL 32068
RPT	52687	02/21/2014	Reynolds, Brandon Keith	02/02/1993		Forits College - Orange Park	875 Westgate Dr.	Jacksonville, FL 32221
RPT	52688	02/21/2014	Thornton, Tremayne Antonion	03/04/1973		Forits College - Orange Park	6990 Camfield St	Jacksonville, FL 32222
RPT	52689	02/24/2014	Mays, Marquita Lynette	05/17/1984	Cvs Caremark		212 Madison Ave	Saint Marys, GA 31558

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RPT	52690	02/24/2014	Namin, Shahab Mansouri	09/11/1991			5555 W Atlantic Blvd	Margate, FL 33063
RPT	52691	02/24/2014	Martin, Pedro Luis	10/08/1986			2884 Tennis Club Dr #702	West Palm Beach, FL 33417
RPT	52692	02/24/2014	Martinez, Valmis	05/24/1982	Hialeah Adult Education Center		2595 W 12Th Ave Apt 4	Hialeah, FL 33010
RPT	52693	02/24/2014	Petrin, Sandra	03/03/1972	Publix Super Market, Inc.		33 Pope Ln	Palm Coast, FL 32164
RPT	52694	02/24/2014	Koch, Melanie	01/02/1955	1492 Pharma Group Corp.		5212 White Sand Circle Ne	Saint Petersburg, FL 33703
RPT	52695	02/24/2014	O'Brien, Mahalia Karen	05/09/1976	Walgreens		2301 S Congress Ave 1313	Boynton Beach, FL 33426
RPT	52696	02/24/2014	Mennenga, Kandace Ann	09/27/1971	Other	Rite Aid	5537 Gillot Boulevard	Port Charlotte, FL 33981
RPT	52697	02/24/2014	Lopez, Ivanna	10/18/1994	Other	Miami Lakes Educational Center	8861 Nw 196Th St	Hialeah, FL 33018
RPT	52698	02/24/2014	Fengarinas, Rebecca Aileen	04/03/1974	Publix Super Market, Inc.		15287 Coot Rd.	Brooksville, FL 34614
RPT	52699	02/24/2014	Echevarria, Melissa	03/10/1990	Other	Mci Institute Of Technology	5236 Cannon Way	West Palm Beach, FL 33415
RPT	52700	02/24/2014	Roth, Jared Scott	12/30/1991	Publix Super Market, Inc.		3525 Nw 14Th Avenue	Gainesville, FL 32605
RPT	52701	02/24/2014	Ralston, Nicole	06/21/1986	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52702	02/24/2014	Will, Thomas Frederick	02/18/1991	Publix Super Market, Inc.		36301 East Lake Road	Palm Harbor, FL 34685
RPT	52703	02/24/2014	Wilson, Jennifer Sable	11/26/1990	Cvs Caremark		815 Se Bayou Ave	Stuart, FL 34994
RPT	52704	02/24/2014	Valdez, Janelle	12/10/1994	Cvs Caremark		6708 Pomander Ave	New Port Richey, FL 34653
RPT	52705	02/24/2014	Woods, Earlyere Arnold	05/06/1959	Other	Ultimate Medical Academy	6535 North Blue Angel Pkwy	Pensacola, FL 32526
RPT	52706	02/24/2014	Robinson, Sri Imani	11/30/1991	Pinellas County Job Corps Center		528 88Th Ave. N. Apt. 2	St. Petersburg, FL 33702
RPT	52707	02/24/2014	Scott, Lacretia	09/22/1992	Pinellas County Job Corps Center		500 22Nd St S	St. Petersburg, FL 33712
RPT	52708	02/25/2014	Lawhorn, Kelsey M	06/17/1992	Publix Super Market, Inc.		1924 Pomegranate Court	Ocoee, FL 34761
RPT	52709	02/25/2014	Payne, Trinelle Melissa	10/05/1991	Cvs Caremark		143 Pine Rustle Lane	Auburndale, FL 33823

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RPT	52710	02/25/2014	Pelletier, Renee Adele	10/13/1988	Target Pharmacy		3599 W Hillsboro Blvd	Deerfield Beach, FL 33433
RPT	52711	02/25/2014	Oliva, Angelica Helen	09/11/1992			1750 W. 37Th St.	Hialeah, FL 33012
RPT	52712	02/25/2014	Pacheco, Jessica	03/11/1985	Other	Everest Institute	12743 Nw 98 Place	Hialeah Gardens, FL 33018
RPT	52713	02/25/2014	Mcdougle, Gianna Brenee	07/22/1994	University Of Florida		1141 Kendall Town Blvd. Apt.4211	Jacksonville, FL 32225
RPT	52714	02/25/2014	Koetzle, Danielle L	11/19/1992	Other	Ultimate Medical Academy	6263 93Rd Terrace #4201	Pinellas Park, FL 33782
RPT	52715	02/25/2014	Negron, Jonathan O	10/14/1991	Other	Ultimate Medical Academy	14879 Swallowtail Ct #101	Tampa, FL 33613
RPT	52716	02/25/2014	Deleva, Anthony Richard	10/02/1995	Cvs Caremark		11412 Royal Palm Blvd	Coral Springs, FL 33065
RPT	52717	02/26/2014	Mack-Stevenson, Jacqueline S	09/15/1977	Other	Sanford Brown Institute	9 9 Kings Circle	Brooksville, FL 34601
RPT	52718	02/26/2014	Matos, Elisandra	11/03/1989	Miami Sunset Adult Education Center		35 West 55 St	Hialeah, FL 33012
RPT	52719	02/26/2014	Pruitt, Alicia Bridgette	06/25/1983			8903 Glades Rd G13	Boca Raton, FL 33434
RPT	52720	02/26/2014	Jackson, Latisha Tonnise	10/10/1971			2605 Parkwood Drive	Brunswick, GA 31520
RPT	52721	02/26/2014	Leyva, Yuriam	07/26/1984			4742 West Flagler St	Miami, FL 33134
RPT	52722	02/26/2014	Merritt, Sylvia	12/14/1978	Cvs Caremark		732 Suncrest Loop Apt.208	Casselberry, FL 32707
RPT	52723	02/26/2014	Hastings, Ashley M	10/05/1991	Kash N' Karry Food Stores, Inc		4514 Edith St	New Port Richey, FL 34652
RPT	52724	02/26/2014	Jefferson, Andrea	08/16/1983	Cvs Caremark		9541 103Rd St Apt 1212	Jacksonville, FL 32210
RPT	52725	02/26/2014	Klee, Crystal Lynn	04/12/1984			8903 Glades Rd	Boca Raton, FL 33434
RPT	52726	02/26/2014	Nance, Cody Blue Jr	02/17/1993	University Of Florida		27348 Mistflower Dr	Wesley Chapel, FL 33544
RPT	52727	02/26/2014	Martinez, Genaya Ana	10/31/1977			14000 Us. 1	Juno Beach, FL 33408
RPT	52728	02/26/2014	Nunez, Yuranis	11/27/1987	Other	Professional Training Centers	12151 Sw 202 St. Apt2105	Miami, FL 33177
RPT	52729	02/26/2014	Anthony, Jordan Lauren	01/31/1995	Cvs Caremark		3617 3617 Old Dixie Why	Mims, FL 32754
RPT	52730	02/26/2014	Quiros-Barria, Jeziel A	09/22/1995	Other	Ultimate Medical Academy	5411 Tangerine Drive	Zephyrhills, FL 33542
RPT	52731	02/26/2014	Hedman, Helki	04/09/1982	Miami Sunset Adult Education Center		6460 Sw 129 Pl #1803	Miami, FL 33183
RPT	52732	02/26/2014	Saint Fleur, Betsey	08/10/1991	Cvs Caremark		5152 Sylvania Ave	North Port, FL 34291
RPT	52733	02/26/2014	Yhlen, Michelle Lynn	08/12/1992	Other	Everest University	621 621 Dubuque Ave	Palm Bay, FL 32909

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RPT	52734	02/26/2014	Scott-Jordan, Shanquria Denise	12/31/1990	Other	Everest University	1626 Flower Mound Lane Apt 3	Cocoa, FL 32922
RPT	52735	02/26/2014	Fredericksen, Maureen Anne	11/22/1956	Cvs Caremark		7563 Se Maricamp Rd	Ocala, FL 34472
RPT	52736	02/26/2014	Tiburcio, Jennifer	03/04/1991	Cvs Caremark		213 Mississippi Woods Lane	Orlando, FL 32824
RPT	52737	02/26/2014	Campbell, Sean Thomas	07/12/1990			808 North Cypress Ave	Green Cove Springs, FL 32043
RPT	52738	02/26/2014	Williams, Johntavia Andrea	07/20/1989	Cvs Caremark		1539 Bloomingdale Rd	Jacksonville, FL 32221
RPT	52739	02/26/2014	Barnhart, Deidre Nicole	07/13/1994			737 Mango Drive	West Palm Beach, FL 33415
RPT	52740	02/26/2014	Summerhays, Chase Alexander	02/05/1992	Other	Everest University Jacksonville	8450 Gate Parkway West Apt 1124	Jacksonville, FL 32216
RPT	52741	02/26/2014	Rosario, Angel Luis	05/05/1992	Walgreens		8505 N Campbell Road	Lakeland, FL 33805
RPT	52742	02/26/2014	Carner, Micheal Joseph	05/11/1983			1025 W. Fairbanks	
RPT	52743	02/26/2014	Simmons, Anterika M	05/01/1989	Other	Fortis College	27040 Sw 134Th Place	Naranja, FL 33032
RPT	52744	02/26/2014	Taylor, Rolando	03/02/1993	Other	Fortis College	12460 Sw 187Th Street	Miami, FL 33177
RPT	52745	02/26/2014	Vega, John N	03/03/1993	Other	Fortis College	21019 Sw 118Th Ave	Miami, FL 33177
RPT	52746	02/26/2014	Griggs, Shaunta S	02/27/1987			3065 Grandola Drive	Orlando, FL 32811
RPT	52747	02/26/2014	Alexander, Christopher Lee	04/01/1985			Box 140203	Gainesville, FL 32614
RPT	52748	02/26/2014	Scigliano, Genevieve Nicole	01/22/1991	Cvs Caremark		4651 Sw 74Th Ter	Davie, FL 33314
RPT	52749	02/26/2014	Arroyo, Audrey	07/26/1982			650 Se 28Th Pl Apt B	Ocala, FL 34471
RPT	52750	02/26/2014	Rymer, Meagan Lea	04/20/1978	Ominicare, Inc.		8603 Florida Mining Blvd.	Tampa, FL 33634
RPT	52751	02/26/2014	Aponte Rivera, Naiomi Marie	10/16/1990	Walgreens		3298 South John Young Parkway	Kissimmee, FL 34746
RPT	52752	02/27/2014	Ku, Baokou Elizabeth	03/04/1991			15602 North Dale Mabry Hwy	Tampa, FL 33618
RPT	52753	02/27/2014	Naranjo, Brianna Marie	01/13/1995	Cvs Caremark		148 6964 Sw 148Th Lane	Davie, FL 33331
RPT	52754	02/27/2014	Iannella, Sandra Lee	05/31/1980	Walgreens		961 Chatham Way	Palm Harbor, FL 34683
RPT	52755	02/27/2014	Miles, Samantha Kaye	04/16/1990			7827 Landolakes Blvd	Land O Lakes, FL 34638
RPT	52756	02/27/2014	Misra, Anita	05/15/1993	Publix Super Market, Inc.		3489 Laurel Mill Dr. 3489 Laurel Mill Dr.	Orange Park, FL 32065

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RPT	52757	02/27/2014	Lachmansingh, Janieta	12/09/1972	Cvs Caremark		11100 Pines Boulevard	Pembroke Pines, FL 33026
RPT	52758	02/27/2014	Lopez-Torres, Raiza Daliz	05/23/1987	Walgreens		10309 Bridlewood Ave	Orlando, FL 32825
RPT	52759	02/27/2014	Everson, Tyler James	12/18/1993	Walgreens		1947 Fruitville Rd.	Sarasota, FL 34236
RPT	52760	02/27/2014	Ramhit, Vishal Brandon	08/13/1990	Cvs Caremark		417 East Acre Dr	Plantation, FL 33317
RPT	52761	02/27/2014	West, Bonita	01/09/1958	Other	Everest Institute	5255 Nw 29 Avenue Apt. #507	Miami, FL 33142
RPT	52762	02/27/2014	Dufrane, Jessica L	03/20/1989	Other	Medical Instuite Of Palm Beach	803 Ridge Road Unit 1	Lantana, FL 33462
RPT	52763	02/27/2014	Schmitz, Cassandra L	09/06/1991	Other	Sanford Brown Institute Of Tampa	2213 Bodrick Circle Apt 102	Brandon, FL 33511
RPT	52764	02/27/2014	Zivkovic, Zvezdan	04/05/1988	Cvs Caremark		12750 S. Militarytrail	Boynton Beach, FL 33436
RPT	52765	02/27/2014	Smiley, Rashima A	08/28/1993		Fortis Institute - Palm Springs	4550 Lantana Rd.	Lake Worth, FL 33463
RPT	52766	02/27/2014	Melton, Tamara Leigh	12/20/1989	Walgreens		999 Sebastian Blvd	Sebastian, FL 32958
RPT	52767	02/27/2014	Beltramini, Megan Elizabeth	06/09/1985	Cvs Caremark		90 Regina Blvd	Beverly Hills, FL 34465
RPT	52768	02/27/2014	Hall, Matthew Lawton	08/06/1958			Box 67	Intercession City, FL 33848
RPT	52769	02/27/2014	George, Shatarra	04/09/1991	Walgreens		409 S. Lanier Rd.	Havana, FL 32333
RPT	52770	02/27/2014	Gonzalez Alvarez, Maritza	12/26/1963			8181 Nw South River Dr. Lot B-241	Medley, FL 33166
RPT	52771	02/27/2014	Brinley, Jean Marie	05/11/1964			5 Southern Cross Ln #106	Boynton Beach, FL 33436
RPT	52772	02/27/2014	Bruno, Robert Michael	02/05/1958			18 S Wadsworth Ave	Beverly Hills, FL 34465
RPT	52773	02/27/2014	Cunningham, Andrew Jon	10/10/1986	Other	Orange County Public Schools Winter Park Tech	5453 Lake Margaret Drive Unit F	Orlando, FL 32812
RPT	52774	02/27/2014	Atwell, Kaitlyn Ann	01/10/1992	Cvs Caremark		21 Pineapple Drive	Palm Coast, FL 32164
RPT	52775	02/27/2014	Hucher, Manouchka	02/05/1982	Other	Everest University	839 N Powerline Rd	Pompano Beach, FL 33069
RPT	52776	02/27/2014	Delgado, Ivette Vesquez	08/23/1983	Other	Sanford Brown	8164 Canterbury Lake Blvd	Tampa, FL 33619
RPT	52777	02/27/2014	Cremades, Javier D	01/02/1972	Hialeah Adult Education Center		2595 W 12Th Ave Apt 4	Hialeah, FL 33010
RPT	52778	02/27/2014	Hinton, Heather Christina	04/30/1986	Other	Seminole State College	8451 Milano Drive Apt 17-35	Orlando, FL 32810

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RPT	52779	02/27/2014	Ajavon, Kwame Lamar	03/31/1989	Other	Florida State College Of Jacksonville	800 Broward Road Apt E101	Jacksonville, FL 32218
RPT	52780	02/27/2014	Schwartz, Jessica Kristin	01/27/1995	University Of Florida		6025 Fiori Drive	Crestview, FL 32539
RPT	52781	02/27/2014	Arias, Jacklyn Tyler	04/12/1991	Walgreens		1005 South 19Th St	Fernandina Beach, FL 32034
RPT	52782	02/27/2014	Cardona, Janys	02/15/1986	Miami Sunset Adult Education Center		4608 Nw 195 St	Miami Garden, FL 33055
RPT	52783	02/27/2014	Best, Betty Jacquelyn	09/12/1961	Walgreens		8337 South Park Circle	Orlando, FL 32819
RPT	52784	02/27/2014	Friberg, Christa Gail	02/25/1986	Other	University Of Florida College Of Pharmacy	3580 Lake Center Dr Apt 2206	Mount Dora, FL 32757
RPT	52785	02/27/2014	Buckalew, Wanda Diane	04/29/1975	Cvs Caremark		1505 Booth Drive	Valrico, FL 33594
RPT	52786	02/28/2014	Pietila, Wendy Hamilton	06/25/1977	Walgreens		8337 South Park Cir	Orlando, FL 32819
RPT	52787	02/28/2014	Garcia, Argen Muriel	12/16/1987	Other	University Of Florida - College Of Pharmacy	10420 W Forest Hill Blvd	Wellington, FL 33414
RPT	52788	02/28/2014	Geisler, Jerry Ronald Jr	09/10/1952	Walgreens		3619 U.S. Hwy. 27 North	Sebring, FL 33872
RPT	52789	02/28/2014	Dapo, Vanesa Demirovic	07/09/1990	Walgreens		13300 Walsingham Rd. #65	Largo, FL 33774
RPT	52790	02/28/2014	Butruch, Rebecca	08/14/1989	Walgreens		3619 U.S. Hwy. 27 N.	Sebring, FL 33870
RPT	52791	02/28/2014	Baugher, Rebecca Dawn	10/28/1980	Walgreens		215 Cauley Lane	Bunnell, FL 32110
RPT	52792	02/28/2014	Burrows, Timothy Moreland	06/11/1973	Other	University Of Florida - College Of Pharmacy	13198 98Th Ave N	Seminole, FL 33776
RPT	52793	02/28/2014	Alindo, Darlene Jemimah De Jesus	10/28/1991	Publix Super Market, Inc.		4495 Roosevelt Blvd	Jacksonville, FL 32210
RPT	52794	02/28/2014	Ellis, Francis Martin Iii	07/28/1982	Walgreens		307 East Ridge Dr.	Eustis, FL 32726
RPT	52795	02/28/2014	Philbrook, Danielle Irene Margaret	12/16/1991			900 N. Robert Ave.	Arcadia, FL 34266
RPT	52796	02/28/2014	Munoz, Daniel	07/16/1988	Walgreens		1213 Palm Bay Rd Ne	Melbourne, FL 32905
RPT	52797	02/28/2014	Joseph, Ruthchelle	11/01/1988	Walgreens		120 221 N.W 120Th Street	Miami, FL 33168
RPT	52798	02/28/2014	Maynard, Tiffany Elena	07/01/1988	Walgreens		4747 Sw Collage Rd 200	Ocala, FL 34474
RPT	52799	02/28/2014	Ramirez, Thalia Z	07/18/1995	Cvs Caremark		12344 Se 86Th Ave	Belleview, FL 34420
RPT	52800	02/28/2014	Richard, Elizabeth Marilyn	12/11/1993	Other	Mcfatter Technical Center	3660 Birch Terrace	Davie, FL 33330

COMPAS DataMart Reporting System
New License Report for 2208 : Registered Pharmacy Technician
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Processed: 3/13/2014 6:41:57AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RPT	52801	02/28/2014	Evans, Crystal Tiffany	02/25/1986	Other	Sanford Brown Institute	2704 2704 Canal Rd.	Miramar, FL 33025
RPT	52802	02/28/2014	Letteri, Nicholas Stephen	05/17/1990	Walgreens		811 Fairway Cove Lane Unit 204	Bradenton, FL 34212
RPT	52803	02/28/2014	Bullock, Jessica	03/14/1979	Other	Sanford Brown Institute	2241 Fluorshire Drive	Brandon, FL 33511
RPT	52804	02/28/2014	Ivan, Reenu	10/04/1986	Walgreens		200 Southern Breeze Drive	Minneola, FL 34715
RPT	52805	02/28/2014	Fields, Imoni S	05/07/1991	Other	Sanford Brown Institute Tampa	5908 Trevors Way	Tampa, FL 33625
RPT	52806	02/28/2014	Menendez, Alexander	11/10/1982	Walgreens		126 Clifton Rd	Hollywood, FL 33023
RPT	52807	02/28/2014	Louis, Jenyce J	03/09/1990	Walgreens		2355 Ne 26Th Street	Fort Lauderdale, FL 33305
RPT	52808	02/28/2014	Nazario, Samantha	08/02/1993	Walgreens		17012 Worthington Circle	Mascotte, FL 34753
RPT	52809	02/28/2014	Lex, William	03/17/1955	Other	Pass Assured	2655 Gulf To Bay Blvd.	Clearwater, FL 33759
RPT	52810	02/28/2014	Nadella, Judith Jane	03/05/1956	Walgreens		2195 66Th Street	St Petersburg, FL 33710
RPT	52811	02/28/2014	Osoka, Mukhwanna Jahi	09/02/1992	Walgreens		2159 Nursery Rd	Clearwater, FL 33764
RPT	52812	02/28/2014	Cadin, Colleen Rose	07/21/1981	Walgreens		1200 Floral Springs Blvd Apt. 28107	Port Orange, FL 32129
RPT	52813	02/28/2014	Pepi, Christina Ashley	01/19/1995	Publix Super Market, Inc.		13 Rolling Place	Palm Coast, FL 32164
RPT	52814	02/28/2014	Uddin, Taj Abedin	11/03/1993		Winn-Dixie	4371 Johns Cemetery Rd	Middleburg, FL 32068
RPT	52815	02/28/2014	Ramrup, Bianca	04/03/1994	Other	First Coast Technical College	940 South Forest Creek Drive	St.Augustine, FL 32092
RPT	52816	02/28/2014	Nunez Sosa, Anay M	07/09/1987	University Of Florida		6901 Sw 147Th Avenue Apt 1B	Miami, FL 33193
RPT	52817	02/28/2014	Teel, Myra	01/28/1958	Pinellas County Job Corps Center		8545 East Yellow Leg Court	Inverness, FL 34450
RPT	52818	02/28/2014	Jones Vidal, Christina Marie	08/03/1988	Other	Everest University	4 Fir Trail Drive	Ocala, FL 34472

Total Records: **956**

Division of
Medical Quality Assurance

MQA

Processed: 3/13/2014 6:46:36AM

COMPAS DataMart Reporting System
New License Report for 2203 : Consultant Pharmacist
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PU	7370	01/06/2014	Barrett, Samantha S				3092 Marion Ave	Margate, FL 33063
PU	7371	01/06/2014	Williams, Patrick James				2308 Valdavia St.	Saint Augustine, FL 32092
PU	7372	01/08/2014	Kwiat, Hayley Victoria	06/30/1986			7195 State Road 70	Bradenton, FL 34203
PU	7373	01/10/2014	Das, Nivedita	06/24/1973			340 Bamboo Rd	Palm Beach Shores, FL 33404
PU	7374	01/13/2014	Radomski, Alex Anthony	05/21/1981			809 East Marion Avenue	Punta Gorda, FL 33950
PU	7375	01/15/2014	Ezenwa, Uchenna Chinenye				983 Sw 176 Terrace	Pembroke Pines, FL 33029
PU	7376	01/17/2014	Farag, Christine V				3753 Becontree Pl	Oviedo, FL 32765
PU	7377	01/22/2014	Pai, Sulbha Yogesh	05/10/1976			7081 Nw Turtle Walk	Boca Raton, FL 33487
PU	7378	01/22/2014	Jang, Jasmine Meesoon	10/18/1973			3530 Mystic Pointe Dr Apt #2708	Aventura, FL 33180
PU	7379	01/22/2014	Marten, Craig C				5340 Jubilee Way	Margate, FL 33063
PU	7380	01/23/2014	Eisenman, Melissa Kaye				686 Golden Beach Drive	Golden Beach, FL 33160
PU	7381	01/23/2014	Eisenman, Monica Lynn				686 Golden Beach Drive	Golden Beach, FL 33160
PU	7382	01/23/2014	Jampani, Rebecca Jean				3531 Boatwright Way W	Jacksonville, FL 32216
PU	7383	01/24/2014	Omole, Ramat Aderemi				1561 Sw 194Th Terrace	Pembroke Pines, FL 33029
PU	7384	01/28/2014	Inaganti, Sujay Kumar	08/15/1976			7410 Colbury Ave	Windermere, FL 34786
PU	7385	01/28/2014	Joseph, Jacinta Ann-Marie	12/23/1958			8723 Busch Oaks St	Tampa, FL 33617
PU	7386	01/30/2014	Agbi, Jequita T				2542 Cooper Way	Wellington, FL 33414
PU	7387	02/03/2014	Lopez, Jacquelyn L				10340 Nw 11 Street	Plantation, FL 33322
PU	7388	02/03/2014	Leader, Alexandra				416 Ne 7Th St Apt. B	Gainesville, FL 32601
PU	7389	02/04/2014	Tepe, Ashley N				665 Palm Dr	Satellite Beach, FL 32937
PU	7390	02/06/2014	Scholtz, Dana Cheri	10/10/1987			3850 Oakhill Drive	Titusville, FL 32780
PU	7391	02/14/2014	Munyon, Lindsay Marie	07/17/1989			2637 Stanmore Ct.	Orlando, FL 32817
PU	7392	02/14/2014	Tew, Tommy Lamar	07/30/1958			196 Derby Woods Dr	Lynn Haven, FL 32444
PU	7393	02/17/2014	Valentine, James William	09/03/1970			3554 Soft Breeze Circle	Melbourne, FL 32904

COMPAS DataMart Reporting System
New License Report for 2203 : Consultant Pharmacist
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Processed: 3/13/2014 6:46:36AM

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PU	7394	02/17/2014	Norwood-Williams, Carlette Elaine				5007 Bellflower Court	Melbourne, FL 32940
PU	7395	02/21/2014	Francis, Kamila Radonova	11/12/1970			17309 Sw 8Th Street	Pembroke Pines, FL 33029
PU	7396	02/21/2014	Willis, Monica Lee	10/23/1974			1758 Highland View Dr	Saint Augustine, FL 32092
PU	7397	02/24/2014	King, Jasmine Nicole	02/09/1980			2944 Minuteman Lane	Brandon, FL 33511
PU	7398	02/24/2014	Johnson, Keri Ann	11/27/1985			13401 Summerlin Rd	Fort Myers, FL 33919
PU	7399	02/26/2014	Lent, Amanda Gayle				2833 Columbus Ave	Clermont, FL 34715
PU	7400	02/26/2014	Carbone, Timothy Michael				5799 N W Allyse Dr	Port Saint Lucie, FL 34986
PU	7401	02/27/2014	Parrish, Kristen Marie	01/11/1976			814 Pheasant Run Ct West	Port Orange, FL 32127
PU	7402	02/27/2014	Shah, Ankit Piyushkumar	07/18/1979			1285 Talon Way	Melbourne, FL 32934
PU	7403	02/28/2014	Novoa, Tenim Sosa	07/07/1983			11904 Sw 13 Ct	Davie, FL 33325

Total Records: **34**

Division of
Medical Quality Assurance

MQA

Processed: 3/13/2014 6:47:22AM

COMPAS DataMart Reporting System
New License Report for 2204 : Nuclear Pharmacist
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location

Total Records:

Division of
Medical Quality Assurance

MQA

Processed: 3/13/2014 6:48:05AM

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
1/ 1/2014 - 2/28/2014

Sort Order: Original License Date

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27347	01/02/2014	Huong Luu, Pharmd, Inc				17400 Irvine Blvd Suite P	Tustin, CA 92780
PH	27348	01/03/2014	Silver Lake Pharmacy, Llc				32729 Radio Rd	Leesburg, FL 34788
PH	27349	01/03/2014	Walgreen Co.				2615 Burnsed Blvd	The Villages, FL 32163
PH	27350	01/03/2014	South Central Florida Dialysis Partners,				1552 Boren Dr Ste 100	Ocoee, FL 34761
PH	27351	01/03/2014	St. Francis Of Assisi Wildlife Associati				5580 Salem Road	Quincy, FL 32352
PH	27352	01/03/2014	Health Promote Pharmacy				12701 South John Young Parkway #120	Orlando, FL 32837
PH	27353	01/03/2014	Baya Nursing And Rehabilitation Center				587 Se Ermine Avenue	Lake City, FL 32025-6126
PH	27354	01/03/2014	Osprey Nursing And Rehabilitation Llc				1104 North Main Street	Bushnell, FL 33513-5045
PH	27355	01/03/2014	Lehigh-Hma				1500 Lee Blvd	Lehigh Acres, FL 33936
PH	27356	01/03/2014	Halo Rx Llc				703 N Broadway Ste 3	Ada, OK 74820
PH	27357	01/06/2014	Recovery Village At Umatilla, Llc				633 Umatilla Blvd	Umatilla, FL 32784
PH	27358	01/07/2014	Wal-Mart Stores East, Lp				1794 22Nd St South	Saint Petersburg, FL 33712
PH	27359	01/08/2014	Rx Pro Of Ms, Inc				1005 Market St	Port Gibson, MS 39150
PH	27360	01/08/2014	Florida Hospital Waterman, Inc.				1000 Waterman Way	Tavares, FL 32778
PH	27361	01/09/2014	In Home Health, Llc				13650 Metropolis Avenue Suite 105	Fort Myers, FL 33912
PH	27362	01/09/2014	Healthcare Pharmacy Llc				1838 Healthcare Drive Suite-B	Trinity, FL 34655
PH	27363	01/09/2014	Ops International Incorporated				6700 Conroy Road Ste 155	Orlando, FL 32835
PH	27364	01/13/2014	Florida Health Sciences Center, Inc				16011 Tampa Palms Blvd, West	Tampa, FL 33647
PH	27365	01/13/2014	Tamimi Pharmacy, Llc				12643 North 56Th Street	Tampa, FL 33617
PH	27366	01/15/2014	Publix Super Markets, Inc.				13178 North Dale Mabry Highway	Tampa, FL 33618
PH	27367	01/15/2014	Life Line Home Care Services, Inc.				3740 St. Johns Bluff Rd Suite 1	Jacksonville, FL 32224

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27368	01/15/2014	Relevant Compounding, Llc				9329 State Route 220 Suite C	Waverly, OH 45690
PH	27369	01/15/2014	Lmd Holdings, Ltd				4477 W. 118Th Street Ste 100	Hawthorne, CA 90250
PH	27370	01/15/2014	Total Care Rx, Inc				2480 Delta Lane	Elk Grove Village, IL 60007
PH	27371	01/15/2014	Independence Holding Company Llc				14 E Washington Suite C	Champaign, IL 61820
PH	27372	01/15/2014	Central Rexall Drugs, Inc.				125 E. Thomas St.	Hammond, LA 70401
PH	27373	01/16/2014	Aids Healthcare Foundation				700 Se 3Rd Avenue Suite 100	Fort Lauderdale, FL 33316
PH	27374	01/16/2014	Mount Sinai Center Of Florida, Inc.				4300 Alton Road	Miami Beach, FL 33140
PH	27375	01/16/2014	People'S Custom Rx & Clinical Care Cente				785 Brookhaven Circle East	Memphis, TN 38117
PH	27376	01/16/2014	Valley View Drugs Inc				13966 Valley View Ave	La Mirada, CA 90638
PH	27377	01/21/2014	Halsted Pharmacy Inc.				1460 N. Halsted St Ste 101	Chicago, IL 60642
PH	27378	01/21/2014	Access Recovery Solutions, Llc				16244 S Military Trail Suite 100	Delray Beach, FL 33484
PH	27379	01/21/2014	Sunny Pharmacy & Discount Inc				2140 Nw 36 Street	Miami, FL 33142
PH	27380	01/21/2014	Pvrx Pharmacy Corp				10327 Nw 27 Ave	Miami, FL 33147
PH	27381	01/21/2014	P & H Pharmacy Discount, Inc				9527 Sw 40Th St	Miami, FL 33165
PH	27382	01/21/2014	Youth Services International, Inc.				3090 Powerline Road	Pompano Beach, FL 33069
PH	27383	01/21/2014	Bi-County Medical Supply, Inc.				8377 Pines Boulevard	Pembroke Pines, FL 33024
PH	27384	01/21/2014	Nolbis Pharmacy Discount Inc				710 Palm Ave	Hialeah, FL 33010
PH	27385	01/21/2014	Publix Super Markets, Inc.				1520 John Sims Parkway East	Niceville, FL 32578
PH	27386	01/21/2014	Mary Hitchcock Memorial Hospital				One Medical Center Drive	Lebanon, NH 03756
PH	27387	01/22/2014	Pharmscript Of Florida Llc				1804 W. Hillsboro Blvd	Deerfield Beach, FL 33442

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27388	01/22/2014	Dialysis Clinic, Inc.				3760 N W 83Rd Street Suite 3	Gainesville, FL 32606
PH	27389	01/22/2014	Shafa Pharmacy				11476 Okeechobee Blvd	Royal Palm Beach, FL 33411
PH	27390	01/23/2014	Publix Super Markets, Inc.				8140 W Mcnab Rd	North Lauderdale, FL 33068
PH	27391	01/23/2014	Shands Teaching Hospitals And Clinics In				3951 N W 48Th Terrace Suite 211	Gainesville, FL 32606
PH	27392	01/23/2014	Life Worth Living Foundation, Inc.				6488 Currin Drive	Orlando, FL 32835
PH	27393	01/23/2014	Cadi Health, Llc				1936 West Flagler Street	Miami, FL 33135
PH	27394	01/23/2014	Galencare, Inc				119 Oakfield Dr.	Brandon, FL 33511
PH	27395	01/23/2014	Shands Teaching Hospital And Clinics, In				1600 Sw Archer Road	Gainesville, FL 32610
PH	27396	01/23/2014	New Port Richey Hospital Inc.				9330 State Road 54	Trinity, FL 34655
PH	27397	01/24/2014	Amber Enterprises, Inc.				323 Norristown Road Suite 100	Ambler, PA 19002
PH	27398	01/24/2014	Sims Pharmacy, Llc				1177 Gulf Breeze Pkwy	Gulf Breeze, FL 32561
PH	27399	01/24/2014	Superior Biologics Ii, Inc.				2050 E. Algonquin Road Suite 606	Schaumburg, IL 60173
PH	27400	01/24/2014	Hca Health Services Of Florida, Inc				14000 Fivay Road	Hudson, FL 34667
PH	27401	01/24/2014	Lee Memorial Health System				13681 Doctor'S Way	Fort Myers, FL 33912
PH	27402	01/24/2014	Flagler Hospital Inc				400 Health Park Blvd	Saint Augustine Beac, FL 32086
PH	27403	01/24/2014	Munroe Regional Health Systems				1500 Sw 1St Ave	Ocala, FL 34474
PH	27404	01/24/2014	New Lifecare Hospitals Of Sarasota, Llc				6150 Edgelake Drive	Sarasota, FL 34240
PH	27405	01/24/2014	Pharmerica Drug Systems, Llc				3690 Nw 53 St Ste 104	Fort Lauderdale, FL 33309
PH	27406	01/24/2014	Hca Health Services Of Florida, Inc.				11375 Cortez Blvd	Brooksville, FL 34613
PH	27407	01/24/2014	Select Specialty Hospital Orlando, Inc.				5579 South Orange Avenue	Orlando, FL 32809

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27408	01/24/2014	J-M Ward Enterprises, Llc				9048 Bonita Beach Rd Se	Bonita Springs, FL 34135
PH	27409	01/24/2014	Lta Alliance Llc				408 Cypress Gardens Blvd	Winter Haven, FL 33880
PH	27410	01/24/2014	Florida Health Care Plan, Inc.				4932 W State Road 46 Unit 1000	Sanford, FL 32771
PH	27411	01/24/2014	Epic Care Pharmacy Llc				3948 D Pembroke Road	Pembroke Park, FL 33021
PH	27412	01/24/2014	Adventist Health System Sunbelt Healthca				582 Monroe Rd Ste 1412 B	Sanford, FL 32771
PH	27413	01/24/2014	Green Hope Pharmacy Inc				5309 Sw 8Th Street	Miami, FL 33134
PH	27414	01/24/2014	Ops International Incorporated				6700 Conroy Road Ste 155	Orlando, FL 32835
PH	27415	01/24/2014	Bardmoor Surgery Center, Llc				8787 Bryan Dairy Rd Ste 300	Largo, FL 33777
PH	27416	01/24/2014	Epic Community Services, Inc.				3574 U.S. 1 South	Saint Augustine, FL 32086
PH	27417	01/27/2014	Brent Moore Pharmacy Services				11414 E. 51St Suite A	Tulsa, OK 74146
PH	27418	01/27/2014	Sarasota County Public Hospital District				1700 South Tamiami Trail	Sarasota, FL 34239
PH	27419	01/27/2014	Baycare Home Care, Inc.				8452 118Th Avenue North	Largo, FL 33773
PH	27420	01/27/2014	Longleaf Surgery Center, Llc				3010 Starkey Blvd.	New Port Richey, FL 34655
PH	27421	01/27/2014	Adventist Health System/Sunbelt, Inc.				1300 West Oak St Suite A	Kissimmee, FL 34741
PH	27422	01/27/2014	Emergency Pharmacy, Inc.				4742 West Flagler St	Coral Gables, FL 33134
PH	27423	01/27/2014	Ktj Enterprises				622 Colorado Ave	Stuart, FL 34994
PH	27424	01/28/2014	Edge Pharmacy Services, Llc				856 Hercules Drive Suite 30	Colchester, VT 05446
PH	27425	01/28/2014	Hendry County Hospital Authority				524 W. Sagamore	Clewiston, FL 33440
PH	27426	01/28/2014	Infusion Systems Of Swfl				1826 Bay Scout Drive	Fort Myers, FL 33907

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27427	01/28/2014	Core Health Pharmacy				1661 N Hiatus Road	Pembroke Pines, FL 33026
PH	27428	01/28/2014	Marlins Pharmacy & Discount Inc.				439-441 Nw 12 Ave	Miami, FL 33128
PH	27429	01/29/2014	Cape Memorial Hospital				636 Del Prado Blvd	Cape Coral, FL 33990
PH	27430	01/29/2014	South Broward Hospital District				3501 Johnson Street	Hollywood, FL 33021
PH	27431	01/29/2014	South Broward Hospital District				1005 Joe Dimaggio Way	Hollywood, FL 33021
PH	27432	01/29/2014	Ithrive Health, Llc				5415 W. Cedar Lane	Bethesda, MD 20814
PH	27433	01/29/2014	Surgcenter Of Palm Beach Gardens, Llc				900 Village Square Crossing Suite 100	Palm Beach Gardens, FL 33410
PH	27434	01/30/2014	Vallejos Pharmacy, Corp				4750 Nw 7 St	Miami, FL 33126
PH	27435	01/31/2014	Total Renal Research, Inc				825 South 8Th Street Suite 300	Minneapolis, MN 55404
PH	27436	01/31/2014	Americure Rx - Florida Llc				5736 Clark Rd	Sarasota, FL 34233
PH	27437	01/31/2014	Goldenrod Pharmacy Llc				2223 S Goldenrod Rd	Orlando, FL 32822
PH	27438	01/31/2014	George Pharmacy, Inc.				2566 S. Atlantic Ave	Daytona Beach Shores, FL 32118
PH	27439	01/31/2014	Aap Pharmacy, Inc				171 Westward Drive	Miami Springs, FL 33166
PH	27440	01/31/2014	P. A Pharmacy Inc.				9722 Sw 184Th St	Cutler Ridge, FL 33157
PH	27441	01/31/2014	Oak Creek Pharmacy, Llc				8607 F Street	Omaha, NE 68127
PH	27442	01/31/2014	A.J. & H International, Inc.				18648 Mckay Dr Suite 110	Humble, TX 77338
PH	27443	02/03/2014	Frensenius Medical Care Pharmacy Service				11001 Danka Way North Suite 2	Saint Petersburg, FL 33716
PH	27444	02/03/2014	Ultimate Care Dialysis Center, Llc				2720 Sw 97Th Avenue Suite 201	Miami, FL 33165
PH	27445	02/03/2014	Roses Pharmacy Llc				2168 Nw 7Th St.	Miami, FL 33125
PH	27446	02/03/2014	Lowlite Investments, Inc				6700 Conroy Rd Ste 140	Orlando, FL 32835
PH	27447	02/04/2014	West Florida - Tch, Llc				6001 Webb Road	Tampa, FL 33615

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27448	02/04/2014	Sarasota Doctors Hospital, Inc				5731 Bee Ridge Rd	Sarasota, FL 34233
PH	27449	02/05/2014	North Collier Hospital				11190 Health Park Blvd	Naples, FL 34110
PH	27450	02/05/2014	Southern Baptist Hospital Of Florida, In				800 Prudential Dr	Jacksonville, FL 32207
PH	27451	02/05/2014	Focus Rx Pharmacy Services Inc.				1361 Lincoln Avenue Unit #9	Holbrook, NY 11741
PH	27452	02/05/2014	Baptist Hospital				1000 W. Moreno Street	Pensacola, FL 32501
PH	27453	02/05/2014	Health First Infusion				1959 West 9Th Street #A	Riviera Beach, FL 33404
PH	27454	02/05/2014	North Broward Hospital District				1600 S. Andrews Avenue	Fort Lauderdale, FL 33316
PH	27455	02/05/2014	Zynex Medical, Inc.				9990 Park Meadows Drive	Lone Tree, CO 80124
PH	27456	02/05/2014	Life Worth Living Foundation, Inc.				6488 Currin Drive	Orlando, FL 32835
PH	27457	02/05/2014	Life Worth Living Foundation, Inc.				6488 Currin Drive	Orlando, FL 32835
PH	27458	02/05/2014	Walgreens Of North Carolina, Inc				8431 Garvey Dr. Suite 121	Raleigh, NC 27616
PH	27459	02/05/2014	Shapa Inc				7560 Greenville Avenue	Dallas, TX 75231
PH	27460	02/05/2014	Madawaska Pharmacy, Llc				104 Main St	Madawaska, ME 04756
PH	27461	02/06/2014	Specialty Pharmacy Services, Inc				800 E. Melbourne Ave	Melbourne, FL 32901
PH	27462	02/06/2014	Wells Pharmacy Network, Llc				1210 Sw 33 Ave	Ocala, FL 34474
PH	27463	02/06/2014	Annalice Llc				1992 Alt U S Highway 19	Tarpon Springs, FL 34689
PH	27464	02/06/2014	West Boca Medical Center, Inc.				21644 State Rd 7	Boca Raton, FL 33428
PH	27465	02/06/2014	Pharmaceutical Specialties, Inc.				4330 South Manhattan Avenue	Tampa, FL 33611
PH	27466	02/06/2014	Healthscripts Specialty Pharmacy, Llc				13020 Dairy Ashford Suite 301	Sugar Land, TX 77478
PH	27467	02/06/2014	Philidor Rx Services, Llc				330 S. Warminster Road Suite 350	Hatboro, PA 19040
PH	27468	02/06/2014	Hospice Of St. Francis, Inc				1240 Grumman Place	Titusville, FL 32780

COMPAS DataMart Reporting System
New License Report for 2205 : Pharmacy
1/ 1/2014 - 2/28/2014

Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27469	02/06/2014	Latin Quarters Drug Store Inc.				425 Sw 22Nd Ave Suite #E1	Miami, FL 33135
PH	27470	02/06/2014	Munroe Regional Health System				8550 Ne 138Th Lane Bldg 400	Lady Lake, FL 32159
PH	27471	02/06/2014	Munroe Regional Health System				324 Se 24Th St	Ocala, FL 34471
PH	27472	02/06/2014	University Of South Florida Board Of Tru				1400 N. Hwy 441 Bldg 810	The Villages, FL 32159
PH	27473	02/06/2014	Rigal Pharmacy Llc				3180 N W 7Th St	Miami, FL 33125
PH	27474	02/06/2014	Lee Memorial Health System				9981 S. Healthpark Drive	Fort Myers, FL 33908
PH	27475	02/07/2014	Bioscrip Infusion Services, Llc				5912 Breckenridge Parkway Suite E	Tampa, FL 33610
PH	27476	02/07/2014	Grasso Enterprises Llc				31007 Ih 10 West Ste 108	Boerne, TX 78006
PH	27477	02/10/2014	Mdg International Holdings Llc				803 Nw 2Nd Avenue	Pompano Beach, FL 33060
PH	27478	02/10/2014	Yargol Dialysis, Llc				7220 Cypress Gardens Blvd	Winter Haven, FL 33884
PH	27479	02/10/2014	Maz Pharmacy Discount Corp				3825 W. 16Th Ave Suite #6	Hialeah, FL 33012
PH	27480	02/10/2014	Tampa Family Health Center, Inc.				5611 N Sheldon Rd	Tampa, FL 33615
PH	27481	02/10/2014	Spar Usa Llc.				545 N Virginia Avenue	Winter Park, FL 32789
PH	27482	02/10/2014	Le Vt Inc.				11967 Sheldon Road	Tampa, FL 33626
PH	27483	02/11/2014	Crestview Hospital Corporation				151 Redstone Ave S E	Crestview, FL 32539
PH	27484	02/11/2014	Reception And Medical Center				7765 South County Road 231	Lake Butler, FL 32054
PH	27485	02/11/2014	Naples Community Hospital				350 7Th Street North	Naples, FL 34102
PH	27486	02/11/2014	American Mail Order Pharmacy, Inc.				23290 Schoenherr	Warren, MI 48089
PH	27487	02/11/2014	Ideal Care Pharmacy Inc				1621 Ave U	Brooklyn, NY 11229
PH	27488	02/11/2014	Dohmen Life Science Services, Llc				17877 Chesterfield Airport Rd	Chesterfield, MO 63005
PH	27489	02/11/2014	Robert'S South Bank Pharmacy, Inc				1625 Atlantic Blvd	Jacksonville, FL 32207

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27490	02/11/2014	Tomeldon Co. Inc.				1921 W. Pioneer Parkway	Arlington, TX 76013
PH	27491	02/11/2014	Express Scripts Pharmacy, Inc.				6225 Annie Oakley Drive	Las Vegas, NV 89120
PH	27492	02/11/2014	Express Scripts Pharmacy, Inc.				255 Phillipi Rd.	Columbus, OH 43228
PH	27493	02/11/2014	Express Scripts Pharmacy, Inc.				4750 E 450 South	Whitestown, IN 46075
PH	27494	02/11/2014	Medical Priority Pharmacy, Llc				1671 West 37Th Street Bay 6	Hialeah, FL 33012
PH	27495	02/11/2014	Suncoast Community Health Centers Inc.				7728 Palm River Road	Tampa, FL 33619
PH	27496	02/11/2014	Heart Of Florida Cardiovascular Center,				294 Patterson Street Suite B	Haines City, FL 33844
PH	27497	02/11/2014	Wal-Mart Stores East, Lp				9020 Ulmerton Road	Largo, FL 33771
PH	27498	02/12/2014	Town And Country Compounding And Consult				106 Prospect St	Ridgewood, NJ 07450
PH	27499	02/13/2014	Key West Hma				5900 College Road Attn: Pharmacy Dept	Key West, FL 33040
PH	27500	02/13/2014	Artesia Pharmacy, Inc				11090 E. Artesia Blvd Suite H	Cerritos, CA 90703
PH	27501	02/13/2014	Jackson County Hospital District				4250 Hospital Drive	Marianna, FL 32446
PH	27502	02/13/2014	St. Joseph'S Hospital, Inc.				4211 Van Dyke Road	Lutz, FL 33558
PH	27503	02/13/2014	West Kendall Baptist Hospital				9555 Sw 162Nd Avenue	Miami, FL 33196
PH	27504	02/13/2014	Select Specialty Hospital Orlando, Inc				2250 Bedford Rd	Orlando, FL 32803
PH	27505	02/13/2014	Park Shore Drug Inc				600 Ansin Boulevard	Hallandale Beach, FL 33009
PH	27506	02/14/2014	St. Verena Llc.				13910 Fivay Road Suite 3	Hudson, FL 34667
PH	27507	02/14/2014	Sterile Compounding Pharmacy, Llc				7381 114Th Ave Ste 405A	Largo, FL 33773
PH	27508	02/14/2014	Marion Surgery Center, Llc				2207 S W 1St Ave	Ocala, FL 34471
PH	27509	02/14/2014	Sunset Pharmacy Discount Inc				40 St 8259 Sw	Miami, FL 33155

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27510	02/14/2014	Gsp Healthcare Llc				2130 Michigan Ave	Kissimmee, FL 34744
PH	27511	02/14/2014	Wildlife Rescue Coalition Of Northeast F				6853 Seaboard Avenue	Jacksonville, FL 32244
PH	27512	02/17/2014	University Hospital & Medical Center				7201 N University Drive	Tamarac, FL 33321
PH	27513	02/17/2014	Select Specialty Hospital-Gainesville, I				2708 Sw Archer Rd	Gainesville, FL 32608
PH	27514	02/17/2014	Pino Pharmacy				1350 Sw 57 Ave Suite 105	West Miami, FL 33144
PH	27515	02/17/2014	Lee County Sheriff'S Office Main Jail				2115 Dr. Mlk Jr. Blvd	Fort Myers, FL 33901
PH	27516	02/17/2014	Lee County Sheriff'S Office Core Facilit				2501 Ortiz Avenue	Fort Myers, FL 33905
PH	27517	02/17/2014	Kindred Hospitals East, Llc				801 Oak Street	Green Cove Springs, FL 32043
PH	27518	02/17/2014	Larkin Community Hospital Inc				7031 S W 62Nd Ave	Miami, FL 33143
PH	27519	02/18/2014	Tenet Good Samaritan, Inc.				1309 N. Flagler Dr	West Palm Beach, FL 33401
PH	27520	02/18/2014	Osceola Sc, Llc				2906 17Th St	Saint Cloud, FL 34769
PH	27521	02/18/2014	Transitional Hospitals Corporation Of Ta				4801 North Howard Ave	Tampa, FL 33603
PH	27522	02/18/2014	Kindred Hospital East, L.L.C.				4555 South Manhattan Ave	Tampa, FL 33611
PH	27523	02/18/2014	Jupiter Drugs Llc				1025 Military Trail	Jupiter, FL 33458
PH	27524	02/18/2014	Adventist Healthcare System				7050 Gall Blvd	Zephyrhills, FL 33541
PH	27525	02/18/2014	Pharmacy Corporation Of America				1950 Commonwealth Lane	Tallahassee, FL 32303-3196
PH	27526	02/18/2014	Lee Memorial Health System				8931 Colonial Ctr Dr Suite 200	Fort Myers, FL 33905
PH	27527	02/18/2014	Norwood Pharmacy, Llc				2572 Metro Blvd	Maryland Heights, MO 63043
PH	27528	02/18/2014	University Of Md Medical System Outpatie				22 South Greene Street	Baltimore, MD 21201
PH	27529	02/18/2014	Maxor National Pharmacy Services Llc				102 Sw 3Rd Avenue	Amarillo, TX 79101

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27530	02/19/2014	Holmes Regional Medical Center				1425 Malabar Rd Ne	Palm Bay, FL 32907
PH	27531	02/19/2014	West Gables Rehabilitation Hospital, Llc				2525 Sw 75Th Avenue	Miami, FL 33155
PH	27532	02/19/2014	Pacifico National Inc				1515 Elizabeth St Suite J	Melbourne, FL 32901
PH	27533	02/19/2014	Tallahassee Memorial Healthcare				1260 Metropolitan Blvd	Tallahassee, FL 32312
PH	27534	02/19/2014	Orlando Pharmacy Inc				2909 North Orange Avenue	Orlando, FL 32804
PH	27535	02/20/2014	Coconut Creek Dialysis Center, Llc				3508 N. University Drive Suite 300 A	Sunrise, FL 33351
PH	27536	02/20/2014	Ready Pharmacy Inc.				5782 West Flagler St	Miami, FL 33144
PH	27537	02/20/2014	Adolescent Treatment Center Of Palm Beac				4445 Pine Forest Drive	Lake Worth, FL 33463
PH	27538	02/20/2014	Publix Super Markets, Inc.				4860 Davis Blvd	Naples, FL 34104
PH	27539	02/20/2014	Murray Overhill Pharmacy, Inc				32 W. State St	Media, PA 19063
PH	27540	02/20/2014	Martin Memorial Medical Center				10000 Sw Innovation Way	Port Saint Lucie, FL 34987
PH	27541	02/21/2014	Pegasus Pharmacy				2050 Springdale Rd Unit 500	Cherry Hill, NJ 08003
PH	27542	02/21/2014	Kindred Hospital Palm Beach, Llc				5555 W Blue Heron Blvd	Riviera Beach, FL 33418
PH	27543	02/21/2014	Carolina Pharmacy And Discount Co				4705 Sw 8Th Street #1	Miami, FL 33134
PH	27544	02/21/2014	Bay Rx Pharmacy Llc				610 Baldwin Plaza	Panama City, FL 32405
PH	27545	02/24/2014	Kindred Hospitals East, Llc				1859 Van Buren Street	Hollywood, FL 33020
PH	27546	02/24/2014	Coram Alternate Site Services, Inc.				3439 North 12Th Avenue Suite A & B	Pensacola, FL 32503
PH	27547	02/24/2014	Coram Healthcare Corporation Of Southern				12006 Miramar Parkway	Miramar, FL 33025
PH	27548	02/24/2014	Kindred Hospitals East, L.L.C.				5190 Sw 8Th Street	Coral Gables, FL 33134
PH	27549	02/24/2014	Naples Hma, Llc				6101 Pine Ridge Road	Naples, FL 34119

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
PH	27550	02/24/2014	North Broward Hospital District				6401 North Federal Hwy	Fort Lauderdale, FL 33308
PH	27551	02/24/2014	North Broward Hospital District				3000 Coral Hills Dr	Coral Springs, FL 33065
PH	27552	02/24/2014	Hope Of Southwest Florida				9470 Healthpark Circle	Fort Myers, FL 33908
PH	27553	02/24/2014	Bethesda Health, Inc				2815 S. Seacrest Blvd	Boynton Beach, FL 33435
PH	27554	02/24/2014	Bethesda Health, Inc				9655 Boynton Beach Blvd	Boynton Beach, FL 33472
PH	27555	02/24/2014	Palm Springs General Hospital Inc.				1475 West 49 Street 3Rd Floor	Hialeah, FL 33012
PH	27556	02/24/2014	Kindred Hospitals East, Llc				1500 Sw 1St Avenue 5Th Floor	Ocala, FL 34471
PH	27557	02/24/2014	Victoria Healthcare, Inc.				955 N W 3Rd Street	Miami, FL 33128
PH	27558	02/24/2014	Kindred Hospital Bay Area St. Petersburg				3030 6Th Street South	Saint Petersburg, FL 33705
PH	27559	02/25/2014	West Florida- Mht, Llc				2901 W. Swann Ave	Tampa, FL 33609
PH	27560	02/25/2014	My Script Llc				25410 Goddard Rd	Goddord, MI 48180
PH	27561	02/25/2014	Public Health Trust				160 Nw 170Th Street	North Miami Beach, FL 33169
PH	27562	02/25/2014	Pharmacy Discount Service Inc.				4894 Nw 7Th St	Miami, FL 33126
PH	27563	02/25/2014	Trustedmedrx Inc.				6971 North Federal Highway Suite 203	Boca Raton, FL 33487
PH	27564	02/25/2014	Accredo Health Group, Inc				6272 Lee Vista Blvd Suite 100	Orlando, FL 32822
PH	27565	02/25/2014	Talimena Dialysis, Llc				15600 Nw 15Th Ave Ste D	Miami, FL 33169-5609
PH	27566	02/25/2014	New Pharmacy And Store Corp				1204 East 4 Ave	Hialeah, FL 33010
PH	27567	02/25/2014	Publix Super Markets, Inc.				525 Bay Isles Pkwy	Longboat Key, FL 34228
PH	27568	02/26/2014	Synergy Pharmacy Services, Inc				31201 Us Hwy 19 N Ste 2	Palm Harbor, FL 34684
PH	27569	02/26/2014	S P Pharmacy Corp				5587 Sw 8Th St.	Coral Gables, FL 33134
PH	27570	02/26/2014	La Botica Pharmacy Inc.				10550 Nw 77 Court Suite 109	Hialeah Gardens, FL 33016
PH	27571	02/26/2014	Pac Shores Pharmacy Llc				9416 Ne 2Nd Ave	Miami Shores, FL 33138

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PH	27572	02/26/2014	Tampa Family Health Centers				5611 N. Sheldon Rd	Tampa, FL 33615
PH	27573	02/26/2014	Ncrnc Inc				700 N. Palmetto Street	Leesburg, FL 34748
PH	27574	02/26/2014	Curant Health Florida, Llc				7209 Bryan Dairy Road	Largo, FL 33777
PH	27575	02/26/2014	Hospice Of Palm Beach County, Inc.				300 North Point Parkway Suite #301	West Palm Beach, FL 33407
PH	27576	02/27/2014	Sacred Heart Health System, Inc.				5151 N. Ninth Avenue	Pensacola, FL 32504
PH	27577	02/27/2014	Sun Pharmacy, Llc				3320 Scherer Dr. Suite A	Saint Petersburg, FL 33716
PH	27578	02/27/2014	Pharmaceutical Care Consultants Of Fl				21000 Boca Rio Road Suite A-29	Boca Raton, FL 33433
PH	27579	02/27/2014	Bio-Medical Applications Of Florida, Inc				457 Carlton Street	Wauchula, FL 33873
PH	27580	02/27/2014	Nxstage Jacksonville, Llc				2777 University Blvd West Suite 39	Jacksonville, FL 32217
PH	27581	02/27/2014	A V Pharma Llc				1545 University Blvd N	Jacksonville, FL 32211
PH	27582	02/27/2014	Formula Pharmacy, Inc.				11180 West Flagler Street Suite 2	Miami, FL 33174
PH	27583	02/28/2014	Jupiter Medical Center, Inc				1210 S. Old Dixie Hgwy	Jupiter, FL 33458
PH	27584	02/28/2014	Hill Country Compounding Pharmacy				1310 Rr 620 S Ste A-1	Austin, TX 78734
PH	27585	02/28/2014	Healthspan Integrated Care				5420 Lancaster Drive	Brooklyn Heights, OH 44131
PH	27586	02/28/2014	Kindred Hospitals East, Llc				1516 East Las Olas Blvd	Fort Lauderdale, FL 33301
PH	27587	02/28/2014	Suncoast Hospice				11701 S. Belcher Rd Suite 126	Largo, FL 33773
PH	27588	02/28/2014	Life Save Rx, Llc				207 E Robertson Street Suite B	Brandon, FL 33511

Total Records: **242**

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Prof	Organization Name	DBA Name	Rank	License #	File #	Issue Dte	Modifier Effct Dte	Mod Cde	Lic Status	Mailing Address	Phone	County
2205	A V PHARMA LLC	CITIZEN PHARMACY	PH	27581	20822	02/27/2014	02/12/2014	3PTR	CLEAR	PO BOX 600047 JACKSONVILLE, FL 32260		St Johns
2205	ADVANCED SPECIALTY PHARMACY OF TAMPA, LL	ADVANCED SPECIALTY PHARMACY OF TAMPA, LL			20678		01/21/2014	3PTR	APPL IN PROC	2901 W BUSCH BLVD STE 104 TAMPA, FL 33618		Hillsborough
2205	ALL CHILDREN'S HOSPITAL, INC	ALL CHILDREN'S OUTPATIENT CARE, TAMPA			20945		02/26/2014	2PTR	APPL IN PROC	12220 BRUCE B DOWNS BOULEVARD TAMPA, FL 33612		Hillsborough
2205	ALL CHILDREN'S HOSPITAL, INC		PH	27630	20955	03/07/2014	02/27/2014	3PTR	CLEAR	501 6TH AVENUE SOUTH SAINT PETERSBURG, FL 33701		Pinellas
2205	ALL CHILDREN'S HOSPITAL, INC.	ALL CHILDREN'S OUTPATIENT CARE, TAMPA			20958		02/27/2014	2PTR	APPL IN PROC	12220 BRUCE B. DOWNS BLVD TAMPA, FL 33612		Hillsborough
2205	ALL-MED SERVICES OF FLORIDA, INC	UNIVITA			20938		02/26/2014	3PTR	APPL IN PROC	3700 COMMERCE PARK WAY MIRAMAR, FL 33025		Broward
2205	AMERICURE RX - FLORIDA LLC	MEDISERV PHARMACY SERVICES	PH	27436	20706	01/31/2014	01/28/2014	3PTR	CLEAR	5736 CLARK RD SARASOTA, FL 34233		Sarasota
2205	BAPTIST MEDICAL CTR OF BEACHES	BAPTIST MEDICAL CNTR BEACHES			20660		01/16/2014	3PTR	APPL IN PROC	1350 13TH AVE SOUTH JACKSONVILLE BEACH, FL 32250		Duval
2205	BAYCARE HOME CARE, INC	BAYCARE PHARMACY	PH	25601	18480	07/28/2011	01/16/2014	3PTR	CLEAR	1840 MEASE DRIVE SUITE 100 SAFETY HARBOR, FL 34695	(727) 499-0085	Pinellas
2205	BAYFRONT HMA MEDICAL CENTER LLC	BAYFRONT HEALTH ST. PETERSBURG			20966		02/28/2014	3PTR	APPL IN PROC	701 6TH STREET SOUTH SAINT PETERSBURG, FL 33701		Pinellas
2205	BETHESDA HOSPITAL INC.	BETHESDA HOSPITAL EAST	PH	42	6		02/24/2014	2PTR	CLEAR	2815 S SEACREST BLVD BOYNTON BEACH, FL 33435-7934		Palm Beach
2205	BILLS PRESCRIPTION CENTER, INC.	BILLS PRESCRIPTION CENTER, INC.			20902		02/20/2014	3PTR	APPL IN PROC	20 EAST BRANDON BOULEVARD BRANDON, FL 33511		Hillsborough
2205	BIOSCRIP INFUSION SERVICES, LLC	CAREPOINT PARTNERS			20726		01/31/2014	3PTR	APPL IN PROC	3986 BOULEVARD CENTER DRIVE SUITE 1 JACKSONVILLE, FL 32207		Duval
2205	BIOSCRIP INFUSION SERVICES, LLC	BIOSCRIP INFUSION SERVICES	PH	27475	20733	02/07/2014	01/31/2014	3PTR	CLEAR	5912 BRECKENRIDGE PARKWAY SUITE E TAMPA, FL 33610		Hillsborough
2205	BIOSCRIP INFUSION SERVICES, LLC	BIOSCRIP INFUSION SERVICES	PH	27591	20969	03/03/2014	02/28/2014	3PTR	CLEAR	5505 JOHNS ROAD SUITE 700 TAMPA, FL 33634		Hillsborough
2205	BUDGET DISCOUNT SALES CORP	SOBE COMPOUNDING APOTHECARY			20833		02/13/2014	3PTR	APPL IN PROC	13150 S W 134 ST MIAMI, FL 33186		Miami-Dade
2205	CADI HEALTH, LLC	CADI HEALTH, LLC	PH	27393	20639	01/23/2014	01/08/2014	3PTR	CLEAR	1936 WEST FLAGLER STREET MIAMI, FL 33135		Miami-Dade
2205	CAPE MEMORIAL HOSPITAL	CAPE CORAL HOSPITAL	PH	27429	20692	01/29/2014	01/24/2014	3PTR	CLEAR	636 DEL PRADO BLVD CAPE CORAL, FL 33990		Lee
2205	CARDINAL HEALTH 414, LLC	CARDINAL HEALTH	PH	18980	11049	01/16/2003	02/28/2014	3PTR	CLEAR	7000 CARDINAL PLACE Q & R DEPT, NPS DUBLIN, OH 43017	(614) 757-7570	Unknown
2205	CARDINAL HEALTH 414, LLC	CARDINAL HEALTH	PH	27589	20967	03/03/2014	02/28/2014	3PTR	CLEAR	7000 CARDINAL PLACE Q & R DEPT NPS DUBLIN, OH 43017		Unknown
2205	CAREMAX PHARMACY 725 LLC	CAREMAX PHARMACY	PH	27672	20879	03/12/2014	02/18/2014	3PTR	CLEAR	PO BOX 54668 JACKSONVILLE, FL 32245		Duval
2205	CAROLINA PHARMACY AND DISCOUNT CO	CAROLINA PHARMACY AND DISCOUNT CO	PH	27543	20680	02/21/2014	01/21/2014	3PTR	CLEAR	4705 SW 8TH STREET #1 MIAMI, FL 33134		Miami-Dade

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Prof	Organization Name	DBA Name	Rank	License #	File #	Issue Dte	Modifier Effct Dte	Mod Cde	Lic Status	Mailing Address	Phone	County
2205	CHAPTERS HEALTH PHARMACY, LLC.	CHAPTERS HEALTH PHARMACY	PH	23387	16024	05/21/2008	01/27/2014	3PTR	CLEAR	12470 TELECOM DRIVE SUITE 300 WEST TEMPLE TERRACE, FL 33637	(813) 470-7444	Hillsborough
2205	CITRUS MEMORIAL HEALTH FOUNDATION	CITRUS MEMORIAL HEALTH SYSTEM			20843		02/17/2014	3PTR	APPL IN PROC	502 W. HIGHLAND BLVD INVERNESS, FL 34452		Citrus
2205	CORAM ALTERNATE SITE SERVICES, INC.	CORAM SPECIALTY INFUSION SERVICES, AN AP	PH	27546	20886	02/24/2014	02/18/2014	3PTR	CLEAR	555 17TH STREET SUITE 1500 DENVER, CO 80202		Unknown
2205	CORAM HEALTHCARE CORPORATION OF FLORIDA	CORAM SPECIALTY INFUSION SERVICES, AN AP			20932		02/25/2014	3PTR	APPL IN PROC	555 17TH STREET SUITE 1500 DENVER, CO 80202		Unknown
2205	CORAM HEALTHCARE CORPORATION OF SOUTHERN	CORAM SPECIALTY INFUSION SERVICES, AN AP	PH	27547	20898	02/24/2014	02/20/2014	3PTR	CLEAR	555 17TH STREET SUITE 1500 DENVER, CO 80202		Unknown
2205	CORE HEALTH PHARMACY	CORE HEALTH PHARMACY	PH	27427	20480	01/28/2014	01/28/2014	2PTR	CLEAR	1661 N HIATUS ROAD PEMBROKE PINES, FL 33026		Broward
2205	CRESTVIEW HOSPITAL CORPORATION	NORTH OKALOOSA MEDICAL CENTER	PH	27483	20799	02/11/2014	02/10/2014	3PTR	CLEAR	151 REDSTONE AVE S E CRESTVIEW, FL 32539		Okaloosa
2205	CURANT HEALTH FLORIDA, LLC	CURANT HEALTH FLORIDA, LLC	PH	27574	20866	02/26/2014	02/17/2014	3PTR	CLEAR	7209 BRYAN DAIRY ROAD LARGO, FL 33777		Pinellas
2205	CYSTIC FRIBROSIS PHARMACY, INC				20912		02/21/2014	3PTR	APPL IN PROC	3901 E COLONIAL DR STE D ORLANDO, FL 32803		Orange
2205	D & S ENTERPRISES OF VERO BEACH, LLC	MILLER'S HEALTHMART PHARMACY	PH	27604	20787	03/04/2014	02/10/2014	3PTR	CLEAR	777 37TH STREET SUITE C-100 VERO BEACH, FL 32960		Indian River
2205	DOCTORS HOSPITAL, INC	DOCTOR'S HOSPITAL	PH	22110	14542	06/30/2006	02/27/2014	3PTR	CLEAR	5000 UNIVERSITY DRIVE CORAL GABLES, FL 33146	786-308-3401	Miami-Dade
2205	DOCTORS' MEMORIAL HOSPITAL	DOCTOR'S MEMORIAL HOSPITAL	PH	12038	3020	07/01/1992	02/21/2014	3PTR	CLEAR	333 NORTH BYRON BUTLER PARKWAY PERRY, FL 32347	(850) 584-0833	Taylor
2205	DR. P PHILLIPS HOSPITAL		PH	9168	1603	10/24/1985	02/27/2014	3PTR	CLEAR	9400 TURKEY LAKE RD ORLANDO, FL 32819-8001	(321) 842-8102	Orange
2205	ENGLEWOOD COMMUNITY HOSPITAL	COLUMBIA ENGLEWOOD COMMUNITY HOSPITAL	PH	9064	1567	09/04/1985	02/27/2014	3PTR	CLEAR	700 MEDICAL BLVD ENGLEWOOD, FL 34223-3964		Sarasota
2205	ENSLEY PHARMACY, INC.	ENSLEY PHARMACY			20766		02/05/2014	3PTR	WITHDREW	8814 NORTH PALAFOX STREET #C PENSACOLA, FL 32534-3029		Escambia
2205	EPIC COMMUNITY SERVICES, INC.	EPIC RECOVERY CENTER, LLC	PH	27416	20689	01/24/2014	01/23/2014	3PTR	CLEAR	1400 OLD DIXIE HIGHWAY SAINT AUGUSTINE, FL 32084		St Johns
2205	FLORIDA HOSPITAL HOME INFUSION, LLP		PH	12210	3137	12/03/1992	01/15/2014	3PTR	CLEAR	556 FLORIDA CENTRAL PKWY SUITE 1044 LONGWOOD, FL 32750	407-865-5489	Seminole
2205	FLORIDA HOSPITAL HOME INFUSION, LLP	FLORIDA HOSPITAL HOME INFUSION, TAMPA DI	PH	27037	19891	08/23/2013	01/15/2014	3PTR	CLEAR	556 Florida Central Parkway Suite 1044 LONGWOOD, FL 32750		Seminole
2205	FLORIDA HOSPITAL ZEHPYRHILLS, INC	FLORIDA HOSPITAL ZEPHYRHILLS	PH	2003	287		02/18/2014	3PTR	CLEAR	7050 GALL BLVD ZEPHYRHILLS, FL 33541-1347		Pasco
2205	FLORIDA PAIN & REHABILITATION ASSO. INC.	NPI RX			20821		02/12/2014	3PTR	APPL IN PROC	5365 W. ATLANTIC AVE SUITE 504 DELRAY BEACH, FL 33484		Palm Beach
2205	FORMULA PHARMACY, INC.	FORMULA PHARMACY, INC.	PH	27582	20831	02/27/2014	02/14/2014	3PTR	CLEAR	11180 WEST FLAGLER STREET SUITE 2 MIMI, FL 33174		Miami-Dade

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Prof	Organization Name	DBA Name	Rank	License #	File #	Issue Dte	Modifier Effct Dte	Mod Cde	Lic Status	Mailing Address	Phone	County
2205	FRENSENIUS MEDICAL CARE PHARMACY SERVICE	FMC PHARMACY SERVICES	PH	27443	20697	02/03/2014	01/24/2014	3PTR	CLEAR	11001 DANKA WAY NORTH SUITE 2 SAINT PETERSBURG, FL 33716		Pinellas
2205	G AND R PHARMACY, INC	G AND R PHARMACY			20965		02/28/2014	2PTR	APPL IN PROC	2432 W ELM BLOSSOM ST BEVERLY HILLS, FL 34465		Citrus
2205	GALENCARE, INC	BRANDON REGIONAL HOSPITAL	PH	27394	20642	01/23/2014	01/09/2014	3PTR	CLEAR	119 OAKFIELD DR. BRANDON, FL 33511		Hillsborough
2205	GALENCARE, INC, COL NORTHSIDE HOSPITAL	NORTHSIDE HOSPITAL			20662		01/17/2014	3PTR	APPL IN PROC	6000 49TH ST. NORTH SAINT PETERSBURG, FL 33709		Pinellas
2205	GARDENS DRUGS, INC.	GARDENS DRUGS			20670		01/07/2014	3PTR	APPL IN PROC	2100 45th Street #B-1 WEST PALM BEACH, FL 33407		Palm Beach
2205	GATTOLINE ENTERPRISES, INC.	FAMILY CARE PHARMACY			20837		02/14/2014	3PTR	APPL IN PROC	1505 WREYNOLDS ST PLANT CITY, FL 33563		Hillsborough
2205	GOLDEN HILLS PHARMACY, LLC	GOLDEN HILLS PHARMACY, LLC			20621		01/02/2014	3PTR	APPL IN PROC	6998 N US HWY 27 SUITE 104 OCALA, FL 34482		Marion
2205	GREENWOOD HEALTHCARE LLC		PH	27610	20916	03/05/2014	02/18/2014	2PTR	CLEAR	3801 W LAKE MARY BLVD SUITE 127 LAKE MARY, FL 32746	407-405-7767	Seminole
2205	GS TAMPA RD, INC	TAMPA ROAD PHARMACY			20922		02/24/2014	3PTR	APPL IN PROC	2488 JOHNNA COURT PALM HARBOR, FL 34685		Pinellas
2205	GSP HEALTHCARE LLC		PH	27510	20767	02/14/2014	02/05/2014	2PTR	CLEAR	13726 LAKE CAWOOD DRIVE WINDERMERE, FL 34786		Orange
2205	GUARDIAN PHARMACY OF NW FLORIDA, LLC	GUARDIAN PHARMACY OF NWFL			20927		02/24/2014	3PTR	APPL IN PROC	100 PREMIER DRIVE UNIT 2 CRESTVIEW, FL 32539		Okaloosa
2205	HAINES CITY H.M.A. INC	HEART OF FLORIDA HOSPITAL-PHARMACY			20890		02/19/2014	3PTR	APPL IN PROC	40100 HIGHWAY 27 DAVENPORT, FL 33837		Polk
2205	HEALTHSOUTH OF SEA PINES LIMITED PARTNER	HEALTHSOUTH SEA PINES REHABILITATION HOS	PH	27620	20840	03/06/2014	02/14/2014	2PTR	CLEAR	101 EAST FLORIDA AVE MELBOURNE, FL 32901		Brevard
2205	HEALTHSOUTH REHABILITATION HOSPITAL OF M	HEALTHSOUTH REHABILITATION HOSPITAL OF M			20820		02/12/2014	2PTR	APPL IN PROC	20601 OLD CUTLER ROAD MIAMI, FL 33189		Miami-Dade
2205	HERNANDO HMA, LLC	BROOKSVILLE REGIONAL HOSPITAL	PH	16430	6947	02/17/1999	02/17/2014	3PTR	CLEAR	17240 Cortez Blvd BROOKSVILLE, FL 34601		Hernando
2205	HHCS PHARMACY INC	FREEDOM PHARMACY	PH	27660	20887	03/12/2014	02/18/2014	3PTR	CLEAR	3901 E COLONIAL DR STE C ORLANDO, FL 32803		Orange
2205	HOBBS PHARMACY UNITED, INC	HOBBS NURSING HOME PHARMACY			20797		02/10/2014	3PTR	APPL IN PROC	135 N. BANANA RIVER DRIVE MERRITT ISLAND, FL 32952		Brevard
2205	HOBBS PHARMACY UNITED, INC	HOBBS PHARMACY			20808		02/11/2014	3PTR	APPL IN PROC	133 N. BANANA RIVER DRIVE MERRITT ISLAND, FL 32952		Brevard
2205	HOME CARE SOLUTIONS, INC.				20953		02/28/2014	3PTR	APPL IN PROC	630 WYMORE RD SUITE 370 MAITLAND, FL 32751		Orange
2205	HOMETOWN SUPERMARKETS, LLC	HOMETOWN PHARMACY - OLD TOWN			20964		02/28/2014	3PTR	APPL IN PROC	PO BOX 821 OLD TOWN, FL 32680		Dixie
2205	HOPE OF SOUTHWEST FLORIDA, INC	HOPE HOSPICE	PH	13242	3930	02/09/1995	02/24/2014	3PTR	CLEAR	9470 HEALTH PARK CIRCLE FORT MYERS, FL 33908		Lee
2205	HOSPICE OF PALM BEACH COUNTY, INC.	SPECTRUM HEALTH PHARMACY	PH	27575	20712	02/26/2014	01/29/2014	3PTR	CLEAR	300 NORTH POINT PARKWAY SUITE #301 WEST PALM BEACH, FL 33407		Palm Beach

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2205	INFUSION PARTNERS OF MELBOURNE, LLC	INFUSION PARTNERS OF MELBOURNE	PH	27590	20968	03/03/2014	02/28/2014	2PTR	CLEAR	3040 VENTURE LANE, BAY #103 MELBOURNE, FL 32934		Brevard
2205	JUPITER MEDICAL CENTER, INC.		PH	7247	897	04/25/1979	02/28/2014	2PTR	CLEAR	1210 S OLD DIXIE HWY JUPITER, FL 33458-7205		Palm Beach
2205	KIDS HOME CARE, INC.		PH	15728	6247	12/24/1997	02/26/2014	3PTR	CLEAR	550 9TH AVENUE SOUTH ST PETERSBURG, FL 33701	(800) 428-3990	Pinellas
2205	KINDRED HOSPITAL EAST, L.L.C.	KINDRED HOSPITAL-BAY AREA	PH	15948	6466	05/04/1998	02/18/2014	3PTR	CLEAR	4555 S MANHATTAN AVE TAMPA, FL 33611-2305		Hillsborough
2205	KINDRED HOSPITAL PALM BEACH, LLC	KINDRED HOSPITAL PALM BEACHES	PH	23457	16062	06/26/2008	02/21/2014	3PTR	CLEAR	5555 W BLUE HERON BLVD RIVIERA BEACH, FL 33418	561-840-0754	Palm Beach
2205	KINDRED HOSPITAL PALM BEACH, LLC	KINDRED HOSPITAL PALM BEACHES	PH	27542	20829	02/21/2014	02/13/2014	3PTR	CLEAR	5555 W BLUE HERON BLVD RIVIERA BEACH, FL 33418		Palm Beach
2205	KINDRED HOSPITALS EAST LLC	KINDRED HOSPITAL OCALA	PH	21400	13773	07/06/2005	02/24/2014	3PTR	CLEAR	1500 SW 1ST AVE. 5TH FLOOR OCALA, FL 34471		Marion
2205	KINDRED HOSPITALS EAST, L.L.C.	TRANSITIONAL HOSPITAL CORP. OF HOLLYWOO	PH	12802	3566	03/17/1994	02/24/2014	2PTR	CLEAR	PHARMACY DEPARTMENT 1859 VAN BUREN STREET HOLLYWOOD, FL 33020	(954) 920-9000	Broward
2205	KINDRED HOSPITALS EAST, L.L.C.	KINDRED HOSPITAL-BAY AREA-ST. PETERSBURG	PH	16009	6527	06/04/1998	02/24/2014	3PTR	CLEAR	3030 6TH STREET SOUTH ST PETERSBURG, FL 33705		Pinellas
2205	KINDRED HOSPITALS EAST, L.L.C.	KINDRED HOSPITAL-SOUTH FLORIDA-CORAL GAB	PH	27548	20901	02/24/2014	02/20/2014	3PTR	CLEAR	5190 SW 8TH STREET CORAL GABLES, FL 33134		Miami-Dade
2205	KINDRED HOSPITALS EAST, LLC	KINDRED HOSPITAL-S. FL-FT LAUDERDALE	PH	16136	6653	08/11/1998	02/27/2014	3PTR	CLEAR	1516 EAST LAS OLAS BLVD FT LAUDERDALE, FL 33301	(954) 764-8900	Broward
2205	KINDRED HOSPITALS EAST, LLC	KINDRED HOSPITAL OCALA, FL	PH	27556	20832	02/24/2014	02/13/2014	3PTR	CLEAR	1500 SW 1ST AVENUE 5TH FLOOR OCALA, FL 34471		Marion
2205	KINDRED HOSPITALS EAST, LLC	KINDRED HOSPITAL S. FL-HOLLYWOOD	PH	27545	20884	02/24/2014	02/18/2014	2PTR	CLEAR	1859 VAN BUREN STREET HOLLYWOOD, FL 33020		Broward
2205	KME RX INC.	MEDICAP PHARMACY			20906		02/20/2014	3PTR	APPL IN PROC	3491 S. CONGRESS AVE. PALM SPRINGS, FL 33461		Palm Beach
2205	L AND H PHARMA CORP	CALOOSA PHARMACY			20939		02/26/2014	3PTR	APPL IN PROC	8 DEL PRADO BLVD SOUTH UNIT F CAPE CORAL, FL 33990		Lee
2205	LA BOTICA PHARMACY INC.	LA BOTICA PHARMACY INC.	PH	27570	20749	02/26/2014	02/03/2014	3PTR	CLEAR	10550 NW 77 COURT SUITE 109 HIALEAH GARDENS, FL 33016		Miami-Dade
2205	LAKELAND FAMILY PHARMACY, LLC	LAKELAND FAMILY PHARMACY	PH	27609	20704	03/05/2014	01/27/2014	3PTR	CLEAR	605 WEST MEMORIAL BOULEVARD LAKELAND, FL 33815		Polk
2205	LARGO MEDICAL CENTER, INC.	LARGO MEDICAL CENTER			20724		01/31/2014	3PTR	APPL IN PROC	201 14TH STREET SW LARGO, FL 33770		Pinellas
2205	LARGO MEDICAL CTR. INC	INDIAN ROCKS MEDICAL			20739		02/03/2014	3PTR	APPL IN PROC	2025 INDIAN ROCKS ROAD SOUTH LARGO, FL 33774		Pinellas
2205	LARKIN COMMUNITY HOSPITAL INC	LARKIN COMMUNITY HOSPITAL	PH	27518	20825	02/17/2014	02/12/2014	3PTR	CLEAR	7031 S W 62ND AVE MIAMI, FL 33143		Miami-Dade
2205	LE VT INC.	V & T PHARMACY	PH	27482	20683	02/10/2014	01/22/2014	3PTR	CLEAR	4811 SCOTT RD LUTZ, FL 33558		Hillsborough
2205	LIFE SAVE RX, LLC	LIFE SAVE RX, LLC	PH	27588	20940	02/28/2014	02/26/2014	2PTR	CLEAR	207 E ROBERTSON STREET SUITE B BRANDON, FL 33511		Hillsborough

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2205	LIFE WORTH LIVING FOUNDATION, INC.	LIFE WORTH LIVING PHARMACY	PH	27392	20638	01/23/2014	01/08/2014	3PTR	ERROR	6488 CURRIN DRIVE ORLANDO, FL 32835		Orange
2205	LIFE WORTH LIVING FOUNDATION, INC.	LIFE WORTH LIVING PHARMACY	PH	27456	20658	02/05/2014	01/14/2014	3PTR	CLEAR	6488 CURRIN DRIVE ORLANDO, FL 32835		Orange
2205	LIFE WORTH LIVING FOUNDATION, INC.	LIFE WORTH LIVING PHARMACY	PH	27457	20745	02/05/2014	02/05/2014	3PTR	CLEAR	6488 CURRIN DRIVE ORLANDO, FL 32835		Orange
2205	MARTIN MEMORIAL MED CTR INC	MARTIN HOSPITAL SOUTH	PH	12065	3036	07/29/1992	02/24/2014	3PTR	CLEAR	2100 S E SALERNO RD Attn: Pharmacy Dept. STUART, FL 34997		Martin
2205	MARTIN MEMORIAL MEDICAL CENTER	TRADITION MEDICAL CENTER	PH	27540	20735	02/20/2014	01/31/2014	3PTR	CLEAR	10000 SW INNOVATION WAY ATTN: Pharmacy PORT SAINT LUCIE, FL 34987		St.Lucie
2205	MARTIN MEMORIAL MEDICAL CENTER	MARTIN HOSPITAL SOUTH			20925		02/24/2014	3PTR	APPL IN PROC	2100 SE SALERNO RD ATTN: Pharmacy STUART, FL 34997		Martin
2205	MARTIN MEMORIAL MEDICAL CENTER INC	MARTIN MEDICAL CENTER	PH	2175	357		02/25/2014	3PTR	CLEAR	200 Hospital Avnue Attn: Pharmacy Dept. STUART, FL 34995-2396		Martin
2205	MARTIN MEMORIAL MEDICAL CENTER INC	MARTIN MEDICAL CENTER	PH	27668	20930	03/12/2014	02/25/2014	3PTR	CLEAR	200 HOSPITAL AVE. STUART, FL 34995		Martin
2205	MED SOLUTIONS PHARMACY, INC.	MED SOLUTIONS PHARMACY, INC.			20674		01/21/2014	2PTR	APPL IN PROC	1078 S. POWERLINE RD. DEERFIELD BEACH, FL 33442		Broward
2205	MEDI-PHYSICS, INC	GE HEALTHCARE	PH	12132	3087	10/05/1992	02/26/2014	3PTR	CLEAR	4175 W. NEW HAVEN AVENUE SUITE 3 MELBOURNE, FL 32904	(321) 255-7847	Brevard
2205	MEDI-PHYSICS, INC.	GE HEALTHCARE	PH	11269	2552	09/06/1990	02/26/2014	3PTR	CLEAR	7802 WOODLAND CENTER BLVD TAMPA, FL 33614	(813) 290-8747	Hillsborough
2205	MEDI-PHYSICS, INC.	GE HEALTHCARE	PH	11272	2554	09/12/1990	02/28/2014	3PTR	CLEAR	10725-10731 MARKS WAY MIRAMAR, FL 33025	(305) 628-2001	Broward
2205	MEDI-PHYSICS, INC.	GE HEALTHCARE			20943		02/26/2014	3PTR	APPL IN PROC	4175 W. NEW HAVEN SUITE 3 MELBOURNE, FL 32904		Brevard
2205	MEDI-PHYSICS, INC.	GE HEALTHCARE			20952		02/28/2014	3PTR	APPL IN PROC	10725 MARKS WAY MIRAMAR, FL 33025	954-432-4255	Broward
2205	MEDI-PHYSICS. INC.	GE HEALTHCARE			20941		02/26/2014	3PTR	APPL IN PROC	7802 WOOD LAND CENTER BLVD TAMPA, FL 33614		Hillsborough
2205	MEDICINE CHEST-SPANISH SPRINGS TOWN SQUA	MEDICINE CHEST			20682		01/22/2014	3PTR	APPL IN PROC	1150 PAIGE PLACE THE VILLAGES, FL 32159		Lake
2205	METROPOLITAN HEALTH COMMUNTY SERVICES				20984		02/24/2014	3PTR	APPL IN PROC	5959 NW 7TH STREET MIAMI, FL 33126	305-264-1000	Miami-Dade
2205	MIAMI INTERNATIONAL MEDICAL CENTER, LLC	MIAMI INTERNATIONAL MEDICAL CENTER			20909		02/21/2014	3PTR	APPL IN PROC	11221 ROE AVENUE, #320 LEAWOOD, KS 66211		Unknown
2205	MIAMI INTERNATIONAL MEDICAL CENTER, LLC				20910		02/21/2014	3PTR	APPL IN PROC	11221 ROE AVENUE Suite 320 LEAWOOD, KS 66211		Unknown
2205	MULBERRY PHARMACY INC.	MULBERRY PHARMACY INC	PH	27597	20923	03/03/2014	02/24/2014	3PTR	CLEAR	PO BOX 767 MULBERRY, FL 33860		Polk
2205	NAPLES COMMUNITY HOSPITAL INC		PH	1884	264		02/25/2014	3PTR	CLEAR	350 7TH ST N NAPLES, FL 34102	(239) 624-3784	Collier
2205	NAPLES HMA LLC	PHYSICIANS REGIONAL MEDICAL CENTER-COLLI			20889		02/19/2014	3PTR	APPL IN PROC	8300 COLLIER BLVD NAPLES, FL 34114		Collier

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2205	NAPLES HMA, LLC	PHYSICIANS REGIONAL MEDICAL CENTER	PH	27549	20737	02/24/2014	01/31/2014	3PTR	CLEAR	6101 PINE RIDGE ROAD NAPLES, FL 34119		Collier
2205	NEW ERA PHARMACEUTICALS LLC	NEW ERA SPECIALTY PHARMACY			20830		02/13/2014	3PTR	APPL IN PROC	3350 NW 53RD ST STE 102-104 FORT LAUDERDALE, FL 33309		Broward
2205	NOLBIS PHARMACY DISCOUNT INC	NOLBIS PHARMACY	PH	27384	20634	01/21/2014	01/07/2014	3PTR	CLEAR	710 PALM AVE HIALEAH, FL 33010		Miami-Dade
2205	NORTH BROWARD HOSPITAL DISTRICT	BROWARD HEALTH MEDICAL CENTER	PH	27454	20651	02/05/2014	01/14/2014	3PTR	CLEAR	1600 S. ANDREWS AVENUE FORT LAUDERDALE, FL 33316		Broward
2205	NORTH BROWARD HOSPITAL DISTRICT	BROWARD HEALTH CORAL SPRINGS	PH	27551	20659	02/24/2014	01/16/2014	3PTR	CLEAR	3000 CORAL HILLS DR CORAL SPRINGS, FL 33065		Broward
2205	NORTH BROWARD HOSPITAL DISTRICT	BROWARD HEALTH IMPERIAL POINT	PH	27550	20663	02/24/2014	01/17/2014	3PTR	CLEAR	6401 NORTH FEDERAL HWY FORT LAUDERDALE, FL 33308		Broward
2205	NORTH FLORIDA REGIONAL MEDICAL CENTER, I				20897		02/20/2014	3PTR	APPL IN PROC	6500 W NEWBERRY ROAD GAINESVILLE, FL 32605		Alachua
2205	NORTHWEST MEDICAL CENTER	NORTHWEST MEDICAL CENTER	PH	27644	20785	03/11/2014	02/07/2014	3PTR	CLEAR	2801 NORTH STATE RD 7 MARGATE, FL 33063		Broward
2205	NOTAMI HOSPITALS OF FLORIDA INC	LAKE CITY MEDICAL CENTER			20888		02/18/2014	3PTR	APPL IN PROC	340 N W COMMERCE DRIVE LAKE CITY, FL 32055		Columbia
2205	OKALOOSA HOSPITAL, INC.	COLUMBIA TWIN CITIES HOSPITAL	PH	2131	337		02/17/2014	3PTR	CLEAR	2190 HIGHWAY 85 NORTH NICEVILLE, FL 32578		Okaloosa
2205	OMNICARE PHARMACY OF FLORIDA, LP	OMNICARE OF JACKSONVILLE	PH	27616	20924	03/06/2014	02/24/2014	3PTR	CLEAR	9143 PHILLIPS HWY SUITE 533 JACKSONVILLE, FL 32256		Duval
2205	OMNICARE PHARMACY OF FLORIDA, LP	OMNICARE OF PANAMA CITY			20931		02/25/2014	3PTR	APPL IN PROC	2605 W. 23RD ST PANAMA CITY, FL 32405		Bay
2205	OMNICARE PHARMACY OF FLORIDA, LP	OMNICARE OF SOUTH FLORIDA			20933		02/25/2014	3PTR	APPL IN PROC	2955 WEST CORPORATE LAKES BLVD SUITE 600 WESTON, FL 33331		Broward
2205	OMNICARE PHARMACY OF FLORIDA, LP	OMNICARE OF TAMPA			20934		02/25/2014	3PTR	APPL IN PROC	8603 FLORIDA MINING BLVD TAMPA, FL 33034		
2205	OMNICARE PHARMACY OF FLORIDA, LP	OMNICARE OF CENTRAL FLORIDA			20937		02/26/2014	3PTR	APPL IN PROC	4150 CHURCH STREET SUITE 1030 SANFORD, FL 32771		Seminole
2205	OMNICARE PHARMACY OF FLORIDA, LP	OMNICARE OF FORT MYERS			20946		02/26/2014	3PTR	APPL IN PROC	10251 METRO PARKWAY FORT MYERS, FL 33966		Lee
2205	OPS INTERNATIONAL INCORPORATED	OLYMPIA PHARMACY	PH	27363	20618	01/09/2014	01/02/2014	3PTR	CLEAR	6700 CONROY ROAD STE 155 ORLANDO, FL 32835		Orange
2205	OPS INTERNATIONAL INCORPORATED	OLYMPIA PHARMACY	PH	27414	20619	01/24/2014	01/02/2014	3PTR	CLEAR	6700 CONROY ROAD STE 155 ORLANDO, FL 32835		Orange
2205	OPTIMUM HEALTH PHARMACY, LLC	OPTIMUM HEALTH PHARMACY, LLC			20652		01/14/2014	3PTR	APPL IN PROC	2920 LITHIA PINE CREST ROAD UNIT D VALRICO, FL 33596		Hillsborough
2205	OPTION CARE ENTERPRISES, INC.	WALGREENS INFUSION SERVICES	PH	27603	20710	03/04/2014	01/28/2014	3PTR	CLEAR	P O BOX 377 DEERFIELD, IL 60015		Unknown
2205	OSCEOLA SC, LLC	ST. CLOUD REGIONAL MEDICAL CENTER	PH	27520	20876	02/18/2014	02/17/2014	3PTR	CLEAR	2906 17TH ST SAINT CLOUD, FL 34769		Osceola

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2205	OSCEOLASC, LLC	ST. CLOUD REGIONAL MEDICAL CENTER	PH	21744	14191	12/27/2005	02/18/2014	3PTR	CLEAR	2906 17TH STREET SAINT CLOUD, FL 34769	407-498-3630	Osceola
2205	P & H PHARMACY DISCOUNT, INC	D & H PHARMACY DISCOUNT	PH	27381	20532	01/21/2014	01/21/2014	2PTR	CLEAR	9527 SW 40TH ST MIAMI, FL 33165		Miami-Dade
2205	P. A PHARMACY INC.	P. A PHARMACY INC.	PH	27440	20691	01/31/2014	01/23/2014	3PTR	CLEAR	9722 SW 184TH ST CUTLER RIDGE, FL 33157		Miami-Dade
2205	PAC SHORES PHARMACY LLC	SHORES VILLAGE PHARMACY	PH	27571	20881	02/26/2014	02/18/2014	3PTR	CLEAR	9416 NE 2ND AVE MIAMI SHORES, FL 33138		Miami-Dade
2205	PACIFICO NATIONAL INC	AMEX PHARMACY	PH	27532	20778	02/19/2014	02/06/2014	3PTR	CLEAR	1515 ELIZABETH ST SUITE J MELBOURNE, FL 32901		Brevard
2205	PALM BEACH GARDENS COMMUNITY HOSPITAL IN	PALM BEACH GARDENS MEDICAL CENTER			20818		02/12/2014	3PTR	APPL IN PROC	3360 BURNS ROAD PALM BEACH GARDENS, FL 33410		Palm Beach
2205	PALM BEACH PHARMACEUTICALS, INC	PALM BEACH PHARMACEUTICALS, INC			20947		02/28/2014	3PTR	APPL IN PROC	8409 NORTH MILITARY TRAIL SUITE 125 PALM BEACH GARDENS, FL 33410		Palm Beach
2205	PALM SPRINGS GENERAL HOSPITAL		PH	2235	385		02/24/2014	3PTR	OBLIGATIONS	1475 W 49TH ST HIALEAH, FL 33012-3275		Miami-Dade
2205	PALM SPRINGS GENERAL HOSPITAL INC.	PALM SPRINGS GENERAL HOSPITAL INC.	PH	27555	20761	02/24/2014	02/04/2014	3PTR	CLEAR	1475 WEST 49 STREET 3RD FLOOR HIALEAH, FL 33012		Miami-Dade
2205	PASCO REGIONAL MEDICAL CENTER, LLC	PASCO REGIONAL MEDICAL CENTER	PH	17414	9434	08/09/2000	02/27/2014	3PTR	CLEAR	13100 FORT KING ROAD DADE CITY, FL 33525	(352) 521-1185	Pasco
2205	PASCO REGIONAL MEDICAL CENTER, LLC	PASCO REGIONAL MEDICAL CENTER			20871		02/17/2014	3PTR	APPL IN PROC	13100 FORT KING ROAD DADE CITY, FL 33525		Pasco
2205	PEE JAY, INC	PRESCRIPTIONS UNLIMITED VC	PH	27664	20738	03/12/2014	01/31/2014	3PTR	CLEAR	2521 13TH ST. SUITE A-1 SAINT CLOUD, FL 34769		Osceola
2205	PENSACOLA APOTHECARY	PENSACOLA APOTHECARY	PH	27595	20819	03/03/2014	02/12/2014	3PTR	CLEAR	825 EAST BURGESS ROAD PENSACOLA, FL 32504		Escambia
2205	PHARMACEUTICAL CARE CONSULTANTS OF FL	SKIP'S PHARMACY	PH	27578	20838	02/27/2014	02/14/2014	3PTR	CLEAR	21000 BOCA RIO ROAD SUITE A-29 BOCA RATON, FL 33433		Palm Beach
2205	PHARMACY MEDICAL SERVICES INC	PHARMACY MEDICAL SERVICES INC #2			20963		02/28/2014	3PTR	APPL IN PROC	3850 COCONUT CREEK PARKWAY COCONUT CREEK, FL 33066		Broward
2205	PHARMAKARE LLC	MEDPLUS PHARMACY			20765		02/05/2014	3PTR	APPL IN PROC	1657 CROOKED OAK DR. ORANGE PARK, FL 32065		Clay
2205	PINO PHARMACY	PINO PHARMACY	PH	27514	20686	02/17/2014	01/22/2014	3PTR	CLEAR	1350 SW 57 AVE SUITE 105 WEST MIAMI, FL 33144		Miami-Dade
2205	PORT CHARLOTTE HMA, INC	PEACE RIVER REGIONAL MEDICAL CENTER	PH	27605	20779	03/04/2014	02/06/2014	3PTR	CLEAR	2500 HARBOR BLVD PORT CHARLOTTE, FL 33952		Charlotte
2205	PRAXIS SPECIALTY PHARMACY LLC				20810		02/11/2014	3PTR	APPL IN PROC	103 WEST VANDALIA SUITE 100 EDWARDSVILLE, IL 62025		Unknown
2205	PRECISION RX COMPOUNDING LLC	PRECISION RX COMPOUNDING LLC	PH	26572	19625	12/12/2012	02/06/2014	3PTR	CLEAR	10323 Cross Creek Blvd Suite A TAMPA, FL 33647		Hillsborough
2205	PROFESSIONAL PHARMACY & COMPOUNDING SERV	PPCS			20645		01/14/2014	3PTR	APPL IN PROC	3921 NW 7TH STREET MIAMI, FL 33126		Miami-Dade

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Prof	Organization Name	DBA Name	Rank	License #	File #	Issue Dte	Modifier Effct Dte	Mod Cde	Lic Status	Mailing Address	Phone	County
2205	PROFESSIONAL PHARMACY & COMPOUNDING SERV	PPCS			20657		01/16/2014	3PTR	APPL IN PROC	3921 N W 7TH STREET MIAMI, FL 33126		Miami-Dade
2205	PRONTO-MED INC	BIO CARE PHARMACY			20643		01/14/2014	3PTR	APPL IN PROC	1409 NE 26TH ST WILTON MANORS, FL 33305		Broward
2205	PUBLIC HEALTH TRUST	JACKSON NORTH MEDICAL CENTER	PH	22558	15044	02/19/2007	02/25/2014	3PTR	CLEAR	160 NW 170TH STREET N. MIAMI BEACH, FL 33169	(305) 585-7458	Miami-Dade
2205	PUBLIC HEALTH TRUST	JACKSON NORTH MEDICAL CENTER	PH	27561	20839	02/25/2014	02/14/2014	3PTR	CLEAR	160 NW 170TH STREET NORTH MIAMI BEACH. FL 33169		Miami-Dade
2205	PUBLIX SUPER MARKET, INC.	PUBLIX PHARMACY #0339			20641		01/07/2014	3PTR	APPL IN PROC	P O BOX 32018 ATTN: LICENSE LAKELAND, FL 33802		Polk
2205	PUBLIX SUPER MARKETS, INC	PUBLIX PHARMACY #0581			20873		02/17/2014	3PTR	APPL IN PROC	P O BOX 32018 LAKELAND, FL 33802	863-688-7407	Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #1441	PH	27366	20647	01/15/2014	02/05/2014	3PTR	CLEAR	P O BOX 32027 LAKELAND, FL 33802		Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #1461	PH	27385	20648	01/21/2014	01/07/2014	3PTR	CLEAR	P O BOX 32027 ATTN: LICENSES LAKELAND, FL 33802		Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #1458	PH	27538	20770	02/20/2014	02/05/2014	3PTR	CLEAR	P O BOX 32027 LAKELAND, FL 33802	863-688-7407	Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #0028			20771		02/05/2014	3PTR	APPL IN PROC	P.O. BOX 32027 LAKELAND, FL 33802		Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #0872			20772		02/05/2014	3PTR	APPL IN PROC	P O BOX 32018 LAKELAND, FL 33802	863-688-7407	Polk
2205	PUBLIX SUPER MARKETS, INC.		PH	27567	20773	02/25/2014	02/06/2014	3PTR	CLEAR	P O BOX 32027 LAKELAND, FL 33802	863-688-7407	Polk
2205	PUBLIX SUPER MARKETS, INC.	PUBLIX PHARMACY #0785			20774		02/07/2014	3PTR	APPL IN PROC	P O BOX 32018 LAKELAND, FL 33802	863-688-7407	Polk
2205	PUTNAM COMMUNITY MEDICAL CENTER, LLC	PUTMAN COMMUNITY MEDICAL CENTER	PH	17362	9361	07/07/2000	02/25/2014	3PTR	CLEAR	611 ZEAGLER DRIVE PALATKA, FL 32177	(386) 328-5711	Putnam
2205	RECEPTION AND MEDICAL CENTER	RECEPTION AND MEDICAL CENTER	PH	27484	20644	02/11/2014	01/14/2014	3PTR	CLEAR	7765 SOUTH COUNTY ROAD 231 LAKE BUTLER, FL 32054		Union
2205	RIGAL PHARMACY LLC	RIGAL PHARMACY LLC	PH	27473	20684	02/06/2014	01/22/2014	3PTR	CLEAR	3180 N W 7TH ST MIAMI, FL 33125		Miami-Dade
2205	ROBERT'S SOUTH BANK PHARMACY, INC	ROBERT'S SOUTH BANK PHARMACY, INC	PH	27489	20711	02/11/2014	01/29/2014	3PTR	CLEAR	1625 ATLANTIC BLVD JACKSONVILLE, FL 32207		Duval
2205	ROSSY MEDICAL INC.	HEALTH CENTER PHARMACY	PH	24179	16858	07/16/2009	02/05/2014	2PTR	CLEAR	6360 W OAKLAND PARK BLVD. SUNRISE, FL 33313		Broward
2205	S P PHARMACY CORP	S P PHARMACY CORP	PH	27569	20635	02/26/2014	01/07/2014	3PTR	CLEAR	5587 SW 8TH ST. CORAL GABLES, FL 33134		Miami-Dade
2205	SACRED HEART HEALTH SYSTEM INC		PH	2143	342		02/27/2014	3PTR	CLEAR	5151 N 9TH AVE PENSACOLA, FL 32504-8721	(850) 416-7712	Escambia
2205	SACRED HEART HEALTH SYSTEM, INC.	SACRED HEART HOSPITAL OF PENSACOLA	PH	27576	20828	02/27/2014	02/13/2014	3PTR	CLEAR	5151 N NINTH AVENUE PENSACOLA, FL 32504		Escambia
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2419			20845		02/13/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2417	PH	27674	20846	03/12/2014	02/13/2014	3PTR	CLEAR	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2411			20847		02/13/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2409			20848		02/13/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32254		Duval

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2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2404			20849		02/13/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2400			20850		02/13/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2448			20851		02/13/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE # 2446			20852		02/13/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2444	PH	27675	20853	03/12/2014	02/14/2014	3PTR	CLEAR	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2443			20854		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2435			20855		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2427			20856		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2521			20857		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2465			20858		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2475			20860		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE # 2515			20861		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2519			20862		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC				20863		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2480			20864		02/14/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC				20865		02/17/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2525			20867		02/17/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2513			20868		02/17/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE # 2509			20869		02/17/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SAMSON MERGER SUB, LLC	WINN DIXIE #2505			20870		02/17/2014	3PTR	APPL IN PROC	P.O. BOX 2209 JACKSONVILLE, FL 32203		Duval
2205	SARASOTA DOCTORS HOSPITAL, INC	DOCTORS HOSPITAL OF SARASOTA	PH	27448	20636	02/04/2014	01/07/2014	3PTR	CLEAR	5731 BEE RIDGE RD SARASOTA, FL 34233		Sarasota
2205	SARASOTA MANATEE JEWISH HOUSING COUNCIL	JEWISH HOUSING COUNCIL PHARMACY			20624		01/02/2014	3PTR	APPL IN PROC	1951 NORTH HONORE AVE SARASOTA, FL 34235		Sarasota
2205	SEBASTIAN HOSPITAL, LLC	SEBASTIAN RIVER MEDICAL CENTER			20970		02/28/2014	3PTR	APPL IN PROC	13695 U S HIGHWAY 1 SEBASTIAN, FL 32958		Indian River
2205	SEBASTIAN HOSPITAL, LLC	SEBASTIAN RIVER MEDICAL CENTER	PH	12719	3510	02/04/1994	02/28/2014	3PTR	CLEAR	13695 US #1 NORTH SEBASTIAN, FL 32958		Indian River
2205	SELECT SPECIALTY HOSPITAL - PANAMA CITY,		PH	19775	11906	01/07/2004	02/25/2014	3PTR	CLEAR	4714 GETTYSBURG ROAD LEGAL MECHANICSBURG, PA 17055	(850) 473-4980	Unknown
2205	SELECT SPECIALTY HOSPITAL-PALM BEACH INC	SELECT SPECIALTY HOSPITAL-PALM BEACH	PH	23118	15696	12/11/2007	02/24/2014	3PTR	CLEAR	4714 GETTYSBURG ROAD LEGAL DEPT MECHANICSBURG, PA 17055	(717) 972-1100	Unknown
2205	SELECT SPECIALTY HOSPITAL-TALLAHASSEE, I	SELECT SPECIALTY HOSPITAL-TALLAHASSEE	PH	22737	15123	06/04/2007	02/20/2014	3PTR	CLEAR	4714 GETTYSBURG ROAD MECHANICSBURG, PA 17055	(717) 972-1100	Unknown
2205	SHANDS TEACHING HOSPITAL AND CLINICS, IN	UF HEALTH SHANDS HOSPITAL	PH	27395	20650	01/23/2014	01/14/2014	3PTR	CLEAR	1600 SW ARCHER ROAD GAINESVILLE, FL 32610		Alachua

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2205	SHRX, LLC	BAY HARBOR DRUGS			20746		02/03/2014	3PTR	APPL IN PROC	1015 KANE CONC OURSE BAL HARBOUR, FL 33154	954-649-8202	Miami-Dade
2205	SIMS PHARMACY, LLC	GULF BREEZE APOTHECARY	PH	27398	20649	01/24/2014	01/14/2014	3PTR	CLEAR	1177 GULF BREEZE PKWY GULF BREEZE, FL 32561		Santa Rosa
2205	SKYEMED INC	SKYEMED PHARMACY & INFUSION SERVICES	PH	27629	20936	03/07/2014	02/26/2014	3PTR	CLEAR	1332 N. FEDERAL HWY POMPANO BEACH, FL 33062		Broward
2205	SOUTH BROWARD HOSPITAL DISTRICT	MEMORIAL HOSPITAL MIRAMAR	PH	21084	13210	01/25/2005	02/25/2014	3PTR	CLEAR	1901 SW 172ND AVE MIRAMAR, FL 33029		Broward
2205	SOUTH BROWARD HOSPITAL DISTRICT	MEMORIAL HOSPITAL PEMBROKE	PH	13455	4103	06/30/1995	02/26/2014	3PTR	CLEAR	7800 SHERIDAN STREET PEMBROKE PINES, FL 33024	(954) 883-8418	Broward
2205	SOUTH BROWARD HOSPITAL DISTRICT	MEMORIAL HOSPITAL PHARMACY	PH	27430	20681	01/29/2014	01/22/2014	3PTR	CLEAR	3501 JOHNSON STREET HOLLYWOOD, FL 33021		Broward
2205	SOUTH BROWARD HOSPITAL DISTRICT	JOE DIMAGGIO CHILDREN'S HOSPITAL	PH	27431	20696	01/29/2014	01/24/2014	2PTR	CLEAR	1005 JOE DIMAGGIO WAY HOLLYWOOD, FL 33021		Broward
2205	SOUTH MIAMI HOSPITAL, INC.	SOUTH MIAMI HOSPITAL			20895		02/20/2014	3PTR	APPL IN PROC	6200 SW 73 ST SOUTH MIAMI, FL 33143		Miami-Dade
2205	SPAR USA LLC.	SIGNATURE PHARMACY	PH	27481	20667	02/10/2014	01/21/2014	3PTR	CLEAR	545 N VIRGINIA AVENUE WINTER PARK, FL 32789		Orange
2205	SPECIALTY PHARMACY SERVICES, INC	SPECIALTY PHARMACY SERVICES, INC	PH	27461	20736	02/06/2014	01/31/2014	3PTR	CLEAR	800 E. MELBOURNE AVE MELBOURNE, FL 32901		Brevard
2205	STANLEY LONG TERM CARE PHARMACY OF FL LL		PH	22885	15366	08/28/2007	02/19/2014	3PTR	CLEAR	1228 TECH BLVD TAMPA, FL 33619	(813) 549-7271	Hillsborough
2205	STANLEY LTC OF FLORIDA	STANLEY PHARMACY	PH	27612	20893	03/05/2014	02/19/2014	3PTR	CLEAR	1228 TECH BLVD TAMPA, FL 33619		Hillsborough
2205	STARX PHARMACY	STARX PHARMACY			20835		02/14/2014	3PTR	APPL IN PROC	802 E DIXIE AVE LEESBURG, FL 32748		Lake
2205	SUN PHARMACY, LLC	SUN PHARMACY	PH	27577	20841	02/27/2014	02/14/2014	3PTR	CLEAR	3320 SCHERER DR. SUITE A SAINT PETERSBURG, FL 33716		Pinellas
2205	TALLAHASSEE MEMORIAL HEALTHCARE	TALLAHASSEE MEMORIAL HEALTHCARE NORTHEAS	PH	27533	20723	02/19/2014	01/31/2014	3PTR	CLEAR	1300 MICCOSUKEE RD PHARMACY SERVICES ATTN: CLARENCE HERRING TALLAHASSEE, FL 32308		Leon
2205	TAMIMI PHARMACY, LLC	SALHAB PHARMACY	PH	27365	20617	01/13/2014	01/02/2014	3PTR	CLEAR	12643 NORTH 56TH STREET TAMPA, FL 33617		Hillsborough
2205	TAMPA FAMILY HEALTH CENTER, INC.	TFHC #29 - SHELDON PHARMACY	PH	27480	20620	02/10/2014	01/02/2014	2PTR	CLEAR	P.O. BOX 82969 TAMPA, FL 33682		Hillsborough
2205	TAMPA FAMILY HEALTH CENTERS	TFHC #29 - NEW SHELDON	PH	27572	20917	02/26/2014	02/18/2014	2PTR	CLEAR	P.O. BOX 82969 TAMPA, FL 33682		Hillsborough
2205	TECH PHARMACY SERVICES, INC	ADVANCED PHARMACY			20687		01/22/2014	3PTR	APPL IN PROC	45 SKYLINE DRIVE SUITE 1011 LAKE MARY, FL 32746		Seminole
2205	TENET GOOD SAMARITAN, INC.	GOOD SAMARITAN HOSPITAL	PH	17994	10047	07/01/2001	02/17/2014	3PTR	CLEAR	1309 N FLAGLER DRIVE PHARMACY DEPARTMENT WEST PALM BCH, FL 33401	(561) 650-6304	Palm Beach
2205	TENET GOOD SAMARITAN, INC.	GOOD SAMARITAN HOSPITAL	PH	27519	20844	02/18/2014	02/17/2014	3PTR	CLEAR	1309 N. FLAGLER DR WEST PALM BEACH, FL 33401		Palm Beach
2205	TENET HEALTHSYSTEM NORTH SHORE, INC.	NORTH SHORE MEDICAL CENTER - FMC CAMPUS	PH	27594	20791	03/03/2014	02/10/2014	3PTR	CLEAR	1100 N W 95 STREET MIAMI, FL 33350		

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2205	TOWERS PHARMACY INC	BAPTIST MEDICAL PARK PHARMACY			20842		02/17/2014	3PTR	APPL IN PROC	9400 UNIVERSITY PARKWAY SUITE 118 PENSACOLA, FL 32514		Escambia
2205	UNIVERSITY COMMUNITY HOSPITAL, INC.	FLORIDA HOSPITAL TAMPA			20776		02/05/2014	3PTR	APPL IN PROC	3100 EAST FLETCHER AVE TAMPA, FL 33613		Hillsborough
2205	UNIVERSITY COMMUNITY HOSPITAL, INC.	FLORIDA HOSPITAL CARROLLWOOD			20826		02/12/2014	3PTR	APPL IN PROC	7171 NORTH DALE MABRY HWY ATTN: PHARMACY TAMPA, FL 33614		Hillsborough
2205	UNIVERSITY COMMUNITY HOSPITAL, INC.	FLORIDA HOSPITAL CONNERTON			20904		02/20/2014	2PTR	APPL IN PROC	9441 HEALTH CENTER DR ATTN: PHARMACY LAND O LAKES, FL 34637		Pasco
2205	VARIETY CHILDREN'S HOSPITAL	MIAMI CHILDREN'S HOSPITAL			20768		02/05/2014	3PTR	APPL IN PROC	3100 SW 62ND AVE MIAMI, FL 33155		Miami-Dade
2205	VIERA HOSPITAL INC	VIERA HOSPITAL			20827		02/13/2014	2PTR	APPL IN PROC	8745 N WICKHAM RD MELBOURNE, FL 32940		Brevard
2205	WALGREEN CO.	WALGREENS #15209			20788		02/10/2014	3PTR	APPL IN PROC	P.O. BOX 901 DEERFIELD, IL 60015		Unknown
2205	WEST FLORIDA - TCH, LLC	TOWN & COUNTRY HOSPITAL	PH	27447	20740	02/04/2014	02/03/2014	3PTR	CLEAR	6001 WEBB ROAD TAMPA, FL 33615		Hillsborough
2205	WEST FLORIDA HOSPITAL	WEST FLORIDA HOSPITAL			20685		01/22/2014	3PTR	APPL IN PROC	8383 N. DAVIS HWY PENSACOLA, FL 32514		Escambia
2205	WEST FLORIDA- MHT, LLC	MEMORIAL HOSPITAL OF TAMPA	PH	27559	20903	02/25/2014	02/20/2014	3PTR	CLEAR	2901 W SWANN AVE TAMPA, FL 33609		Hillsborough
2205	WEST GABLES REHABILITATION HOSPITAL, LLC	WEST GABLES REHABILITATION HOSPITAL	PH	21514	13868	09/12/2005	02/19/2014	2PTR	CLEAR	2525 SW 75TH AVE MIAMI, FL 33155		Miami-Dade
2205	WEST KENDALL BAPTIST HOSPITAL	WEST KENDALL BAPTIST HOSPITAL	PH	27503	20798	02/13/2014	02/10/2014	3PTR	CLEAR	9555 SW 162ND AVENUE MIAMI, FL 33196		Miami-Dade
2205	WSRX HEALTHCARE LLC	WINTER SPRINGS SPECIALTY PHARMACY	PH	27663	20622	03/12/2014	01/02/2014	2PTR	CLEAR	239 CALLIOPE STREET OCOEE, FL 34761		Orange
2205	ZUMA PHARMACY INC				20880		02/18/2014	2PTR	APPL IN PROC	554 HIALEAH DRIVE HIALEAH, FL 33010		Miami-Dade

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New License Report for 2209 : Pharmacy Technician Training Program

1/ 1/2014 - 2/28/2014

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Rank	Lic Nbr	Issue Date	Licensee Name	Birth Date	EDU Provider	EDU Institution	PL Address	PL Location
RTTP	476	01/02/2014	Allied Health And Technical Training Ins				7205- 7207 West Oakland Park Blvd	Lauderhill, FL 33313
RTTP	477	01/07/2014	Shivaji Group Inc				5875 San Juan Ave Suite C	Jacksonville, FL 32210
RTTP	478	01/07/2014	National Compounding Company Inc				1824 59Th St West	Bradenton, FL 34209
RTTP	479	01/07/2014	Fortis Institute				9022 South Us Highway 1	Port Saint Lucie, FL 34952
RTTP	480	01/09/2014	Radhika Corp				145 E. Broad St	Groveland, FL 34736
RTTP	481	01/10/2014	Leon Medical Centers				12515 Sw 88Th St.	Miami, FL 33186
RTTP	482	01/10/2014	Life Extension Pharmacy Inc.				5990 N Federal Highway	Fort Lauderdale, FL 33308
RTTP	483	01/13/2014	I.V. Stat, Inc.				279 Texas Parkway	Crestview, FL 32536
RTTP	484	01/14/2014	Mathew Management Inc				2090 Gulf Tobay Blvd	Clearwater, FL 33765
RTTP	485	01/15/2014	University Of West Florida, Continuing E				1100 University Parkway Bldg 77	Pensacola, FL 32514
RTTP	486	01/21/2014	Leon Medical Centers				2020 West 64 St	Hialeah, FL 33016
RTTP	487	01/21/2014	Leon Medical Centers				7950 Nw 2 St	Miami, FL 33126
RTTP	488	01/22/2014	Bay Street Pharmacy Inc				7746 Bay Street	Sebastian, FL 32958
RTTP	489	01/22/2014	Brooksville Drugs Inc.				80 Ponce Deleon Blvd	Brooksville, FL 34601
RTTP	490	01/23/2014	Costco Wholesale Corporation				2101 Waterbridge Blvd	Orlando, FL 32837
RTTP	491	01/24/2014	Boca Raton Pharmacy, Inc.				4802 Nw 2 Avenue	Boca Raton, FL 33431
RTTP	492	01/27/2014	International Academy Of Design & Techno				3725 W. Grace Street	Tampa, FL 33607
RTTP	493	01/27/2014	International Academy Of Design & Techno				3725 W. Grace Street	Tampa, FL 33607
RTTP	494	01/28/2014	Brashear'S Vital Care Corporation				206 W. Dampier Street	Inverness, FL 34450
RTTP	495	01/28/2014	Lorenzo Walker Institute Of Technology				3702 Estey Avenue	Naples, FL 34104

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RTTP	496	01/28/2014	Caremax Pharmacy Llc				2789 Park Street	Jacksonville, FL 32205
RTTP	497	02/05/2014	Cheek And Scott Drugs Inc.				1520 Ohio Ave. South	Live Oak, FL 32064
RTTP	498	02/06/2014	Palm Beach Vocational Institute, Inc				901 N. Congress Avenue Suite C-201	Boynton Beach, FL 33426
RTTP	499	02/06/2014	Lantana Pharmacy Incorporated				3206 Lantana Rd	Lantana, FL 33462
RTTP	500	02/07/2014	Blanding Health Mart Pharmacy, Llc				5136 Blanding Blvd	Jacksonville, FL 32210
RTTP	501	02/07/2014	Emerald Hills Pharmacy				3000 Stirling Road Suite 120	Hollywood, FL 33021
RTTP	502	02/10/2014	Leon Medical Centers				7490 Nw 68 St.	Miami, FL 33166
RTTP	503	02/10/2014	Smart Choice Group Inc				1478 N. State Rd 7	Lauderhill, FL 33313
RTTP	504	02/12/2014	Palm Coast Pharmacy				9 Pine Cone Dr Suite #109	Palm Coast, FL 32137
RTTP	505	02/14/2014	Azof Enterprises, Inc.				1870 Se Port St Lucie Blvd	Port Saint Lucie, FL 34952
RTTP	506	02/14/2014	Lake Technical Center, Inc.				2001 Kurt Street	Eustis, FL 32726
RTTP	507	02/17/2014	Havana Ltc Pharmacy				3818 S. Himes Ave Ste 1	Tampa, FL 33611
RTTP	508	02/20/2014	A To Z Pharmacy Inc.				9039 Little Rd	New Port Richey, FL 34654
RTTP	509	02/20/2014	Neptune Beach Pharmacy Llc				1529 Atlantic Blvd	Neptune Beach, FL 32266
RTTP	510	02/24/2014	Dispensing Physician Consultants, Inc.				4900 Linton Blvd Suite 21/22	Delray Beach, FL 33445
RTTP	511	02/26/2014	St Rebekah Pharmacy Inc.				500 West Granada Blvd Suite 4	Ormond Beach, FL 32174
RTTP	512	02/28/2014	Florida Atlantic University				777 Glades Road S E 308	Boca Raton, FL 33431

Total Records: **37**

Provider Name	Provider #	Course Name	Course #	Status	Approved Date
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419	PHA SS98: NEUROLOGICAL AND PSYCHIATRIC DISORDERS	20-428075	APPROVED	1/31/2014
FLORIDA PHARMACY ASSOCIATION	50-754	HIV AIDS UPDATE	20-432650	APPROVED	2/28/2014
FLORIDA PHARMACY ASSOCIATION	50-754	INITIAL CERTIFICATION FOR ORDERING AND EVALUATING LABORATORY STUDIES	20-432613	APPROVED	2/28/2014
AKH INC. ADVANCING KNOWLEDGE IN HEALTHCARE	50-2560	HIV/AIDS 1 HOUR UPDATE FOR FLORIDA HEALTH PROFESSIONALS 2013-2015	20-409121	APPROVED	1/8/2014
FLORIDA SOCIETY OF HEALTH SYSTEM PHARMACISTS	50-3036	REDUCING MEDICATION ERRORS THROUGH IMPLEMENTING A CONTINUOUS QUALITY IMPROVEMENT PROGRAM	20-425390	APPROVED	1/22/2014
PUTNAM COMMUNITY MEDICAL CENTER	50-13181	INFECTION PREVENTION	20-427317	APPROVED	1/31/2014
FREECE.COM	50-3515	PREVENTING MEDICATION ERRORS IN PHARMACY PRACTICE	20-430280	APPROVED	2/20/2014
FLORIDA A&M UNIVERSITY COLLEGE OF PHARMACY AND PHARMACEUTICAL SCIENCES	50-3072	HEALTH EQUITY: AN INTERPROFESSIONAL APPROACH TO IMPROVE HEALTH IN THE UNDERSERVED	20-428277	APPROVED	2/14/2014
FREECE.COM	50-3515	THE GRAYING OF HIV	20-426526	APPROVED	2/28/2014
DADE COUNTY PHARMACY ASSN C/O ACEVES	50-2488	18TH ANNUAL SOUTH FLORIDA RESIDENCY SEMINAR ON THE ROAD TO PROVIDING PRIMARY CARE SERVICES - RCE SUN	20-418312	APPROVED	1/8/2014
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419	A SYSTEMATIC APPROACH TO CONSULTANT PHARMACY SERVICES	20-426219	APPROVED	1/31/2014
FLORIDA SOCIETY OF HEALTH SYSTEM PHARMACISTS	50-3036	PREVENTING MEDICATION ERRORS WITH INSULIN- A SYSTEMS-BASED APPROACH	20-427877	APPROVED	1/22/2014
FLORIDA PHARMACY ASSOCIATION	50-754	REDUCING MEDICATION ERRORS THROUGH IMPLEMENTING A CQI PROGRAM	20-432638	APPROVED	2/28/2014
FLORIDA PHARMACY ASSOCIATION	50-754	REGULATORY AND LAW CONFERENCE	20-424711	APPROVED	1/8/2014
DADE COUNTY PHARMACY ASSN C/O ACEVES	50-2488	18TH ANNUAL SOUTH FLORIDA RESIDENCY SEMINAR ON THE ROAD TO PROVIDING PRIMARY CARE SERVICES - RCE SUN	20-418311	APPROVED	1/8/2014
FLORIDA SOCIETY OF HEALTH SYSTEM PHARMACISTS	50-3036	NORTHEAST SOCIETY RESIDENT FORUM 2014	20-425701	APPROVED	1/24/2014
FLORIDA PHARMACY ASSOCIATION	50-754	FPA PAIN MANAGEMENT CONFERENCE	20-432634	APPROVED	2/28/2014
BAPTIST HEALTH	50-178	FIRST COAST INFECTIOUS DISEASE/CLINICAL MICROBIOLOGY SYMPOSIUM 2014	20-419874	APPROVED	1/8/2014
LITECH INSTITUTE, INC.	50-14732	MEDICATION SAFETY AND THE PHARMACY TECHNICIAN	20-421782	APPROVED	1/8/2014
FLORIDA PHARMACY ASSOCIATION	50-754	AN OVERVIEW OF HIV AIDS MANAGEMENT	20-431456	APPROVED	2/20/2014
FLORIDA PHARMACY ASSOCIATION	50-754	REDUCING MEDICATION ERRORS THROUGH IMPLEMENTING A CONTINUOUS QUALITY IMPROVEMENT PROGRAM	20-424713	APPROVED	1/8/2014
NOVA SOUTHEASTERN UNIVERSITY COLLEGE OF PHARMACY	50-2759	INTEGRATIVE NUTRITION	20-429311	APPROVED	2/20/2014
UNIVERSITY OF FLORIDA COLLEGE OF PHARMACY	50-2419	MINIMIZING THE RISK OF POLYPHARMACY IN THE OLDER ADULT	20-418964	APPROVED	1/8/2014

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Individual Name	Title of Course	Hours Offered
Deborah Williams	Pri-Med South Annual Conference	19 hours of general credit
Lesa Maria Martino	Primary Care: Dermatology and Oral Dermatology Review	19 hours of general credit
Madhurie Maharaj	Optimal Management of HIV Disease & Hepatitis Clinical Conference	14 hours of general credit
Carlos Palacios	Optimal Management of HIV Disease & Hepatitis Clinical Conference	14 hours of general credit
David Mafdali	Pri-Med South Annual Conference	18 hours of general credit
Beatriz Morales	ACCP Ambulatory Care Preparatory Review	12 hours of Consultant Recertification
Amtus Sami Shafiq	Optimal Management of HIV Disease & Hepatitis Clinical Conference	14 hours of general credit
Kristen Fanning Parker	ASHP Midyear Clinical Meeting	15 hours of Consultant Recertification
LaWanda Johnson	Scope of Pain	3 hours of Consultant Recertification

Individual Name	Title of Course	Hours Offered
Tevieca Johnson	HIV 501 Update	5 hours of General
David Mafdali	Pri-Med Annual Conference	2 hours of Med Error

MEETING MINUTES
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
FULL BOARD MEETING

February 11-12, 2014
The Florida Hotel & Conference Center
1500 Sand Lake Road
Orlando, FL 32809
(407) 859-1500

Board Members:
Jeffrey J. Mesaros, PharmD, Chair, Orlando
Michele Weizer, PharmD, Vice-Chair, Boca Raton
Leo J. "Lee" Fallon, BPharm, PhD, The Villages
Albert Garcia, BPharm, MHL, Miami
Debra B. Glass, BPharm, Tallahassee
Gavin Meshad, Consumer Member, Sarasota
Mark Mikhael, PharmD, Orlando
Jeenu Philip, BPharm, Jacksonville
Lorena Risch, Consumer Member, Bradenton

Board Staff:
Tammy Collins, Acting Executive Director
Christy Robinson, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:
David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General

Department of Health Staff:
Yolonda Green, Assistant General Counsel
Matthew Witters, Assistant General Counsel

Tuesday, February 11, 2014 – 1:00p.m.

1:04 p.m. Call to Order by Jeffrey J. Mesaros, PharmD, Chair

Mrs. Risch was not present.

Dr. Mesaros thanked Mr. Garcia for his role and service as the Chair to the Board of Pharmacy over the past year.

TAB 1 REPORTS

A. Chair's Report – Jeffrey J. Mesaros, PharmD, Chair

1. 2014 Board Member Assignments

Dr. Mesaros informed the Board members of their appointments to the various Board of Pharmacy committees. The results were as follows:

Rules Committee	Compounding Rules Committee	Prescription Drug Abuse Committee
Dr. Mesaros (Chair)	Dr. Weizer (Chair)	Mr. Meshad (Chair)
Mrs. Glass	Dr. Fallon	Dr. Fallon
Dr. Mikhael	Mrs. Glass	Mrs. Glass
Mr. Phillip	Dr. Mikhael	Mr. Philip
Dr. Weizer		

Application Review Committee – Mrs. Glass and Dr. Mikhael
Legislative Liaison – Mr. Philip
Unlicensed Activity Liaison – Dr. Mikhael
Prescription Drug Monitoring Program Liaison – Mr. Philip

Wholesale Advisory Committee – Mr. Garcia
Tripartite Committee – Dr. Fallon (Chair)
Budget Liaison – Dr. Weizer
DEA Liaison – Mr. Garcia
Weight of the State Liaison – Mr. Garcia

2. 2014 Association Meeting Assignments

Dr. Mesaros informed the Board members of their association meeting assignments for 2014. The results were as follows:

FSHP House of Delegates – Dr. Wiezer
NABP Annual Meeting – Dr. Mesaros with Mrs. Glass as the alternate.
NABP District III – Dr. Mesaros with Mrs. Glass as the alternate.
NABP MPJE/NAPLEX/FPGEE – Mrs. Glass
FPA Law & Regulatory Conference – Dr. Mikhael
FPA April Clinical Conference – Dr. Mikhael
FPA May Law & Clinical Conference – Dr. Mikhael
FPA Annual Convention – Dr. Fallon
FPA Southeastern Gathering – Dr. Fallon

B. Acting Executive Director's Report – Tammy Collins

Ms. Collins and Dr. Mesaros informed the Board and audience that Florida will be hosting the annual MALTAGON meeting in October 2014. Dr. Mesaros stated that the meeting will be held in the St. Petersburg, Florida area.

1. Compounding Rules Committee Report – Michele Weizer, PharmD

Dr. Weizer provided a brief overview of the proceedings from the February 10, 2014 Compounding Rules Committee and requested Mr. Flynn provide an overview of the Federal Legislation that was discussed.

Mr. Flynn gave a brief introduction to The Drug Quality & Security Act and provided an overview of the exemptions provided in Section 503A. Mr. Flynn discussed outsourcing facilities and explained their exemptions from the "new drug application" and "directions for use" but stated the facilities must comply with the manufacturer's current good manufacturing practices. Mr. Flynn went on to illustrate some potential issues for the Board: "Can you compound without being an outsourcing facility?" and "Who will regulate outsourcing facilities?"

Dr. Weizer stated to the Board that Rule 64B16-27.700 may need to be altered to add language stating that office-use compounding must be in compliance with the Federal Legislation. Dr. Weizer then went on to discuss the changes made to Rule 64B16-27.797 including the addition of language describing low-volume compounding of hazardous items as no more than 40 doses a month.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to approve the language revisions to Rule 64B16-27.797. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Dr. Weizer reported that the legislation regarding the out-sourcing facilities and non-resident pharmacies has been redrafted to include provisions requiring non-resident pharmacies to be compliant with USP797 and provides Florida the authority to inspect the non-resident pharmacies at the cost of the pharmacy.

2. Update on Executive Director Position – Michele Weizer, PharmD

Dr. Weizer informed the Board that interviews for the position were held and that the Board is still accepting applications to fill the position.

Dr. Mesaros thanked Ms. Tammy Collins for her hard work acting as Executive Director during the search for a new permanent Executive Director.

3. 2014 Legislative Update Summary

Ms. Collins provided an update to some current legislation that includes provisions to require prescriptions to have the date formatted a particular way.

Mr. Garcia expressed his concerns and stated that would not support the legislation due to the fact that the he believes the legislation doesn't increase safety to the public nor prevent any prescription fraud from occurring.

Dr. Mesaros stated that legislation may cause a delay issue.

Dr. Mesaros then introduced Chapter 465.014 dealing with direct supervision of pharmacy technicians as the next topic for discussion.

Dr. Weizer provided data and examples from the profession showing how increased distractions and errors can lead to deaths. Dr. Weizer then went on to state that increased technicians ratios will lead to an increased amount of errors.

Mr. Garcia stated that increased technician ratios would reduce errors because each tech would be better able to focus on each particular function due to the decreased amount of distractions.

Mr. Philip spoke in support of Mr. Garcia's comments and went on to state that increased technician ratios would allow the pharmacist to dedicate more time to performing high-level pharmacist functions. Mr. Philip went on to state that the appropriate technician ratio should be determined by the particular practice setting and that the pharmacist should have the right to use his professional judgment in making that determination.

Dr. Mikhael stated that the appropriate technician ratio is highly dependent on the type of practice. Dr. Mikhael went on to state his opposition to the legislation and that the Board should retain the authority to determine if an increased technician ratio is appropriate for a particular practice setting.

Mrs. Glass stated that the Board should also consider that there is not currently a limit to the amount of technicians in training and pharmacist interns that are counted towards the ratio when deciding whether or not to raise the technician ratio.

Dr. Fallon stated that he doesn't feel that an increase to the technician ratio would necessarily cause more errors though he would be more comfortable with a 4:1 ratio in his particular practice setting. Dr. Fallon went on to stress the importance of increased education for pharmacy technicians and increased pay for pharmacy technicians.

Mr. Meshad stated that he believes the technician ratio should be left alone and that if a pharmacist wants an exemption to the current technician ratio, they should have to come before the Board.

Bob Parrado approached the Board and pointed out that all the states without a ratio combined don't fill as many prescriptions as Florida and stated that volume directly relates to errors. Mr. Parrado also pointed out that technician's hours are getting cut too much as it is now.

Dr. Mesaros referenced a previous discussion regarding registered pharmacy technicians performing non-technician functions and whether or not they are counted towards the ratio. Dr. Mesaros then went on to state that he doesn't feel the 3:1 ratio is currently working for all practice settings.

Dr. Mesaros questioned if "amount of technicians allowed to supervise" can be added as a licensing condition, to which Ms. Green and Mr. Witters of prosecution services confirmed.

Mr. Meshad reiterated the fact that a jump from 1:1 to 6:1 is a drastic change and stated his belief that the small group that will benefit will be greatly outnumbered by the larger amount that won't benefit.

Dr. Weizer stated that "education for pharmacy technicians" needs to be added to the rules committee agenda and that the Board needs to start requiring certification as a licensing requirement to go along with the current registration format.

Ms. Collins stated the process in place for approval and ratification of technician ratios as it currently stands.

Dr. Mesaros requested that the Board suspend the rest of this discussion until the end the day.

Ms. Collins provided an update to the current PDMP Bill language and the new use of the pharmacy trust fund to pay for the database.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to support the use of the trust fund to support the PDMP but not to increase the application fees to do so. (Motion was not voted on due to continued discussion)

Brian Kahan approached the Board to state that the PDMP is in financial distress and that there is a risk that the funds could get swept and never make it to the PDMP. Mr. Kahan went on to state that the Board should take a formal stance in support of the funds being directly allocated to the PDMP.

Dr. Weizer withdrew her motion from above with Dr. Mikhael withdrawing his second.

Motion: by Mr. Meshad, seconded by Dr. Fallon, to support the current legislation. Motion carried.

4. Update on Sterile Compounding Permits

Ms. Collins provided an update on the sterile compounding permits. Ms. Collins stated that there have been 75 licenses issued and that there are currently 85 open applications. Ms. Collins then went on to state that a second notice letter was sent out on January 27, 2014 regarding the new permit.

5. Approval of MAD-ID CE Course and Retrospective Approval for CE Participants – Michele Weizer, PharmD

Dr. Weizer gave an overview of the application and request by MAD-ID for retrospective approval for CE approval.

Dr. Weizer requested the Board approve the request and stated that the program does meet the requirements for a consultant program.

Motion: by Dr. Weizer, seconded by Dr. Fallon, to approve request. Motion carried.

C. Attorney General's Report – Lynette Norr, Assistant Attorney General

1. Rules Report

Lynette Norr gave an overview of the new format of the rules report and then went to report that 5 rules have been adopted since the last Board of Pharmacy meeting. Ms. Norr stated Rule 64B16-28.901, 28.450, 30.001, 28.301, and 28.810 as the newly adopted rules. Ms. Norr then stated Rule 64B16-28.140, 28.608, 28.303, and 28.100 are currently in progress.

2. Requests for Declaratory Statements

a. BTV Pharmacy

Jennifer Baun was present on behalf of BTV Pharmacy.

Mr. Flynn advised the Board that they cannot make a declaratory statement in response to an individual's particular situation. Mr. Flynn then stated for the above reason, the Board cannot issue a declaratory statement for this particular matter.

Motion: by Dr. Fallon, seconded by Mr. Garcia, to deny issuance of a declaratory statement. Motion carried.

b. Florida Hospital Home Infusion, LLP

Motion: by Dr. Mesaros, seconded by Mr. Garcia, to move request for a declaratory statement to the April Board of Pharmacy meeting. Motion carried.

3. Request for Variance of Waivers – TeamCare Pharmacy Service

Mark Schneider was present on behalf of TeamCare Pharmacy Service and sworn in by the court reporter.

Mr. Schneider described his business model and explained why he doesn't necessarily work a typical 40 hour work week. Mr. Schneider then stated that his business is not open to the general public and has no desire to open up a community pharmacy.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to allow variance of waivers with the conditions that the non-sterile compounding take place separate from the sterile compounding and that the non-sterile compounding be compliant with USP Chapter 795. Motion carried.

D. Prosecution Services Report – Yolonda Green, Assistant General Counsel

Ms. Green provided the Prosecution Services Report and stated that the Pharmacy team is still planning on adding another member in the future.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to allow prosecution to continue prosecuting old cases. Motion carried.

E. Chief Investigative Services Report – Mark Whitten

Tammy Collins gave the chief investigative report on behalf of Mr. Mark Whitten. Ms. Collins reported that dispensing practitioners started with 8,168 facilities and 3,835 have been completed. Ms. Collins then stated that Pharmacy started with 5.335 facilities and 3.064 inspections have been completed so far.

TAB 2 BUSINESS – Jeffrey J. Mesaros, PharmD, Chair

A. Request for Reductive of Hours – Debra Glass, BPharm

Mrs. Glass noted the increased amount of requests for reduction of hours and proposed the Board potentially create guidelines for this matter.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to approve the request by United Care Pharmacy. Motion carried.

The Board announced that they would hear the request for reduction of hours by AM Health, LLC.

Sophia Frankel was present on behalf of AM Health, LLC and sworn in by the court reporter.

Motion: by Mr. Garcia, seconded by Dr. Fallon, to allow Board staff to confirm that all requirements are met and approve the reduction of hours if said requirements are met. Motion carried.

B. NABP Verified Pharmacy Program – Scotti Russell, R.Ph.

Scotti Russell was present on behalf of the National Association of Boards of Pharmacy (NABP). Ms. Russell gave a brief overview of the functions of the NABP and then went on to give an explanation of the NABP Verified Pharmacy Program.

C. Ratification of Issued Licenses/Certificates & Staffing Ratios

1. Pharmacist (Licensure) (Client 2201) – 147
2. Pharmacist (Exam Eligibility) (Client 2201) – 77
3. Pharmacist Interns (Client 2202) – 150
4. Registered Pharmacy Technicians (Client 2208) – 790
5. Consultant Pharmacist (Client 2203) – 16
6. Nuclear Pharmacist (Client 2204) – 0
7. Pharmacies/Facilities (Client 2205) – 158
8. Registered Pharmacy Technician Ratios (2:1 or 3:1)- 109
9. Pharmacy Technician Training Program (Client 2209) - 36
10. CE Providers – 7
11. CE Courses – 9
12. CE Individual Requests (Approved) – 0
13. CE Individual Requests (Denied) - 2

Motion: by Mrs. Glass, seconded by Dr. Fallon, to ratify C #1-13. Motion carried.

D. Review and Approval of Minutes

1. December 3-4, 2013 Meeting Minutes

Motion: by Mrs. Glass, seconded by Dr. Fallon, to approve the minutes. Motion carried.

Dr. Mesaros requested the Board conclude their discussion on direct supervision of technicians and technician staffing ratios.

Mr. Meshad proposed the idea of allowing a 6:1 technician ratio as long as the Board kept oversight.

Dr. Mikhael requested representatives of the various associations express their stance on the issue.

Pam White (Florida Society of Health-System Pharmacists) approached the Board and stated that FSHP is in opposition to the proposed legislation.

Gore Alvarez (Florida Pharmacy Association) approached the Board and stated that the FPA is in opposition to the proposed legislation.

Motion: by Mrs. Glass, seconded by Mr. Meshad, to support a 3:1 ratio and anything above a 3:1 ratio should remain subject to Board approval. Motion carried.

Public Comments:

Dr. Jeff Mesaros opened the floor up to public comments:

Motion: by Mrs. Glass, seconded by Dr. Weizer, to adjourn the meeting at 5:40p.m. Motion carried.

Wednesday, October 9, 2013 – 9:00 a.m
9:02 a.m. Call To Order by Jeff J. Mesaros, PharmD

Mrs. Risch was not present.

TAB 3 Rules Committee Report – Jeffrey J. Mesaros, PharmD, Chair

Ms. Norr gave a brief overview of the proceedings from the Rules Committee held on February 11, 2014.

Ms. Norr described the changes made to Rule 64B16-28.303 and requested a vote from the Board.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to approve the changes to the rule. Motion carried.

Motion: by Dr. Mesaros, seconded by Dr. Fallon, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Fallon, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Ms. Norr described the changes to Rule 64B16-26.1031 and requested a vote from the Board.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to approve the changes to the rule. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Mikhael, seconded by Dr. Fallon, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Ms. Norr listed the various rules that were updated to reflect the 4 year record retention rule and requested a vote from the Board.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to approve the changes to the various rules. Motion carried.

Motion: by Dr. Mesaros, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Mikhael, seconded by Mr. Philip, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of $200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

TAB 4 **DISCIPLINARY CASES – Yolonda Green, Assistant General Counsel**

A. SETTLEMENT AGREEMENT– APPEARANCE REQUIRED CASES

A-1 John T. Reading, PS 10065 – Pensacola, FL
Case No. 2012-16088 - PCP Mesaros/Glass

Respondent violated:
Count One: Section 456.072(1)(k) and Section 465.016(1)(r), F.S. (2012), by violating Section 465.022(11)(a), F.S., by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay costs of $1,375.72. Respondent shall pay a fine of $2,000.00 within 90 days.

Respondent was not present nor represented by counsel.

Motion: by Dr. Mikhael, seconded by Mr. Philip, to waive required appearance. Motion carried.

Motion: by Dr. Mikhael, seconded by Mr. Meshad, to reject the Settlement Agreement. Motion carried.

Motion: by Mr. Philip, seconded by Dr. Fallon, for the same Settlement Agreement with the addition of a 12 hour laws and rules CE and a 1 year probationary period. Motion carried.

Motion: by Dr. Mikhael, seconded by Mr. Meshad, to vacate counter offer and allow the department to withdraw the case from the agenda. Motion carried.

A-2 Enrique Moises Pallares, PS 24103 – Weston, FL
Case No. 2013-07014 – PCP: Fallon/Glass

Respondent violated:
Count One: Section 465.016(1)(g), F.S. (2012), by using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed.

Terms of Settlement Agreement: Respondent shall by present. Respondent shall pay a fine of $250.00 within 30 days. Respondent shall pay costs limited to $1,690.79 within 90 days.

Respondent was present and sworn in by the court reporter. Respondent was represented by Kevin Jacob, Esquire.

Motion: by Mr. Philip, seconded by Dr. Mikhael, to accept the Settlement Agreement. Motion carried.

A-3 Michael W. Halfen, PS 32618 – Pensacola, FL
Case No. 2013-02905 – PCP: Fallon/Glass

Respondent violated:
Count One: Section 465.016(1)(r), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012), by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay an administrative fine in the amount of $1,000.00 payable within 90 days. Respondent shall pay costs limited to $664.38. Respondent shall complete an 8 hour Laws and Rules CE within 1 year.

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the Settlement Agreement. Motion carried.

A-4 William Clero, RPT 11309 – Miami, FL
Case No. 2013-05745 – PCP: Weizer/Meshad

Respondent violated
Count One: Section 456.072(1)(a), F.S. (2009), by making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay administrative fine in the amount of $2,000.00 payable within 1year. Respondent shall pay costs not to exceed $2,273.28. Respondent shall be placed on probation for 2 years. Respondent shall complete a 12 hour laws and rules CE to be completed within 1 year.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to allow a continuance on this case. Motion carried.

A-5 Magdi Mikhail Bishara, PS 47410 – Clearwater, FL
Case No. 2013-09121 – PCP: Mesaros/Risch

This case was granted a continuance to a future Board meeting.

A-6 Praven Ananthula, PS 42006 – Orlando, FL
Case No. 2012-12301 – PCP – Fallon/Glass

Count One: Respondent violated Section 465.016(1)(g), F.S. (2012), by furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay administrative fine in the amount of $1,000.00 payable within 90 days. Respondent must pay costs of $1,724.90 within 90 days. Respondent must completed an 8 hour med errors CE.

Respondent was present and sworn in by the court reporter. Respondent was represented by Lance Leider, Esquire.

Motion: by Dr. Mikhael, seconded by Mr. Philip, to accept the Settlement Agreement. Motion carried.

A-7 Serenity Pharmacy, Corp., PH 26021 – Miami, FL
Case No. 2012-18539 – PCP Mesaros/Risch

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Section 499.005(18), F.S. (2012), by violating Rule 61N-1.012(10(a), F.A>C., which requires that records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component.

Terms of Settlement Agreement: Respondent shall be present. Respondent shall pay a fine of $5,000.00 within 90 days. Respondent shall pay costs limited to $2,500.00 within 90 days. Respondent shall be placed on probation for a period of one year that includes semi-annual inspections at the respondent's cost and an appearance before the Board in the final 3 months of probationary period.

Respondent was not present nor represented by counsel.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to waive required appearance. Motion carried.

Motion: by Mr. Meshad, seconded by Mr. Philip, to reject the Settlement Agreement. Motion carried.

Motion: by Mr. Meshad, seconded by Mr. Philip, for revocation of licensure. Motion carried.

B. DETERMINATION OF WAIVER

DOW-1 Cantonment Pharmacy Inc., PH 2748 – Cantonment, FL
Case No. 2012-16087 – PCP Mesaros/Glass

Respondent was not present nor represented by counsel.

Count One: Respondent 465.023(1)(c), F.S. (2012), by violating Section 465.015(2)(c), F.S. (2012), by selling or dispensing drugs as defined in Section 465.003(8) without first being furnished with a prescription.

Motion: by Dr. Mikhael, seconded by Mr. Garcia, to accept the investigative report into evidence for the purposes of imposing a penalty, find that respondent was properly served and has waived the right to a formal hearing, adopt the findings, facts, and conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Administrative Fine of $2,000.00 and costs of $879.72.

This case was granted a continuance.

Motion: by Mr.Meshad, seconded by Mr. Fallon, to have the Pharmacy inspected. Motion carried.

DOW-2 Gulf Medical Services, Inc., PH 18700 – Milton, FL
Case No. 2013-02904 – PCP Fallon/Glass

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-27.797-(1)(i)(4), F.A.C., which requires storage of high-risk level CSPs to be stored within specified time periods, in the absence of a sterility test for the high-risk CSPs.
Count Two: Respondent has violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-27.797(1)(i)(7), F.A.C., which requires that all compounding personnel complete a media-filled test that represents high-level compounding on a semi-annual basis.

DOW-2 was withdrawn from the agenda.

DOW-3 SAR Pharmacy Discount, Inc., PH 25265 – Miami, FL
Case No. 2012-16646 – PCP Fallon/Glass

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), F.A.C., by failing to notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and/or notify the Board of Pharmacy which permittee is receive the prescription files.

Respondent was not present nor represented by counsel.

Motion: by Mr. Philip, seconded by Dr. Weizer, to accept the investigative report into evidence for the purposes of imposing a penalty, find that respondent was properly served and has waived the right to a formal hearing, adopt the findings, facts, and conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Revocation

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the recommendations of the Department. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to allow prosecution to withdraw their motion to assess costs. Motion carried.

DOW-4 SAR Pharmacy Discount, Inc., PH 25266 – Miami, FL
Case No2012-16637 – PCP Fallon/Glass

Respondent was not present nor represented by counsel.

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.202(3), F.A.C., by failing to notify the Board of Pharmacy in writing as to the effective date of closure, return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy, and/or notify the Board of Pharmacy which permittee is receive the prescription files.

Motion: by Dr. Weizer, seconded by Mr. Meshad, to accept the investigative report into evidence for the purposes of imposing a penalty, find that respondent was properly served and has waived the right to a formal hearing, adopt the findings, facts, and conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Revocation

Motion: by Dr. Weizer, seconded by Mr. Meshad, to accept the recommendations of the Department. Motion carried.

Motion: by Dr. Weizer, seconded by Mr. Meshad, to allow prosecution to withdraw their motion to assess costs. Motion carried.

DOW-5 Latoria Denise Jones, RPT 45081 – Sebastian, FL
Case No. 2013-12375 – PCP – Fallon/Glass

Respondent was not present nor represented by counsel.

Count One: Respondent violated Section 465.016(1)(e), F.S. (2012-2013), by violating Chapter 893, F.S. (2012-2013).

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the investigative report into evidence for the purposes of imposing a penalty, find that respondent was properly served and has waived the right to a formal hearing, adopt the findings, facts, and conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Recommended Penalty: Revocation

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to accept the recommendations of the Department. Motion carried.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to allow prosecution to withdraw their motion to assess costs. Motion carried.

C. VOLUNTARY RELINQUISHMENTS

Motion: by Dr. Weizer, seconded by Dr. Fallon, to accept Voluntary Relinquishments #2,4,5,6, and 7. Motion carried.

VR-1 Beverly Lynn Jackson, RPT 38762 – Keystone Heights, FL
Case No. 2013-07018 – PCP Griffin/Mesaros

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Dr. Mikhael, seconded by Mrs. Glass, to accept the Voluntary Relinquishment. Motion carried.

VR-2 Patrick Carpenter, PSI 13115 – St. Augustine, FL

Case No. 2013-05817 – PCP – (None)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See group motion above.

VR-3 Samuel E. Wahba, PS 27213 – Palm Harbor, FL
Case No. 2013-07373 – PCP – Meshad/Weizer

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

Motion: by Mrs. Glass, seconded by Dr. Fallon, to accept the Voluntary Relinquishment. Motion carried.

VR-4 1st Choice Pharmacy, PH 24233 – Ft. Lauderdale, FL
Case No. 2013-15021 – PCP – (Waived)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See group motion above.

VR-5 1st Choice Pharmacy, PH 25895 – Ft. Lauderdale, FL
Case No. 2013-15019 – PCP Waived

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See group motion above.

VR-6 Leyva Coralia Perez, PSI 21750 – Miami, FL
Case No. 2013-13537 – PCP – (Waived)

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See group motion above.

VR-7 Jeffrey Alan Sussman, PS 18577 – Coral Springs, FL
Case No. 2011-12057 – PCP – Risch/Mullins

The Department suggests that the Board entertain a Motion Accepting the Voluntary Relinquishment executed by Respondent in resolution of this case.

See group motion above.

D. BOARD ACTION BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

I-1 Sanford D. Duckman, PS 27319 – Boynton Beach, FL
Case No. 2013-07508 – PCP – Glass/Mesaros

Respondent was not present nor represented by counsel.

Count One: Respondent violated Section 456.072(1)(k), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012), by failing to ensure a sign in block letters not less than one inch in height stating the hours the prescription department is open each day was displayed either at the main entrance of the establishment or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view, as required by Rule 64B16-28.1081, F.A.C.

Motion: by Mr. Meshad, seconded by Dr. Mikhael, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Mr. Meshad, seconded by Dr. Mikhael, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mr. Meshad, seconded by Dr. Mikhael, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Mr. Meshad, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Costs of $284.32, Administrative fine of $2,000.00, 12 hour laws and rules CE, cannot be a prescription department manager for 1 year.

Motion: by Mr. Philip, seconded by Dr. Mikhael, to accept the recommendations of the Department. Motion carried.

I-2 La Perla Pharmacy, Inc., PH 24200 – Miami, FL
Case No. 2012-18263. PCP – Meshad/Weizer

Respondent was not present nor represented by counsel.

Count One: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.109, F.A.C.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Administrative fine of $2,000.00, costs of $1,142.56, and probationary period of 1 year with semi-annual inspections at respondents costs.

Motion: by Mr. Philip, seconded by Dr. Fallon, to accept the recommendations of the Department. Motion carried.

I-3 Franako Pharmacy, Inc., PH 25600 – West Palm Beach, FL
Case No. 2013-07506 – PCP Glass/Mesaros

Kwame Kyerematen was present on behalf of Franako Pharmacy and sworn in by the court reporter. Respondent was not represented by counsel.

Count One: Respondent violated Section 456.072(1)(k), F.S. (2012), by violating Section 465.022(11)(a), F.S. (2012), by failing to ensure a sign in block letters not less than one inch in height stating the hours the prescription department is open each day was displayed either at the main entrance of the establishment or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view, as required by Rule 64B16-28.1081, F.A.C.
Count Two: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.140(4), F.A.C., by failing to ensure that the written record for each batch/sub-batch of a compounded product under Rule 64B16-27.700, F.A.C. included all the required information.
Count Three: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.140(3)(d), F.A.C., by failing to ensure that each individual pharmacist who dispenses or refills a prescription drug order verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document within seven days from the date of dispensing.
Count Four: Respondent violated Section 465.023(1)(c), F.S. (2012), by violating Rule 64B16-28.110, F.A.C., by failing to ensure that deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date in which date has been reached were removed from stock.

Motion: by Mr. Philip, seconded by Dr. Mikhael, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Dr. Mikhael, seconded by Mr. Philip, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mr. Philip, seconded by Dr. Mikhael, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Dr. Mikhael, seconded by Mr. Philip, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Fine of $2,500.00, costs of $610.63, and probationary period of 1 year with semi-annual inspections at the respondents cost.

Motion: by Mr. Philip, seconded by Dr. Mikhael, to accept the recommendations of the Department with the amendment that the fine is eliminated. Motion carried.

I-4 James M. Maister, PS 34202 – Wesley Chapel, FL.
Case No. 2010-19143 – PCP Meshad/Weizer

Respondent was present and sworn in by the court reporter. Respondent was represented by Ed Bayo, Esquire.

Count One: Respondent violated Section 465.016(1)(e), F.S. (2010), by a violation of 893.13(7)(a)9, F.S. (2009), by attempting to obtain a controlled substance by fraud, a third degree felony.

Motion: by Mrs. Glass, seconded by Mr. Philip, to accept the investigative report into evidence for the purposes of imposing a penalty. Motion carried.

Motion: by Mrs. Glass, seconded by Mr. Philip, to find that respondent was properly served and has requested a formal hearing. Motion carried.

Motion: by Mrs. Glass, seconded by Mr. Philip, to adopt the findings and facts as set forth in the Administrative Complaint. Motion carried.

Motion: by Mrs. Glass, seconded by Mr. Philip, to adopt the conclusions of law set forth in the Administrative Complaint and find that this constitutes a violation of the Pharmacy Practice Act. Motion carried.

Departments Recommendation: Costs of $2,165.07, 12 hour laws and rules CE, and 3 year probationary period to run concurrent with PRN contract.

Dr. Martha Brown (Professional Resource Network) stated that respondent has been in complete compliance with terms of the PRN contract.

Motion: by Mr. Garcia, seconded by Dr. Fallon, to accept the recommendations of the Department. Motion carried.

TAB 5 APPLICATIONS REQUIRING BOARD REVIEW – Debra Glass, BPharm

A. Examination Applicants

1. Michael Alan Donato, File: 44245 – Melbourne, FL

Respondent was present and sworn in by the court reporter. Respondent was represented by Edwin Bayo, Esquire.

Dr. Martha Brown (Professional Resource Network) state that the applicant has been in complete compliance with PRN contract.

Motion: by Mrs. Glass, seconded by Dr. Fallon, to accept the application and require applicant to comply with same conditions of final order DOH-12-13495 MQA. Motion carried with Mr. Garcia in opposition.

B. Pharmacy Intern Applications.

1. Curtis Michael Drees, File: 19170 – Fort Loramie, OH

Respondent was not present nor represented by counsel.

Motion: by Mrs. Glass, seconded by Mr. Garcia, to reject the application. Motion carried.

2. Kaitlyn Nemecek, File: 19562 – Tampa, FL

Respondent was not present nor represented by counsel.

Motion: by Mrs. Glass, seconded by Dr. Fallon, to accept the application. Motion carried.

3. Rafa Khundkar, File: 20080 – Miami, FL

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Mrs. Glass, seconded by Mr. Philip, to accept the application. Motion carried.

4. Saige Elizabeth Kaufman, File: 20305 – Auburn AL

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Mr. Meshad, seconded by Dr. Fallon, to grant pending a PRN evaluation. If deemed safe to practice, the Board Chair will have authority to grant license. Motion carried.

5. Dmitriy Matev, File: 19902 – Jacksonville, FL

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Mrs. Glass, with no second. Motion failed.

Motion: by Dr. Fallon, seconded by Mrs. Glass, to grant pending a PRN evaluation. If deemed safe to practice, the Board Chair will have authority to grant license. Motion carried.

6. Jonathan James Samuelson, File: 19539 – Tampa, FL

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Mrs. Glass, seconded by Dr. Weizer, to accept the application. Motion failed.

Motion: by Mr. Garcia, seconded by Mr. Meshad, to grant pending a PRN evaluation. If deemed safe to practice, the Board Chair will have authority to grant license. Motion carried with Dr. Weizer, Dr. Mikhael, and Mrs. Glass in opposition.

C. Registered Pharmacy Technician Applications.

1. Kayla Cerritos, File: 51118 – Clearwater, FL

Respondent was not present nor represented by counsel.

Motion: by Mrs. Glass, seconded by Dr. Mikhael, to grant continuance and require an appearance at one of the next two Board meetings. Motion carried.

2. Wandey Alexis, File: 43696 – Boca Raton, FL

Respondent was not present nor represented by counsel.

Motion: by Mr. Garcia, seconded by Dr. Weizer, to grant continuance and require an appearance at one the next two Board meetings. Motion carried.

3. April B. Watson, File: 53982 – Jay, FL

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Dr. Fallon, seconded by Dr. Mikhael, to accept the application. Motion carried.

D. Pharmacy Permit Applications

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1. American Specialty Pharmacy, Inc., File: 20481 – Plano, TX

Respondent was not present nor represented by counsel.

Mr. Garcia recused himself from making a determination on this application.

Motion: by Dr. Weizer, seconded by Dr. Mikhael, to reject the application. Motion carried.

2. Trinity Care Solutions, LLC, File 20149 – Ocala, FL

Ann Frank was present on behalf of Trinity Care Solutions, LLC and sworn in by the court reporter. Respondent was represented by William Furlow, Esquire.

Dr. Fallon recused himself from making a determination on this application.

Motion: by Mr. Garcia, seconded by Mr. Meshad, to grant continuance and require an appearance at one of the next two Board meetings. Motion carried.

TAB 6 LICENSURE ISSUES

A. Request for Termination of Probation

1. Douglas Kassan – License: 28503 – St. Petersburg, FL

Respondent was not present nor represented by counsel.

Motion: by Mr. Garcia, seconded by Dr. Weizer, to accept the request for termination of PRN contract. Motion carried.

B. Request for Board Appearance

1. Michael Shane Miller – File: 42786 – Gate City, VA

(This case was moved to the beginning of TAB 4)

Respondent was present and sworn in by the court reporter.

Motion: by Dr. Fallon, seconded by Dr. Mikhael, that the respondent has met the criteria required by final order and to issue the license immediately. Motion carried.

C. Appeal of Intent to Deny Licensure

1. Joshua Klasinski – File: 51724 – Sarasota, FL

Respondent was present and sworn in by the court reporter. Respondent was not represented by counsel.

Motion: by Mr. Garcia, seconded by Dr. Weizer, to reject the application. Motion carried.

2. Town and Country Compounding and Consulting Services, LLC – File: 20032 – Ridgewood, NJ

John Herr was present on behalf of Town and Country Compounding and Consulting Services, LLC and sworn in by the court reporter. Respondent was represented by Edwin Bayo, Esquire.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to vacate denial and approve application. Motion carried.

Dr. Mikhael brought up the topic of provider status for discussion.

Mr. Flynn suggested navigating the association members to get a sense of the general consensus on the topic and reporting back to the Board.

Dr. Weizer stated to the Board and audience that the deadline to apply for the special sterile compounding permit is March 21, 2014. Dr. Weizer also reminded everyone that if you have not received your permit in the mail by March 21, 2014, you cannot sterile compound until said permit has been received.

Ms. Norr requested the Board members submit any rule numbers they would like added to the April rules agenda by Friday, February 14, 2014.

Public Comments:

Dr. Mesaros opened the floor up to public comments:

Motion: by Mr. Meshad, seconded by Dr. Fallon, to adjourn the meeting at 2:34pm. Motion carried.

March 14, 2014

Edward D. Rickert
30 N. LaSalle Street Suite 2800
Chicago, IL 60602

RE: MedAvail Technologies

Dear Mr. Rickert:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Tuesday, April 1, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 1:00 p.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

March 14, 2014

Ed Bayo
2022-2 Raymond Diehl Road
Tallahassee, FL 32308

RE: MedAvail Technologies

Dear Mr. Bayo:

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If you have any questions regarding this information, please contact me at 850-245-4444 ext: 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

MedAvail MedCenter™

Presentation to Florida State Board of Pharmacy

October 8 , 2013

Med

duct Introduction

e MedAvail MedCenter™ is a *RPh*-controlled remote dispensing lution for Rx and OTCs.

e MedAvail MedCenter™ provides confidential, real-time professior vice and counseling via a robust audio/video link.

ccuracy checks and verification are recorded for each Rx dispensed.

pharmacist must approve every dispense of Rx to a patient

pharmacist inspects each item at several stages during dispense (ie ventory retrieval, labelling, dispense to patient).

Med

ere Does This Technology Fit In?

ldresses Pharmacy access issue to rural areas and provides
ter hours dispensing

1S data reports that up to 50% of prescriptions are never fil

edCenter improves access to a pharmacist by facilitating sa
cure and timely dispensing at the point of care

edCenter integrates 21st century technology with the
ıportant role of the pharmacist in Rx and OTC dispensing

Med

dCenter: Exterior At a Glance

Video

ideo (w/audio) is presented
upper screen and with the
ed camera

ased Access

Scanner and ID code only
ccess to components that
is authorized to access.

Inventory Loading

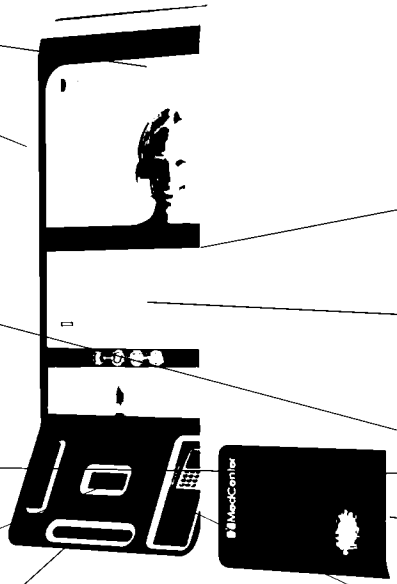
is performed using the
oad door. Access can only
ted to approved individuals.

Cards & ID

card scanner for ID
ion and benefits card

tion Scanning

canner with multi-size and
ge document handling
also handles e-scripts)



Audio

Hi-fidelity hands free ster
system tuned and optimiz
privacy. **Handset option f
additional privacy.**

Touch Screen

Touchscreen user interfac
software branded and cus

Dispense Bay

Secure dispense bay deliv
medication and required
at completion of transact

Payment

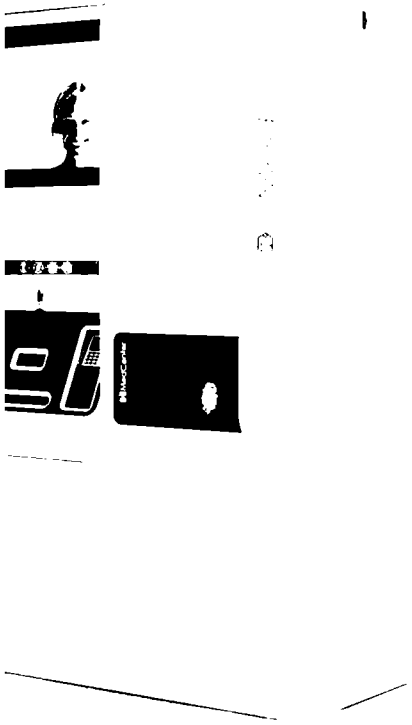
Payment support with car
and PIN pad for credit, de
loyalty cards

Med

dCenter: Security Features and Access

Vault

tion is protected in a secure
steel wall protects areas
the patient interface



Security Access

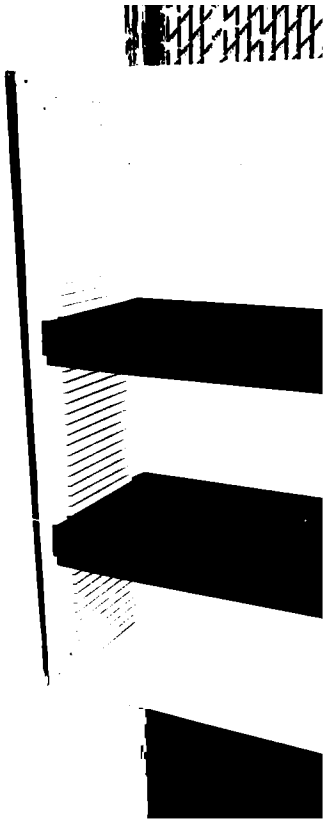
Access is granted via a security card scanner and unique pin. Access is restricted to areas that personnel are authorized for. I.e. RPh/Tech can access loading door, maintenance tech can access printer paper.

Loading Door

The loading bay door can only be accessed by authorized personnel. No vault access to medication is granted with the loading door open.

Medication Stocking

Stocking of the MedCer
by opening the loading
placing medication item
of the appropriate size.
door is closed the Med
individually place items
inventory.



dCenter Dispensing Process – One of Several Use Cases

1. **Patient provides proof of ID**

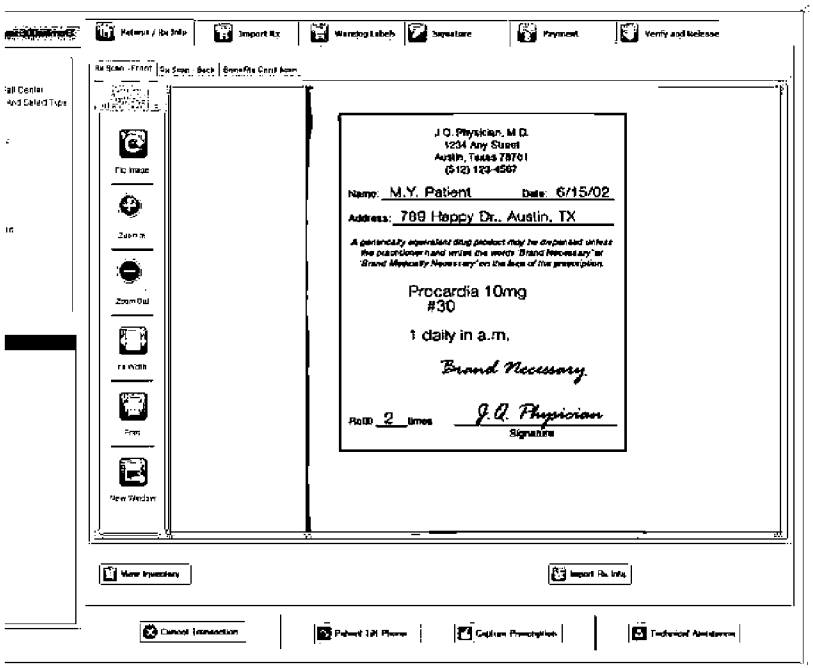
2. **Patient submits or accesses their prescription**
   - Paper prescription inserted into scanner, OR
   - Technician pulls up e-Rx/refill

3. **Pharmacists and Technicians communicate with patient via Live ?**
   Audio and Video connection . Pharmacists provide medication c
   and verify prescriptions before dispensing.

4. **Accuracy and Accountability**
   - Pharmacy Management System utilized for prescription processing/adjudication
   - Fully tracked and auditable
   - Bar code identification of product by unit
   - **RPh performs final visual verification of Rx package/ label before dispense.**
   - **No HIPAA data is stored/persisted in/on the MedCenter**

Med

Prescription Interpretation and Data Entry



- The MedCenter accepts both eRx and paper prescriptions.

- When a paper prescription is inserted, the RPh sees a high resolution scan and can zoom for enhanced viewing.

- A RPh is responsible for interpretation of all prescriptions.

Hospital	X	X
Retail	X	X
Mail Order	X	X

ACY TO THE CUSTOMER.

Drug Selection and Labeling

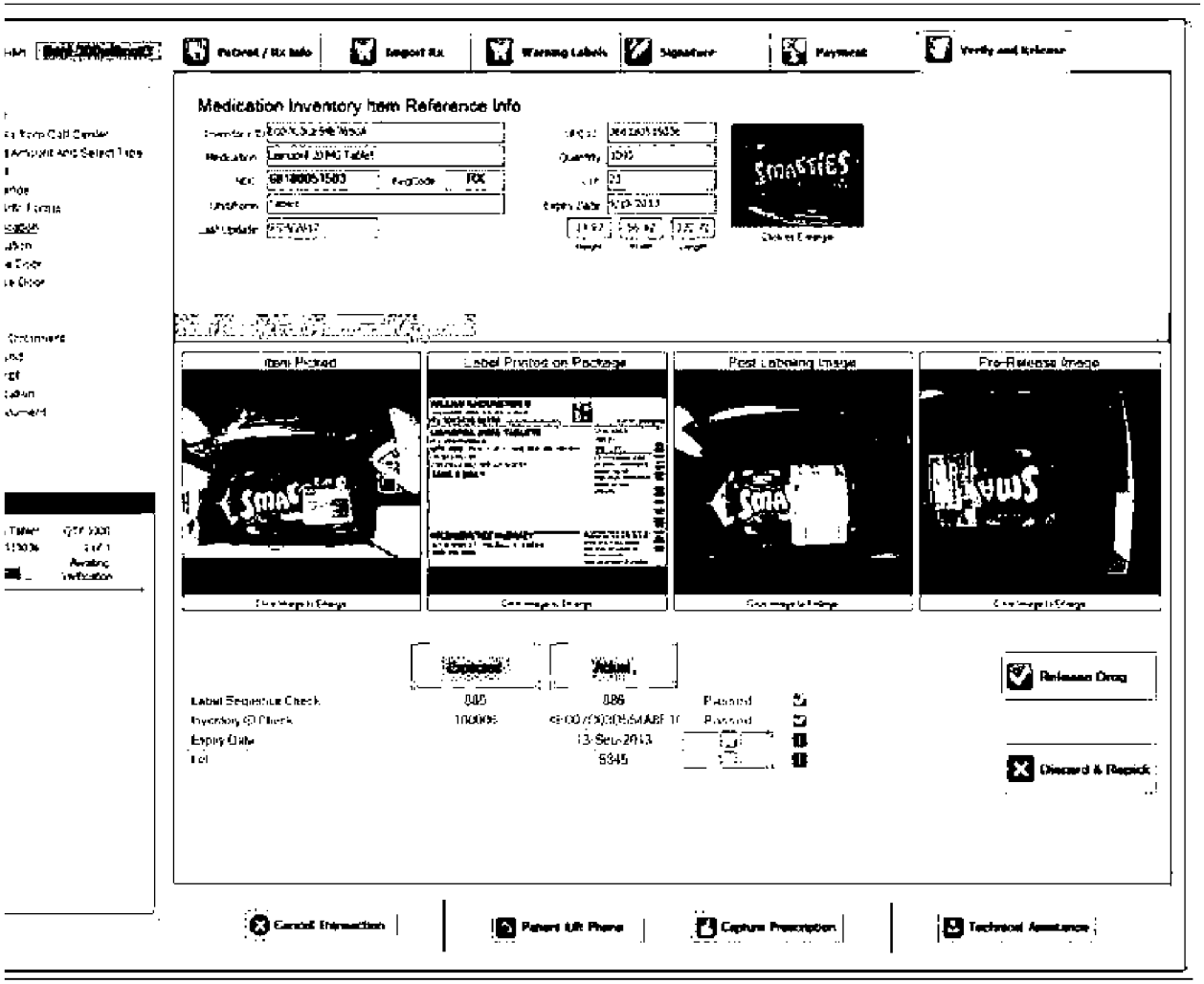
Prescriptions are processed by MedCenter and a Rx number is generated.

Medication is selected via robotics using barcode technology then labeled.

No items are dispensed until the RPh does a final product check and provides approval.

Hospital	x	x	x
Retail	x	x	x
Mail Order			x

Final Verification



- MedCenter allows the RPh to proc patient's Rx while viewing their Rx history.
- The RPh can use built in interactior checks.
- The RPh verifies the medication an compares it with electronic checks.
- Expiration date is checked and RPh approves the Rx for dispensing.

Hospital	x
Retail	x
Mail Order	x

Patient Counseling

Ph counsels the patient via a 2 way audio/visual
ication.

Ph can counsel on all new Rx items or require a
f they deem it necessary.

quired patient education and documentation is
and dispensed along with the medication.

t privacy is protected with privacy panels and an
handset.

Hospital	x
Retail	x
Mail Order	x

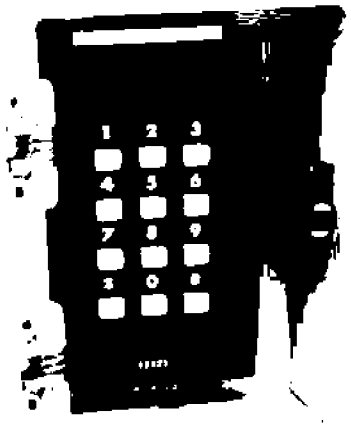
Security

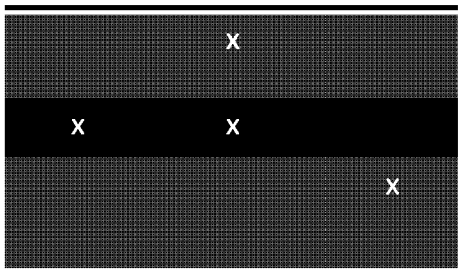
ɛdCenter is equipped with alarms and
ıg.

ɡ, maintenance, and service functions can
erformed by authorized personnel.

ɔntrol consists of an electronic swipe card
idually assigned access codes.

ion is kept in a steel vault with sensors
ıs on all points of access.





er Devices

	How they work	MedAvail MedCenter™
ıeds 	• Physician Dispensing – no pharmacist involvement	•A Pharmacist is involved in **eve** dispense of prescription medic 
ıs 	• Pickup of refills only • Pharmacy can be called if there are questions about the medication (audio only) • Business model does not support point-of-care dispensing	•New and refill prescriptions ca filled for the patient while they •The Pharmacist engages the pa using both audio and video in dispenses of prescription medic • System enables point of care dispensing

Med

ployment Channels

spital – Allows patients discharged from the hospital or emergency partment to receive their medication before going home.

nic – Ensures that patients have received their medications and have bee ucated.

tail – Can provide Rx and OTC fulfilment in retail pharmacy when in-stor armacy is closed (ie 24 hour availability of Rx and OTC).

her – Employer sites (as an adjunct to on-site healthcare); Long Term Ca cilities; VA Hospitals; Prisons

Deployments of the MedCenter offer opportunities for greater access to pharmacy vices, and enhance compliance by ensuring fulfilment at the point of care.

Med

rent Regulations

le 64B16-28.141 defines requirements for an Automated Pharmacy stem in a Community Pharmacy.

- Under this rule, technology such as the MedAvail MedCenter™ is considered a Patient Accessed Automated Pharmacy System.

atute 465.0235 states that the following sites may be serviced by an tomated pharmacy system in a location different from that of the armacy:

- Long Term Care facility
- Hospice
- State correctional institution

Med

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201305906

ELIZABETH JAMES,
RESPONDENT.

NOTICE

TO: ELIZABETH JAMES
1568 NW 113TH WAY
PEMBROKE PINES, FL 33026

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Judson Searcy, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Elizabeth James, R.Ph.
DOH Case Number 2013-05906
DATE: January 31, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Elizabeth James
Subject's Address of Record:	1568 NW 113th Way Pembroke Pines, FL 33026
Enforcement Address:	1568 NW 113th Way Pembroke Pines, FL 33026
Subject's License No:	47984 **Rank:** PS
Licensure File No:	39963
Initial Licensure Date:	8/2/2011
Board Certification:	No
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	465.016(1)(g), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	October 24, 2013; Glass & Fallon
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU-Fort Lauderdale
Materials Submitted:	Memorandum to the Board Settlement Agreement Exhibit A – Administrative Complaint Election of Rights Notification Letter Probable Cause Memorandum Final Investigative Report with Exhibits 1-17

DISCIPLINARY GUIDELINES:

Section 465.016(1)(g), Florida Statutes (2012):

($250 fine and complete approved CE course in prevention of medication errors of no less than 8 hours) to revocation

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count AC alleging violations of Section 465.016(1)(g), F.S., for a misfill.

On or about February 13, 2013, Respondent erroneously dispensed Morphine Sulfate 20mg/mL to an assisted living facility for patient B.R.'s use, when B.R. was prescribed Morphine 10mg/5mL.

Respondent returned an Election of Rights electing to accept the Settlement Agreement.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **Case No. 2013-05906**

ELIZABETH JAMES, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above named parties hereby offer this Settlement Agreement (Agreement) and agree to entry of a Final Order of the Board of Pharmacy (Board) incorporating this Agreement as disposition of the Administrative Complaint, in lieu of any other administrative proceedings. The terms herein become effective only if and when a Final Order accepting this Agreement is issued by the Board and filed with the Department of Health Agency Clerk.

In considering this Agreement, the Board may review all materials gathered during the investigation of this case. If this Agreement is rejected, it, and its presentation to the Board, shall not be used against either party.

STIPULATED FACTS

1. At all times material to this matter, Respondent was a pharmacist in the State of Florida holding license number 47984.

2. The Department charged Respondent with an Administrative Complaint that was properly served upon Respondent with violations of Chapters 456 and/or 465, Florida Statutes. A true and correct copy of the Administrative Complaint is attached hereto and incorporated by reference as Exhibit A.

3. Respondent neither admits nor denies the factual allegations contained in the Administrative Complaint.

STIPULATED LAW

1. Respondent admits that he/she is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department and the Board.

2. Respondent admits that the stipulated facts, if proven true, constitute violations of Chapter 456 and/or 465, Florida Statutes as alleged in the Administrative Complaint.

3. Respondent agrees that the Agreement is a fair, appropriate, and reasonable resolution of this pending matter.

PROPOSED DISPOSITION

1. **Appearance** - Respondent, Elizabeth James, R.Ph., shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine and Costs** - The Respondent shall pay an administrative fine in the amount of **TWO HUNDRED AND FIFTY DOLLARS ($250.00)** and investigative costs not to exceed **ONE THOUSAND SEVEN HUNDRED EIGHTY-ONE DOLLARS AND SEVENTY-FIVE CENTS ($1,781.75)** within one year from the date of entry of the Final Order. Payment shall be made to the Board of Pharmacy and mailed to, DOH-Compliance Management Unit, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3276, Attention: Pharmacy Compliance Officer. **Payment must be made by cashier's check or money order ONLY.** Personal checks will **NOT** be accepted.

3. **Continuing Education** - The Respondent shall enroll in and successfully complete a course in the **Prevention of Medication Errors** of no less than **eight (8) hours**. This shall be in addition to other normally required continuing education courses. Verification of course content and

course completion must be submitted to the Pharmacy Compliance Officer within six (6) months from the date of the Final Order accepting this Settlement Agreement. The Board will retain jurisdiction for the purpose of enforcing continuing education requirements.

4. The Respondent shall not violate Chapter 456 or 465, Florida Statutes, the rules promulgated pursuant thereto, any other state or federal law, rule, or regulation relating to the practice or the ability to practice pharmacy. Violation of an order from another state/jurisdiction shall constitute grounds for violation of the Final Order accepting this Settlement Agreement.

5. It is expressly understood that this Settlement Agreement is subject to the approval of the Department and the Board, and has no force and effect until a Final Order is entered accepting this Settlement Agreement.

6. This Settlement Agreement is executed by the Respondent for the purpose of avoiding further administrative action by the Board of Pharmacy regarding the acts or omissions specifically set forth in the Administrative Complaint attached hereto. In this regard, Respondent authorizes the Board to review and examine all investigative file materials

concerning Respondent prior to, or in conjunction with, consideration of the Agreement. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that presentation to, and consideration of, this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration or resolution of these proceedings. Respondent shall offer no evidence, testimony or argument that disputes or contravenes any stipulated fact or conclusion of law.

7. Respondent and the Department fully understand that this Settlement Agreement and subsequent Final Order incorporating same will in no way preclude additional proceedings by the Board and/or Department against the Respondent for acts or omissions not specifically set forth in the Administrative Complaint attached hereto. This Agreement relates solely to the current disciplinary proceedings arising from the above-mentioned Administrative Complaint and does not preclude further action by other divisions, departments, and/or sections of the Department, including but not limited to the Agency for Health Care Administration's Medicaid Program Integrity Office.

8. The Respondent waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

9. Respondent waives all rights to appeal and further review of this Agreement and these proceedings.

WHEREFORE, the parties hereto request the Board enter a Final Order accepting and implementing the terms of the Settlement Agreement contained herein.

SIGNED this 18 day of November, 2013.

Elizabeth James, R.Ph.
2013-05906

STATE OF FLORIDA

COUNTY OF Broward

Before me personally appeared Elizabeth James whose identity is known to be by Florida Driver's License (type of identification), and who under oath, acknowledges that his/her signature appears above. Sworn to and subscribed by Respondent before me this 18th day of November, 2013.

Notary Public
My Commission Expires: July 6th 2015

MOHAMED AZEEZ
Notary Public - State of Florida
My Comm. Expires Jul 6, 2015
Commission # EE 109467

APPROVED this 23rd day of January, 2014.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Judson Searcy
Assistant General Counsel
FBN: 98772
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, BIN #C-65
Tallahassee, Florida 32399-3265
Telephone (850) 245-4444 ex. 8100
Facsimile (850) 245-4683
Email: judson.searcy@flhealth.gov

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-05906**

ELIZABETH JAMES, R.Ph.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Elizabeth James, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the State of Florida, having been issued license number PS 47984.

EXHIBIT
A

3. Respondent's address of record is 1568 NW 113th Way, Pembroke Pines, Florida 33026.

4. At all times material to this Administrative Complaint, patient B.R. was a resident at Vi at Lakeside Village, an assisted living facility located in Lantana, Florida.

5. At all times material to this Administrative Complaint, patient B.R. had a prescription for Morphine 10mg/5mL.

6. Morphine is prescribed to treat pain. According to Section 893.03(2), Florida Statutes, morphine is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of morphine may lead to severe psychological or physical dependence.

7. On or about February 13, 2013, Respondent erroneously dispensed Morphine Sulfate 20mg/mL to Vi at Lakeside Village for B.R.'s use.

8. Section 465.016(1)(g), Florida Statutes (2012), provides that using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed constitutes grounds for disciplinary action by the Board of Pharmacy.

9. Respondent furnished upon prescription an ingredient or article different from the ingredient or article prescribed by dispensing Morphine Sulfate 20mg/mL for patient B.R. when B.R. was not actually prescribed Morphine Sulfate 20mg/mL.

10. Based on the foregoing, Respondent has violated Section 465.016(1)(g), Florida Statutes (2012), by furnishing upon prescription an ingredient or article different in any manner from the ingredient or article prescribed.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 24th **day of** October, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

JUDSON SEARCY
Assistant General Counsel
Fla. Bar No. 98772
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444 ex. 8100
Facsimile: (850) 245-4683
Email: judson.searcy@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 25 2013

PCP: 10/24/2013

PCP Members: Glass & Fallon

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

ELECTION OF RIGHTS
Case Name: Elizabeth James, R.Ph Case No. 2013-05906

PLEASE SELECT ONLY 1 OF THE 3 OPTIONS

An Explanation of Rights is attached. If you do not understand these options, please consult with your attorney or contact the attorney for the Prosecution Services Unit at the address/phone number listed at the bottom of this form.

OPTION 1. ____ **I do not dispute the allegations** of fact in the Administrative Complaint, but do wish to be accorded a hearing, pursuant to Section 120.57(2), Florida Statutes, at which time I will be permitted to submit oral and/or written evidence in mitigation of the complaint to the Board.

OPTION 2. X **I do not dispute the allegations** of fact contained in the Administrative Complaint and **waive my right** to object or to be heard. I request that the Board enter a final order pursuant to Section 120.57, Florida Statutes.

OPTION 3. ____ **I do dispute the allegations** of fact contained in the Administrative Complaint and request this to be considered a petition for formal hearing, pursuant to Sections 120.569(2)(a) and 120.57(1), Florida Statutes, before an Administrative Law Judge appointed by the Division of Administrative Hearings. **I specifically dispute the following paragraphs of the Administrative Complaint:**

_____

_____

In addition to the above selection, I also elect the following:

(X) I accept the terms of the Settlement Agreement, have signed and am returning the Settlement Agreement **or** I am interested in settling this case.

( ) I do not wish to continue practicing and have signed and returned the Voluntary Relinquishment of licensure form.

Regardless of which option I have selected, I understand that I will be given notice of time, date, and place when this matter is to be considered by the Board for Final Action. Mediation under Section 120.573, Florida Statutes, is not available in this matter. (Please sign and complete all the information below.)

_____
Respondent's signature
Address: 1568 NW 113th Way
Pembroke Pines, FL 33026

Lic. No. _____

Phone No. _____

Fax No. _____

STATE OF FLORIDA
COUNTY OF Broward
Before me personally appeared ELIZABETH JAMES whose identity is known to be by Florida Driver License (type of identification), and who under oath, acknowledges that his/her signature appears above. Sworn to and subscribed by Respondent before me this 19 day of November, 2013.

_____
Notary Public
My Commission Expires: July 6th 2015

MOHAMED AZEEZ
Notary Public - State of Florida
My Comm Expires Jul 6, 2015
Commission # EE 109467

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Judson Searcy, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 245-4444; FAX (850) 245-4683- TDD 1-800-955-8771

January 28, 2014

Elizabeth James
1668 NW 113 Way
Pembroke Pines, FL 33016

Re: DOH vs. Elizabeth James, R.Ph
DOH Case Number: 2013-05906

Dear Ms. James:

I am in receipt of the settlement agreement executed by you on November 18, 2013, concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. Please be advised your case will be set at the convenience of the Department and/or the Board and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Judson Searcy
Assistant General Counsel

JS/ab

MEMORANDUM OF FINDING OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy
RE: **DOH v. Elizabeth James, R.Ph.**
DOH Case Number 2013-05906

MEMBERS: Leo J. "Lee" Fallon, BPharm, Ph.D and Debra Glass, BPharm

DATE OF PCP: October 24, 2013 **AGENDA ITEM: A-7(JS)**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative report, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(g), Florida Statutes (2012)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

Debra Glass RPh 10/24/13

Chair, Probable Cause Panel Date
Board of Pharmacy

JS/ab

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201302802

MILLENIUM PHARMACY INC.,
RESPONDENT.

NOTICE

TO: MILLENIUM PHARMACY INC.
836 WEST FLAGLER STREET
MIAMI, FL 33130

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Jodi-Ann V. Livingstone, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Millenium Pharmacy Inc.
DOH Case Number 2013-02802
DATE: February 3, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Millenium Pharmacy Inc.
Subject's Address of Record:	836 West Flagler Street Miami, FL 33130
Enforcement Address:	836 West Flagler Street Miami, FL 33130
Subject's License No:	25300 **Rank:** PH
Licensure File No:	18220
Initial Licensure Date:	2/23/2011
Board Certification:	No
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s)	Count I: Section 465.023(1)(c), F.S.(2012), by violating rule of the Board of Pharmacy, through a violation of Rule 64B16-27.420(4)(a), F.A.C. Count II: Section 465.023(1)(c), F.S.(2012), by violating rule of the Board of Pharmacy, through a violation of Rule 64B16-28.102(5)(a), F.A.C. Count III: Section 465.023(1)(c), F.S.(2012), by violating rule of the Board of Pharmacy, through a violation of Rule 64B16-28.110(4)(a), F.A.C.

	Count IV: Section 465.023(1)(c), F.S.(2012), by violating rule of the Board of Pharmacy, through a violation of Rule 64B16-28.118(4)(a), F.A.C.
Prior Discipline:	None
Probable Cause Panel:	July 30, 2013 Michele Weizer, PharmD and Gavin Meshad
Subject's Attorney:	Pro Se
Complainant/Address:	Department of Health/Investigative Services Unit-Miami ISU
Materials Submitted:	Memorandum to the Board Settlement Agreement Exhibit A - Administrative Complaint Board Notification Letter Election of Rights Cost Summary Report Respondent's Documents PCP Memo Final Investigative Report with Exhibits 1-5

DISCIPLINARY GUIDELINES:

64B16-28.110-- Min: $500 fine	Max: One (1) year probation and $2,000 fine (if drugs dispensed, one (1) year suspension)
Rule 64B16-28.102(5)(a) -- Min: $100 fine	Max: One (1) year probation and $2,000 fine

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

Inspection violation. Minor deficiencies noted.

Mitigating /Aggravating Conditions

Terms of Settlement Agreement:

1. Appearance
2. Costs limited to $2000

3. Fine of $1000
4. Correction of deficiencies

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

V. **CASE NO. 2013-02802**

MILLENIUM PHARMACY, INC.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Millenium Pharmacy, Inc., was a permitted pharmacy in the state of Florida, having been issued permit number PH 25300. Respondent's mailing address of record is 836 West Flagler Street, Miami, Florida 33130.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **ONE THOUSAND DOLLARS ($1,000).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **30 days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **two thousand dollars and no cents ($2,000)**. Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320, within 30 days from the date the Final Order is filed with the Department Clerk.

4. **Correction of Alleged Deficiencies** - At its sole expense, but without admitting any specific deficiency or violation, Respondent shall correct and address all deficiencies and violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law, within thirty days of the filing of the Final Order incorporating this Settlement Agreement. Failure to correct and address all deficiencies and violations listed or alleged in the Administrative Complaint will be considered a violation of the Final Order incorporating this Settlement Agreement.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto;

or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or

contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his/her mailing address and his/her practice address with the Board of Pharmacy

and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 10 day of September, 2013.

Andy Armas
MILLENIUM PHARMACY, INC.

STATE OF Florida

COUNTY OF Dade

Before me personally appeared Andy ARMAS, whose identity is known to me or by Florida Driver's License (type of identification), and who, under oath, acknowledges that his/her signature appears above.
Sworn to and subscribed before me this 11 day of September, 2013.

BEATRIZ CARREON
MY COMMISSION # EE118933
EXPIRES November 06, 2015
(407) 398-0153 FloridaNotaryService.com

Notary Public
My Commission Expires:

APPROVED this 11th day of September, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Jodi-Ann V. Johnson
Assistant General Counsel

Counsel for Petitioner
Jodi-Ann V. Johnson
Florida Bar No. 0073525
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: 850.245.4444
Fax: 850.245.4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-02802**

MILLENIUM PHARMACY, INC.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Millenium Pharmacy, Inc., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted pharmacy within the state of Florida, having been issued permit number PH 25300

EXHIBIT
tabbies
A

3. Respondent's address of record is 836 West Flagler Street, Miami, Florida 33130.

4. On or about January 31, 2013, a Department of Health (DOH) inspector performed an inspection of Respondent.

5. During the January 31, 2013, inspection, deficiencies were noted by the DOH inspector, including on or more of the following:

a. pharmacy technicians, J.T., was not properly identified. J.T. was not wearing a badge;

b. no current Facts and Comparisons;

c. expired medication found in active stock; and

d. copy of inventory for purchased medication missing lot numbers.

6. Section 465.023(1)(c), Florida Statutes (2012), provides that the Department or the Board of Pharmacy may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465 or any of the rules of the Board of Pharmacy or of Chapter 499, Florida Statutes.

COUNT ONE

7. Petitioner realleges and incorporates paragraphs one (1) through six (6) as if fully set forth herein.

8. Rule 64B16-27.420(4)(a), Florida Administrative Code, provides that all registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as a "registered pharmacy technician".

9. During the January 31, 2013, inspection, a registered pharmacy technician was not properly identified.

10. Based upon the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-27.420(4)(a), Florida Administrative Code, by failing to to insure a registered pharmacy technician was properly identified.

COUNT TWO

11. Petitioner realleges and incorporates paragraphs one (1) through six (6) as if fully set forth herein.

12. Rule 64B16-28.102(5)(a), Florida Administrative Code, states that the following shall be provided for the prescription department of each pharmacy: A current pharmacy reference compendium such as the United States Pharmacopoeia/National Formulary, the U.S. Dispensatory, USP DI, (United States Pharmacopoeial Drug Information), the Remington Practice of Pharmacy, Facts and Comparisons or an equivalent thereof sufficient in scope to meet the professional practice needs of that pharmacy, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida. It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

13. During the January 31, 2013, inspection, Respondent did not have a copy of a current Facts and Comparisons.

14. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), through a violation of Rule 64B16-28.102(5)(a), Florida Administrative Code, by failing to have a copy of a current Facts and Comparisons.

COUNT THREE

15. Petitioner realleges and incorporates paragraphs one (1) through six (6) as if fully set forth herein.

16. Rule 64B16-28.110, Florida Administrative Code, provides persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

17. During the January 31, 2013, inspection, the DOH inspector found outdated pharmaceuticals included in the active stock.

18. Based upon the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.110, Florida Administrative Code, by failing to remove from the prescription department all pharmaceuticals which bear upon the container an expiration date which has been reached.

COUNT FOUR

19. Petitioner realleges and incorporates paragraphs one (1) through six (6) as if fully set forth herein.

20. Rule 64B16-28.118(4), Florida Administrative Code, requires that no pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions: (1) In a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to in-patients, the unused medication may be returned to the pharmacy for redispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any.

21. During the January 31, 2013, inspection, the DOH investigator noted that copy of inventory for purchased medication was missing lot numbers.

22. Based upon the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.118(4), Florida

Administrative Code, because copy of inventory for purchased medication was missing lot numbers.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's permit, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 30th **day of** July **, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Jodi-Ann V. Johnson
Assistant General Counsel
Fla. Bar No. 0073525
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Jodi-Ann_Johnson@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUL 30 2013

/JVJ
PCP: 7.30.2013
PCP Members: Meshad and Weizer

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

January 23, 2014

VIA US MAIL

Millenium Pharmacy, Inc.
836 West Flagler Street
Miami, Florida 33130

Re: DOH vs. Millenium Pharmacy, Inc.
DOH Case Number: 2013-02802

Dear Mr. Armas:

I am in receipt of the Settlement Agreement executed by you on September 11, 2013, concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for **April 2, 2014**, at the **Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607**. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank you for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Jodi-Ann V. Johnson
Assistant General Counsel

JAVJ/pb

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Complaint Cost Summary

Complaint Number: 201302802

Subject's Name: MILLENIUM PHARMACY INC.

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	10.50	$671.79
Legal:	4.30	$457.32
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	15.40	$1,162.05
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,162.05

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MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Millenium Pharmacy, Inc. (JVJ)**
Case Number: 2013-02802

MEMBERS: MW **Michele Weizer, PharmD and Gavin Meshad**

DATE OF PCP: July ~~May~~ **30, 2013** **AGENDA ITEM: A-2**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-27.420(4)(a), Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), through a violation of Rule 64B16-28.102(5)(a), Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.110, Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), by violating a rule of the Board of Pharmacy, through a violation of Rule 64B16-28.118(4), Florida Administrative Code;

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **other** _____

Michele Weizer PharmD BCPS MW 7/30/2013
Chair, Probable Cause Panel Date
Board of Pharmacy

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10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201209524

ROBERT M BOJARZIN,
RESPONDENT.

NOTICE

TO: ROBERT M BOJARZIN
19300 LA SERENA DR
FT MYERS, FL 33967

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

Rick Scott
Governor

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BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201209524

ROBERT M BOJARZIN,
RESPONDENT.

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TO: BRANDON NICHOLS
9128 STRADE PLACE SUITE 10200
NAPLES, FL 34108

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BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201209524

ROBERT M BOJARZIN,
RESPONDENT.

NOTICE

TO: KEVIN W. CREWS
9128 STRADA PLACE SUITE 10200
NAPLES, FL 34108

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Jodi-Ann V. Livingstone, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Robert M. Bogarzin, R.Ph.
DOH Case Number 2012-09524
DATE: February 3, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Robert M. Bojarzin, R.Ph.
Subject's Address of Record:	19300 La Serena Drive Ft. Myers, Florida 33967
Enforcement Address:	19300 La Serena Drive Ft. Myers, Florida 33967
Subject's License No:	19647 **Rank:** PS
Licensure File No:	9109
Initial Licensure Date:	8/7/1982
Board Certification:	No
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	Section 465.015(1)(g), F.S.(2010)
Prior Discipline:	4070, DOH-00-0050; 4080,04/08/1992
Probable Cause Panel:	February 28, 2013 Mullins and Glass
Subject's Attorney:	Brandon M. Nichols, Esquire Wicker, Smith, O'Hara, McCoy & Ford, P.A. 9128 Strada Place Suite 10200 Naples, Florida 34108
Complainant/Address:	Department of Health/Investigative Services Unit-Ft. Myers
Materials Submitted:	Memorandum to the Board

Settlement Agreement
Amended Administrative Complaint
Board Notification Letter
Election of Rights
Cost Summary
Supplemental Investigative Report dated 10-09-12
PCP Memo
456 Materials
Final Investigative Report
Exhibits 1-9

DISCIPLINARY GUIDELINES:
Min: $250 fine, CE in prevention of medication errors (8 hours)

Max: Revocation

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

Case involving misfill due to transcription error.

Mitigating /Aggravating Conditions

Terms of Settlement Agreement:

1. Appearance
2. Costs limited to $2773.05
3. Fine of $500
4. CE in Medication Errors (8 hours)

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-09524**

ROBERT M. BOJARZIN, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Robert M. Bojarzin, RPh, was a licensed pharmacist in the state of Florida, having been issued license number PS 19647. Respondent's mailing address of record is 19300 La Serena Drive, Fort Myers, Florida 33967.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

3. Respondent neither admits nor denies the factual allegations contained in the Administrative Complaint.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, Robert M. Bojarzin, R.Ph., shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **FIVE HUNDRED DOLLARS** ($500.00). The fine shall be paid by

Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within six (6) months from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND, SEVEN HUNDRED SEVENTY-THREE DOLLARS AND FIVE CENTS** ($2,773.05). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within six (6) months from the date the Final Order is filed with the Department Clerk. **Payment must be made by cashier's check or money order ONLY.** Personal Checks shall **NOT** be accepted.

4. **CE Course**- Respondent shall successfully complete a Continuing Education Course on the subject of Medication Errors consisting of at least 8 hours of credit, which has been approved by the Florida Board

of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the

Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional

proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and Incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 3rd day of June, 2013

Robert M Bojarzin, RPh

ROBERT M. BOJARZIN, RPH
CASE NO. 2012-09524

STATE OF Florida

COUNTY OF Collier

Before me personally appeared Robert M. Bojarzin, RPh, whose identity is known to me or by drivers license (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 3rd day of June, 2013.

Notary Public
My Commission Expires:

DARLA A. TARTAGLIA
MY COMMISSION # DD 901860
EXPIRES: October 23, 2013
Bonded Thru Notary Public Underwriters

APPROVED this 4th day of June, 2013

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Jodi-Ann V. Johnson

Jodi-Ann V. Johnson
Assistant General Counsel
Fla. Bar No. 73525
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444 ext. 8113
Facsimile: (850) 245-4683
Email: jodi-ann_johnson@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-09524**

ROBERT M. BOJARZIN, R.PH.,

RESPONDENT.

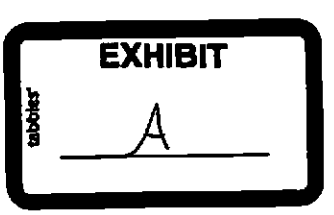
_____/

AMENDED ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Amended Administrative Complaint (Complaint) before the Board of Pharmacy against Respondent, Robert M. Bojarzin, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist in the state of Florida, having been issued license PS 19647.



3. Respondent's address of record is 19300 La Serena Drive, Fort Myers, Florida 33967.

4. At all times material to this Complaint, Respondent was employed as a pharmacist by North Collier Hospital (NCH) in Naples, Florida.

5. On or about June 5, 2011, T.O., a 79-year-old male, was admitted to NCH was admitted to NCH due to a left distal fibula fracture. T.O. reported falling at home and striking his ankle after a vigorous workout. The hospital recommended surgical intervention.

6. Upon admission to NCH, Hospitalist Dr. J.H. performed T.O.'s initial physical and medical history. T.O. indicated to J.H. that he took cholesterol medication. T.O.'s initial blood pressure at admission was 128/60. T.O. did not indicate to Dr. J.H. that he had hypertension.

7. On or about June 6, 2011, at approximately 4:41 a.m., Respondent entered enalapril (Vasotec) 20 mg 1 tablet PO (by mouth), and nifedipine (Procardia) 30 mg PO daily into T.O.'s medical chart. The record noted that the ordering provider was Dr. J.H.; however, no order for the two medications was seen in T.O.'s medical records.

8. Enalapril is an angiotensin converting enzyme (ACE) inhibitor used to treat hypertension and congestive heart failure.

9. Nifedipine is a calcium channel blocker used to treat hypertension and chest pain.

10. T.O. underwent surgery on his left fibula on or about June 7, 2011, without any complications.

11. On or about June 9, 2011, at approximately 8:00 a.m., T.O.'s blood pressure had fallen to 84/47.

12. On or about June 9, 2011, T.O. was evaluated by Dr. F.Q.C. Dr. F.Q.C. noted that T.O. had developed acute renal failure.

13. A review of the records revealed that Respondent had entered the enalapril and nifedipine from another patient's chart into patient T.O.'s chart.

14. T.O. was discharged on or about June 11, 2011, after T.O.'s renal function and blood pressure returned to baseline.

15. Respondent admitted to the transcription error.

16. Section 465.016(1)(g), Florida Statutes (2010), provides that using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article

prescribed, except as authorized in s. 465.019(6) or s. 465.025 is grounds for discipline.

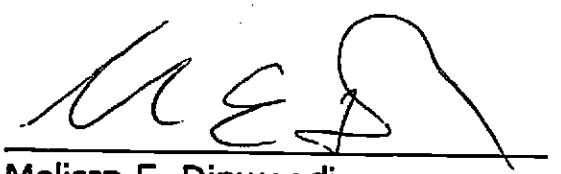
17. As set forth above, on or about June 6, 2011, Respondent transcribed prescriptions for enalapril and nifedepine from another patient's medical record into patient T.O.'s chart. T.O. was not prescribed enalapril or nifedepine.

18. Based on the foregoing, Respondent has violated Section 465.015(1)(g), Florida Statutes (2010), by using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in s. 465.019(6) or s. 465.025.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's permit, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 28 **day of** February, **2013.**

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health



Melissa E. Dinwoodie
Assistant General Counsel
Fla. Bar No. 76466
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444 ext. 8174
Facsimile: (850) 245-4683
Email: Melissa_Dinwoodie@doh.state.fl.us

/MED

PCP: February 28, 2013
PCP Members: Mullins and Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

June 13, 2013

VIA US MAIL

Brandon M. Nichols, Esquire
Wicker, Smith, O'Hara, McCoy & Ford, P.A.
9128 Strada Place, Suite 10200,
Naples, Florida 34108-2683

Re: DOH vs. Robert M. Bojarzin, R.Ph.
DOH Case Number: 2012-09524

Dear Mr. Nichols:

I am in receipt of the Settlement Agreement executed by your client on June 3, 2013 concerning the above referenced case.

Our office is now making preparation for this Settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for **August 14, 2013**, at the **Rosen Plaza Hotel, 9700 Internatonal Drive, Orlando, Florida 32819**. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank you for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Jodi-Ann V. Johnson
Assistant General Counsel

JAVJ/pb

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Complaint Cost Summary

Complaint Number: 201209524

Subject's Name: BOJARZIN, ROBERT M

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.40**	**$23.05**
Investigation:	**8.00**	**$489.54**
Legal:	**15.20**	**$1,579.58**
Compliance:	**0.00**	**$0.00**
	**********	**********
Sub Total:	**23.60**	**$2,092.17**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$2,092.17**

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Robert M. Bojarzin, R.Ph.**
Case Number: 2012-09524

MEMBERS: **Leo Fallon and Gavin Meshad**

DATE OF PCP: **December 18, 2012** **AGENDA ITEM: A-6**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(g), Florida Statutes (2010), by using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in s. 465.019(6) or s. 465.025.

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**

a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **other** _____

Leo J. Fallon PhD 12/18/2012

Chair, Probable Cause Panel Date
Board of Pharmacy

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Robert M. Bojarzin, R.Ph.**
Case Number: 2012-09524

MEMBERS: **DeAnn Mullins and Debra Glass**

DATE OF PCP: **February 28, 2013** **AGENDA ITEM: AAC-1**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.015(1)(g), Florida Statutes, by using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(1)(6) or Section 465.025.

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

____ **other** **AMENDED ADMINISTRATIVE COMPLAINT**

DeAnn Mullins 7/9/13

Chair, Probable Cause Panel Date
Board of Pharmacy

BOARD 9/14/12 -

PCP memo - Berkley - 20:2-11079

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Rick Scott
Governor

FLORIDA DEPARTMENT OF HEALTH

John H. Armstrong, MD
State Surgeon General

October 24, 2012

Kevin W. Crews, Esquire
Wicker, Smith, O'Hara, McCoy & Ford, P.A.
9128 Strada Place, Suite 10200
Naples, Florida 34108-2683

Re: Complaint No. 2012-09524 Robert M. Bojarzin, R.Ph.

Dear Mr. Crews

Pursuant to section 456.073(10), Florida Statutes, enclosed a CD containing a copy the Department's complete investigative file in Complaint No. 2012-09524. Section 456.073(10), Florida Statutes provides in part:

> . . . Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. The subject may file a written response to the information contained in the investigative file. Such response must be filed within 20 days of mailing by the department, unless an extension of time has been granted by the department. . . .

Pursuant to the provisions of section 456.073(10), Florida Statutes, your written response must be received by no later than twenty (20) days from the date of this letter. Any requests for an extension of time must be made to my office prior to the expiration of the original twenty (20) days.

The password for the CD is: 456. Please call with any questions, 850-245-4640, ext. 8174.

Respectfully,

Melissa E. Dinwoodie
Assistant General Counsel

MED/crl

Enclosures: CD Investigative File (2012-09524)
Invoice #: MQPR13-187

PROSECUTION SERVICES UNIT
4052 BALD CYPRESS WAY, BIN # C65
TALLAHASSEE FLORIDA 32399-3265

PHONE: (850) 245-4640

TO Kevin Crews Esquire
9128 Strada Place
Suite 10200
Naples Florida 34108

INVOICE NUMBER MQPR13-187

DATE October 10, 2012

SERVICES RENDERED		**AMOUNT**
(copy)	___ Pages @$.15 Per Page	$
	___ Pages @$.75 Per Page (Color Copied)	$
	1 CD @ $8.00 Each	$ 8.00
	Charge to Certify Above Copies	$
	X-Ray Duplication Charge:	$
	Research Charge (if over one half hour) At $__per hour x __hours	$
	Postage & Handling Fees:	$
	TOTAL AMOUNT DUE UPON RECEIPT	$ 8.00

Payment Options: Cashier Check or Money Order made payable to:

Florida DOH, Division of MQA

Please reference the INVOICE NUMBER on your Payment—Mail to the above address.

Organization Code: 64-22-10-01-022

Expense Code: 497000

EO Code: PA

Profession: Pharmacy

Case Name: Robert Bojarzin

Case Number: 2012-09524

Lillich, Christine

From: trackingupdates@fedex.com
Sent: Thursday, October 25, 2012 1:08 PM
To: Lillich, Christine
Subject: FedEx Shipment 793922736223 Delivered

This tracking update has been requested by:

Company Name:	Dept. of Health/PSU
Name:	Christine Lillich
E-mail:	Christine_Lillich@doh.state.fl.us

Our records indicate that the following shipment has been delivered:

Invoice number:	Case # 2012-09524
Purchase order number:	456 Request
Reference:	64221001022
Ship (P/U) date:	Oct 24, 2012
Delivery date:	Oct 25, 2012 1:05 PM
Sign for by:	B.BEKICH
Delivery location:	NAPLES, FL
Delivered to:	Receptionist/Front Desk
Service type:	FedEx Standard Overnight
Packaging type:	FedEx Pak
Number of pieces:	1
Weight:	1.00 lb.
Special handling/Services:	Deliver Weekday
Tracking number:	793922736223

Shipper Information	Recipient Information
Christine Lillich	Michael R. DLugo
Dept. of Health/PSU	Wicker, Smith, et al
4040 Esplanade Way	9128 STRADA PL
Suite 101	STE 10200
Tallahassee	NAPLES
FL	FL
US	US
32399	34108

Please do not respond to this message. This email was sent from an unattended mailbox. This report was generated at approximately 12:07 PM CDT on 10/25/2012.

To learn more about FedEx Express, please visit our website at fedex.com.

All weights are estimated.

To track the latest status of your shipment, click on the tracking number above, or visit us at fedex.com.

This tracking update has been sent to you by FedEx on the behalf of the Requestor noted above. FedEx does not validate the authenticity of the requestor and does not validate, guarantee or warrant the authenticity of the request, the requestor's message, or the accuracy of this tracking update. For tracking results and fedex.com's terms of use, go to fedex.com.

Thank you for your business.

Spam
Not spam
Forget previous vote

From: (850) 245-4640
Christine Lillich
Dept. of Health/PSU
4040 Esplanade Way
Suite 101
Tallahassee, FL 32399

Origin ID: TLHA

FedEx Express

J12201210150325

Ship Date: 24OCT12
ActWgt: 1.0 LB
CAD: 100583107/INET3300

Delivery Address Bar Code

SHIP TO: (407) 649-8118
Michael R. DLugo
Wicker, Smith, et al
9128 STRADA PL
STE 10200
NAPLES, FL 34108

BILL SENDER

Ref # 64221001022
Invoice # Case # 2012-09524
PO # 456 Request
Dept #

THU - 25 OCT A2
STANDARD OVERNIGHT

TRK# 0201 7939 2273 6223

XH IMMA

34108
FL-US
RSW

515G1/9CCB/AA44

After printing this label:
1. Use the 'Print' button on this page to print your label to your laser or inkjet printer.
2. Fold the printed page along the horizontal line.
3. Place label in shipping pouch and affix it to your shipment so that the barcode portion of the label can be read and scanned.

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Use of this system constitutes your agreement to the service conditions in the current FedEx Service Guide, available on fedex.com.FedEx will not be responsible for any claim in excess of $100 per package, whether the result of loss, damage, delay, non-delivery,misdelivery,or misinformation, unless you declare a higher value, pay an additional charge, document your actual loss and file a timely claim.Limitations found in the current FedEx Service Guide apply. Your right to recover from FedEx for any loss, including intrinsic value of the package, loss of sales, income interest, profit, attorney's fees, costs, and other forms of damage whether direct, incidental,consequential, or special is limited to the greater of $100 or the authorized declared value. Recovery cannot exceed actual documented loss.Maximum for items of extraordinary value is $1,000, e.g. jewelry, precious metals, negotiable instruments and other items listed in our ServiceGuide. Written claims must be filed within strict time limits, see current FedEx Service Guide.

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Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201315707

NUBIA ORTEGA,
RESPONDENT.

NOTICE

TO: NUBIA ORTEGA
2750 SW 128 AV
MIAMI, FL 33175

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
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Vision: To be the Healthiest State in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Christopher A. Jurich, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Nubia Ortega, R.Ph.
DOH Case Number 2013-15707
DATE: January 9, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Nubia Ortega, R.Ph.
Subject's Address of Record:	2750 S.W. 128th Avenue Miami, FL 33175
Enforcement Address:	2750 S.W. 128th Avenue Miami, FL 33175
Subject's License No:	29230 **Rank:** PS
Licensure File No:	18244
Initial Licensure Date:	3/9/1994
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation:	**Count I:** Section 456.072(1)(k), F.S. (2013) by violating Section 465.022(11)(a), F.S. by failing to ensure compliance with Rule 64B16-28.109(1), F.A.C. **Count II:** Section 456.072(1)(k), F.S. (2013), by violating Section 465.022(11)(a), F.S. by failing to ensure compliance with Rule 64B16-28.109(5), F.A.C.
Prior Discipline:	None

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row • Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Probable Cause Panel:	December 19, 2013 Jeffrey Mesaros and Mark Mikhael
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU Miami
Materials Submitted:	Memorandum to the Board Settlement Agreement - signed Exhibit A – Administrative Complaint Election of Rights Notification Letter Cost Summary PCP Memorandum Final Investigative Report Exhibits 1 thru 3

CAJ/crl

Disciplinary Guidelines:

Count I: Minimum of $500 fine and 12 hours of Laws and Rules course or MPJE to a maximum of 1 year probation and $2000 fine.

Count II: Minimum of $500 fine and 12 hours of Laws and Rules course or MPJE to a maximum of 1 year probation and $2000 fine.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

At all times material to the Administrative Complaint, Respondent was the prescription department manager of record for Biosic-Winzeler, Inc. (the Permittee), a community pharmacy located in Miami, Florida. At approximately 1:30 p.m. on or about July 5, 2013, the Department conducted a routine inspection of the Permittee which revealed the following: (a) the Permittee did not have a licensed pharmacist present and on duty, (b) the Permittee's prescription department was open and had a line of customers waiting to be served; and (c) A.M., a registered pharmacy technician, was standing in the prescription department.

Terms of Settlement:

- Appearance
- $1,000 Fine
- Costs limited to $1,645.02
- 12 hours continuing education course on Laws and Rules

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-15707**

NUBIA ORTEGA, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Nubia Ortega, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 29230. Respondent's mailing address of record is 2750 Southwest 128th Avenue, Miami, Florida 33175.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **ONE THOUSAND DOLLARS ($1,000.00)**. The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within **30 days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND SIX HUNDRED FORTY FIVE DOLLARS AND TWO CENTS ($1,645.02).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order is filed with the Department Clerk.

4. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of **LAWS AND RULES** consisting of **TWELVE (12) HOURS** of credit, which has been approved by the Florida Board of Pharmacy, within **one (1) year** of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or

receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Future Conduct**- Respondent shall not violate Chapters 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent

authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within ten (10) days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 8 day of January, 2014.

Nubia Ortega, R.Ph.
Case No. 2013-15707

STATE OF FLORIDA
COUNTY OF MIAMI-DADE

Before me personally appeared NUBIA D. ORTEGA, whose identity is known to me or by FL DRIVER LIC #. _____ (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 8TH day of JANUAR, 2014.

EDUARDO A. AREAS MY COMMISSION EXPIRES August 6, 2014 #DD 979832 Bonded thru Notary Public Underwriters NOTARY PUBLIC, STATE OF FLORIDA

Notary Public
My Commission Expires:

APPROVED this 9th day of January, 2014.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Christopher A. Jurich
Assistant General Counsel

Counsel for Petitioner
Christopher A. Jurich
Florida Bar No. 0099014
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444 ext. 8174
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-15707**

NUBIA ORTEGA, R.Ph.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Nubia Ortega, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 29230.

EXHIBIT A

3. Respondent's address of record is 2750 Southwest 128th Avenue, Miami, Florida 33175.

4. At all times material to this Administrative Complaint, Respondent was the prescription department manager (PDM) of Biosic-Winzeler, Inc., d/b/a Farmacia 22-24 (the Permittee), located at 10404 West Flagler Street, Suite 20-21, Miami, Florida 33174.

5. At approximately 1:30 p.m. on or about July 5, 2013, a Department inspector conducted a routine inspection of the Permittee and noted the following:

a. The Permittee did not have a licensed pharmacist present and on duty; and/or

b. The Permittee's prescription department was open and had a line of customers was waiting to be served; and/or

c. A.M., a registered pharmacy technician, was standing in the Permittee's prescription department.

COUNT ONE

6. Petitioner realleges and incorporates paragraphs one through five as if fully set forth herein.

7. Section 456.072(1)(k), Florida Statutes (2013), provides that failing to perform any statutory or legal obligation placed upon a licensee constitutes grounds for disciplinary action.

8. Section 465.022(11)(a), Florida Statutes (2013), provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

9. Rule 64B16-28.109(1), Florida Administrative Code, provides that the prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty.

10. As stated above, during the inspection on or about July 5, 2013, the Permittee's prescription department was open and receiving customers while a licensed pharmacist was not present and not on duty.

11. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2013), by violating Section 465.022(11)(a), Florida Statutes, by failing to ensure the permittee's compliance with Rule 64B16-28.109(1), Florida Administrative Code, which

provides that the prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty.

COUNT TWO

12. Petitioner realleges and incorporates paragraphs one through five as if fully set forth herein.

13. Section 456.072(1)(k), Florida Statutes (2013), provides that failing to perform any statutory or legal obligation placed upon a licensee constitutes grounds for disciplinary action.

14. Section 465.022(11)(a), Florida Statutes (2013), provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

15. Rule 64B16-28.109(5), Florida Administrative Code, provides that whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter, or remain in the prescription department.

16. As set forth above, during the inspection on or about July 5, 2013, registered pharmacy technician A.M. was present in the Permittee's prescription department when a licensed pharmacist was not present and on duty.

17. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2013), by violating Section 465.022(11)(a), Florida Statutes, by failing to ensure the permittee's compliance with Rule 64B16-28.109(5), Florida Administrative Code, which states that whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter, or remain in the prescription department.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 19th **day of** December, **2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Christopher A. Jurich

CHRISTOPHER A. JURICH
Assistant General Counsel
Fla. Bar No. 0099014
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: christopher.jurich@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE DEC 19 2013

/CAJ

PCP Meeting: December 19, 2013
PCP Members: Jeffrey Mesaros, Mark Mikhael

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

February 5, 2014

VIA US MAIL

Nubia Ortega, R.Ph.
2750 S.W. 128th Avenue
Miami, Florida 33175

Re: DOH vs. Nubia Ortega, R.Ph.
DOH Case Number: 2013-15707

Dear Nubia Ortega:

I am in receipt of the settlement agreement executed by you on January 8, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Christopher A. Jurich
Assistant General Counsel

CAJ/crl

Complaint Cost Summary

Complaint Number: 201315707

Subject's Name: ORTEGA, NUBIA

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.50	$27.45
Investigation:	6.00	$383.08
Legal:	2.90	$295.67
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	9.40	$706.20
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$706.20

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Nubia Ortega, R.Ph. (CAJ)**
Case Number: 2013-15707

MEMBERS: **Mark Mikhael and Jeffrey Mesaros**

DATE OF PCP: **December 19, 2013** **AGENDA ITEM: A-02**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Count I: Section 456.072(1)(k), Florida Statutes (2013), by violating Section 465.022(11)(a), Florida Statutes by failing to ensure compliance with Rule 64B16-28.109(1), Florida Administrative Code

Count II: Section 456.072(1)(k), Florida Statutes (2013), by violating Section 465.022(11)(a), Florida Statutes, by failing to ensure compliance with Rule 64B16-28.109(5), Florida Administrative Code

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **other,** _____

Mary Collier for Jeffrey Mesaros 2/24/14
Chair, Probable Cause Panel Date
Board of Pharmacy

CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS.

CASE NO. 201314316

NADMI AHMED QAYED,
RESPONDENT.

NOTICE

TO: NADMI AHMED QAYED
15051 PROSPECT
DEARBORN, MI 48126

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Christopher Jurich, Assistant General Counsel CJ CDC 2-4-14
RE: Settlement Agreement
SUBJECT: DOH v. Nadmi Ahmed Qayed, R.Ph.
DOH Case Number 2013-14316
DATE: February 4, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Nadmi Ahmed Qayed, R.Ph.
Subject's Address of Record:	15051 Prospect Dearborn, MI 48126
Enforcement Address:	15051 Prospect Dearborn, MI 48126
Subject's License No:	48803 **Rank:** PS
Licensure File No:	41227
Initial Licensure Date:	3/21/2012
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegations:	Section 465.016(1)(h), Florida Statutes (2013)
Prior Discipline:	None
Probable Cause Panel:	December 12, 2013 Mikhael and Mesaros
Subject's Attorney:	Pro Se

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complainant/Address:	(Self-Report) Nadmi Ahmed Qayed 15051 Prospect Dearborn, MI 48126
Materials Submitted:	Board Notice of Hearing Memorandum to the Board Settlement Agreement, signed Exhibit A – Administrative Complaint Election of Rights Notification Letter Cost Summary Final Investigative Report Exhibits 1 thru 2

CAJ/crl

Disciplinary Guidelines

Minimum of same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes to a maximum of same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes to $10,000 fine and revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

On or about August 14, 2013, Respondent entered into a consent order with the Michigan Board of Pharmacy, whereby disciplining Respondent's pharmacist license in the state of Michigan for having filled fraudulent prescriptions and dispensed controlled substances to himself and one or more patients without a legitimate prescription. The offense underlying Respondent's discipline by the Michigan Board of Pharmacy would also constitute a violation of Chapter 465, Florida Statutes.

Terms of Settlement:

- Appearance
- $5,000 Fine
- Costs limited to $1,250.52
- Probation for 1 year with standard terms
- CE course: 12 hours of Laws and Rules

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-14316**

NADMI AHMED QAYED, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Nadmi Ahmed Qayed, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 48803. Respondent's mailing address of record is 15051 Prospect, Dearborn, Michigan 48126.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **FIVE THOUSAND DOLLARS ($5,000.00)**. The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within **30 days** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND TWO HUNDRED FIFTY DOLLARS AND FIFTY TWO CENTS ($1,250.52).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order is filed with the Department Clerk.

4. **Probation**- Respondent's Florida pharmacist license shall be placed on probation for **1 (one) year**. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respondent shall not work at or for more than 2 pharmacies during each quarter of the probationary period, unless Respondent obtains prior written approval from the Board.

b. Respondent shall submit written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall include Respondent's license number, current address, and phone number; current name, address, and phone number of each pharmacy in which Respondent is engaged in the practice of pharmacy; the names of all pharmacists, pharmacy interns, pharmacy technicians, relief pharmacists, and prescription department managers working with Respondent. These reports shall be submitted to the Compliance Officer every three (3) months in a manner as directed by the compliance officer.

c. Respondent shall ensure that his employer submits written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall contain the name,

address, license number, and phone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working in the prescription department where Respondent practices, and provide a brief description of Respondent's duties, responsibilities, and working schedule. These reports shall be submitted to the Compliance Officer every three (3) months in a manner as directed by the compliance officer.

d. Respondent shall make a mandatory appearance before the Board of Pharmacy during Respondent's last three (3) months of probation. The Board retains the right to extend Respondent's term of probation or to impose additional restrictions, conditions or limitations on Respondent's license.

5. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of **LAWS AND RULES** consisting of **TWELVE (12) HOURS** of credit, which has been approved by the Florida Board of Pharmacy, within **one (1) year** of the filing of a

Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

6. **Future Conduct**- Respondent shall not violate Chapters 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

7. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

9. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

11. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

12. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

13. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within ten (10) days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 9th day of January, 2014.

Nadmi Ahmed Qayed, R.Ph.
Case No. 2013-14316

STATE OF MI
COUNTY OF Wayne

Before me personally appeared Nadmi Qayed, whose identity is known to me or by DRIVER LICENSE (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 9 day of January, 2014.

SOMAYA ELKATTAN
Notary Public - Michigan
Wayne County
My Commission Expires Jul 16, 2018
Acting in the County of Wayne

Notary Public
My Commission Expires: 7-16-18

APPROVED this 13th day of January, 2014.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Christopher A. Jurich
Assistant General Counsel

Counsel for Petitioner
Christopher A. Jurich
Florida Bar No. 0099014
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444 ext. 8174
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-14316**

NADMI AHMED QAYED, R.PH.,

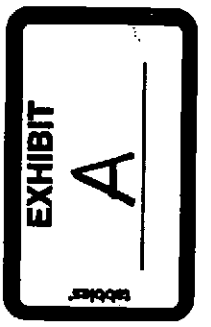
RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Nadmi Ahmed Qayed, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 48803.



3. Respondent's address of record is 15051 Prospect, Dearborn, Michigan 48126.

4. The Michigan Board of Pharmacy is the regulatory agency that governs the profession of pharmacy in the state of Michigan.

5. Respondent's pharmacist license number in the state of Michigan is 53-02-033396.

6. On or about August 14, 2013, Respondent entered into a Consent Order with the Michigan Board of Pharmacy, whereby disciplining Respondent's pharmacist license in the state of Michigan for having filled fraudulent prescriptions and having dispensed controlled substances to himself and one or more patients without a legitimate prescription.

7. The offense underlying Respondent's discipline by the Michigan Board of Pharmacy in paragraph six would also constitute a violation of Chapter 465, Florida Statutes.

8. Section 465.016(1)(h), Florida Statutes (2013), provides that having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter constitutes grounds for denial of a license or disciplinary action.

9. As stated above, Respondent entered into a Consent Order, with the Michigan Board of Pharmacy, whereby disciplining Respondent's pharmacist license in the state of Michigan for an offense that would constitute a violation of Chapter 465, Florida Statutes.

10. Based on the foregoing, Respondent has violated Section 465.016(1)(h), Florida Statutes (2013), having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 12th **day of** December **, 2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Christopher A. Jurich

CHRISTOPHER A. JURICH
Assistant General Counsel
Fla. Bar No. 0099014
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: christopher.jurich@flhealth.gov

/CAJ

PCP Meeting: December 12, 2013
PCP Members: Mark Mikhael, Jeffrey Mesaros

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 12 2013

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

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February 5, 2014

VIA US MAIL

Nadmi Ahmed Qayed, R.Ph.
15051 Prospect
Dearborn, MI 48126

Re: DOH vs. Nadmi Ahmed Qayed, R.Ph.
DOH Case Number: 2013-14316

Dear Nadmi Ahmed Qayed:

I am in receipt of the settlement agreement executed by you on January 9, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Christopher A. Jurich

Christopher A. Jurich
Assistant General Counsel

CAJ/crl

Complaint Cost Summary

Complaint Number: 201314316

Subject's Name: QAYED, NADMI AHMED

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.50**	**$27.45**
Investigation:	**1.50**	**$90.52**
Legal:	**2.20**	**$224.33**
Compliance:	**0.00**	**$0.00**
	**********	**********
Sub Total:	**4.20**	**$342.30**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$342.30**

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Nadmi Ahmed Qayed, R.Ph. (CAJ)**
Case No. 2013-14316

MEMBERS: Mark Mikhael and Jeffrey Mesaros

DATE OF PCP: **December 12, 2013** **AGENDA ITEM: A-07**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(h), Florida Statutes (2013)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

Larry Collins for Jeffrey Mesaros 2/24/14
Chair, Probable Cause Panel Date
Board of Pharmacy

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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Mission:
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Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201217794

KELLIE QUINN FLOOD,
RESPONDENT.

NOTICE

TO: KELLIE QUINN FLOOD
129 NW MAGNOLIA LAKES BLVD.
PORT SAINT LUCIE, FL 34986

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201217794

KELLIE QUINN FLOOD,
RESPONDENT.

NOTICE

TO: BRIAN KAHAN
2300 NW CORPORATE BLVD #123
KAHAN HEIMBERG, PLC
BOCA RATON, FL 33431

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

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Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Christopher A. Jurich, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Kellie Quinn Flood, R.Ph. a/k/a Kellie Quinn Hill, R.Ph.
DOH Case Number 2012-17794
DATE: February 4, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Kellie Quinn Flood, R.Ph.
Subject's Address of Record:	129 NW Magnolia Lakes Blvd. Port Saint Lucie, FL 34986
Enforcement Address:	129 NW Magnolia Lakes Blvd. Port Saint Lucie, FL 34986
Subject's License No:	49433 **Rank:** PS
Licensure File No:	42195
Initial Licensure Date:	8/6/2012
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	Yes
Allegation:	Section 465.016(1)(f), Florida Statutes (2013)
Prior Discipline:	None
Probable Cause Panel:	January 9, 2014 Debra Glass and Mark Mikhael

Subject's Attorney: Brian Kahan
2300 Nw Corporate Blvd #123
Kahan Heimberg, Plc
Boca Raton, FL 33431

Complainant/Address: DOH/CSU

Materials Submitted: Memorandum to the Board
Settlement Agreement - signed
Exhibit A – Administrative Complaint
Election of Rights
Notification Letter
Cost Summary
Defense Attorney Document 02-03-14
Defense Attorney Document 01-28-14
PCP Memorandum
Final Investigative Report
Exhibits 1 thru 3

Disciplinary Guidelines:

Minimum of $3,000 fine and 1 year suspension follow by one year probation to a maximum of revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

On or about September 4, 2013, in the Nineteenth Judicial Circuit Court, in and four St. Lucie County, Respondent entered a plea of nolo contendere to one count of grand theft of a controlled substance, a third degree felony, in violation of Section 812.014, Florida Statutes. Grand theft of a controlled substance is a crime which directly relates to the practice of pharmacy.

Terms of Settlement:

- Appearance
- $3,000 Fine payable within 12 months
- Costs limited to $1,514.82 payable within 12 months
- Probation for 5 years running concurrent with Respondent's PRN monitoring contract

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-17794**

KELLIE QUINN FLOOD, R.Ph.,
a/k/a KELLIE QUINN HILL, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Kellie Quinn Flood, R.Ph., a/k/a Kellie Quinn Hill, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 49433. Respondent's mailing address of record is 129 Northwest Magnolia Lakes Boulevard, Port Saint Lucie, Florida 34986.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that she is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **THREE THOUSAND DOLLARS ($3,000.00)**. The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within **12 months** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FIVE HUNDRED AND FOURTEEN DOLLARS AND EIGHTY TWO CENTS ($1,514.82).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **12 months** from the date the Final Order is filed with the Department Clerk.

4. **Probation**- Respondent's Florida pharmacist license shall be placed on probation for **five (5) years running concurrent with the Professionals Recovery Network (PRN) monitoring contract beginning April 12, 2013, and terminating April 11, 2018.** During the period of probation, Respondent shall comply with all terms and conditions of the Order of the Nineteenth Judicial Circuit Court in and for

St. Lucie County ("Court Order") entered on September 4, 2013. Subject to the conditions of supervision from the Court Order, Respondent shall be further subject to the following terms and conditions:

a. Respondent shall not work at or for more than 2 pharmacies during each quarter of the probationary period, unless Respondent obtains prior written approval from the Board.

b. Respondent shall submit written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall include Respondent's license number, current address, and phone number; current name, address, and phone number of each pharmacy in which Respondent is engaged in the practice of pharmacy; the names of all pharmacists, pharmacy interns, pharmacy technicians, relief pharmacists, and prescription department managers working with Respondent. These reports shall be submitted to the Compliance Officer

every 3 months in a manner as directed by the compliance officer.

c. Respondent shall ensure that her employer submits written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall contain the name, address, license number, and phone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working in the prescription department where Respondent practices, and provide a brief description of Respondent's duties, responsibilities, and working schedule. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer.

d. Respondent shall make a mandatory appearance before the Board of Pharmacy during Respondent's last three (3) months of probation. The Board retains the

right to extend Respondent's term of probation or to impose additional restrictions, conditions or limitations on Respondent's license.

5. **Future Conduct**- Respondent shall not violate Chapters 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent

authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within ten (10) days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 31st day of January, 2014.

Kellie Quinn Flood, R.Ph.
a/k/a Kellie Quinn Hill, R.Ph.
Case No. 2012-17794

STATE OF Florida
COUNTY OF St. Lucie

Before me personally appeared Kellie Quinn Hill, whose identity is known to me or by FLDL (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 31st day of January, 2014.

Notary Public
My Commission Expires:
10/14/2016

YENIA NOY-BARRIOS
Notary Public, State of Florida
Commission # EE 840445
My comm. expires Oct. 14, 2016

APPROVED this 3rd day of February, 2014.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Christopher A. Jurich

Christopher A. Jurich
Assistant General Counsel

Counsel for Petitioner
Christopher A. Jurich
Florida Bar No. 0099014
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444 ext. 8174
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-17794**

KELLIE QUINN FLOOD, R.Ph.,
a/k/a KELLIE QUINN HILL, R.Ph.,

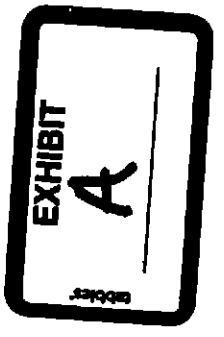
RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Kellie Quinn Flood, R.Ph., a/k/a Kellie Quinn Hill, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license PS 49433.



3. Respondent's address of record is 129 Northwest Magnolia Lakes Boulevard, Port Saint Lucie, Florida 34986.

4. On or about November 21, 2012, Respondent was arrested for stealing medications from her employer, CVS Pharmacy, and charged with grand theft of a controlled substance, a third degree felony, in violation of Section 812.014, Florida Statutes.

5. On or about September 4, 2013, in case number 2012-CF-003447-A, in the Nineteenth Judicial Circuit Court, in and for St. Lucie County, Respondent entered a plea of nolo contendere to one count of grand theft of a controlled substance, a third degree felony, in violation of Section 812.014, Florida Statutes.

6. Grand theft of a controlled substance is a crime which directly relates to the practice of, or the ability to practice, pharmacy.

7. Section 465.016(1)(f), Florida Statutes (2013), provides that having been convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy constitutes grounds for disciplinary action. A plea of nolo contendere constitutes a conviction for purposes of this provision.

8. As set forth above, Respondent entered a plea of nolo contendere to one count of grand theft of a controlled substance, a crime which directly relates to the ability to practice pharmacy or the practice of pharmacy.

9. Based on the foregoing, Respondent has violated Section 465.016(1)(f), Florida Statutes (2013), having been convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy constitutes grounds for disciplinary action; a plea of nolo contendere constitutes a conviction for purposes of this provision.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 9th **day of** January **, 2014.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Christopher A. Jurich

CHRISTOPHER A. JURICH
Assistant General Counsel
Fla. Bar No. 0099014
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: christopher.jurich@flhealth.gov

/CAJ

PCP Meeting: January 9, 2014
PCP Members: Debra Glass & Mark Mikhael

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 10 2014

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

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Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

February 6, 2014

VIA US MAIL

Brian Kahan, Esquire
Kahan Heimberg
2300 NW Corporate Blvd.
Suite 123
Boca Raton, Florida 33431

Re: DOH v. Kellie Quinn Flood, R.Ph. a/k/a Kellie Quinn, R.Ph.
DOH Case Number: 2012-17784

Dear Mr. Kahan:

I am in receipt of the settlement agreement executed by your client on January 31, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Christopher A. Jurich
Assistant General Counsel

CAJ/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complaint Cost Summary

Complaint Number: 201217794

Subject's Name: FLOOD, KELLIE QUINN

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.70**	**$38.36**
Investigation:	**4.40**	**$241.07**
Legal:	**4.40**	**$449.53**
Compliance:	**0.00**	**$0.00**
	**********	**********
Sub Total:	**9.50**	**$728.96**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$728.96**

Jurich, Christopher

From: Brian A. Kahan [Bkahan@kahanlaw.com]
Sent: Monday, February 03, 2014 1:37 PM
To: Jurich, Christopher
Subject: Kellie Hill
Attachments: Exec. Election of Rights and SO.pdf

Christopher:

Attached, please find the executed EOR and SO. I look forward to resolving this case at the Tampa meeting in April.

Brian A. Kahan, Esq.
bkahan@kahanlaw.com
To assist with the efficient work flow, please make sure to copy pharman@kahanlaw.com with all requests.

KAHAN HEIMBERG

Kahan Heimberg, PLC
2300 N.W. Corporate Blvd.
Suite 123
Boca Raton, FL 33431
Office: (561) 392-9000
Fax: (561) 405-6467

Please consider the environment before printing this email.

PLEASE UPDATE YOUR RECORDS WITH OUR OUR NEW FIRM NAME AND ADDRESS

Jurich, Christopher

From: Brian A. Kahan [Bkahan@kahanlaw.com]
Sent: Tuesday, January 28, 2014 12:02 PM
To: Jurich, Christopher
Subject: RE: 2012-17794 Kellie Flood
Attachments: Flood Kellie 2012-17794 Settlement Agreement.redlined.doc

Christopher:

Attached, please find my draft revisions redlined for your review. Please let me know what you think? I welcome your assistance in this matter.

From: Christopher.Jurich@flhealth.gov [mailto:Christopher.Jurich@flhealth.gov]
Sent: Thursday, January 23, 2014 2:56 PM
To: Brian A. Kahan
Subject: 2012-17794 Kellie Flood

Brian,

Please redline the attached settlement agreement pursuant to our phone conversation and return it for my review.

Thanks,

<<Flood, Kellie 2012-17794 Settlement Agreement.doc>>

Christopher A. Jurich, Assistant General Counsel
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(850) 245-4444 ext. 8174

How am I communicating? Please contact my supervisor.

Please note: effective October 1, 2013, email addresses for DOH employees will change to: firstname.lastname@flhealth.gov

My new email address: christopher.jurich@flhealth.gov

See Section 119.071(d)1., Florida Statutes (2010).

DOH Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

Vision: Healthiest State in the Nation

Values: (ICARE)
Innovation: We search for creative solutions and manage resources wisely.
Collaboration: We use teamwork to achieve common goals & solve problems.
Accountability: We perform with integrity & respect.
Responsiveness: We achieve our mission by serving our customers & engaging our partners.
Excellence: We promote quality outcomes through learning & continuous performance improvement.

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Kellie Quinn Flood, R.Ph (CAJ)**
a/k/a Kellie Quinn Hill, R.Ph.
Case Number: 2012-17794

MEMBERS: **Debra Glass and Mark Mikhael**

DATE OF PCP: **January 9, 2014** **AGENDA ITEM: A-7**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(f), Florida Statutes (2013)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

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____ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other**

Sara Collins for Debra Glass 2/24/14
Chair, Probable Cause Panel Date
Board of Pharmacy

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Florida
HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201120031

EDY PAYOUTE,
RESPONDENT.

NOTICE

TO: EDY PAYOUTE
158 RIDGEMONT CIR SE
PALM BAY, FL 32909

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201120031

EDY PAYOUTE,
RESPONDENT.

NOTICE

TO: ROBERT NICHOLSON
707 N.E. THIRD AVENUE, SUITE 301
FT. LAUDERDALE, FL 33304

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: **Settlement Agreement**
SUBJECT: DOH v. Edy Payoute, R.Ph.
DOH Case Number 2011-20031
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Edy Payoute, R.Ph.
Subject's Address of Record:	158 Ridgemont Circle SE Palm Bay, FL 32909
Enforcement Address:	158 Ridgemont Circle SE Palm Bay, FL 32909
Subject's License No:	37775 **Rank:** PS
Licensure File No:	26055
Initial Licensure Date:	7/10/2003
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation:	Section 456.072(1)(k), F.S. (2011, 2012), by violating Section 465.016(1)(r), F.S. (2011, 2012) through a violation of Section 465.022(11)(a), F.S. (2011, 2012) as required by Rule 64B16-28.110, F.A.C.
Prior Discipline:	None
Probable Cause Panel:	December 12, 2013 Mesaros and Mikhael

Subject's Attorney:	Robert Nicholson, Esquire 707 N.E. Third Avenue, Suite 301 Ft. Lauderdale, FL 33304
Complainant/Address:	Department Of Health/ISU - Ft. Lauderdale
Materials Submitted:	Memorandum to the Board Settlement Agreement – signed Exhibit A – Administrative Complaint Notification Letter Cost Summary PCP Memorandum

GUIDELINES:

From a $2,000 fine up to Revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count administrative complaint that alleges that the Respondent was the prescription department manager of record of a permitted pharmacy that on two occasions was found to have expired medications in its active stock.

Settlement Terms:

- Appearance
- $2,500 Administrative Fine
- Costs limited to $2,000
- CE – Laws and Rules w/in one year of FO
- Probation – One Year

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-20031**

EDY PAYOUTE, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **EDY PAYOUTE, R.Ph.**, was a licensed pharmacist in the state of Florida, having been issued license number PS 37775. Respondent's mailing address of record is 158 Ridgemont Circle, SE, Palm Bay, Florida 32909.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**: Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine:** The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND FIVE HUNDRED DOLLARS ($2,500).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320,**

Tallahassee, Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**: The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount **TWO THOUSAND TWO HUNDRED SIXTY-SIX DOLLARS AND FIFTY CENTS ($2,266.50)**. Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **ONE YEAR** from the date the Final Order is filed with the Department Clerk.

4. **Continuing Education**: The Respondent shall successfully complete a Continuing Education Course on the subject of **LAWS AND RULES OF PHARMACY** consisting of **EIGHT HOURS** of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the

continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Probation-** Respondent shall be placed on **ONE YEAR** of probation. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respondent shall not function as a prescription department manager in any Florida permitted pharmacy during the term of probation;

b. The Respondent shall submit monthly reports identifying the prescription department manager of record at the permit in which the Respondent is employed. The reports shall be submitted by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320**.

c. Respondent shall make a mandatory appearance before the Board of Pharmacy during the last three months of probation.

6. **Correction of Alleged Deficiencies:** At its sole expense, but without admitting any specific deficiency or violation, Respondent shall immediately, or at least forthwith, correct and address all deficiencies and violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law.

7. **Future Conduct**: Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

8. **Violation of Terms:** It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

9. **No Force or Effect until Final Order:** It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

10. **Purpose of Agreement:** This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

11. **Not Preclude Additional Proceedings:** Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

12. **Waiver of Attorney's Fees and Costs:** Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

13. **Waiver of Procedural Rights:** Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

14. **Current Addresses:** Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

15. **Time of the Essence:** Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 9 day of JANUARY, 2014.

Edy Payoute

EDY PAYOUTE, R.PH.
CASE NO. 2011-20031

STATE OF Florida

COUNTY OF Broward

Before me personally appeared Edy Payoute, whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 9 day of January, 2014.

Janine Bartels
COMMISSION # EE 200260
EXPIRES: MAY 20, 2016
www.AaronNotary.com

Notary Public
My Commission Expires: 5/20/16

APPROVED this 5 day of February, 2014.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel

Counsel for Petitioner
Matthew G. Witters
Florida Bar No. 0091245
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-20031**

EDY PAYOUTE, R.PH.,

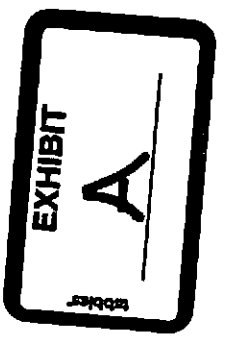
RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Edy Payoute, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacist within the State of Florida, having been issued license number PS 37775.



3. Respondent's address of record is 158 Ridgemont Circle Southeast, Palm Bay, Florida 32909.

4. At all times material to this Administrative Complaint, Respondent was the Prescription Department Manager (PDM) of Kiskeya Investment Group, LLC (Kiskeya) located at 3880 West Broward Boulevard, Suite 7, Plantation, Florida 33312.

5. On or about October 26, 2011, a Department inspector conducted an inspection of Kiskeya.

6. The Department's inspector found expired medications in the refrigerator.

7. On or about December 21, 2012, a Department inspector conducted an inspection of Kiskeya.

8. The Department's inspector found expired medications not removed from the shelves.

9. The following chart illustrates the expired medications found during the inspection on or about December 21, 2012:

Medication	Lot Number	Expiration Date
1 bottle of Furosemide 40mg, 1000 tablets	CAB0229AC	November 2012
1 bottle of Metoprolol Tartrate 100mg	GKJ1157	November 2012
1 bottle of Simvastatin 20mg, 1000 tablets	MK9521	November 2012

1 bottle of Fluconzaole 50mg, 30 tablets	Y02708	September 2012
1 bottle of Topiramate 100mg, 60 tablets	BF710015	June 2012
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension, 600mg/42.9mg/5ml	BF3605	November 2012
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension 400mg/57mg/5m	BD0131	October 2012
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension 125mg/5ml	BC7440	September 2012
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension 400mg/5ml	BA4010122-A	July 2012
1 box of Adapalene Cream, 0.1% Net WT 45 grams	264J	October 2012
1 box of Fluconazole 10mg/ml	0848902	December 1, 2012
1 bottle of Indomethacin 25mg, 100 capsules	TE09048	September 2012
2 boxes of Sumatriptan Succinate 25mg, 9 tablets each box	2135549	February 2012
1 box of Clotrimazole Cream USP 1%	1BT0067	November 2012
1 box of Fluconazole for oral suspension 40mg/ml	0843803	December 1, 2012

10. Section 456.072(1)(k), Florida Statutes (2011, 2012), provides that failing to perform any statutory or legal obligation placed upon a licensee is grounds for disciplinary action.

11. Section 465.016(1)(r), Florida Statutes (2011, 2012), provides that violating any provision of chapter 465 or chapter 456, or any rules adopted pursuant thereto, constitutes grounds for denial of a license or disciplinary action.

12. Section 465.022(11)(a), Florida Statutes (2011, 2012), provides, in pertinent part, that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

13. Rule 64B16-28.110, Florida Administrative Code, states persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

14. As set forth above, Respondent, as the prescription department manager, failed to ensure the permittee's compliance with the rule requiring removal of deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which has been reached from the stock, as required by Rule 64B16-28.110, Florida Administrative Code.

15. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2011, 2012), by violating Section 465.016(1)(r), Florida Statutes (2011, 2012), through a violation of Section 465.022(11)(a), Florida Statutes (2011, 2012), by failing to ensure that deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached were removed from stock, as required by Rule 64B16-28.110, Florida Administrative Code.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 12 **day of** December, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew.witters@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 12 2013

PCP: December 12, 2013
PCP Members: Dr. Mesaros and Dr. Mikhael

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

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Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

February 7, 2014

VIA US MAIL

Robert Nicholson, Esquire
707 N.E. Third Avenue
Suite 301
Ft. Lauderdale, Florida 33304

Re: DOH v. Edy Payoute, R.Ph.
DOH Case Number: 2011-20031

Dear Mr. Nicholson:

I am in receipt of the settlement agreement executed by your client on January 9, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complaint Cost Summary

Complaint Number: 201120031

Subject's Name: PAYOUTE, EDY

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.03	$59.35
Investigation:	27.60	$1,696.99
Legal:	14.70	$1,545.42
Compliance:	0.05	$1.61
	**********	**********
Sub Total:	43.38	$3,303.37
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$3,303.37

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Edy Payoute, R.Ph. (MGW)**
Case Number: 2011-20031

MEMBERS: **Mark Mikhael and Jeffrey Mesaros**

DATE OF PCP: **December 12, 2013** **AGENDA ITEM: A-02**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ Probable cause exists and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(k), Florida Statutes (2011, 2012) by violating Section 465.016(1)(r), Florida Statutes (2011, 2012) through a violation of Section 465.022(11)(a), Florida Statutes (2011, 2012)

___ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

Sandy Cobles for Jeffrey Mesaros, 2/24/14
Chair, Probable Cause Panel Date
Board of Pharmacy

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS.

ALAN C ZIMMER,
RESPONDENT.

CASE NO. 201212992

NOTICE

TO: ALAN C ZIMMER
8074 SEVERN DR. APT. A
BOCA RATON, FL 33433

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201212992

ALAN C ZIMMER,
RESPONDENT.

NOTICE

TO: WILLIAM FURLOW
2022-2 RAYMOND DIEHL ROAD
TALLAHASSEE, FL 32308

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

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John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel MGW
RE: **Settlement Agreement**
SUBJECT: DOH v. Alan C. Zimmer, R.Ph.
DOH Case Number 2012-12992
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Alan C. Zimmer, R.Ph.
Subject's Address of Record:	8074 Severn Drive Apt. A Boca Raton, FL 33433
Enforcement Address:	8074 Severn Dr. Apt. A Boca Raton, FL 33433
Subject's License No:	23369 **Rank:** PS
Licensure File No:	12485
Initial Licensure Date:	8/11/1987
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation:	Section 456.072(1)(x), F.S. (2011)
Prior Discipline:	4013, 01/06/1997
Probable Cause Panel:	December 18, 2012 Fallon and Meshad

Subject's Attorney:	William Furlow Grossman, Furlow & Bayó 2022-2 Raymond Diehl Road Tallahassee, FL 32308
Complainant/Address:	DOH/PSU
Materials Submitted:	Memorandum to the Board Settlement Agreement – signed Exhibit A – Administrative Complaint Election of Rights – Request for Administrative Hearing Involving Disputed Issues of Material Fact Notification Letter Cost Summary Defense Attorney Document dated 01-07-13 PCP Memorandum

GUIDELINES:

From a $1,000 fine up to Revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count administrative complaint alleging that the Respondent failed to timely report to the Board in writing a conviction for driving under the influence.

Settlement Terms:

- Appearance
- $1,000 Fine
- Costs not to exceed $1,438.31
- CE – Laws and Rules within one year of Final Order

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-12992**

ALAN C. ZIMMER, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Alan C. Zimmer, R.Ph., was a registered pharmacist in the state of Florida, having been issued license number PS 23369. Respondent's mailing address of record is 8074 Severn Drive, Apartment A, Boca Raton, Florida 33433.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, Alan C. Zimmer, R.Ph., shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **ONE THOUSAND DOLLARS** ($1,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-**

6320, within **1 YEAR** from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FOUR HUNDRED THIRTY-EIGHT DOLLARS AND THIRTY-ONE CENTS ($1,438.31)**. Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **1 YEAR** from the date the Final Order is filed with the Department Clerk. **Payment must be made by cashier's check or money order ONLY.** Personal Checks shall **NOT** be accepted.

4. **CE Course**- Respondent shall successfully complete a Continuing Education Course on the subject of Laws and Rules consisting of 12 hours of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education

hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 29 day of May, 2013

ALAN C. ZIMMER, R.Ph.
CASE # 2012-12992

STATE OF Florida

COUNTY OF Clay

Before me personally appeared Alan C. Zimmer, R.Ph., whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 29th day of May, 2013.

ALISIA S LEWIS
MY COMMISSION # EE110520
EXPIRES July 07, 2015
(407) 398-0153 FloridaNotaryService.com

Notary Public
My Commission Expires: 7/7/15

APPROVED this 6 day of February, 201_.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

MATTHEW G. WITTERS
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: matthew_witters@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-12992**

ALAN C. ZIMMER, R.Ph.,

RESPONDENT.
_____/

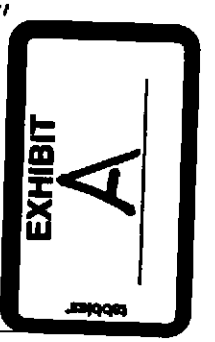
ADMINISTRATIVE COMPLAINT

Petitioner Department of Health, by and through its undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Alan C. Zimmer, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Order, Respondent was a licensed registered pharmacist operating within the State of Florida, pursuant to Chapter 465, Florida Statutes, holding license number PS 23369.

3. Respondent's address of record is 8074 Severn Drive, Apartment A, Boca Raton, Florida 33433.



4. On or about December 2, 2011, in the County Court for the Fifteenth Judicial Circuit, in and for Palm Beach County, Florida, in case number 2011CT014956ASB, Respondent entered a plea of guilty to one (1) count of driving under the influence, a misdemeanor in violation of Section 316.193(1), Florida Statutes.

5. Respondent failed to report the plea of guilty to the Board of Pharmacy, in writing, within thirty (30) days of the date Respondent entered the plea.

6. Section 456.072(1)(x), Florida Statutes (2011), provides that failing to report to the board, or the department if there is no board, in writing within thirty (30) days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction is grounds for disciplinary action.

7. Respondent failed to report the plea of guilty to driving under the influence to the Board of Pharmacy in writing within thirty (30) days of the date Respondent entered the plea.

8. Based on the foregoing, Respondent violated Section 456.072(1)(x) Florida Statutes (2011), which provides that failing to report to the board, or the department if there is no board, in writing within thirty

(30) days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction constitutes grounds for discipline.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 18 **day of** December, **2012**.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

for

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE DEC 18 2012

PCP: December 18, 2012
PCP Members: Meshad S. Fallon

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Mission:
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Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

February 6, 2014

VIA US MAIL

William Furlow, Esquire
Grossman, Furlow & Bayó
2022-2 Raymond Diehl Road
Tallahassee, Florida 32308

Re: DOH v. Alan C. Zimmer, R.Ph.
DOH Case Number: 2012-12992

Dear Mr. Furlow:

I am in receipt of the settlement agreement executed by your client on May 29, 2013 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complaint Cost Summary

Complaint Number: 201212992

Subject's Name: ZIMMER, ALAN C

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.00	$57.62
Investigation:	0.70	$40.33
Legal:	4.50	$477.76
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	6.20	$575.71
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$575.71

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HEALTH

Rick Scott
Governor

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Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201022564

ANTHONY R CARILLI,
RESPONDENT.

NOTICE

TO: ANTHONY R CARILLI
608 XANADU PLACE
JUPITER, FL 33477

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

HEALTH

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201022564

ANTHONY R CARILLI,
RESPONDENT.

NOTICE

TO: ANTHONY R CARILLI
19315 N. RIVERSIDE DR.
JUPITER, FL 33469

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201022564

ANTHONY R CARILLI,
RESPONDENT.

NOTICE

TO: WILLIAM FURLOW
2022 RAYMOND DIEHL ROAD, STE 2
TALLAHASSEE, FL 32308-3881

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
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MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: **Settlement Agreement**
SUBJECT: DOH v. Anthony R. Carilli, R.Ph.
DOH Case Number 2010-22564
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Anthony R. Carilli, R.Ph.
Subject's Address of Record:	19315 N. Riverside Drive Jupiter, FL 33469
Enforcement Address:	608 Xanadu Place Jupiter, FL 33477
Subject's License No:	23041 **Rank:** PS
Licensure File No:	12175
Initial Licensure Date:	8/12/1987
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation(s):	Section 456.072(1)(k), Florida Statutes (2010, 2011) by violating Section 465.016(1)(r), Florida Statutes (2010, 2011), through a violation of Section 465.022(11)(a), Florida Statutes (2010, 2011), by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

Prior Discipline:	None
Probable Cause Panel:	January 9, 2014 Glass and Mikhael
Subject's Attorney:	William Furlow 2022-2 Raymond Diehl Road Tallahassee, FL 32308-3881
Complainant/Address:	DOH/ISU - Miami
Materials Submitted:	Memorandum to the Board Settlement Agreement – signed Exhibit A – Administrative Complaint Notification Letter Cost Summary PCP Memorandum

GUIDELINES:

From a $2,000 fine up to Revocation

PRELIMINARY CASE REMARKS

This is a one count administrative complaint which alleges that the Respondent was the prescription department manager of record of a permitted pharmacy, which during two separate inspections which was found to have outdated and mislabeled medications in its active stock.

Settlement Terms:

- Appearance
- Costs limited to $1,500
- CE – Laws and Rules w/in 1 year of FO

MGW/crl

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2010-22564**

ANTHONY R. CARILLI, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Anthony R. Carilli, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 23041. Respondent's mailing address of record is 19315 N. Riverside Drive, Jupiter, Florida 33477.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition

2. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND FIVE HUNDRED DOLLARS ($1,500).** Total costs shall be assessed when the

Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

3. **Continuing Education**: The Respondent's prescription department manager of record shall successfully complete a Continuing Education Course on the subject of **LAWS AND RULES OF PHARMACY** consisting of **EIGHT HOURS** of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

4. **Future Conduct** - Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

5. **Violation of Terms** - It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

6. **No Force or Effect until Final Order** - It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

7. **Purpose of Agreement** - This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that

the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

8. **Not Preclude Additional Proceedings** - Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

9. **Waiver of Attorney's Fees and Costs** - Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

10. **Waiver of Procedural Rights** - Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

11. **Current Addresses** - Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the

Compliance Officer of any change of mailing address or practice address within 10 days of the change.

12. **Time of the Essence** - Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 17TH day of JUNE, 2014.

MARGAUX HAYLES
Notary Public - State of Florida
My Comm. Expires Mar 2, 2017
Commission # EE 850231
Bonded Through National Notary Assn.

Anthony R. Carilli, R.Ph.
Case Number 2010-22564

STATE OF FLORIDA

COUNTY OF PALM BEACH

Before me personally appeared ANTHONY CARILLI whose identity is known to me ~~or by~~ _____ (~~type of identification~~), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 17TH day of JANUARY, 2014.

Notary Public
My Commission Expires: MARCH 2ND 2017

APPROVED this 6 day of February, 2014.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel

Counsel for Petitioner
Matthew G. Witters
Florida Bar No. 0091245
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: 850.245.4444
Fax: 850.245.4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2010-22564**

ANTHONY R. CARILLI, R.Ph.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Anthony R. Carilli, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued permit number PS 23041.

3. Respondent's address of record is 19315 N. Riverside Drive, Jupiter, Florida 33469.

4. At all times material to this complaint, Respondent was the prescription department manager (PDM) or record for Anthony's Drugs (Permittee) located in Palm Beach Gardens, Florida.

5. Section 465.022(11)(a), Florida Statutes (2011), states "[t]he prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs."

6. On or about January 3, 2012, a Department inspector attempted to conduct a routine inspection of Permittee at 9121 N. Military Trail, Suite 106, Palm Beach Gardens, Florida 33410.

7. On or about January 3, 2012, the Department inspector noted the following deficiencies during the course of this inspection:

a. Medication not properly labeled as required by Rule 64B16-28.108(3), Florida Administrative Code; and/or

b. Outdated medication in the prescription department's active stock as prohibited by Rule 64B16-28.110, Florida Administrative Code; and/or

c. Certified daily log not properly maintain as required by Rule 64B16-27.797(3)(e), Florida Administrative Code.

8. Section 465.072(1)(k), Florida Statutes (2011), provides that failing to perform any statutory or legal obligation placed upon a licensee is grounds for disciplinary action.

9. Section 465.016(1)(r), Florida Statutes (2011), provides that violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, constitutes grounds for denial of a license or disciplinary action.

10. Section 465.022(11)(a), Florida Statutes (2011), provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

11. Respondent as PDM failed to ensure the Permittee's compliance with the rules of the Board of Pharmacy as noted by the deficiencies set forth above in paragraphs seven.

12. Based on the foregoing, Respondent has violated Section 456.072(1)(k), Florida Statutes (2011) by violating Section 465.016(1)(r),

Florida Statutes (2011), through a violation of Section 465.022(11)(a), Florida Statutes (2011), by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 9 **day of** January, **2014.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew.witters@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 10 2014

PCP: January 9, 2014
PCP Members: Glass and Mikhael

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

February 6, 2014

VIA US MAIL

William Furlow, Esquire
Grossman, Furlow & Bayó
2022-2 Raymond Diehl Road
Tallahassee, Florida 32308

Re: DOH v. Anthony R. Carilli, R.Ph.
DOH Case Number: 2010-22564

Dear Mr. Furlow:

I am in receipt of the settlement agreement executed by your client on January 17, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complaint Cost Summary

Complaint Number: 201022564

Subject's Name: CARILLI, ANTHONY R

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**1.20**	**$69.14**
Investigation:	**3.60**	**$242.80**
Legal:	**2.80**	**$288.28**
Compliance:	**0.00**	**$0.00**
	**********	**********
Sub Total:	**7.60**	**$600.22**
Expenses to Date:		**$250.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$850.22**

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Anthony R. Carilli, R.Ph. (MGW)**
Case No. 2010-22564

MEMBERS: **Debra Glass and Mark Mikhael**

DATE OF PCP: **January 9, 2014** **AGENDA ITEM: A-2**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ Probable cause exists and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(k), Florida Statutes (2010) by violating Section 465.016(1)(r), Florida Statutes (2011), through a violation of Section 465.022(11)(a), Florida Statutes (2011)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**

a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **other** _____

Larry Collins for Debra Glass 20 Jan 2014
Chair, Probable Cause Panel Date
Board of Pharmacy

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the Healthiest State in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201022563

ANTHONY'S DRUGS,
RESPONDENT.

NOTICE

TO: ANTHONY'S DRUGS
9121 N MILITARY TRAIL STE 106
PALM BEACH GARDENS, FL 33410

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201022563

ANTHONY'S DRUGS,
RESPONDENT.

NOTICE

TO: WILLIAM FURLOW
2022 RAYMOND DIEHL ROAD, STE 2
TALLAHASSEE, FL 32308-3881

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

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Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

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Rick Scott
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John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel MGW GRL
RE: Settlement Agreement
SUBJECT: DOH v. Anthony's Drugs
DOH Case Number 2010-22563
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Anthony's Drugs
Subject's Address of Record:	9121 N Military Trail Suite 106 Palm Beach Gardens, FL 33410
Enforcement Address:	9121 N Military Trail Suite 106 Palm Beach Gardens, FL 33410
Subject's License No:	24221 **Rank:** PH
Licensure File No:	16840
Initial Licensure Date:	8/19/2009
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No

Allegations:	COUNT I: Section 465.023(1)(c), Florida Statutes (2010, 2011), through a violation of Rule 64B16-28.110, Florida Administrative Code, by having expired medication in the prescription department's active stock. COUNT II: Section 465.023(1)(c), Florida Statutes (2010, 2011), by violating Rule 64B16-28.140(3)(e), Florida Administrative Code, by failing to properly maintain a daily log as required by Board Rule. COUNT III: Section 465.023(1)(c), Florida Statutes (2010, 2011), by violating Rule 64B16-28.108(3), Florida Administrative Code, by failing to properly label medication found with the Respondent's prescription department.
Prior Discipline:	None
Probable Cause Panel:	January 9, 2014 Glass and Mikhael
Subject's Attorney:	William Furlow 2022 Raymond Diehl Road, Ste 2 Tallahassee, FL 32308-3881 850-385-1314
Complainant/Address:	Department Of Health/Investigative Services Unit-Miami
Materials Submitted:	Memorandum to the Board Settlement Agreement – signed Exhibit A – Administrative Complaint Notification Letter Cost Summary Expert Materials – Opinion, Questions 456 Materials PCP Memorandum

GUIDELINES:

Count I: From $500 for possession to $1,000 for dispensing up to Revocation.
Count II: No Guideline
Count III: From a $250 fine and a twelve hour laws and rules course up to $2,500 and one year of probation.

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

This is a three count administrative complaint which alleges that during two separate inspections outdated and mislabeled medications were found in the Respondent's active stock.

Settlement Terms:

- Appearance
- $3,000 Administrative Fine
- Costs limited to $3,000
- Probation – 2 Years – semi-annual inspections at the Respondent's Cost

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2010-22563**

ANTHONY'S DRUGS,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **Anthony's Drugs**, was a licensed pharmacy in the state of Florida, having been issued license number PH 24221. Respondent's mailing address of record is 9121 N. Military Trail, Suite 106, Palm Beach Gardens, Florida 33410.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**: Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine:** The Board of Pharmacy shall impose an administrative fine of **THREE THOUSAND HUNDRED DOLLARS ($3,000).** The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**: The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **THREE THOUSAND DOLLARS ($3,000).** Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order is filed with the Department Clerk.

4. **Probation-** Respondent shall be placed on **TWO YEARS** of probation. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. The Department shall conduct semi-annual inspections to ensure compliance with the laws and rules at Respondent's physical location at Respondent's cost.

b. Respondent shall make a mandatory appearance before the Board of Pharmacy during the last three (3) months of probation.

5. **Correction of Alleged Deficiencies:** At its sole expense, but without admitting any specific deficiency or violation, Respondent shall immediately, or at least forthwith, correct and address all deficiencies and violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law.

6. **Future Conduct**: Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

7. **Violation of Terms:** It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order:** It is expressly understood that this Settlement Agreement is subject to approval by the

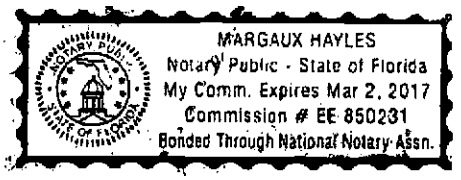
Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

9. **Purpose of Agreement:** This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings:** Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 17TH day of JANUARY, 2014.



Anthony's Drugs
CASE NO. 2010-22563

STATE OF FLORIDA

COUNTY OF PALM BEACH

Before me personally appeared ANTHONY CARLLI, whose identity is known to me ~~or by~~ _____ (~~type of identification~~), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 17TH day of JANUARY, 2014.

Notary Public
My Commission Expires: MARCH 2ND 2017

APPROVED this 6 day of February, 2014.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel

Counsel for Petitioner
Matthew G. Witters
Florida Bar No. 0091245
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2010-22563**

ANTHONY'S DRUGS,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Anthony's Drugs, and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 24221.

3. Respondent's address of record is 9121 N. Military Trail, Suite 106, Palm Beach Gardens, Florida 33410.

EXHIBIT A

4. On or about October 26, 2010, a Department conducted a routine inspection of Respondent at 9121 N. Military Trail, Suite 106, Palm Beach Gardens, Florida 33410.

5. On or about October 26, 2010, the Department inspector noted the following deficiencies during the course of this inspection:

a. Outdated medication in the prescription department's active stock as prohibited by Rule 64B16-28.110, Florida Administrative Code; and/or

b. Certified daily log not properly maintain as required by Rule 64B16-28.140(3)(e), Florida Administrative Code.

6. On or about January 3, 2012, a Department inspector conducted a routine inspection of Respondent at 9121 N. Military Trail, Suite 106, Palm Beach Gardens, Florida 33410.

7. On or about January 3, 2012, the Department inspector noted the following deficiencies during the course of this inspection:

a. Medication not properly labeled as required by Rule 64B16-28.108(3), Florida Administrative Code; and/or

b. Outdated medication in the prescription department's active stock as prohibited by Rule 64B16-28.110, Florida Administrative Code; and/or

c. Certified daily log not properly maintained as required by Rule 64B16-27.797(3)(e), Florida Administrative Code.

COUNT I

8. Petitioner realleges and incorporates paragraphs one through seven, as if fully set forth herein.

9. Section 465.023(1)(c), Florida Statutes (2010, 2011), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any rules of the Board of Pharmacy.

10. Rule 64B16-28.110, Florida Administrative Code, requires that persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached.

11. On or about October 26, 2010, and on or about January 3, 2012, during a routine inspection of the Respondent, a Department inspector found outdated medications in the Respondent's active stock.

12. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2010, 2011), through a violation of Rule 64B16-28.110, Florida Administrative Code, by having expired medication in the prescription department's active stock.

COUNT II

13. Petitioner realleges and incorporates paragraphs one through seven, as if fully set forth herein.

14. Section 465.023(1)(c), Florida Statutes (2010), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any rules of the Board of Pharmacy.

15. Rule 64B16-28.140(3)(e), Florida Administrative Code, requires that a community pharmacy maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data

processing system that day has been reviewed by him or her and is correct as entered.

16. On or about October 26, 2010, during a routine inspection, a Department inspector noted that the Respondent failed to properly maintain a daily log.

17. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2010), by violating Rule 64B16-28.140(3)(e), Florida Administrative Code, by failing to properly maintain a daily log as required by Board Rule.

COUNT III

18. Petitioner realleges and incorporates paragraphs one through seven, as if fully set forth herein.

19. Section 465.023(1)(c), Florida Statutes (2011), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any rules of the Board of Pharmacy.

20. Rule 64B16-28.108(3), Florida Administrative Code, sets for the requirements for the label on the immediate container of a repackaged product or a multiple unit prepackaged drug product.

21. On or about January 3, 2012, during a routine inspection of the Respondent, a Department inspector noted that medication found within the Respondent's prescription department was not properly labeled.

22. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2011), by violating Rule 64B16-28.108(3), Florida Administrative Code, by failing to properly label medication found with the Respondent's prescription department.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 9 **day of** January, **2014.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew.witters@flhealth.gov

PCP: January 9, 2014
PCP Members: Glass and Mikhael

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

February 6, 2014

VIA US MAIL

William Furlow, Esquire
Grossman, Furlow & Bayó
2022-2 Raymond Diehl Road
Tallahassee, Florida 32308

Re: DOH v. Anthony's Drugs
DOH Case Number: 2010-22563

Dear Mr. Furlow:

I am in receipt of the settlement agreement executed by your client on January 17, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complaint Cost Summary

Complaint Number: 201022563

Subject's Name: ANTHONY'S DRUGS

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.20	$69.14
Investigation:	15.10	$998.86
Legal:	14.40	$1,495.75
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	30.70	$2,563.75
Expenses to Date:		$375.00
Prior Amount:		$0.00
Total Costs to Date:		$2,938.75

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Rick Scott
Governor

FLORIDA DEPARTMENT OF HEALTH

Steven L. Harris, M.D., M.Sc.
Interim State Surgeon General

April 19, 2012

William Furlow, Esquire
Grossman, Furlow & Bayo, LLC
2202-2 Raymond Diehl Road
Tallahassee, Florida 32308

Re: Complaint No. 2010-22563 Anthony's Drugs

Dear Mr. Furlow:

Pursuant to section 456.073(10), Florida Statutes, enclosed a CD containing a copy the Department's complete investigative file in Complaint No. 2010-22563 Section 456.073(10), Florida Statutes provides in part:

> . . . Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. The subject may file a written response to the information contained in the investigative file. Such response must be filed within 20 days of mailing by the department, unless an extension of time has been granted by the department. . . .

Pursuant to the provisions of section 456.073(10), Florida Statutes, your written response must be received by no later than twenty (20) days from the date of this letter. Any requests for an extension of time must be made to my office prior to the expiration of the original twenty (20) days.

The password for the CD is: 456. Please call with any questions, 850-245-4640, ext. 8172.

Respectfully,

Matthew G. Witters
Assistant General Counsel

Enclosures: Investigative File 2010-22563
Invoice #: MQPR12-665

cc: file

Lillich, Christine

From: Barber Lucy [l.barber@gfblawfirm.com]
Sent: Wednesday, April 18, 2012 4:41 PM
To: Lillich, Christine
Subject: Anthony Carilli, DOH Case No. 2010.22564 and Anthony Drugs, DOH Case No. 2010.22563
Attachments: Executed CA.2010.22563.041812.pdf; Executed CA.2010.22564.041812.pdf

Christine,

Attached please find the executed confidentiality agreements in the above referenced cases. When the investigative files are ready let me know and I will come and pick up the CDs. Thanks.

Lucy J. Atkins, Paralegal
FRP # 249891
Assistant to William M. Furlow
Grossman, Furlow & Bayo', LLC
2022-2 Raymond Diehl Road
Tallahassee, Florida 32308
Phone: 850-385-1314 x 1006
Fax: 850-385.3953
Cell: 850.510.1554
l.barber@gfblawfirm.com

FLORIDA DEPARTMENT OF HEALTH

Charlie Crist
Governor

Ana M. Viamonte Ros, M.D., M.P.H.
State Surgeon General

Acknowledgement of and
Agreement to Maintain Patient Confidentiality
Case # 2010-22563

I Anthony Dreyer am the Subject of an investigation by the Department of Health. As the Subject of such an investigation, I am entitled to inspect or receive a copy of the investigative report, including any expert witness report or patient records connected with the investigation pursuant to Section 456.073(10), Florida Statutes, if I agree in writing to maintain the confidentiality of any information received under this provision, until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to section 456.057, F.S. I was provided with a copy of section 456.057, F.S. and understand my duty to maintain the confidentiality of the patient's records that I received and or inspected.

I understand the cost associated with duplicating x-rays and I want ( ) do not want ( ) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this 18 day of April, ~~2011.~~ 2012

Anthony R. Carelli.
NAME

Before me personally appeared Anthony Carelli whose identity is known to be by FL Dr License (type of identification), and who under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed by Respondent before me this 18 day of April, ~~2011.~~ 2012

Patricia Caswell
Notary Public **Patricia Caswell**

My Commission Expires: PATRICIA CASWELL
MY COMMISSION # EE128136
EXPIRES September 19, 2015
(407) 398-0153 FloridaNotaryService.com

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Anthony's Pharmacy (MGW)**
Case Number: 2010-22563

MEMBERS: **Debra Glass and Mark Mikhael**

DATE OF PCP: **January 9, 2014** **AGENDA ITEM: A-1**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

_X_ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Count I: **Section 465.023(1)(c), Florida Statutes (2010, 2011), through a violation of Rule 64B16-28.110, Florida Administrative Code**

Count II: **Section 465.023(1)(c), Florida Statutes (2010), by violating Rule 64B16-28.140(3(e), Florida Administrative Code**

Count III: **Section 465.023(1)(c), Florida Statutes (2011), by violating Rule 64B16-28.108(3), Florida Administrative Code**

___ Probable Cause was **not** found in this case

___ In lieu of probable cause, issue **letter of guidance**

___ Case requires **expert review**

___ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

Jenny Collins for Debra Glass 20 Jan 2014
Chair, Probable Cause Panel Date
Board of Pharmacy

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HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307523

SETON PHARMACY, INC,
RESPONDENT.

NOTICE

TO: SETON PHARMACY, INC
1 SHIRCLIFF WAY
JACKSONVILLE, FL 32204

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307523

SETON PHARMACY, INC,
RESPONDENT.

NOTICE

AND: MARTIN DIX
106 EAST COLLEGE AVE SUITE 1200
TALLAHASSEE, FL 32301

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Florida Department of Health
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MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. Seton Pharmacy, Inc.
DOH Case Number 2013-07523
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Seton Pharmacy, Inc.
Subject's Address of Record:	1 Shircliff Way Jacksonville, FL 32204
Enforcement Address:	3 Shircliff Way Jacksonville, FL 32204
Subject's License No:	17629 **Rank:** PH
Licensure File No:	9711
Initial Licensure Date:	12/19/2000
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation(s):	Section 456.072(1)(k), Florida Statutes (2009-2012), by violating Section 465.023(1)(c), Florida Statutes (2009-2012), through a violation of Section 499.005(15), Florida Statues (2009-2012), which prohibits the sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Prior Discipline:	None
Probable Cause Panel:	December 12, 2013 Mikhael and Mesaros
Subject's Attorney:	Martin Dix 106 East College Ave Suite 1200 Tallahassee, FL 32301
Complainant/Address:	DOH/ISU - Jacksonville
Materials Submitted:	Memorandum to the Board Settlement Agreement – signed Exhibit A – Administrative Complaint Election of Rights Notification Letter Cost Summary Defense Attorney Document dated 01-08-14 PCP Memorandum Final Investigative Report Exhibits 1 thru 9

GUIDELINES:

From a $2,000 fine up to Revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count administrative complaint which alleges that the Respondent entered into an agreement with an organization to provide medication in exchange for advertising. It was discovered that the Respondent was shipping prescription medications to an individual affiliated with this organization who was not licensed to receive prescription medications.

Settlement Terms:

- Appearance
- Costs not to exceed $2,139.00.
- CEs – Respondent's PDM to complete Laws and Rules within one year of Final Order.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07523**

SETON PHARMACY, INC.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **SETON PHARMACY, INC.**, was a licensed pharmacy in the state of Florida, having been issued license number PH 41324. Respondent's mailing address of record is 3 Shircliff Way, Jacksonville, Florida 32204.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that it is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**: Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Costs**: The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND ONE HUNDRED THIRTY-NINE DOLLARS ($2,139.00)**. Total costs shall be

assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **90 days** from the date the Final Order is filed with the Department Clerk.

3. **Continuing Education:** The Respondent's prescription department manager of record shall successfully complete a Continuing Education Course on the subject of **LAWS AND RULES OF PHARMACY** consisting of **TWELVE HOURS** of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

4. **Correction of Alleged Deficiencies:** At its sole expense, but without admitting any specific deficiency or violation, Respondent shall immediately, or at least forthwith, correct and address all deficiencies and

violations listed or alleged in the Administrative Complaint, to the extent necessary to comply with Florida law.

5. **Future Conduct**: Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

6. **Violation of Terms:** It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

7. **No Force or Effect until Final Order:** It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

8. **Purpose of Agreement:** This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials

concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

9. **Not Preclude Additional Proceedings:** Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

10. **Waiver of Attorney's Fees and Costs:** Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

11. **Waiver of Procedural Rights:** Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

12. **Current Addresses:** Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

13. **Time of the Essence:** Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 7th day of January, 2014.

SETON PHARMACY
CASE NO. 2013-07523

STATE OF Florida

COUNTY OF Duval

Before me personally appeared Mood Chishdar whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 7th day of January, 2014.

LISA ZATKOS
MY COMMISSION EXPIRES
March 16, 2016
NOTARY PUBLIC STATE OF FLORIDA

Lisa Zatkos
Notary Public
My Commission Expires: 3-16-16

APPROVED this 6 day of February, 201_.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel

Counsel for Petitioner
Matthew G. Witters
Florida Bar No. 0091245
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07523**

SETON PHARMACY, INC.,

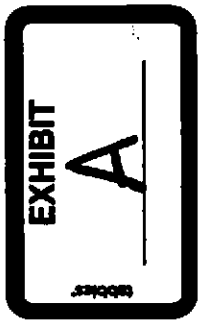
RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health files this Administrative Complaint before the Board of Pharmacy against Respondent Seton Pharmacy, Inc. and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 17629.



3. Respondent's address of record is 1 Shircliff Way, Jacksonville, Florida 32204.

4. Respondent's address may be 3 Shircliff Way, Jacksonville, Florida 32204.

5. From in or about April 2010 through in or about June 2012, Respondent had an agreement to provide medications to the JS, a professional sports team located Jacksonville, Florida through Dr. M.H., the team physician for the JS.

6. As a part of this agreement, D.K., the director of sports medicine for the JS would order and receive prescription medications from Respondent.

7. D.K. is not authorized to purchase or possesses prescription drugs in the state of Florida.

8. From in or about April 2010 through in or about June 2012, D.K. ordered and received prescription medications from Respondent without a corresponding valid prescription and were not authorized by Dr. M.H.

9. Section 456.072(1)(k), Florida Statues (2009-2012), provides that failing to perform any statutory or legal obligation placed upon a licensee is grounds for disciplinary action.

10. Section 465.023(1)(c), Florida Statues (2009-2012), provides that a pharmacy permittee may be subject to discipline for a violation of any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893.

11. Section 499.005(15), Florida Statues (2009-2012), prohibits the sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

12. Respondent failed to perform a statutory or legal obligation by in or about April 2010 through in or about June 2012, transferring prescription drugs to D.K., an individual not authorized under the law of the jurisdiction to possess prescription drugs.

13. Based on the foregoing, Respondent violated Section 456.072(1)(k), Florida Statutes (2009-2012), by violating Section 465.023(1)(c), Florida Statutes (2009-2012), through a violation of Section 499.005(15), Florida Statues (2009-2012), which prohibits the sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 12 **day of** December, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew.witters@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE DEC 12 2013

PCP: December 12, 2013

DOH v. Seton Pharmacy, Inc.
Case No. 2013-07523
AC – 499

PCP Members: Dr. Mesaros and Dr. Mikhael

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

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Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

February 7, 2014

VIA US MAIL

Martin R. Dix
Akerman LLP
106 East College Avenue
Suite 1200
Tallahassee, Florida 32301

Re: DOH v. Seton Pharmacy, Inc.
DOH Case Number: 2013-07523

Dear Mr. Dix:

I am in receipt of the settlement agreement executed by your client on January 7, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complaint Cost Summary

Complaint Number: 201307523

Subject's Name: SETON PHARMACY, INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	6.80	$337.42
Legal:	7.80	$805.82
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	15.20	$1,176.18
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,176.18

Martin R. Dix

Akerman LLP
Suite 1200
106 East College Avenue
Tallahassee, FL 32301
Tel: 850.224.9634
Fax: 850.222.0103

martin.dix@akerman.com

January 8, 2014

VIA E-MAIL AND U.S. MAIL

Matthew G. Witters, Assistant General Counsel
Florida Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399

Re: DOH Case 2013-07523 – Seton Pharmacy, Inc.
Settlement Agreement

Dear Matt:

Enclosed is the Settlement Agreement (the "Agreement") for the above-referenced case. The Agreement is signed by Moody Christian, President of Seton Pharmacy, Inc. Also enclosed is a completed Election of Rights form. Note that we have included language preserving our client's right to challenge the Administrative Complaint should the Settlement Agreement not be accepted by the Board.

Please forward a copy of the fully executed Settlement Agreement to me and let me know when it is scheduled before the Board.

Thank you for your assistance in this matter.

Sincerely,

Martin R. Dix

MRD/pld

Enclosures

cc: Jon Debardeleben
Hugh Middlebrooks
Charzetta James

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Seton Pharmacy, Inc. (MGW)**
Case Number: 2013-07523

MEMBERS: **Mark Mikhael and Jeffrey Mesaros**

DATE OF PCP: **December 12, 2013** **AGENDA ITEM: A-03**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(k), Florida Statutes (2009-2012), by violating Section 465.023(1)(c), Florida Statutes (2009-2012) through a violation of Section 499.005(15), Florida Statutes (2009-2012)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **other**, _____

Amy Collier for Jeffrey Mesaros, 2/24/14
Chair, Probable Cause Panel Date
Board of Pharmacy

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Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307522

RYAN MATTHEW SOEHLIG,
RESPONDENT.

NOTICE

TO: RYAN MATTHEW SOEHLIG
716 CASTLEDALE CT
JACKSONVILLE, FL 32259

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201307522

RYAN MATTHEW SOEHLIG,
RESPONDENT.

NOTICE

AND: MARTIN DIX
106 EAST COLLEGE AVE SUITE 1200
TALLAHASSEE, FL 32301

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel MGW
RE: Settlement Agreement
SUBJECT: DOH v. Ryan Matthew Soehlig, R.Ph.
DOH Case Number 2013-07522
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Ryan Matthew Soehlig, R.Ph.
Subject's Address of Record:	716 Castledale Court Jacksonville, FL 32259
Enforcement Address:	716 Castledale Court Jacksonville, FL 32259
Subject's License No:	41324 **Rank:** PS
Licensure File No:	32841
Initial Licensure Date:	7/17/2006
Board Certification:	No
Required to Appear:	Yes
Current PRN Contract:	No
Allegation:	Section 456.072(1)(k), Florida Statutes (2011, 2012), by violating by violating Section 465.022(11)(a), Florida (2011, 2012), by failing to ensure the permittee's Compliance with all rules under those chapters as they Relate to the practice of the profession of pharmacy and the sale of prescription drugs
Prior Discipline:	None

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4684

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Probable Cause Panel: December 12, 2013
Dr. Mesaros & Dr. Mikhael

Subject's Attorney: Martin Dix
Akerman LLP
106 East College Ave Suite 1200
Tallahassee, FL 32301

Complainant/Address: DOH/ISU - Jacksonville

Materials Submitted:
Memorandum to the Board
Settlement Agreement – signed
Exhibit A – Administrative Complaint
Election of Rights
Notification Letter
Cost Summary
Defense Attorney Document dated 01-08-14
PCP Memorandum
456 Materials
Final Investigative Report
Exhibits 1 thru 9

GUIDELINES:

From a $2,000 fine up to Revocation.

PRELIMINARY CASE REMARKS: SETTLEMENT AGREEMENT

This is a one count administrative complaint which alleges that the Respondent was the PDM of a permitted pharmacy which was found to be shipping prescription medications to an individual that was not licensed to receive prescription medications.

Settlement Terms:

- Appearance
- Costs not to exceed $1,000
- CEs- Laws and Rules within one year of Final Order

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07522**

RYAN MATTHEW SOEHLIG, R.Ph.,

RESPONDENT.

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, **RYAN MATTHEW SOEHLIG, R.Ph.**, was a licensed pharmacist in the state of Florida, having been issued license number PS 41324. Respondent's mailing address of record is 716 Castledale Court, Jacksonville, Florida 32259.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**: Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Costs**: The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND DOLLARS ($1,000.00)**. Total costs shall be assessed when the Settlement

Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within **ONE YEAR** from the date the Final Order is filed with the Department Clerk.

3. **Continuing Education**: The Respondent's prescription department manager of record shall successfully complete a Continuing Education Course on the subject of **LAWS AND RULES OF PHARMACY** consisting of **TWELVE HOURS** of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

4. **Future Conduct**: Respondent shall not violate Chapter 456, 465, 499, or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

5. **Violation of Terms:** It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

6. **No Force or Effect until Final Order:** It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

7. **Purpose of Agreement:** This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that

the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

8. **Not Preclude Additional Proceedings:** Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

9. **Waiver of Attorney's Fees and Costs:** Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

10. **Waiver of Procedural Rights:** Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

11. **Current Addresses:** Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the

Compliance Officer of any change of mailing address or practice address within 10 days of the change.

12. **Time of the Essence:** Time is of the essence in all respects concerning this agreement.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 7th day of January, 2014

RYAN MATTHEW SOEHLIG, R.Ph.
CASE NO. 2013-07522

STATE OF Florida

COUNTY OF Saint Johns

Before me personally appeared Ryan Soehlig, whose identity is known to me or by Florida Driver License (type of identification), and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 7 day of January, 2014

Notary Public
My Commission Expires: 10.24.2017

SHARON ADAMS
Notary Public - State of Florida
My Comm. Expires Oct 24, 2017
Commission # FF 066034

APPROVED this 6 day of February, 201_.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel

Counsel for Petitioner
Matthew G. Witters
Florida Bar No. 0091245
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399
Tel.: (850) 245-4444
Fax: (850) 245-4683

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-07522**

RYAN MATTHEW SOEHLIG, R.Ph.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner Department of Health files this Administrative Complaint before the Board of Pharmacy against Respondent Ryan Matthew Soehlig, R.Ph. and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued permit number PS 41324.

3. Respondent's address of record is 716 Castledale Court, Jacksonville, Florida 32259.

4. From on or about July 12, 2010 through on or about July 23, 2013, Respondent was the prescription department manager ("PDM") of Seton Pharmacy ("Seton") located in Jacksonville, Florida.

5. Section 465.022(11)(a), Florida Statutes (2011, 2012), states "[t]he prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs."

6. Section 499.005(15), Florida Statues (2011-2012), prohibits the sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

7. As the PDM, Respondent was responsible for ensuring the Permittee complied with Chapter 499, Florida Statutes

8. From on or about July 1, 2011 through in or about June 2012, Seton had an agreement to provide medications to the JS, a professional

sports team located Jacksonville, Florida through Dr. M.H., the team physician for the JS.

9. As a part of this agreement, D.K., the director of sports medicine for the JS would order and receive prescription medications from Seton.

10. D.K. is not authorized to purchase or possesses prescription drugs in the state of Florida.

11. From in or about July 1, 2011 through in or about June 2012, D.K. ordered and received prescription medications from Seton that were not authorized by Dr. M.H.

12. Section 456.072(1)(k), Florida Statues (2011, 2012), provides that failing to perform any statutory or legal obligation placed upon a licensee is grounds for disciplinary action.

13. Section 465.022(11)(a), Florida Statutes (2011, 2012), provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

14. Section 465.023(1)(c), Florida Statues (2011, 2012), provides that a pharmacy permittee may be subject to discipline for a violation of any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893.

15. Section 499.005(15), Florida Statues (2011, 2012), prohibits the sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

16. Respondent as PDM failed to perform a statutory or legal obligation by failing to ensure Seton's compliance with Section 499.005(15), Florida Statute (2011, 2012).

17. Based on the foregoing, Respondent violated Section 456.072(1)(k), Florida Statutes (2011, 2012), by violating by violating Section 465.022(11)(a), Florida Statutes (2011, 2012), by failing to ensure the permittee's compliance with all rules adopted under those chapters as

they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 12 **day of** December **, 2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew.witters@flhealth.gov

PCP: December 12, 2013

DOH v. Ryan Matthew Soehlig, R.Ph.
Case No. 2013-07522
AC – 499

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE DEC 12 2013

PCP Members: Dr. Mesaros and Dr. Mikhael

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

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Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

February 7, 2014

VIA US MAIL

Martin R. Dix
Akerman LLP
106 East College Avenue
Suite 1200
Tallahassee, Florida 32301

Re: DOH v. Ryan Matthew Soehlig, R.Ph.
DOH Case Number: 2013-07522

Dear Mr. Dix:

I am in receipt of the settlement agreement executed by your client on January 7, 2014 concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next meeting of the Florida Board of Pharmacy, scheduled for April 2, 2014 at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, Florida 33607. Please be advised your case will be set at the convenience of the Department and/or the Florida Board of Pharmacy and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-3265
Express mail address: 2585 Merchants Row – Suite 105
PHONE: 850/245-4444 • FAX 850/245-466X

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fldoh

Complaint Cost Summary

Complaint Number: 201307522

Subject's Name: SOEHLIG, RYAN MATTHEW

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.60**	**$32.94**
Investigation:	**5.90**	**$292.75**
Legal:	**1.20**	**$122.35**
Compliance:	**0.00**	**$0.00**
	**********	**********
Sub Total:	**7.70**	**$448.04**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$448.04**

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MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Ryan Matthew Soehlig, R.Ph. (MGW)**
Case Number: 2013-07522

MEMBERS: **Mark Mikhael and Jeffrey Mesaros**

DATE OF PCP: **December 12, 2013** **AGENDA ITEM: A-04**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(k), Florida Statutes (2011, 2012), by violating Section 465.022(11)(a), Florida Statutes (2011, 2012)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other,** _____

Chair, Probable Cause Panel
Board of Pharmacy

2/24/14
Date

September 20, 2013

Martin Dix, Esquire
Akerman Senterfitt
106 East College Avenue
Tallahassee, Florida 32301

Re: Complaint No. 2013-07522 Ryan Matthew Soehlig, R.Ph.

Dear Mr. Dix:

Pursuant to Section 456.073(10), Florida Statutes, enclosed a CD containing a copy the Department's complete investigative file in Complaint No. 2013-07522 Section 456.073(10), Florida Statutes provides in part:

> . . . Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. The subject may file a written response to the information contained in the investigative file. Such response must be filed within 20 days of mailing by the department, unless an extension of time has been granted by the department. . . .

Pursuant to the provisions of section 456.073(10), Florida Statutes, your written response must be received by no later than twenty (20) days from the date of this letter. Any requests for an extension of time must be made to my office prior to the expiration of the original twenty (20) days.

The password for the CD is: 456. Please call with any questions, 850-245-4444, ext. 8172.

Respectfully,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Enclosures: CD Investigative File (2013-07522)
Invoice #: MQPR14-138

DATE: SEPTEMBER 9, 2013

INVOICE NUMBER: MQPR14-138

TO:
Martin Dix Esquire
Akerman Senterfitt
106 East College Avenue
Suite 1200
Tallahassee Florida 32301

SERVICE RENDERED		AMOUNT
(copy)	___ Pages @$.15 Per Page	$
	___ Pages @$.75 Per Page (Color Copied)	$
	1 CD @ $8.00 Each	$ 8.00
	Charge to Certify Above Copies	$
	X-Ray Duplication Charge	
	Research Charge (if over one half hour)	$
	At $__per hour x __hours	$
	Postage & Handling Fees:	
	TOTAL AMOUNT DUE UPON RECEIPT	$ 8.00

Payment Options: Cashier Check or Money Order made payable to:

Florida DOH, Division of MQA

Please reference the INVOICE NUMBER on your Payment—Mail to the below address.

Organization Code: 64-75-10-01-022

Expense Code: 497000

EO Code: PA

Profession: Pharmacy

Case Name: Ryan Soehlig

Case Number: 2013-07522

Acknowledgement of and
Agreement to Maintain Patient Confidentiality

I, Martin R. Dix, the attorney for am the Subject of an investigation by the Department of Health. As the Subject of such an investigation, I am entitled to inspect or receive a copy of the investigative report, including any expert witness report or patient records connected with the investigation pursuant to Section 456.073(10), Florida Statutes, if I agree in writing to maintain the confidentiality of any information received under this provision, until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to Section 456.057, Florida Statutes.

I understand the cost associated with duplicating x-rays and I want ( ) do not want ( ) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this ____ day of _____, 2013.

Ryan Matthew Soehlig, R.Ph.
2013-07522

SIGNED this 19th day of September, 2013 on behalf of Ryan Matthew Soehlig, R.Ph.

Martin R. Dix, Esquire

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HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

CASE NO. 201216088

VS.

JOHN T READING,
RESPONDENT.

NOTICE

TO: JOHN T READING
3407 RIVER GARDEN CIRCLE
PENSACOLA, FL 32514-8113

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Ana Gargollo-McDonald, Assistant General Counsel
RE: Settlement Agreement
SUBJECT: DOH v. John T. Reading, R. Ph.
DOH Case Number 2012-16088
DATE: February 12, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	John T. Reading
Subject's Address of Record:	3407 River Garden Circle Pensacola, FL 32514-8113
Enforcement Address:	3407 River Garden Circle Pensacola, FL 32514-8113
Subject's License No:	10065 **Rank:** PS
Licensure File No:	2099
Initial Licensure Date:	Fifty (50) Year Pharmacist
Board Certification:	No
Required to Appear:	Yes
Current IPN/PRN Contract:	No
Allegation(s):	456.072(1)(k), F.S. (2012) 465.022(11)(a), F.S. (2012) 465.015(2)(c), F.S. (2012)
Prior Discipline:	4075, 02/09/1993
Probable Cause Panel:	September 5, 2013; Mesaros & Glass

Subject's Attorney:	Pro Se
Complainant/Address:	Preston E McDonald 5740 Westmont Road Milton, FL 32583
Materials Submitted:	Memorandum to the Board Settlement Agreement Exhibit A - Administrative Complaint Election of Rights Board Notification Letter Cost Summary Report Probable Cause Memorandum Final Investigative Report with Exhibits

DISCIPLINARY GUIDELINES:

456.072(1)(k), F.S. (2012): From $2,500 fine and two years of probation, to revocation.

465.015(2)(c), FS (2012): From $1,500 fine to revocation.

PRELIMINARY CASE REMARKS: SECTION 120.57(2) HEARING (INFORMAL)

This is the hearing in the matter of taking disciplinary action against the licensee and case number referenced above.

TERMS OF SETTLEMENT:

1. Appearance
2. Administrative Fine in the amount of $2,000.00 payable within 90 days
3. Costs not to exceed $2,063.00 payable within 90 days

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16088**

JOHN T. READING, R.PH.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, John T. Reading, Sr., R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 10065. Respondent's mailing address of record is 3407 River Garden Circle, Pensacola, Florida 32514.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

3. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

4. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

5. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

6. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

7. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND AND SIXTY-THREE DOLLARS** ($2,063.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

8. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

9. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute

a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

10. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

11. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice

the Board or any of its members from further participation, consideration, or resolution of these proceedings.

12. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

13. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

14. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

15. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 28th day of SEPTEMBER, 2013.

JOHN T. READING, R.PH.
CASE NO. 2012-16088

STATE OF FLORIDA

COUNTY OF ESCAMBIA

Before me personally appeared JOHN T. READING, Sr.RPh, R.Ph., whose identity is known to me or by FLDL (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 28th day of SEPTEMBER, 2013.

Notary Public
My Commission number:
My Commission Expires:

BENJAMIN V. FENN
Commission # EE 855488
Expires March 31, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

2013 OCT -1 AM 9:23
PRACTITIONER REGULATION
LEGAL

APPROVED this 25th day of October, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel

Counsel for Petitioner
Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16088**

JOHN T. READING, SR., RPh,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, John T. Reading, Sr., RPh, and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the State of Florida, having been issued license number PS 10065.

EXHIBIT
A

3. Respondent's address of record is 3407 River Garden Circle, Pensacola, Florida 32514.

4. At all times material to this complaint, Respondent was the prescription department manager (PDM) of Cantonment Pharmacy (the Permittee), located at 433 Highway 29 South, Cantonment, Florida 32533.

5. Section 465.022(11)(a), Florida Statutes, provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under Chapter 465, Chapter 499, or Chapter 893, Florida Statutes, as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

6. Section 465.015(2), Florida Statutes (2012), to sell or dispense drugs as defined in Section 465.003(8), Florida Statutes, without first being furnished with a prescription.

7. As the PDM, Respondent was responsible for ensuring the Permittee complied with Sections 465.015(2), Florida Statutes (2012).

8. On or about February 4, 2013, the Department of Health Investigator went to Cantonment Pharmacy, and obtained six (6) azithromycin 250 mg tablets, a prescription only medication, without a valid prescription.

9. Azithromycin is an antibiotic that fights bacteria and is a prescription drug.

10. Section 456.072(1)(k), Florida Statutes (2012), provides that violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto, constitutes grounds for disciplinary action by the Board of Pharmacy.

11. Section 465.022(11)(a), Florida Statutes (2012), provides that the prescription department manager must ensure the permittee's compliance with all rules adopted under Chapter 465, Chapter 499, or Chapter 893, Florida Statutes, as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

12. Section 465.015(2)(c), Florida Statutes (2012), it is unlawful for any person to sell or dispense drugs as defined in Section 465.003(8), Florida Statutes, without first being furnished with a prescription.

13. As set forth above in paragraph 8, on or about February 4, 2013, Respondent failed to ensure the Permittee's compliance with Section 465.015(2)(c), Florida Statutes.

14. Based on the foregoing, Respondent has violated Section 456.072(1)(k), and Section 465.016(1)(r), Florida Statutes (2012), by

violating Section 465.022(11)(a), Florida Statutes, by failing to ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 5th **day of** September, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angel Sanders
DATE: SEP 05 2013

/AGM

PCP: 9/5/13
PCP Members: Meros & Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

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November 6, 2013

John Reading
3407 River Garden Circle
Pensacola, FL 32514-8113

Re: DOH vs. John T. Reading, R.Ph.
DOH Case Number: 2012-16088

Dear Mr. Reading:

I am in receipt of the settlement agreement executed by you on September 28, 2013, concerning the above referenced case.

Our office is now making preparation for this settlement to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. Please be advised your case will be set at the convenience of the Department and/or the Board and you will be notified of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Ana Gargollo-McDonald
Assistant General Counsel

AM/ab

Search | Complaint/Case Number: 201216088 | MAIN | HELP

Complaint Cost Summary

Complaint Number: 201216088

Subject's Name: READING, JOHN T

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	11.70	$743.57
Legal:	4.70	$497.26
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	17.00	$1,273.77
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,273.77

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **John T. Reading, Sr., R.Ph. (AMM)**
Case Number: 2012-16088

MEMBERS: **Cynthia Griffin, PharmD and Jeffrey Mesaros**

DATE OF PCP: **September 5, 2013** **AGENDA ITEM: A-16**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(k), and Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes;

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other**

9/5/13

Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PS 2012-16088

Subject:	Source:
JOHN T. READING SR, RPH 3407 River Garden Circle Pensacola, FL 32514 (850) 477-2499	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PS	10065	PHARMACIST	PHARMACY	7/8/13

Period of Investigation: 4/17/13-7/8/13	Type of Report: FINAL

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. **(n)** Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party. **(dd)** Violating any provision of this chapter **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. **(r)** Violating any provision of this chapter ... **and FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter

Synopsis: This investigation is predicated upon receipt of a complaint (Case Summary and Attachments) **(EXHIBIT 1)** submitted by MCDONALD in regard to READING. MCDONALD, a former pharmacist at Cantonment Pharmacy, alleged staff there are dispensing prescription medications without a prescription including antibiotics, erectile dysfunction oral tablets (Viagra), albuterol inhalers, and possibly non-controlled medications. Allegedly customers come to the pharmacy on a daily basis to purchase Penicillin, Amoxicillin, Flagyl, Diflucan, and cough syrup with codeine without a prescription from a physician. READING is allegedly dispensing these medications without a prescription. On 2/4/13, a Pensacola investigator went to the pharmacy and purchased a "Z-Pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/ Tripolidine Hydrochloride 2.5mg) tablets. On 03/28/13, another Pensacola ISU staff member went to the pharmacy and purchased Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/ Tripolidine Hydrochloride 2.5mg) tablets. The pharmacist was not identified on 2/4/13 or 3/28/13.

READING was notified of the investigation by letter dated 4/17/13 **(EXHIBIT 2)** and was provided a copy of the Case Summary and originating documents from Exhibit 1.

A check of DOH computer licensure records revealed READING is currently licensed as a PHARMACIST. READING earned his Bachelor of Science in Pharmacy from Sanford University in Birmingham, AL (year not indicated) per the resume included with his response **(EXHIBIT 8)**.

No patients were identified; therefore, patient notification was not required.

READING SR. is not known to be represented by an attorney in this matter

On 5/7/13 by US mail, Investigator LANIER received READING statement dated 5/4/13 **(EXHIBIT 8)**. READING denied the allegations.

Related Case: RPT 2012-16092, RPT 2012-16089, PH 2012-16087, PS 2012-16091, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
Ben Lanier 7/8/13 Received Investigative Services	for 7/
Ben Lanier, BI-35, Investigator	Cathy Martin, Investigator Supervisor

Distribution: HQ/ISU

JUL 09 2013

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5. Copy of previous inspections dated 9/22/09, 10/18/10, and 1/23/12 31-33
6. Copy of pictures on CD (13 images) 34-46
7. Copy of the "Cantonment Wine" Formula 47-48
8. READING's response dated 5/4/13 49-61
9. Confidential Index 62

INVESTIGATIVE DETAILS

On 2/4/13, Investigator LANIER drove to Cantonment Pharmacy. Upon entering the pharmacy, "EMILY" the cashier asked how she could help. Investigator LANIER stated he had a sinus infection and EMILY told Investigator LANIER to go to the pharmacy consultation window. Investigator LANIER walked to the consultation window and a man, without a name tag, presumably the pharmacist, with short brown hair and a goatee asked how he could help. Investigator LANIER told him that he had a sinus infection and a swollen throat. Investigator LANIER told him that a friend of his had the same thing recently and a Z-pak seemed to help. The pharmacist asked if Investigator LANIER wanted a Z-pak and Investigator LANIER told him yes. The pharmacist asked if Investigator LANIER was taking any kind of Antihistamine and Investigator LANIER told him no. The pharmacist told Investigator LANIER to also purchase an Antihistamine to clear up his sinuses. Investigator LANIER told him that funds were limited and the man said it would be roughly $31.00 in total. There was no counseling offered on how to take either the Z-pak or Antihistamine. EMILY assisted Investigator LANIER check out and asked for Investigator LANIER's driver's license. EMILY wrote down Investigator LANIER's name, address, and driver's license number in a book. Then Investigator LANIER signed the log and left the pharmacy. While in the pharmacy Investigator LANIER did not see a sign offering the sale of Viagra. A "Z-pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist.

On 3/28/13, Investigator Supervisor CATHY MARTIN presented to Cantonment Pharmacy with complaints of lingering cough and sore throat. The cashier immediately instructed Investigator Supervisor MARTIN to go the pharmacy window. A man with short brown hair and a goatee, presumably the pharmacist but with no name tag, asked what symptoms were present. The symptoms were repeated to the pharmacist, and he instructed Investigator Supervisor MARTIN to select a bottle of Chloraseptic. He stated, with a wink, that he would add an ingredient to relieve the symptoms. He asked if Investigator Supervisor MARTIN was taking any decongestants, and Investigator Supervisor MARTIN responded no. He asked no other questions. A selection of the orange flavored Chloraseptic was made and Investigator MARTIN returned to the pharmacy window. The pharmacist stated that the orange flavor was not very good and to go back and get the red bottle. Investigator MARTIN did so. The pharmacist took the bottle, and a few minutes later he passed a white paper bag with contents to the cashier. The pharmacist stated that he added Lidocaine to the Chloraseptic. The cashier instructed Investigator MARTIN to approach the counter and provide a driver license. Investigator Supervisor MARTIN did so, and the cashier copied information from the driver license to a worn green ledger. The cashier then instructed Investigator Supervisor MARTIN to enter address information in the log and sign where indicated. Investigator MARTIN did so. During this process, Investigator MARTIN asked what the purpose of the log was, and the cashier stated it was for the Sudafed pills being provided. Investigator MARTIN also asked for the pharmacist's name, and the cashier provided a first name of "Gene." She informed the total was $11.10, and Investigator Supervisor MARTIN provided the cashier a $50 bill. Change of $38.90 was provided, and Investigator Supervisor MARTIN thanked the cashier and the pharmacist and left. The cost of the Chloraseptic was $5.12, and a blue bottle with 24 small white pills was also provided for a cost of $5.98. No prescriptions were presented to the pharmacy, and no instructions for taking the medications were provided. Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist. The pharmacist was not identified on 2/4/13 or 3/28/13.

Thirteen pictures of these medications and receipts from both purchases are provided on CD and included as **EXHIBIT 6**.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

EXHIBIT 1 is information forwarded by the Consumer Services Unit (CSU) with the complaint. This information consists of a Case Summary, corrected Case Summary, complaint form by MCDONALD, and the following:

- Complaint narrative by MCDONALD noting he was previously employed at Winn-Dixie pharmacy located nearby Cantonment Pharmacy. While at work on many occasions, he would have customers ask if he could sell them antibiotics. It was explained to them that a prescription was required, and their response was always that they could obtain them from Cantonment Pharmacy. MCDONALD did not believe the customers for the most part, contributing it to Cantonment Pharmacy selling something to the customers and telling them it worked almost as good as antibiotics. Through diverging circumstances, MCDONALD became employed at Cantonment Pharmacy as a pharmacist. The very first day at work not long after they opened, a customer came up and asked him for antibiotics. MCDONALD told the customer that they had to have a prescription for antibiotics. Throughout the day about six different customers asked him for antibiotics and without fail, every day to this date, he had customers telling him they had purchased antibiotics in the past from one registered pharmacy technician (RPT1) or sometimes another registered pharmacy technician (RPT2) was mentioned, and that they would like to purchase some more. MCDONALD refused and always told the customers that a prescription was required. Antibiotics mentioned to MCDONALD that customers had purchased in the past included Penicillin, Amoxicillin, Z-Pak, Keflex, Flagyl, and Diflucan. As corroborating evidence of this practice of selling antibiotics without a prescription to customers, there are large bottles of Penicillin, Amoxicillin, and SMZ-TMP on a counter near the counseling window, which is outside of the area of stock of all other medications, and separate from its normal location (for filling prescriptions).

  MCDONALD also had several male customers ask to purchase Viagra tablets, stating that they had bought them in the past from RPT1 or sometimes RPT2 and wanted some more. MCDONALD refused and always told the customers a prescription was required. MCDONALD stated there are handwritten signs above/below the Viagra tablets on the prescription stock area of "$24" which indicated that customers are charged $24.00 for each Viagra tablet (sold without a prescription). MCDONALD also had a customer come to the counseling window and ask him for an Albuterol inhaler. After MCDONALD explained that a prescription was needed, the customer stated that he had purchased them before from RPT1 and RPT2, and he became irate that MCDONALD would not sell him an Albuterol inhaler.

  Finally, MCDONALD alleged there is a well-known practice in the community that Cantonment Pharmacy sells a "cough syrup" that is mixed at the pharmacy which contains codeine. This is a C-V medication that can be legally sold without a prescription, but it can only be sold by a pharmacist. MCDONALD had several customers tell him they wanted that special "cough syrup" they got from RPT1 or RPT2 in the past. MCDONALD witnessed it being sold to customers by a clerk without consultation of the pharmacist on duty. MCDONALD stated it was a common practice for RPT1 to give medical advice to customers and otherwise infer to customers that he was a licensed pharmacist, and to also sell them prescription medications without a prescription. This was also the case for RPT2, although to a lesser extent.

  MCDONALD listed the licensed employees of the pharmacy who were allegedly guilty of dispensing medications without a prescription. These employees allowed RPT1 to portray himself as a licensed practitioner prescriber or pharmacist. This technician was allowed to perform duties only allowed by

law to be performed by a licensed practitioner prescriber or pharmacist such as 1) diagnosing patients and prescribing prescription medications by virtue of selling the prescription medications to customers without a valid prescription, 2) giving medical advice to customers without consultation of a licensed pharmacist, 3) holding himself as a pharmacist, 4) acting/speaking as a pharmacist over the telephone to other pharmacists in the transfer of prescriptions, without identifying himself as a pharmacy technician, 5) individually selling C-V medications (i.e., cough syrup with codeine) to customers without involvement, consultation, and approval of a pharmacist. MCDONALD noted that the primary principal or violator was RPT1, who had for many years acted as a pharmacist and performed pharmacist-only duties. The owner of the pharmacy is listed as the pharmacist-in-charge, who has a legal responsibility in developing and enforcing policies and procedures for the pharmacy. It is extremely difficult to believe that the owner, although absent from the day to day operations of the pharmacy, is not aware of the violations occurring on a daily basis. The two most recent pharmacists employed by the pharmacy are also participants in these violations by virtue of allowing them to occur while on duty and failing to report them. MCDONALD did not know if those two pharmacists were guilty of selling medications that require a prescription without one, or just knowingly allowed such. MCDONALD stated the pharmacy technicians were not identifying themselves when answering or speaking on the phone and did not regularly wear name tags/badges that readily identify themselves as pharmacy technicians. MCDONALD stated the pharmacy is also in violation by not having an easily accessible sink near the prescription counter.

EXHIBIT 3 is a copy of a letter dated 4/17/13 to MCDONALD informing him of the status of the case.

EXHIBIT 4 is a copy of a letter dated 5/16/13 to READING providing a corrected Case Summary. The original Case Summary made two references to Hydrocodone which should have read Hydrochloride.

EXHIBIT 5 is copies of three previous inspection forms dated 9/22/09, 10/18/10, and 1/23/12 for inspections conducted at Cantonment Pharmacy printed by Investigator LANIER on 4/18/13. The three previous inspections indicate passing results; however, the inspection form dated 9/22/09 indicated there were some improperly labeled medications found.

EXHIBIT 6 is a copy of thirteen pictures placed on CD by Investigator LANIER. The pictures are of prescription medications purchased from Cantonment Pharmacy by Pensacola ISU staff on 2/4/13 and 3/28/13, and the respective receipts, dispensed without providing a prescription. The medications consist of a "Z-pak" (six Azithromycin 250mg tablets, prescription only medication), 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets, Chloraseptic with Lidocaine added (which requires a prescription), and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets.

EXHIBIT 7 is a copy of the formula for the "Cantonment Wine" provided by BENJAMIN FENN, RPH, on 4/26/13 to Investigator LANIER at the Pensacola ISU office.

INTERVIEW OF PRESTON MCDONALD, RPH (PS 33121)–SOURCE:

Address of Record:
5740 Westmont Road
Milton, FL 32583
(850) 983-0916

On 11/26/12, Investigator LANIER interviewed MCDONALD by telephone. MCDONALD stated he quit working at the pharmacy close to a month prior. MCDONALD stated the pharmacy did not keep a record of the medications that customers were buying. MCDONALD stated the cough syrup did not contain full strength codeine and it did not require a prescription, but a pharmacist had to be involved. MCDONALD state Registered Pharmacy Technicians were also providing the cough syrup to customers. MCDONALD stated he could not specifically remember any patient names.

INTERVIEW OF BENJAMIN FENN, RPH (PS 13028)–WITNESS:

Address of Record:
6212 Kristen Dr.
Pensacola, FL 32504
(850) 476-7132

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

FENN stated he worked full time at Cantonment Pharmacy on Mondays, Tuesdays, Thursdays, and Fridays. FENN stated he talked the owner into hiring MCDONALD because he was retiring and FENN was only going to be the on call/relief pharmacist. FENN stated that he was now completely retired; however, if anyone from Cantonment Pharmacy called and asked for him to work a shift that he would. FENN stated Cantonment Pharmacy was the only community pharmacy in Cantonment for about 30 years. FENN stated he was "guilty of all of it." FENN stated he did provide customers with prescription medications without a prescription. FENN stated he helped a lot of sweet black people who would come in mainly with toothaches and ask him for Penicillin. FENN stated he would sell them about a dozen Penicillin tablets to help them. FENN stated he wanted to help people who did not have insurance or who did not have a lot of money. FENN stated he never diagnosed people. FENN would also sell Diflucan to women who were experiencing vaginal problems. FENN stated that during his time there, READING did this for a lot of customers. FENN stated Cantonment Pharmacy was a family pharmacy that helped out the community. FENN stated this behavior had to stop because the times have changed. FENN stated the pharmacy did keep a price right below the Viagra which noted that each pill was $28.00. FENN stated that was also done for the Cialis and Levitra. FENN stated the pharmacy was not making any money off the Viagra because they sold it at cost. FENN stated he also sold Amoxicillin without a prescription. FENN stated he had seen every employee that worked there do it as well, even the pharmacy techs. FENN stated he had seen PH2, READING, RPT1, and RPT2, all do it. FENN stated RPT2 was READING's grandson. FENN stated there was a new pharmacist PH3 that was working there. FENN stated he could not recall PH3's last name, but that he had it written down and he would call Investigator LANIER with the last name. FENN stated Investigator LANIER would not believe how many marriages he thought he saved by selling the Viagra. FENN stated Viagra could be purchased online anyway

and provided Investigator LANIER with a number of (800) 530-6596 to verify it. FENN stated he also thought he had wiped out Syphilis with the antibiotics he sold. FENN stated customers would also come in and ask for extra tablets of what they were already taking and staff, mainly RPT1, would check to see if they had already been previously prescribed the medication before providing it to them. FENN stated he felt taken advantage of by the customers as well because he would help someone out one time and they would keep coming back after that. FENN stated he did not want to make people mad. FENN stated they also sell "Cantonment Wine" (cough syrup). FENN stated every staff member sold the Cantonment Wine, even the cashiers. FENN stated RPT1 and his nieces would premix a large container of the cough syrup. The container was approximately 480cc. FENN stated the cashiers would sell it to their church friends etc. FENN stated it was legal for them to sell it without a prescription. FENN stated he had the formula for the cough syrup written down and he provided a copy to Investigator LANIER **(EXHIBIT 7)**. FENN stated that basically the cough syrup contained Codeine, Guaifenesin, and Benadryl. FENN stated they did keep a log of who the cough syrup was sold to because it contained Codeine. FENN stated the pharmacy techs also sold it and he had to take the blame for that as well because they did it under his watch. FENN stated the cough syrup has been sold there for 30 years. FENN stated RPT1 told him not to worry about it because there was not enough Codeine in it to do anything. RPT1 told FENN someone could drink the whole bottle and not feel any affects. FENN stated he did not trust anyone anymore with Codeine. FENN stated RPT1 was also a federal attorney, but FENN did not believe he was licensed as such anymore. FENN stated RPT1. told him that he was going to get them all out of trouble and that he planned to represent all of them. FENN stated he thought RPT1 wanted to protect him, but he did not feel comfortable with that. FENN stated he wanted to confess his sins and get this off of his mind. FENN stated he was just trying to help people but that it had to come to an end because the times had changed. FENN stated he had spent his whole life trying to help people and that he did not regret it. FENN stated he was now retired and glad, but he still did not want to have to go to Tallahassee and lose his license. FENN stated he never received any complaints from patients or customers or other pharmacists until now. FENN stated this activity could have resulted in adverse problems and that he understood that. FENN stated someone could have been allergic to the medication that was dispensed to them. FENN stated he believed MCDONALD filed this complaint because READING offered to sell MCDONALD the pharmacy for two million dollars, but they withdrew the offer because MCDONALD wanted to turn their pharmacy into a compounding pharmacy. FENN stated he did not want to lose his license but that he would be fine with it if it was necessary because he was guilty. FENN stated he refused to sell to some customers because he was not familiar with them, but he thought some customers were dear friends of READING because the customers would call READING and then READING would call FENN at the pharmacy and tell him to sell to them, so he did. FENN asked to pray with Investigator LANIER for forgiveness of his sins. FENN stated he never dispensed the morning-after pill because he did not want to kill babies. FENN stated the pharmacy had recently gotten in trouble with the DEA. FENN stated the pharmacy was filling prescriptions for a doctor had her patients sign a contract noting they would only get their prescriptions filled at Cantonment Pharmacy. FENN stated another doctor was writing for a lot of tablets on most all of his prescriptions. FENN stated when the DEA came in, they told READING Sr. they were selling way too much Oxycontin and READING gave up their DEA license without any argument. FENN stated he was just trying to keep READING alive these days and really thinks he needs to sell the pharmacy. FENN thanked Investigator LANIER for his time and asked that prayers be said for him.

On the same date, FENN telephoned Investigator LANIER and provided PH3's last name.

On 5/6/13, Investigator LANIER attempted to telephone FENN; however, he was not available and there was no voicemail option. On 5/7/13, FENN telephoned Investigator LANIER and stated he had seen that he missed the

call. Investigator LANIER explained to FENN that a statement was received with his name on it that seemed to provide a conflicting response as to what was discussed on 4/26/13. FENN stated he never saw or read the statement, but allowed RPT1 to write it for him. Investigator LANIER informed FENN that the statement had his name at the bottom of it, as if it was written by him. FENN stated he did not want to tell RPT1 that he had already talked with Investigator LANIER about this matter. FENN stated that what he had previously told Investigator LANIER at the ISU office was the truth. FENN stated Cantonment Pharmacy was a family pharmacy and every employee had sold prescription medications without a prescription. FENN stated RPT2 was spoiled and that READING still called him "sugar boy." FENN stated he was not sure where RPT2 had received his education but READING trained him. FENN stated Cantonment Pharmacy was the only place RPT2 could get a job. FENN stated PH2, RPT2, RPT1 and READING had all sold prescription medications without a prescription. FENN opined that PH3 had done the same; however, he never worked with or witnessed him do it because PH3 started after FENN retired. FENN stated this happened with various medications but no controlled substances. FENN stated Viagra, Z-paks, and other antibiotics were sold without prescriptions. FENN stated he had even sold things in the past to Sheriff's deputies, etc, but times were changing. FENN stated he went along with everything at the pharmacy but should not have. FENN stated the pharmacy kept hiring older people because the young pharmacists did not want to do business the way they did. FENN stated the pharmacy was run by incompetents and that FENN had tried to hold everything together. FENN stated that apparently he "could not get out of their fast enough before he was caught." FENN stated he knew this was going to happen someday. FENN stated the only thing wrong in MCDONALD's complaint was that FENN had always seen the tech's wear name tags.

INTERVIEW OF SUSAN HALFEN, RPH (PS 32697)–WITNESS:

Employment: Winn-Dixie
1550 Hwy 29 North
Cantonment, FL 32533
(850) 968-3318

On 5/10/13 and 5/14/13, Investigator LANIER attempted to telephone HALFEN; however, she was not available and voicemail messages were left requesting a return call.

On 5/15/13, HALFEN returned the call and left a voicemail message for Investigator LANIER stating she was working all day on this date, but that she should be available for Investigator LANIER to call. On the same date, Investigator LANIER returned the call. HALFEN stated she had been a pharmacist at Winn-Dixie for about six years and that their location was very close to Cantonment Pharmacy. HALFEN stated that since she started working at Winn-Dixie pharmacy, one to two customers come in every month or so to try and get prescription medications without a prescription. HALFEN stated these customers were mainly seeking antibiotics and told her that they had gotten them in the past without a prescription from Cantonment Pharmacy. HALFEN stated she also knew Cantonment Pharmacy provided a cough syrup. HALFEN stated she knew pharmacists were allowed to sell the cough syrup. HALFEN stated that was all she really knew about Cantonment Pharmacy's operation.

INTERVIEW/STATEMENT OF JOHN T. READING, SR., RPH–SUBJECT:

Address of Record:
3407 River Garden Circle
Pensacola, FL 32514
(850) 477-2499

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

On 5/7/13 by US mail, Investigator LANIER received READING's statement dated 5/4/13. READING earned his Bachelor of Science in Pharmacy from Sanford University in Birmingham, AL (year not indicated) per the resume included with his response **(EXHIBIT 8)**.

READING denied the allegations and stated MCDONALD was a serial liar. READING stated the nature of the complaint was inappropriate prescribing. READING asked that his resume be read and to note the details of the last few years of medical issues and the fact that he had not been the pharmacist on duty for more than a few hours or more for about a dozen times in the last five or more years. READING denied prescribing anything that was not permitted under Florida law.

READING stated he would be happy to face MCDONALD in person in an interview setting now that he knew what a liar he is, and also an anti-Semitic slug. READING questioned his employees and he apparently never left the prescription department except for bathroom breaks and possibly a sandwich break. That means that anything that he had accused his employees of doing, was done either at his direction, in his presence, or with his approval.

READING stated that he had spent a couple of hours in the pharmacy with MCDONALD showing him around, explaining very specifically that everyone is trained that the pharmacist is the boss at all times, no matter how his staff might customarily do their job. MCDONALD has a good motivation to try to cause trouble for his business. He had worked, until terminated, at Winn-Dixie near them for a few years. MCDONALD knew they had a good business. When MCDONALD was terminated (from Winn-Dixie), he inquired if READING would sell him the business. At READING's age, it did come to mind once in a while and he told him that he would sell it for $2 million dollars, but he would be crazy to buy any pharmacy without putting in some time at the pharmacy. MCDONALD was invited to come to work for them and look things over, for his period of evaluation that he recommended. This was certainly not something READING would have done if the pharmacy was operated in any degree along the lines that he has alleged, BELATEDLY.

READING stated he emphasized BELATEDLY, because after accepting his offer to come and work with his staff and meet their patients, they arranged for a banker to meet with READING's C.P.A to go over their books. MCDONALD came back with an offer to purchase (after having worked at the pharmacy and after having the books examined at his expense) that was about one-forth of what READING had asked initially. READING expected a significantly lower counter offer but nothing as ridiculous as MCDONALD came back with. MCDONALD has said that he would be satisfied if READING's license was revoked and he was fined. READING stated there was nothing in the record to justify such a vindictive attitude or request that would make sense to a normal person, especially considering his age and acuity. This is just a belly-full of bile that MCDONALD has as a result as a frustrated purchaser and an anti-Semite.

READING also provided the following:

- Emergency Declaration by Governor RICK SCOTT
- Memo to employees regarding theft and behavior
- Store Policy Manual Procedures Rule Book

- Memo noting the filling of out of town prescriptions was restricted
- Letter dated 7/18/12 noting an employee had tendered their resignation and MCDONALD would be the pharmacist's replacement.
- Newspaper editorial on READING

On 5/14/13, Investigator LANIER interviewed READING by telephone. READING stated he did write the response that was provided and he was wondering if Investigator LANIER had received it. READING stated he could not honestly say what took place in the pharmacy on a daily basis because he had only visited the pharmacy a handful of times in the last couple years. READING stated he was a 53 year pharmacist and that he still received a paycheck because he was the owner, but that he had been in and out of the Mayo clinic for a couple of years.

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498

Insp # 86062

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT	PERMIT NUMBER		DATE OF INSPECTION
CANTONMENT PHARMACY INC	2748		9/22/2009
DOING BUSINESS AS	DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
	AC5573767		
STREET ADDRESS	TELEPHONE #	EXT.	JOHN T READING
433 HIGHWAY 29 S	850-968-2489		
CITY / COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
CANTONMENT / 27	32533-1401		10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Johnny Reading PTech
3. Karen Bonanno PTech

	SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]		X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]		X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]		X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]		X	
5	Items properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]		X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]		X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]		X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]		X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.		X	
10	Generic drug sign displayed. [465.025(7),F.S.]		X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]		X	
12	Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*	X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]		X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]		X	
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]		X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]		X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]		X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]		X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]		X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]		X	
21	Medication properly labeled [64B16-27.101,F.A.C.]			X
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]		X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]		X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]		X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]		X	

	SATISFACTORY	N/A	YES	NO
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]		X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]		X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]		X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]		X	
30	Controlled substance records readily retrievable. [893.07,F.S.]		X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]		X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]		X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]		X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]		X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]		X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]		X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]		X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]		X	
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]		X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]		X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*		X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]		X	
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]		X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *		X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *	X		
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *	X		
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *	X		

Questions with (*) may be answered n/a (not applicable).

Remarks: Missy Shores PTech. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #21 Two bottles of OTC drug in pharmacy stock without expiration date. #23 Last CQI meeting 9-15-2009. #39 CS inventory 5-1-2009. #44 Logbook. Rx drug purchases from Smith Drug, AmerisourceBergen, Masters, & Top Rx.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative

09-22-2009
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

Exhibit 5

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 498
Insp # 94915

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
CANTONMENT PHARMACY INC		2748		10/18/2010
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
		AC5573767		
STREET ADDRESS		TELEPHONE #	EXT.	JOHN T READING
433 HIGHWAY 29 S		850-968-2489		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
CANTONMENT	27	32533-1401		10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Wilton Glover PS 7751
3. Melissa Shores RPT 21008

	SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]		X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]		X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]		X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]		X	
5	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]		X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]		X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]		X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]		X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.		X	
10	Generic drug sign displayed. [465.025(7),F.S.]		X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]		X	
12	Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*	X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]		X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]		X	
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]		X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]		X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]		X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]		X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]		X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]		X	
21	Medication properly labeled [64B16-27.101,F.A.C.]		X	
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]		X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]		X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]		X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]		X	

	SATISFACTORY	N/A	YES	NO
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]		X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]		X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]		X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]		X	
30	Controlled substance records readily retrievable. [893.07,F.S.]		X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]		X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]		X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]		X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]		X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]		X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]		X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]		X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]		X	
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]		X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]		X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*		X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]		X	
43	Schedule V drug records/sales properly kept. [893.06(3)(a),F.S.]		X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *		X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *	X		
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *	X		
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *	X		

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Leslie Johnson RPT 21005; John Reading, Jr. RPT 21007. #3 DEA expires 8-31-2011. #6 NA. #7 Tech ratio letter 6-22-1994. #23 Last CQI meeting #39 CS inventory #43 Book - OK. #44 Logbook. Rx drug purchases from Smith Drug-Valdosta and AmerisourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative — 10-18-2010 Date — Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

00032

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

File # 498

Insp # 103821

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
CANTONMENT PHARMACY INC		2748		1/23/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
		Ac5573767		
STREET ADDRESS		TELEPHONE #	EXT.	JOHN T READING
433 HIGHWAY 29 S		850-968-2489		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
CANTONMENT	27	32533-1401		10065

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday		
Open	9am	9am	9am	9am	9am	9am	closed	1. Joseph Gibson PS 26203	
Close	6pm	6pm	6pm	6pm	6pm	3pm		2. Benjamin Fenn PS 13028	
								3. Melissa Shores RPT 21008	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]			X	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]		X		
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19	DEA 222 order forms properly completed. [893.07, F.S.]			X	
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			X	
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]		X		
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]		X		
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]			X	
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]		X		
28	Compounding records properly maintained. [64B16-27.700, F.A.C.]*		X		
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]		X		
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Adam Bass RPT 21001; John Reading RPT 21007; Karin Bonano RPT 21006; Leslie Johnson RPT 21005. DEA expires 8-31-2014. #2 Tech ratio letter 6-22-1994. #11 Last CQI meeting 9-1-2011. #12 Future requirement. #18 CS inventory 5-1-2011. #22 Logbook. #23 One incident - Escambia CSO. #24 None since 7-1-2011. CII prescription file survey (60Rxs): Local Practitioner - 97%; Local Patient - 100%; Pain Therapy - 78%; Non-pain Therapy - 22%. No batch compounding. No compounding for practitioner office stock. Rx drug suppliers: Smith Drug-Valdosta; AmericansourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Joseph Gibson, RPh

Institutional Representative

01-23-2012
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201306754

GENE R LACHNEY,
RESPONDENT.

NOTICE

TO: GENE R LACHNEY
716 SKY HAWK DR
PENSACOLA, FL 32506

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Determination of Waiver

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Ana Gargollo-McDonald, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Gene R Lachney, R.Ph.
DOH Case Number 2013-06754
DATE: February 14, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Gene R Lachney
Subject's Address of Record:	716 Sky Hawk Dr Pensacola, FL 32506
Enforcement Address:	716 Sky Hawk Dr Pensacola, FL 32506
Subject's License No:	28290 **Rank:** PS
Licensure File No:	17317
Initial Licensure Date:	3/8/1993
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	465.015(2)(c), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	September 5, 2013; Mesros & Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Department Of Health/Investigative Services Unit-Pensacola
Materials Submitted:	Memorandum to the Board Motion For Determination of Waiver Exhibit A: Administrative Complaint Exhibit B: Copy of Certified Mail Receipt Exhibit C: Affidavit of Service Exhibit D: Affidavit of Non-Receipt – Board Office Exhibit E: Affidavit of Non-Receipt – Agency Clerk Defense Attorney/Respondent Documents Motion to Assess Costs with Attachments

Exhibit A: Affidavit of Fees and Costs Expended
Exhibit 1: Complaint Cost Summary
Exhibit 2: Itemized Cost by Complaint
Supplemental Investigative Report dated 7/31/2013
Probable Cause Memorandum
Final Investigative Report with Exhibits 1-7

Disciplinary Guidelines:
465.015(2)(c), Florida Statutes (2012): from $1,500 fine to Revocation

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

This is a one-count administrative complaint alleging Respondent violated Section 465.015(2)(c), Florida Statutes (2012), by selling or dispensing drugs as defined in Section 465.003(8), Florida Statutes, without first being furnished with a prescription.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2013-06754**

GENE R. LACHNEY, R.PH.,
Respondent.
_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

Petitioner, Department of Health, by and through counsel, moves the Board of Pharmacy to find that Respondent has waived his/her right to elect a method of disposition of the pending Administrative Complaint, to determine that no material facts are in dispute, to conduct a hearing not involving disputed issues of material fact, and to enter a Final Order. As grounds therefore, Petitioner states:

1. An Administrative Complaint was filed against Respondent on September 5, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights form, and Election of Rights forms were sent to Respondent, via certified US mail delivery, on September 18, 2013 (7196 9008 9111 1387 0971). A

signed green receipt card was not returned. A copy of the certified mail receipt is attached as Petitioner's Exhibit B.

3. Thereafter, the Department requested personal service on Respondent, which was successfully completed on October 29, 2013. The affidavit of personal service is attached as Petitioner's Exhibit C.

4. Respondent has not filed with either the Department of Health or the Board of Pharmacy, an Election of Rights form or other responsive pleading in this case within the twenty-one (21) day period to dispute the allegations contained in the Administrative Complaint. Copies of affidavits supporting the same are attached hereto as Petitioner's Exhibits D and E.

5. Rule 28-106.111(2), Florida Administrative Code, provides in pertinent part that:

> . . . persons seeking a hearing on an agency decision which does or may determine their substantial interests shall file a petition for hearing with the agency within 21 days of receipt of written notice of the decision.

6. Rule 28.106.111(4), Florida Administrative Code, provides in pertinent part that:

> . . . any person who received written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters.

7. Respondent has been advised, by a copy of this motion sent to his/her address of record, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

8. The Department has determined that there are no material facts in dispute and has concluded that Respondent has waived his/her right to elect the method of resolution.

9. The Department requests that this Motion and a hearing be placed on the agenda for the next regularly scheduled meeting of the Board of Pharmacy.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived his/her right to elect a method of resolution of this matter, find that there are no material facts in dispute, hold a hearing not involving material issues of disputed fact based on the information contained in the investigative file, find that Respondent violated Chapters 456 and 465, Florida Statutes, as alleged in the Administrative Complaint, impose discipline in accordance with the disciplinary guidelines, and enter a Final Order.

Respectfully submitted,

Ana M. Gargollo-McDonald
Assistant General Counsel
Florida Bar No. 85907
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4681
Email: ana.gargollo-mcdonald@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Determination of Waiver and for Final Order by Hearing Not Involving Disputed Issues of Material Fact has been furnished via U.S. mail this 15th day of January, 2014, to Gene Lachney, 716 Sky Hawk Drive, Pensacola, FL 32506.

Ana M. Gargollo-McDonald
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v.

CASE NO. 2013-06754

GENE R. LACHNEY, RPH,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Gene R. Lachney, and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the State of Florida, having been issued license number PS 28290.

EXHIBIT
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3. Respondent's address of record is 716 Sky Hawk Drive, Pensacola, Florida 32506.

4. At all times material to this Administrative Complaint, Respondent was employed by Cantonment Pharmacy, located at 433 Highway 29 South, Cantonment, Florida 32533.

5. On or about February 4, 2013, the Department of Health Investigator went to Cantonment Pharmacy at 433 Highway 29 South, Cantonment, Florida 32533, and obtained six (6) azithromycin 250 mg tablets, a prescription only medication, without a valid prescription from Respondent.

6. Section 465.015(2)(c), Florida Statutes (2012), it is unlawful for any person to sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription.

7. Azithromycin is an antibiotic that fights bacteria and is a prescription drug.

8. On or about February 4, 2013, Respondent sold or dispensed a drug as defined in Section 465.003(8), Florida Statutes, without first being furnished with a prescription.

9. Based on the foregoing, Respondent violated Section 465.015(2)(c), Florida Statutes (2012), by selling or dispensing drugs as defined in Section 465.003(8), Florida Statutes, without first being furnished with a prescription.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 5th **day of** September, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angela Sanders
DATE: SEP 05 2013

/AGM

PCP: 9/5/13
PCP Members: Meros & Allan

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

7196 9008 9111 1387 0971

TO:

Gene R. Lachney, R.Ph
2013-06754
AM/ab/Stip Pk
Sent 9/18/2013

Gene R. Lachney
716 Sky Hawk Drive
Pensacola, FL 32506

SERVICE	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

EXHIBIT
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Florida Department of Health
Office of the General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-1701
PHONE: 850/245-4444

7196 9008 9111 1387 0971

A. Gargollo-McDonald

VACANT

Gene R. Lachney
716 Sky Hawk Drive
Pensacc

VACANT

C-65

2013 OCT 22 PM 1:22
PRACTITIONER REGULATION
LEGAL

AFFIDAVIT OF SERVICE

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. PS 2013-06754

GENE R. LACHNEY, RPH
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That from 10/28/13-10/29/13, Affiant made a diligent effort to locate Respondent, to serve XX Administrative Complaint and related papers; _____ Order compelling examination(s); _____ Subpoena(s); _____Final order; _____Notice to cease and desist; ____ ESO/ERO and related papers.

3) Check applicable answer below:

XX Affiant made personal service on 10/29/13 by serving the AC to GENE R. LACHNEY, RPh at Cantonment Pharmacy located at 433 Hwy 29 South, Cantonment, FL 32533.

_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of Escambia

Before me, personally appeared Ben Lanier whose identity is known to me by Personally known _____ (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this 29th day of October, 2013.

LORA BOYD
Commission # EE 869098
Expires January 27, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

Notary Public-State of Florida

My Commission Expires

Type or Print Name

Affidavit of Non-Receipt

I, Tammy Collins, hereby certify in my official capacity as custodian for the Board's licensure files that the Board of Pharmacy as of 27 Nov 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Gene R. Lachney, R.Ph.; 2013-06754**, which would affect the Subject's substantial interests or rights.

Tammy Collins
Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Tammy Collins, whose identity is known to me personally and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 5 day of Dec, 2013.

HELAINE ROBISON
MY COMMISSION # EE 138625
EXPIRES: November 17, 2015
Bonded Thru Notary Public Underwriters

Notary Public
My commission expires:

EXHIBIT
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AFFIDAVIT

I, Amy Carraway, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Gene R. Lachney, R.Ph.; 2013-06754**, which would affect the Respondent's substantial interests or rights.

Custodian of Record
Department Clerk's Office

Before me, personally appeared Amy Carraway, whose identity is known to me personally and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 27th day of November, 2013.

Angela Barton
Notary Public

My Commission Expires:

ANGELA BARTON
Notary Public - State of Florida
My Comm. Expires Sep 1, 2017
Commission # FF 49339
Bonded Through National Notary Assn.

EXHIBIT
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STATE OF FLORIDA
DEPARTMENT OF HEALTH

[redacted]

DEPARTMENT OF HEALTH,

PETITIONER,

v.

CASE NO. 2013-06754

GENE R. LACHNEY, R.PH.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Gene R. Lachney, R.Ph., was a licensed pharmacist in the state of Florida, having been issued license number PS 28290. Respondent's mailing address of record is 716 Sky Hawk Drive, Pensacola, Florida 32506.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

3. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

4. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

5. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

6. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

7. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **ONE THOUSAND SEVEN HUNDRED AND FORTY-FIVE DOLLARS** ($1,745.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

8. **CE Course-** Respondent shall successfully complete a Continuing Education Course on the subject of Laws and Rules consisting of 3 hours of credit, which has been approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate

of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

9. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

10. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

11. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

12. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent

authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

13. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

14. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

15. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

16. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 25th day of November, 2013.

Gene R. Lachney, R.PH.
CASE NO. 2013-06754

STATE OF Florida

COUNTY OF Escambia

Before me personally appeared Gene R. Lachney, R.Ph., whose identity is known to me or by personally (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 25 day of November, 2013.

Notary Public
My Commission number:
My Commission Expires:

JOHN T. READING
MY COMMISSION EXPIRES
January 4, 2015
#EE 049147
Bonded thru
Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

APPROVED this _____ day of _____, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

_____
Ana M. Gargollo-McDonald
Assistant General Counsel

Counsel for Petitioner
Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2013-06754

GENE R. LACHNEY, R.PH.,
Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or

after July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto.

3. The investigation and prosecution of this case has resulted in costs in the total amount of $961.00, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	0.50	$27.45
Investigation:	9.90	$615.81
Legal:	3.00	$317.74
Compliance:	0.00	$0.00
Sub Total:	13.40	$961.00
Expenses to Date:		$0.00
Prior		$0.00

Amount:		
Total Costs to Date:		$961.00

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $643.26 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $643.26 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $643.26.

DATED this 15th day of January, 2014.

Ana M. Gargollo-McDonald
Assistant General Counsel
Fla. Bar No. 85907
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: ana.gargollo-mcdonald@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 15th day of January, 2014, to Gene Lachney, 716 Sky Hawk Drive, Pensacola, Florida 32506.

Ana M. Gargollo-McDonald
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

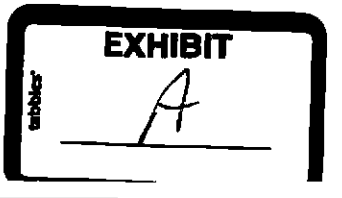
4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2013-06754** (Department of Health v. **GENE R. LACHNEY**) are **NINE HUNDRED SIXTY-ONE DOLLARS AND ZERO CENTS ($961.00).**

6) The costs for DOH case number(s) **2013-06754** (Department of Health v. **GENE R. LACHNEY**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case number(s) **2013-06754** (Department of Health v. **GENE R. LACHNEY**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators



and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 2nd day of December, 2013, by Shane Walters, who is personally known to me.

Notary Signature

TOWANDA B. BURNETT
Commission # EE 838342
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Towanda B. Burnett

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201306754

Subject's Name: LACHNEY, GENE R

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.50	$27.45
Investigatiun:	9.90	$615.81
Legal:	3.00	$317.74
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	13.40	$961.00
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$961.00

EXHIBIT

1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201306754

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA167	0.50	$54.90	$27.45	04/30/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	0.50		**$27.45**			
INVESTIGATIVE SERVICES UNIT						
BI35	0.20	$63.98	$12.80	05/02/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.40	$63.98	$25.59	05/02/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/06/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/06/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/10/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/14/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/14/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/15/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	05/15/2013	76	REPORT PREPARATION
BI35	0.30	$63.98	$19.19	05/17/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/17/2013	76	REPORT PREPARATION
BI35	0.50	$63.98	$31.99	05/30/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.50	$63.98	$31.99	05/30/2013	76	REPORT PREPARATION
BI35	0.30	$63.98	$19.19	05/31/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	05/31/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/05/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/14/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	06/14/2013	76	REPORT PREPARATION
BI35	0.30	$63.98	$19.19	06/26/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	06/26/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/27/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	06/27/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	06/28/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	06/28/2013	76	REPORT PREPARATION

EXHIBIT

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201306754

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
BI35	0.50	$63.98	$31.99	07/01/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	07/01/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	07/02/2013	76	REPORT PREPARATION
BI35	0.50	$63.98	$31.99	07/03/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	07/08/2013	76	REPORT PREPARATION
BI35	0.60	$63.98	$38.39	07/22/2013	6	SUPPLEMENTAL INVESTIGATION
BI35	0.70	$63.98	$44.79	07/30/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	07/31/2013	76	REPORT PREPARATION
BI35	0.20	$46.35	$9.27	10/29/2013	6	SUPPLEMENTAL INVESTIGATION
BI35	0.30	$46.35	$13.91	10/29/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
BI35	0.50	$46.35	$23.18	10/29/2013	76	REPORT PREPARATION
Sub Total	9.90		**$615.81**			

PROSECUTION SERVICES UNIT

HLL106A	0.20	$106.35	$21.27	07/12/2013	25	REVIEW CASE FILE
HLL106A	0.20	$106.35	$21.27	07/16/2013	36	PREPARATION OR REVISION OF LETTER
HLL106A	1.00	$106.35	$106.35	08/02/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL106A	0.80	$106.35	$85.08	09/18/2013	90	POST PROBABLE CAUSE PROCESSING
HLL106A	0.20	$106.35	$21.27	10/07/2013	25	REVIEW CASE FILE
HLL106A	0.20	$106.35	$21.27	10/07/2013	25	REVIEW CASE FILE
HLL106A	0.10	$106.35	$10.64	10/24/2013	37	REVIEW LETTER
HLL106A	0.10	$101.95	$10.20	10/28/2013	37	REVIEW LETTER
HLL106A	0.20	$101.95	$20.39	11/01/2013	103	REVIEW SUPPLEMENTAL REPORT
Sub Total	3.00		**$317.74**			

Total Cost **$961.00**

Time Tracking System
Itemized Cost by Complaint

Complaint 201306754

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/02/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Gene R. Lachney, R.Ph. (AMM)**
Case Number: 2013-06754

MEMBERS: ~~**Cynthia Griffin, PharmD**~~ **and Jeffrey Mesaros**

DATE OF PCP: **September 5, 2013** **AGENDA ITEM: A-17**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.015(2)(c), Florida Statutes (2012);

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

____ Upon **reconsideration**, dismiss

____ **other**

9/5/13

Chair, Probable Cause Panel
Board of Pharmacy

Date

CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498
Insp # 86062

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES
Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
CANTONMENT PHARMACY INC	2748	9/22/2009
DOING BUSINESS AS	DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 433 HIGHWAY 29 S	TELEPHONE # 850-968-2489 EXT.	JOHN T READING
CITY CANTONMENT / COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #
1. Benjamin Fenn PS 13028
2. Johnny Reading PTech
3. Karen Bonanno PTech

	SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]		X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]		X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]		X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]		X	
5	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]		X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]		X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]		X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.)		X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.		X	
10	Generic drug sign displayed. [465.025(7),F.S.]		X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]		X	
12	Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*	X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]		X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]		X	
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]		X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]		X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]		X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]		X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]		X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]		X	
21	Medication properly labeled [64B16-27.101,F.A.C.]			X
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]		X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]		X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]		X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]		X	

	SATISFACTORY	N/A	YES	NO
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]		X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7.F.A.C.]		X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]		X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]		X	
30	Controlled substance records readily retrievable. [893.07,F.S.]		X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]		X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]		X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]		X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]		X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]		X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]		X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]		X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]		X	
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]		X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]		X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*		X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]		X	
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]		X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *		X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *	X		
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *	X		
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *	X		

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Missy Shores PTech. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #21 Two bottles of OTC drug in pharmacy stock without expiration date. #23 Last CQI meeting 9-15-2009. #39 CS inventory 5-1-2009. #44 Logbook. Rx drug purchases from Smith Drug, AmerisourceBergen, Masters, & Top Rx.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative

09-22-2009
Date

Investigator/Sr. Pharmacist Signature

ID CI20

INV 359 Revised 01/07 Replaces 12/02

Exhibit 3

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498

Insp # 94915

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
CANTONMENT PHARMACY INC	2748	10/18/2010
DOING BUSINESS AS	DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 433 HIGHWAY 29 S	TELEPHONE # 850-968-2489 EXT.	JOHN T READING
CITY CANTONMENT / COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Wilton Glover PS 7751
3. Melissa Shores RPT 21008

	SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]		X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]		X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]		X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]		X	
5	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]		X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]		X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]		X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]		X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.		X	
10	Generic drug sign displayed. [465.025(7),F.S.]		X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]		X	
12	Sign with meal break hours of Pharmacist. (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*	X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]		X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]		X	
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]		X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]		X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]		X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]		X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]		X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]		X	
21	Medication properly labeled [64B16-27.101,F.A.C.]		X	
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]		X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]		X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]		X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]		X	
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]		X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]		X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]		X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]		X	
30	Controlled substance records readily retrievable. [893.07,F.S.]		X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]		X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]		X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]		X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]		X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]		X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]		X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]		X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]		X	
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]		X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]		X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*		X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]		X	
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]		X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (a),F.A.C.] *		X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *		X	
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *		X	
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *		X	

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Leslie Johnson RPT 21005; John Reading, Jr. RPT 21007. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter: 6-22-1994. #23 Last CQI meeting #39 CS inventory #43 Book - OK. #44 Logbook. Rx drug purchases from Smith Drug-Valdosta and AmerisourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative

10-18-2010
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

: 00028

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498
Insp # 103821

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
CANTONMENT PHARMACY INC		2748		1/23/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
		Ac5573767		
STREET ADDRESS		TELEPHONE #	EXT.	JOHN T READING
433 HIGHWAY 29 S		850-968-2489		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
CANTONMENT	27	32533-1401		10065

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	1. Joseph Gibson PS 26203	
Open	9am	9am	9am	9am	9am	9am	closed	2. Benjamin Fenn PS 13028	
Close	6pm	6pm	6pm	6pm	6pm	3pm		3. Melissa Shores RPT 21008	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]			X	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	X			
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19	DEA 222 order forms properly completed. [893.07, F.S.]			X	
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			X	
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	X			
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	X			
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]			X	
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	X			
28	Compounding records properly maintained. [64B16-27.700, F.A.C.]*	X			
29	Unit dose records properly maintained. [465.016(1)(i), F.S.] [64B16-28.118, F.A.C.]	X			
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Adam Bass RPT 21001; John Reading RPT 21007; Karin Bonano RPT 21006; Leslie Johnson RPT 21005. DEA expires 8-31-2014. #2 Tech ratio letter 6-22-1994. #11 Last CQI meeting 9-1-2011. #12 Future requirement. #18 CS inventory 5-1-2011. #22 Logbook. #23 One incident - Escambia CSO. #24 None since 7-1-2011.
CII prescription file survey (60Rxs): Local Practitioner - 97%; Local Patient - 100%; Pain Therapy - 78%; Non-pain Therapy - 22%.
No batch compounding. No compounding for practitioner office stock.
Rx drug suppliers: Smith Drug-Valdosta; AmericansourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Joseph Gibson, RPh

Institutional Representative

01-23-2012
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

: 00029

CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201216087

CANTONMENT PHARMACY INC,
RESPONDENT.

NOTICE

TO: CANTONMENT PHARMACY INC
433 HIGHWAY 29 SOUTH
CANTONMENT, FL 32533

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Determination of Waiver

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Ana Gargollo-McDonald, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Cantonment Pharmacy Inc
DOH Case Number 2012-16087
DATE: February 12, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Cantonment Pharmacy Inc
Subject's Address of Record:	433 Highway 29 S Cantonment, FL 32533-1401
Enforcement Address:	433 Highway 29 South Cantonment, FL 32533
Subject's License No:	2748 **Rank:** PH
Licensure File No:	498
Initial Licensure Date:	
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	465.023(1)(c), FS (2012) 465.015(2)(c), FS (2012)
Prior Discipline:	Case #16929, Reprimand
Probable Cause Panel:	September 5, 2013; Mesros & Glass
Subject's Attorney:	Pro Se
Complainant/Address:	Preston E McDonald 5740 Westmont Road Milton, FL 32583

Materials Submitted:

Memorandum to the Board
Motion For Determination of Waiver
Exhibit A - Administrative Complaint
Exhibit B – Copy of Certified Mail Receipt
Exhibit C – Affidavit of Service
Exhibit D – Board Affidavit
Exhibit E – Clerks Affidavit
Motion to Assess Costs with Attachments
Exhibit A – Affidavit of Fees and Costs Expended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
Supplemental Investigative Report dated 7/31/13
Supplemental Investigative Report dated 10/29/13
Probable Cause Memorandum
Correspondence
Final Investigative Report with Exhibits 1-9

Disciplinary Guidelines:
456.023(1)(c), Florida Statutes (2012):
From an administrative fine of up $1,500 fine to Revocation

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

This is a one-count administrative complaint alleging Respondent violated Section 456.023(1)(c), Florida Statutes (2012), by violating Section 465.015(2)(c), Florida Statutes, (2012), by selling or dispensing drugs as defined in s. 465.003(8) without first being furnished with a prescription.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. **CASE NO. 2012-16087**

CANTONMENT PHARMACY, INC.,
Respondent.
_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

Petitioner, Department of Health, by and through counsel, moves the Board of Pharmacy to find that Respondent has waived his/her right to elect a method of disposition of the pending Administrative Complaint, to determine that no material facts are in dispute, to conduct a hearing not involving disputed issues of material fact, and to enter a Final Order. As grounds therefore, Petitioner states:

1. An Administrative Complaint was filed against Respondent on September 5, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights form, and Election of Rights forms were sent to Respondent, via certified US mail delivery, on September 18, 2013 (7196 9008 9111 1387 0964). A signed

green receipt card was not returned. A copy of the certified mail receipt is attached as Petitioner's Exhibit B.

3. Thereafter, the Department requested personal service on Respondent, which was completed on October 29, 2013. The affidavit of personal service is attached as Petitioner's Exhibit C.

4. Respondent has not filed with either the Department of Health or the Board of Pharmacy, an Election of Rights form or other responsive pleading in this case within the twenty-one (21) day period to dispute the allegations contained in the Administrative Complaint. Copies of affidavits supporting the same are attached hereto as Petitioner's Exhibits D and E.

5. Rule 28-106.111(2), Florida Administrative Code, provides in pertinent part that:

> . . . persons seeking a hearing on an agency decision which does or may determine their substantial interests shall file a petition for hearing with the agency within 21 days of receipt of written notice of the decision.

6. Rule 28.106.111(4), Florida Administrative Code, provides in pertinent part that:

> . . . any person who received written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters.

7. Respondent has been advised, by a copy of this motion sent to his/her address of record, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

8. The Department has determined that there are no material facts in dispute and has concluded that Respondent has waived his/her right to elect the method of resolution.

9. The Department requests that this Motion and a hearing be placed on the agenda for the next regularly scheduled meeting of the Board of Pharmacy.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived his/her right to elect a method of resolution of this matter, find that there are no material facts in dispute, hold a hearing not involving material issues of disputed fact based on the information contained in the investigative file, find that Respondent violated Chapters 456 and 465, Florida Statutes, as alleged in the Administrative Complaint, impose discipline in accordance with the disciplinary guidelines, and enter a Final Order.

Respectfully submitted,

Ana M. Gargollo-McDonald
Assistant General Counsel
Florida Bar No. 85907
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4681
Email: ana.gargollo-mcdonald@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Determination of Waiver and for Final Order by Hearing Not Involving Disputed Issues of Material Fact has been furnished via U.S. mail this 9th day of December, 2013, to Cantonment Pharmacy, Inc., 433 Highway 29 South, Cantonment, Florida 32533.

Ana M. Gargollo-McDonald
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2012-16087

CANTONMENT PHARMACY, INC.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Cantonment Pharmacy, Inc., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted pharmacy within the State of Florida, having been issued license number PH 2748.

EXHIBIT
A

3. Respondent's address of record is 433 Highway 29 South, Cantonment, Florida 32533.

4. On or about February 4, 2013, the Department of Health Investigator went to Respondent's address of record at 433 Highway 29 South, Cantonment, Florida 32533, and obtained six (6) azithromycin 250 mg tablets, a prescription only medication, without a valid prescription.

5. Section 465.015(2)(c), Florida Statutes (2012), it is unlawful for any person to sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription.

6. Azithromycin is an antibiotic that fights bacteria and is a prescription drug.

7. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee, if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, violates any of the requirements of Chapter 465, Florida Statutes, Chapter 893, Florida Statutes, or any of the rules of the Board of Pharmacy.

8. As set forth above in paragraph 4, on or about February 4, 2013, Respondent, or any affiliated person, partner, officer, director, or agent of Respondent violated Section 465.015(2)(c), Florida Statutes (2012).

9. Based on the foregoing, Respondent, or any affiliated person, partner, officer, director, or agent of Respondent, has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Section 465.015(2)(c), Florida Statutes (2012), by selling or dispensing drugs as defined in s. 465.003(8) without first being furnished with a prescription.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 5th **day of** September, **2013.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK: Angela Sanders
DATE: SEP 05 2013

/AGM

PCP: 9/5/2013
PCP Members: Mesros & Glass

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

7196 9008 9111 1387 0964

TO:

Cantonment Rx
2012-16087
AM/ab/Stip Pk
Sent 9/18/2013

Cantonment Pharmacy, Inc.
433 Highway 29 South
Cantonment, FL 32533

RECEIPT SERVICE		
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

USPS®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

EXHIBIT
B

USPS Tracking™

Customer Service ›
Have questions? We're here to help.

Tracking Number: 71969008911113870964

Requested label is archived.

Restore Archived Details ›

Product & Tracking Information

Postal Product:

Features:
Certified Mail™

[redacted]

September 25, 2013 , 9:32 am	Delivered	CANTONMENT, FL 32533

Available Options

Track Another Package

What's your tracking (or receipt) number?

Track It

AFFIDAVIT OF SERVICE

DEPARTMENT OF HEALTH
Petitioner

vs

Case No. PH 2012-16087

CANTONMENT PHARMACY
Respondent

COMES NOW, the affiant, who first being duly swom, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That from 10/28/13-10/29/13, Affiant made a diligent effort to locate Respondent, to serve XX Administrative Complaint and related papers; _____ Order compelling examination(s); ____ Subpoena(s); _____Final order; _____Notice to cease and desist; ____ ESO/ERO and related papers.

3) Check applicable answer below:

XX Affiant made personal service on 10/29/13 by serving the AC to GENE R. LACHNEY, RPh at Cantonment Pharmacy located at 433 Hwy 29 South, Cantonment, FL 32533.

_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of Escambia

Before me, personally appeared Ben Lanier whose identity is known to me by Personally known _____ (type of identification) and who, acknowledges that his/her signature appears above.

Swom to or affirmed by Affiant before me this 29th day of October, 2013.

LORA BOYD
Commission # EE 869098
Expires January 27, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

Notary Public-State of Florida

My Commission Expires

Type or Print Name

Affidavit of Non-Receipt

I, Tommy Collins, hereby certify in my official capacity as custodian for the Board's licensure files that the Board of Pharmacy as of 26 Nov 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Cantonment Pharmacy, Inc.; 2012-16087**, which would affect the Subject's substantial interests or rights.

Tommy Collins
Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Tommy Collins, whose identity is known to me personally and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 5 day of Dec, 2013.

HELAINE ROBISON
MY COMMISSION # EE 138625
EXPIRES: November 17, 2015
Bonded Thru Notary Public Underwriters

Notary Public
My commission expires:

AFFIDAVIT

I, Amy Carraway, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Cantonment Pharmacy, Inc.; 2012-16087**, which would affect the Respondent's substantial interests or rights.

Amy Carraway
Custodian of Record
Department Clerk's Office

Before me, personally appeared Amy Carraway, whose identity is known to me personally and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 27th day of November, 2013.

Angela Barton
Notary Public

My Commission Expires:

ANGELA BARTON
Notary Public - State of Florida
My Comm. Expires Sep 1, 2017
Commission # FF 49339
Bonded Through National Notary Assn.

EXHIBIT
E

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-16087

CANTONMENT PHARMACY, INC.,
Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or

> after July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto.

3. The investigation and prosecution of this case has resulted in costs in the total amount of $1,421.71, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	0.60	$32.94
Investigation:	13.50	$846.78
Legal:	5.10	$541.99
Compliance:	0.00	$0.00
Sub Total:	19.20	$1,421.71
Expenses to Date:		$0.00
Prior		$0.00

Amount:		
Total Costs to Date:		$1,421.71

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $879.72 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $879.72 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $879.72.

DATED this 9th day of December, 2013.

Ana M. Gargollo-McDonald
Assistant General Counsel
Fla. Bar No. 85907
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: ana.gargollo-mcdonald@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 9th day of December, 2013, to Cantonment Pharmacy, Inc., 433 Highway 29 South, Cantonment, Florida 32533.

Ana M. Gargollo-McDonald
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

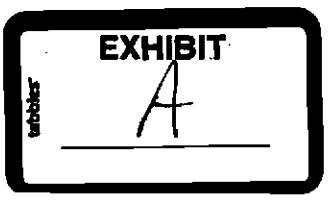
4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-16087** (Department of Health v. **CANTONMENT PHARMACY, INC.**) are **ONE THOUSAND FOUR HUNDRED TWENTY-ONE DOLLARS AND SEVENTY-ONE CENTS ($1,421.71).**

6) The costs for DOH case number(s) **2012-16087** (Department of Health v. **CANTONMENT PHARMACY, INC.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case number(s) **2012-16087** (Department of Health v. **CANTONMENT PHARMACY, INC.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators



and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 2nd day of December, 2013, by Shane Walters, who is personally known to me.

Notary Signature

TOWANDA B. BURNETT
Commission # EE 838342
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Towanda Burnett

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201216087

Subject's Name: CANTONMENT PHARMACY INC

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.60	$32.94
Investigation:	13.50	$846.78
Legal:	5.10	$541.99
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	19.20	$1,421.71
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,421.71

EXHIBIT

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216087

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA115	0.50	$54.90	$27.45	10/30/2012	7	PRELIMINARY INVESTIGATION
HA115	0.50	$54.90	$27.45	04/11/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA115	0.10	$54.90	$5.49	05/16/2013	144	CSU INVESTIGATIVE WORK
Sub Total	**1.10**		**$60.39**			
INVESTIGATIVE SERVICES UNIT						
BI35	0.10	$61.19	$6.12	11/16/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$61.19	$12.24	11/20/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/26/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/27/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/30/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$61.19	$6.12	11/30/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	12/05/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	12/11/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	12/13/2012	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	12/19/2012	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/08/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/09/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/11/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	01/11/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	01/17/2013	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	01/28/2013	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	01/31/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	02/04/2013	58	TRAVEL TIME
BI35	0.10	$63.98	$6.40	02/04/2013	7	PRELIMINARY INVESTIGATION
BI35	0.50	$63.98	$31.99	02/05/2013	7	PRELIMINARY INVESTIGATION
BI35	0.20	$63.98	$12.80	02/08/2013	7	PRELIMINARY INVESTIGATION
BI35	0.10	$63.98	$6.40	03/28/2013	7	PRELIMINARY INVESTIGATION

EXHIBIT
number 2

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201216087

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
BI35	0.30	$63.98	$19.19	04/01/2013	76	REPORT PREPARATION
BI35	0.30	$63.98	$19.19	04/05/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	04/17/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	04/17/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	04/18/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	04/18/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	05/02/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/02/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/06/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/06/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/10/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/14/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	05/15/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	05/15/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	05/16/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.10	$63.98	$6.40	05/17/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	05/17/2013	76	REPORT PREPARATION
BI35	0.40	$63.98	$25.59	05/30/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.40	$63.98	$25.59	05/30/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/05/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/14/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	06/14/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	06/26/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	06/26/2013	76	REPORT PREPARATION
BI35	0.40	$63.98	$25.59	06/27/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.30	$63.98	$19.19	06/27/2013	76	REPORT PREPARATION
BI35	0.10	$63.98	$6.40	06/28/2013	4	ROUTINE INVESTIGATIVE WORK
BI35	0.20	$63.98	$12.80	06/28/2013	76	REPORT PREPARATION
BI35	0.70	$63.98	$44.79	07/01/2013	76	REPORT PREPARATION
BI35	0.30	$63.98	$19.19	07/02/2013	76	REPORT PREPARATION
BI35	0.50	$63.98	$31.99	07/03/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	07/08/2013	76	REPORT PREPARATION
BI35	0.60	$63.98	$38.39	07/22/2013	6	SUPPLEMENTAL INVESTIGATION

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
BI35	0.10	$63.98	$6.40	07/30/2013	6	SUPPLEMENTAL INVESTIGATION
BI35	0.60	$63.98	$38.39	07/30/2013	76	REPORT PREPARATION
BI35	0.20	$63.98	$12.80	07/31/2013	76	REPORT PREPARATION
BI35	0.10	$46.35	$4.64	10/29/2013	6	SUPPLEMENTAL INVESTIGATION
BI35	0.30	$46.35	$13.91	10/29/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
BI35	0.20	$46.35	$9.27	10/30/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**13.00**		**$819.33**			

PROSECUTION SERVICES UNIT

HLL106A	0.70	$106.35	$74.45	07/12/2013	25	REVIEW CASE FILE
HLL106A	0.20	$106.35	$21.27	07/15/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFF
HLL106A	0.10	$106.35	$10.64	07/15/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	07/15/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	07/16/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	07/16/2013	35	TELEPHONE CALLS
HLL106A	0.30	$106.35	$31.91	07/16/2013	36	PREPARATION OR REVISION OF LETTER
HLL106A	0.20	$106.35	$21.27	07/22/2013	115	CONTACT WITH INVESTIGATORS
HLL106A	0.10	$106.35	$10.64	07/30/2013	35	TELEPHONE CALLS
HLL106A	0.10	$106.35	$10.64	07/30/2013	35	TELEPHONE CALLS
HLL106A	0.20	$106.35	$21.27	08/02/2013	103	REVIEW SUPPLEMENTAL REPORT
HLL106A	1.10	$106.35	$116.99	08/02/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL106A	0.10	$106.35	$10.64	09/06/2013	37	REVIEW LETTER
HLL106A	0.90	$106.35	$95.72	09/18/2013	90	POST PROBABLE CAUSE PROCESSING
HLL106A	0.20	$106.35	$21.27	10/07/2013	25	REVIEW CASE FILE
HLL106A	0.20	$106.35	$21.27	10/07/2013	25	REVIEW CASE FILE
HLL106A	0.10	$101.95	$10.20	10/28/2013	37	REVIEW LETTER
Sub Total	**5.10**		**$541.99**			

Time Tracking System
Itemized Cost by Complaint

Complaint 201216087

Report Date 12/02/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
Total Cost			**$1,421.71**			

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 12/02/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PH 2012-16087

Subject:	Source:
CANTONMENT PHARMACY, INC 433 Highway 29 South Cantonment, FL 32533 (850) 968-2489	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PH	2748	PHARMACY	PHARMACY	7/31/13

Period of Investigation: 7/17/13-7/31/13	Type of Report: SUPPLEMENTAL 1

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. **(n)** Exercising influence on the patient or client for the purpose of financial gain **(dd)** Violating any provision of this chapter, **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. **(r)** Violating any provision of this chapter .... **and FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy;

Synopsis: This supplemental report is predicated upon receipt of a PSU Request Form on 7/17/13 from BLONDELL HELLER-HUTCHINSON for ANA GARGOLLO-MCDONALD, Attorney, requesting the Chloraspetic with Lidocaine added purchased on 3/28/13 be tested for the drug. **(EXHIBIT S1-1)**.

INTERVIEW OF ED HUDSON, SUPERVISOR–WITNESS:

Employment: FDLE
1301 N. Palafox Street
Pensacola, FL 32501
(850) 595-2006

On 7/15/13, Investigator Supervisor CATHY MARTIN contacted HUDSON by telephone to inquire who to speak with about testing the evidence in their lab. HUDSON referred Investigator Supervisor MARTIN to the FDLE Chemistry Supervisor, JOEY GRAVES.

INTERVIEW OF JOEY GRAVES, LAB SUPERVISOR–WITNESS:

Employment: FDLE
1301 N. Palafox Street
Pensacola, FL 32501
(850) 595-2077

On 7/15/13, Investigator Supervisor MARTIN attempted to telephone GRAVES; however, his voice mail message stated he was out and would not return until the following week.

RECEIVED-LEGAL
13 AUG -1 PM 2:53

CONTINUED ...

Related Cases: RPT 2012-16092, RPT 2012-16089, PS 2012-16091, PS 2012-16088, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
Ben Lanier 7/31/13	Cathy Martin 7/31/13
Ben Lanier, BI-35, Investigator	Cathy Martin, Investigator Supervisor

Received
Investigative Services
AUG 01 2013

Distribution: HQ/ISU

DOH/MQA
Tallahassee HQ

On 7/22/13, Investigator Supervisor CATHY MARTIN contacted GRAVES by telephone and asked about the possibility of testing for Lidocaine in the bottle of Chloraseptic. GRAVES stated Lidocaine was not a controlled substance and he therefore would only be able to confirm whether Lidocaine was in the Chloraseptic, but not the quantity. He stated he would need an Originating Agency Identifier (ORI) for intake of the Chloraseptic. Investigator Supervisor MARTIN explained DOH was not a law enforcement agency and probably did not have an ORI. GRAVES stated he would check and call back. He did so shortly after and stated he confirmed DOH did not have an ORI and he therefore could not accept and analyze the Chloraseptic. GRAVES referred Investigator Supervisor MARTIN to NMS labs.

INTERVIEW OF DANIELLE FARINA, STAFF–WITNESS:
Employment: NMS Labs
2300 Strattford Ave
Willengrove, PA19090
(866) 522-2216

On 7/22/13, Investigator LANIER interviewed FARINA by telephone. FARINA stated they could test Chloraseptic for Lidocaine. FARINA stated the lab could simply test for the presence of Lidocaine and the testing code was 72101LI.. FARINA stated the cost would be $369.00 and the turnaround time was about two weeks. FARINA stated the lab could also test for the quantity of Lidocaine in the bottle. FARINA stated the cost would be $576.00 and the turnaround time was about three weeks. FARINA stated there would also be a fee to return the specimen if it was needed. FARINA stated if the Chloraseptic was going to be sent to them then the proper forms would be need to be filled out which could be found at nmslabs.com.

INVESTIGATOR'S NOTE: On 7/22/13, Investigator LANIER called the local Quest Diagnostics lab and staff informed they only test patients and not evidence. On the same date, Investigator LANIER searched for other labs that might offer to test the Lidocaine. Investigator LANIER telephoned Avomeen lab at (800) 930-5450 and staff informed they do not perform those test regularly, but that it could be done for about $2,500.00. On the same date, Investigator LANIER telephoned Central Florida Testing Lab and staff informed that test could not be performed in their lab. On the same date, Investigator LANIER attempted to speak with staff at OAS lab at (800) 695-7222; however, no one answered the call and a voicemail message was left requesting a return call. As of the completion of this report the call was not returned.

On 7/22/13, Investigator LANIER provided the cost information to PSU and was informed the matter would be reviewed and a decision made whether to proceed with the testing.

On 7/30/13, Investigator LANIER followed up with PSU and was informed the testing would not be necessary at this time due to the cost.

EXHIBITS:
S1-1. PSU Request Form **(p. 3)**

FLORIDA DEPARTMENT OF HEALTH

Department of Health

JUL 17 2013

PSU REQUEST FORM

ISU/Pensacola

BL35

FROM: Blondell Heller-Hutchison for Ana Gargollo-McDonald, Esq.	TO: ISU Cathy Martin
Date: 7/17/2013	TO: CSU
Phone #: (850) 245-4444 ext. 8133	CC: Ben Lanier, Investigator

Case Number: 2012-16087
Subject: **Cantonment Pharmacy, Inc.**
Requested Completion Date: **8/17/2013**
Board: **Pharmacy**
HL Code: **HLL106A** Status: **67**

(PSU) TYPE OF REQUEST: (describe details below)

- ☐ Process Service* (**Activity Code 160**)
- ☒ Additional Information Requested (**Activity Code 145**)
- ☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Attorney Ana M. Gargollo-McDonald is requesting the Investigator to obtain a requesting for the Chloraseptic that was purchased on March 28, 2013, be tested to find out if any substance, chemical, or drug was added. If the investigator has any additional questions concerning this request please contact attorney Ana Gargollo-McDonald at (850) 245-4444 ext. 8133. Thanking you in advance,

*The following additional information is needed for each service request:
Last Known Address: **433 Highway 29 South, Cantonment, Florida 32533**
Last Known Name & Phone Number: **(850) 968-2489**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☒** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

- ☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)
- ☑ Additional Info Sent to Legal (Activity Code 156)
- ☐ Supp. Investigation Request Cancelled (Activity Code 157)

RECEIVED-LEGAL
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INV FORM 376, Revised 1/12. 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

Exhibit S1-1

Heller-Hutchison, Blondell

From: Heller-Hutchison, Blondell
Sent: Wednesday, July 17, 2013 3:24 PM
To: DL MQA Inv Serv Priority Mail Area1 (BI) Pensacola
Cc: Martin, Cathy S; Lanier, Ben O; Gargollo-McDonald, Ana
Subject: Additional Information Request
Signed By: Blondell_Heller-Hutchison@doh.state.fl.us
Attachments: Cantoment Pharmacy, Inc., (PH, 12-16087) Additional Information Request.doc

Cathy,
Please see the attached additional information request. If you have ony further questions or concerns concerning this request please contact Attorney Ana M. Gargollo-McDonald at (850) 245-4444 ext. 8133 or myself at (850) 245-4444 ext 8109.

Thanking you in advance,

Blondell Heller-Hutchison, MSW, Regulatory Specialist, II
Assistant to Casey L. Cowon & Lauren A. Leikom
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
(850) 245-4444 ext. 8109
(850) 245-4683 Fax Number:
blondell_heller-hutchison@doh.state.fl.us

DOH Mission:

To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

Vision statement: Healthiest State in the Nation.

DOH Values: I.C.A.R.E.

Innovation: We search for creative solutions and manage resources wisely.

Collaboration:We use teamwork to achieve common goals & solve problems.

Accountability:We perform with integrity & respect.

Responsiveness:We achieve our mission by serving our customers & engaging our partners.

Excellence:We promote quality outcomes through learning & continuous performance improvement.

Please visit www.CEAtRenewal.com to learn more.

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Blondell Heller-Hutchison for Ana Gargollo-McDonald, Esq.	TO: ISU Cathy Martin
Date: 7/17/2013	TO: CSU
Phone #: (850) 245-4444 ext. 8133	CC: Ben Lanier, Investigator

Case Number: 2012-16087
Subject: **Cantonment Pharmacy, Inc.**
Requested Completion Date: **8/17/2013**
Board: **Pharmacy**
HL Code: **HLL106A** Status: **67**

(PSU) TYPE OF REQUEST: (describe details below)

☐ Process Service* (**Activity Code 160**)

☒ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Attorney Ana M. Gargollo-McDonald is requesting the Investigator to obtain a requesting for the Chloraseptic that was purchased on March 28, 2013, be tested to find out if any substance, chemical, or drug was added. If the investigator has any additional questions concerning this request please contact attorney Ana Gargollo-McDonald at (850) 245-4444 ext. 8133. Thanking you in advance,

*The following additional information is needed for each service request:
Last Known Address: **433 Highway 29 South, Cantonment, Florida 32533**
Last Known Name & Phone Number: **(850) 968-2489**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☒** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

FLORIDA DEPARTMENT OF HEALTH

Email to:										
Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PH 2012-16087

Subject:	Source:
CANTONMENT PHARMACY, INC 433 Highway 29 South Cantonment, FL 32533 (850) 968-2489	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PH	2748	PHARMACY	PHARMACY	10/29/13

Period of Investigation: 10/28/13-10/29/13	Type of Report: SUPPLEMENTAL 2

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. (n) Exercising influence on the patient or client for the purpose of financial gain **(dd)** Violating any provision of this chapter, **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. **(r)** Violating any provision of this chapter ... **and FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy;

Synopsis: This supplemental report is predicated upon receipt of a PSU Request Form on 10/28/13 from BLONDELL HELLER-HUTCHINSON for ANA GARGOLLO-MCDONALD, Attorney, requesting hand service of the Administrative Complaint (AC) and related documents to CANTONMENT PHARMACY **(EXHIBIT S2-1)**.

INTERVIEW OF GENE R. LACHNEY, RPH–WITNESS:

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

On 10/28/13, Investigator LANIER called CANTONMENT PHARMACY and spoke to LACHNEY. Investigator LANIER informed LACHNEY that an AC needed to be served to CANTONMENT PHARMACY. On the same date, Investigator LANIER provided the AC and related documents for CANTONMENT PHARMACY to LACHNEY at CANTONMENT PHARMACY. LACHNEY stated he would provide the pharmay's documentation to JOHN READING, Owner, PDM. An Affidavit of Service is included as **Exhibit S2-2**.

RECEIVED-LEGAL
13 OCT 31 PM 2:59

EXHIBITS:

S2-1. PSU Request Form with AC and related documents **(pp. 2-23)**
S2-2. Affidavit of Service **(p. 24)**

Related Cases: RPT 2012-16092, RPT 2012-16089, PS 2012-16091, PS 2012-16088, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
Ben Lanier 10/29/13	Cathy Martin 10/30/13
Ben Lanier, BI-35, Investigator	Cathy Martin, Investigator Supervisor

Received
Investigative Services
OCT 31 2013

Distribution: HQ/ISU

Tallahassee HQ

Department of Health

FLORIDA DEPARTMENT OF HEALTH

OCT 28 2013

ISU/Pensacola

PSU REQUEST FORM

B1.35

FROM: Blondell Heller-Hutchison for Ana M. Gargollo-McDonald, Esq.	TO: ISU Cathy Martin
Date: 10/28/2013	TO: CSU
Phone #: (850) 245-4444 ext. 8133	CC: Ben Lanier, Investigator

Case Number: 2012-16087
Subject: **Cantonment Pharmacy, Inc.**
Requested Completion Date: **11/28/2013**
Board: **Pharmacy**
HL Code: **HLL106a** Status: **87**

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **Please have the attached Administrative Complaint, Election of Rights and Stipulation hand served. The respondent's mail is being returned "attempt not known". If the Subject cannot be located, please have a supplemental prepared within thirty (30) days of receipt of this memo along with an affidavit of diligent service/search. Please check the licensure screen as well for hand service. Please complete an Accurint check on this respondent if she cannot be located at the address above. Please state in the affidavit the type of method you used to identify the respondent. Thanking you in advance**

*The following additional information is needed for each service request:
Last Known Address: **433 Highway 29 South, Cantonment, Florida 32533**
Last Known Name & Phone Number: **(850) 968-2489**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☒** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
**IF YES, please send a copy of the original Investigative Report without attachments.

(ISU/CSU) RESPONSE:

☒ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

INV FORM 376, Revised 1/12, 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

13 OCT 31 PM 2:59 RECEIVED-LEGAL

Exhibit S2-1

FLORIDA DEPARTMENT OF HEALTH

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to:

Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Contonment Pharmacy, Inc. (AMM)**
Case Number: 2012-16087

MEMBERS: **Cynthia ~~Griffin~~ Glass, PharmD and Jeffrey Mesaros**

DATE OF PCP: **September 5, 2013** **AGENDA ITEM: A-15**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating Section 465.015(1)(c), Florida Statutes (2012);

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss

___ **other** +

9/5/13

Chair, Probable Cause Panel
Board of Pharmacy

Date

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-16087**

CANTONMENT PHARMACY, INC.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Cantonment Pharmacy, Inc., was a permitted pharmacy within the State of Florida, having been issued license number PH 2748. Respondent's mailing address of record is 433 Highway 29 South, Cantonment, Florida 32533.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

3. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

4. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

5. **Appearance**- Respondent shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

6. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

7. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **TWO THOUSAND TWO HUNDRED AND FORTY-FIVE DOLLARS** ($2,245.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk.

8. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto; or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

9. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute

a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

10. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

11. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice

the Board or any of its members from further participation, consideration, or resolution of these proceedings.

12. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

13. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

14. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

15. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 2nd day of December, 2013.

CANTONMENT PHARMACY, INC.
CASE NO. 2012-16087

STATE OF Florida

COUNTY OF Escambia

Before me personally appeared John T. Reading, SR, whose identity is known to me or by _____ (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 2nd day of December, 2013.

Notary Public

My Commission number:

My Commission Expires:

BENJAMIN V. FENN
Commission # EE 855488
Expires March 31, 2017
Bonded Thru Troy Fain Insurance 800-385-7019

APPROVED this _____ day of _____, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

_____
Ana M. Gargollo-McDonald
Assistant General Counsel

Counsel for Petitioner
Ana M. Gargollo-McDonald
Assistant General Counsel
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Fla. Bar No. 0085907
Telephone: (850) 245-4444 Ext. 8133
Facsimile: (850) 245-4683
ana_gargollo-mcdonald@doh.state.fl.us

STATE OF FLORIDA

DEPARTMENT OF HEALTH

!! CONFIDENTIAL

INVESTIGATIVE REPORT

Office: Area I, Pensacola	Date of Case: 4/8/13	Case Number: PH 2012-16087

Subject:	Source:
CANTONMENT PHARMACY, INC 433 Highway 29 South Cantonment, FL 32533 (850) 968-2489	**PRESTON MCDONALD, RPH** 5740 Westmont Road Milton, FL 32583 (850) 983-0916

Prefix:	License #:	Profession:	Board:	Report Date:
PH	2748	PHARMACY	PHARMACY	7/8/13

Period of Investigation: 4/17/13-7/8/13	Type of Report: FINAL

Alleged Violation: **FS 456.072(1)(k)** Failing to perform any statutory or legal obligation placed upon a licensee. (n) Exercising influence on the patient or client for the purpose of financial gain (dd) Violating any provision of this chapter, **FS 465.015(2)** It is unlawful for any person: **(c)** To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription. **FS 465.016(1)(i)** Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. (r) Violating any provision of this chapter ... and **FS 465.023(1)** The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline **(c)** Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy;

Synopsis: This investigation is predicated upon receipt of a complaint (Case Summary and Attachments) **(EXHIBIT 1)** submitted by MCDONALD in regard to CANTONMENT PHARMACY. MCDONALD, a former pharmacist at CANTONMENT PHARMACY, alleged staff there are dispensing prescription medications without a prescription including antibiotics, erectile dysfunction oral tablets (Viagra), albuterol inhalers, and possibly non-controlled medications. Allegedly customers come to the pharmacy on a daily basis to purchase Penicillin, Amoxicillin, Flagyl, Diflucan, and cough syrup with codeine without a prescription from a physician. On 2/4/13, a Pensacola investigator went to CANTONMENT PHARMACY and purchased a "Z-Pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Tripolidine Hydrochloride 2.5mg) tablets. On 3/28/13, another Pensacola ISU staff member went to the pharmacy and purchased Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Tripolidine Hydrochloride 2.5mg) tablets. The pharmacist was not identified on 2/4/13 or 3/28/13.

CANTONMENT PHARMACY was notified of the investigation by letter dated 4/17/13 **(EXHIBIT 2)** and was provided a copy of the Case Summary and originating documents from Exhibit 1.

A check of DOH computer licensure records revealed CANTONMENT PHARMACY is currently licensed as a PHARMACY.

No patients were identified; therefore, patient notification was not required.

CANTONMENT PHARMACY is not known to be represented by an attorney in this matter.

On 5/21/13 by US mail, Investigator LANIER received a statement from JOHN T. READING JR on behalf of CANTONMENT PHARMACY **(EXHIBIT 8)**. On behalf of CANTONMENT PHARMACY, READING denied the allegations.

Related Cases: RPT 2012-16092, RPT 2012-16089, PS 2012-16091, PS 2012-16088, PS 2012-16090, PS 2013-06754

Investigator/Date:	Approved By/Date:
Ben Lanier 7/8/13	John M. Sh for 7/8/13
Ben Lanier, BI-35, Investigator	Cathy Martin, Investigator Supervisor

Received
Investigative Services
JUL 09 2013

RECEIVED-LEGAL JUL 9 PM 3:09

Distribution: HQ/ISU

DOH/MQA
Tallahassee HQ

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INVESTIGATIVE DETAILS

On 2/4/13, Investigator LANIER drove to Cantonment Pharmacy. Upon entering the pharmacy, "EMILY" the cashier asked how she could help. Investigator LANIER stated he had a sinus infection and EMILY told Investigator LANIER to go to the pharmacy consultation window. Investigator LANIER walked to the consultation window and a man, without a name tag, presumably the pharmacist, with short brown hair and a goatee asked how he could help. Investigator LANIER told him that he had a sinus infection and a swollen throat. Investigator LANIER told him that a friend of his had the same thing recently and a Z-pak seemed to help. The pharmacist asked if Investigator LANIER wanted a Z-pak and Investigator LANIER told him yes. The pharmacist asked if Investigator LANIER was taking any kind of Antihistamine and Investigator LANIER told him no. The pharmacist told Investigator LANIER to also purchase an Antihistamine to clear up his sinuses. Investigator LANIER told him that funds were limited and the man said it would be roughly $31.00 in total. There was no counseling offered on how to take either the Z-pak or Antihistamine. EMILY assisted Investigator LANIER check out and asked for Investigator LANIER's driver's license. EMILY wrote down Investigator LANIER's name, address, and driver's license number in a book. Then Investigator LANIER signed the log and left the pharmacy. While in the pharmacy Investigator LANIER did not see a sign offering the sale of Viagra. A "Z-pak" (six Azithromycin 250mg tablets, prescription only medication) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist.

On 3/28/13, Investigator Supervisor CATHY MARTIN presented to Cantonment Pharmacy with complaints of lingering cough and sore throat. The cashier immediately instructed Investigator Supervisor MARTIN to go the pharmacy window. A man with short brown hair and a goatee, presumably the pharmacist but with no name tag, asked what symptoms were present. The symptoms were repeated to the pharmacist, and he instructed Investigator Supervisor MARTIN to select a bottle of Chloraseptic. He stated, with a wink, that he would add an ingredient to relieve the symptoms. He asked if Investigator Supervisor MARTIN was taking any decongestants, and Investigator Supervisor MARTIN responded no. He asked no other questions. A selection of the orange flavored Chloraseptic was made and Investigator MARTIN returned to the pharmacy window. The pharmacist stated that the orange flavor was not very good and to go back and get the red bottle. Investigator MARTIN did so. The pharmacist took the bottle, and a few minutes later he passed a white paper bag with contents to the cashier. The pharmacist stated that he added Lidocaine to the Chloraseptic. The cashier instructed Investigator MARTIN to approach the counter and provide a driver license. Investigator Supervisor MARTIN did so, and the cashier copied information from the driver license to a worn green ledger. The cashier then instructed Investigator Supervisor MARTIN to enter address information in the log and sign where indicated. Investigator MARTIN did so. During this process, Investigator MARTIN asked what the purpose of the log was, and the cashier stated it was for the Sudafed pills being provided. Investigator MARTIN also asked for the pharmacist's name, and the cashier provided a first name of "Gene." She informed the total was $11.10, and Investigator Supervisor MARTIN provided the cashier a $50 bill. Change of $38.90 was provided, and Investigator Supervisor MARTIN thanked the cashier and the pharmacist and left. The cost of the Chloraseptic was $5.12, and a blue bottle with 24 small white pills was also provided for a cost of $5.98. No prescriptions were presented to the pharmacy, and no instructions for taking the medications were provided. Chloraseptic with Lidocaine added (which requires a prescription) and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets were provided by the pharmacist. The pharmacist was not identified on 2/4/13 or 3/28/13.

Thirteen pictures of these medications and receipts from both purchases are provided on CD and included as **EXHIBIT 6.**

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

EXHIBIT 1 is information forwarded by the Consumer Services Unit (CSU) with the complaint. This information consists of a Case Summary, corrected Case Summary, complaint form by MCDONALD, and the following:

- Complaint narrative by MCDONALD noting he was previously employed at Winn-Dixie pharmacy located nearby CANTONMENT PHARMACY. While at work on many occasions, he would have customers ask if he could sell them antibiotics. It was explained to them that a prescription was required, and their response was always that they could obtain them from CANTONMENT PHARMACY. MCDONALD did not believe the customers for the most part, contributing it to CANTONMENT PHARMACY selling something to the customers and telling them it worked almost as good as antibiotics. Through diverging circumstances, MCDONALD became employed at CANTONMENT PHARMACY as a pharmacist. The very first day at work not long after they opened, a customer came up and asked him for antibiotics. MCDONALD told the customer that he had to have a prescription for antibiotics. Throughout the day about six different customers asked him for antibiotics and without fail, every day to this date, they had customers telling him they had purchased antibiotics in the past from one registered pharmacy technician (RPT1) or sometimes another registered pharmacy technician (RPT2) was mentioned, and that they would like to purchase some more. MCDONALD refused and always told the customers that a prescription was required. Antibiotics mentioned to MCDONALD that customers had purchased in the past included Penicillin, Amoxicillin, Z-Pak, Keflex, Flagyl, and Diflucan. As corroborating evidence of this practice of selling antibiotics without a prescription to customers, there are large bottles of Penicillin, Amoxicillin, and SMZ-TMP on a counter near the counseling window, which is outside of the area of stock of all other medications, and separate from its normal location (for filling prescriptions).

  MCDONALD also had several male customers ask to purchase Viagra tablets, stating that they had bought them in the past from RPT1 or sometimes RPT2 and wanted some more. MCDONALD refused and always told the customers a prescription was required. MCDONALD stated there are handwritten signs above/below the Viagra tablets on the prescription stock area of "$24" which indicated that customers are charged $24.00 for each Viagra tablet (sold without a prescription). MCDONALD also had a customer come to the counseling window and ask him for an Albuterol inhaler. After MCDONALD explained that a prescription was needed, the customer stated that he had purchased them before from RPT1 and RPT2, and he became irate that MCDONALD would not sell him an Albuterol inhaler.

  Finally, MCDONALD alleged there is a well-known practice in the community that CANTONMENT PHARMACY sells a "cough syrup" that is mixed at the pharmacy which contains codeine. This is a C-V medication that can be legally sold without a prescription, but it can only be sold by a pharmacist. MCDONALD had several customers tell him they wanted that special "cough syrup" they got from RPT1 or RPT2 in the past. MCDONALD witnessed it being sold to customers by a clerk without consultation of the pharmacist on duty. MCDONALD stated it was a common practice for RPT1 to give medical advice to customers and otherwise infer to customers that he was a licensed pharmacist, and to also sell them prescription medications without a prescription. This was also the case for RPT2, although to a lesser extent.

  MCDONALD listed the licensed employees of the pharmacy who were allegedly guilty of dispensing medications without a prescription. These employees allowed RPT1 to portray himself as a licensed

practitioner prescriber or pharmacist. This technician was allowed to perform duties only allowed by law to be performed by a licensed practitioner prescriber or pharmacist such as 1) diagnosing patients and prescribing prescription medications by virtue of selling the prescription medications to customers without a valid prescription, 2) giving medical advice to customers without consultation of a licensed pharmacist, 3) holding himself as a pharmacist, 4) acting/speaking as a pharmacist over the telephone to other pharmacists in the transfer of prescriptions, without identifying himself as a pharmacy technician, 5) individually selling C-V medications (i.e., cough syrup with codeine) to customers without involvement, consultation, and approval of a pharmacist. MCDONALD noted that the primary principal or violator was RPT1, who had for many years acted as a pharmacist and performed pharmacist-only duties. The owner of the pharmacy is listed as the pharmacist-in-charge, who has a legal responsibility in developing and enforcing policies and procedures for the pharmacy. It is extremely difficult to believe that the owner, although absent from the day to day operations of the pharmacy, is not aware of the violations occurring on a daily basis. The two most recent pharmacists employed by the pharmacy are also participants in these violations by virtue of allowing them to occur while on duty and failing to report them. MCDONALD did not know if those two pharmacists were guilty of selling medications that require a prescription without one, or just knowingly allowed such. MCDONALD stated the pharmacy technicians were not identifying themselves when answering or speaking on the phone and did not regularly wear name tags/badges that readily identify themselves as pharmacy technicians. MCDONALD stated the pharmacy is also in violation by not having an easily accessible sink near the prescription counter.

EXHIBIT 3 is a copy of a letter dated 4/17/13 to MCDONALD informing him of the status of the case.

EXHIBIT 4 is a copy of a letter dated 5/16/13 to CANTONMENT PHARMACY providing a corrected Case Summary. The original Case Summary made two references to Hydrocodone which should have read Hydrochloride.

EXHIBIT 5 is copies of three previous inspection forms dated 9/22/09, 10/18/10, and 1/23/12 for inspections conducted at CANTONMENT PHARMACY printed by Investigator LANIER on 4/18/13. The three previous inspections indicate passing results; however, the inspection form dated 9/22/09 indicated there were some improperly labeled medications found.

EXHIBIT 6 is a copy of thirteen pictures placed on CD by Investigator LANIER. The pictures are of prescription medications purchased from CANTONMENT PHARMACY by Pensacola ISU staff on 2/4/13 and 3/28/13, and the respective receipts, dispensed without providing a prescription. The medications consist of a "Z-pak" (six Azithromycin 250mg tablets, prescription only medication), 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets, Chloraseptic with Lidocaine added (which requires a prescription), and 24 Aprodine (Pseudoephedrine Hydrochloride 60mg/Triprolidine Hydrochloride 2.5mg) tablets.

EXHIBIT 7 is a copy of the formula for the "Cantonment Wine" provided by [redacted] on 4/26/13 to Investigator LANIER at the Pensacola ISU office.

INTERVIEW OF PRESTON MCDONALD, RPH (PS 33121)–SOURCE:
Address of Record:
5740 Westmont Road
Milton, FL 32583
(850) 983-0916

On 11/26/12, Investigator LANIER interviewed MCDONALD by telephone. MCDONALD stated he quit working at CANTONMENT PHARMACY close to a month prior. MCDONALD stated the pharmacy did not keep a record of the medications that customers were buying. MCDONALD stated the cough syrup did not contain full strength codeine and it did not require a prescription, but a pharmacist had to be involved. MCDONALD stated Registered Pharmacy Technicians were also providing the cough syrup to customers. MCDONALD stated he could not specifically remember any patient names to whom prescription medications were sold.

INTERVIEW OF
Address of Record:

Employment: Cantonment Pharmacy
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

INTERVIEW OF SUSAN HALFEN, RPH (PS 32697)–WITNESS:
Employment: Winn-Dixie
1550 Hwy 29 North
Cantonment, FL 32533
(850) 968-3318

On 5/10/13 and 5/14/13, Investigator LANIER attempted to telephone HALFEN; however, she was not available and voicemail messages were left requesting a return call.

On 5/15/13, HALFEN returned the call and left a voicemail message for Investigator LANIER stating she was working all day on this date, but that she should be available for Investigator LANIER to call. On the same date, Investigator LANIER returned the call. HALFEN stated she had been a pharmacist at Winn-Dixie for about six years and that their location was very close to CANTONMENT PHARMACY. HALFEN stated that since she started working at Winn-Dixie pharmacy, one to two customers come in every month or so to try and get prescription medications without a prescription. HALFEN stated these customers were mainly seeking antibiotics and told her that they had gotten them in the past without a prescription from CANTONMENT PHARMACY. HALFEN stated she also knew CANTONMENT PHARMACY provided a cough syrup. HALFEN stated she knew pharmacists were allowed to sell the cough syrup. HALFEN stated that was all she really knew about CANTONMENT PHARMACY's operation.

INTERVIEW/STATEMENT OF JOHN T. READING, JR., ON BEHALF OF CANTONMENT PHARMACY, INC., PHARMCY–SUBJECT:
Address of Record:
433 Highway 29 South
Cantonment, FL 32533
(850) 968-2489

On 5/17/13, Investigator LANIER interviewed JOHN T. READING by telephone. Investigator LANIER asked READING who would be responding on behalf of the pharmacy and READING stated he would provide a response for the pharmacy in the near future.

On 5/21/13 by US mail, Investigator LANIER received READING statement on behalf of CANTONMENT PHARMACY. READING stated this letter came as a result of the telephone conversation last week. READING stated he would go through the complaint in the same order that MCDONALD had written it.

FS 456.072(1)(k)(n)(dd), FS 465.016 (1)(i)(r), and FS 465.023 (1)(c) all pertain to dispensing without a legitimate prescription. The allegations were denied to each with the exception that for 45 years they have sold many antibiotics for animals (almost exclusively Penicillin injections) and generic Septra DS tablets for horses. CANTONMENT PHARMACY carries a fairly extensive line of almost everything one would need for animals and there is a veterinarian across the street that calls in prescriptions to them. **[INVESTIGATOR'S NOTE:** On 7/2/13, Investigator LANIER spoke with Senior Pharmacist JOHN TAYLOR, who informed that a pharmacist could fill a prescription for an animal if they wanted to, but that a prescription was still required. Any medication that would be required for a human would still be required for an animal.]

READING stated that on 2/4/13, he did not believe he was working at the pharmacy and therefore must claim that he is without knowledge of what went on. On 3/28/13, READING was able to establish that he was definitely not working as that was a long weekend off for him. READING typically works every day until 1:00pm and he is off every other Thursday through Sunday. READING could not say what happened on that date. One of the allegations is that 24 Aprodine were sold to an ISU Investigator and the allegation is that the formula is Pseudoephedrine Hydrocodone 60 mgm and Triprolidine Hydrochloride 2.5 mgm. For sinus decongestant, CANTONMENT PHARMACY sells almost exclusively Aprodine; however, it is always signed for and it has absolutely no Hydrocodone in it. READING stated that if someone wanted to examine their signature log, they would find that the ISU investigator did sign for it as the law required. READING stated the Hydrocodone listed as an ingredient was probably a typographical error in the Case Summary. Everyone at CANTONMENT PHARMACY is periodically tested on the amount of Pseudoephedrine that could be sold at a time and they have never exceeded that quantity.

If a Z-Pak was sold, READING had no knowledge of it, and after questioning, he was no further to answering the question. In regard to the purchase of Chloraseptic with Lidocaine, Chloraseptic is one of their most recommended products. They do not suggest adding anything to it, but frequently suggest getting an item from the grocery store to reduce any swelling that is apparent in their throat. That item is artificial lemon juice and is a standard, well known in the "home remedies" book of most pharmacies. Variations of that theme also include a shot of whiskey and/or a shot of honey. The pharmacy recommends neither of them as they believe that the benefits accrued from the astringent quality of the juice and anything else would dilute that quality. Digging in to the matter, READING was more successful as noted in the answer of another response. Apparently MCDONALD was present that day and their Lidocaine viscous is stored appropriately in the back and at the

bottom of their antibiotic section. READING stated that he had already determined that he was not there on the particular date and perhaps his answer should have just been a simple "denial, or without knowledge."

READING stated no pharmacist ever worked directly with MCDONALD; however, both pharmacy technicians worked quite a bit with MCDONALD, and both deny his allegations. If something as alleged had occurred, it would have been in relatively tight quarters with MCDONALD and so MCDONALD should have stopped anything like he said. When MCDONALD was working for CANTONMENT PHARMACY and people came to the counseling window, MCDONALD was almost always called over to be introduced to the patient and be involved with any discussions.

Every employee, not just technicians and pharmacists, is checked for name tags every day that READING is present. READING stated that over the past inspections, they have never been citied for failure to wear a name tag and only on one occasion have they been asked to do something additional to the prescription files. No inspector has ever said anything about the location of the sink in the prescription department. Leading to it is a doorway that is always open and they have a large opening that the data entry person can look through and see the sink.

Allegations of selling Viagra are probably confused with other pills that they sell a great number of that do not require a prescription. They are not represented as Viagra but they are blue capsules. The name is Orexis and they order them from Amazon.com. They are very popular and are more expensive each time the pharmacy buys them. The pharmacy has other tablets that are generally referred to as "nature pills, for men." They sell a great deal more of them than the Orexis. They have two versions, one is called Bomba and the other is called Bomba-365. None of them require a prescription, but they keep them behind the counter as the men coming to the counseling window do not generally wish for the ladies in the store to know what they are purchasing. The product is placed in a sack with the price on it and the customer takes it to the cash register.

Antibiotic bottles that are kept near the ordering computer and not in the regular section are usually items that they are shopping their suppliers on prices for and usually contain only a few tablets. Two examples are Penicillin and Doxycycline, which have had huge price increases this year. Controlling inventory is key to correct market pricing of prescriptions.

MCDONALD made one allegation of a single request from a customer for an Albuterol inhaler saying that he bought it from the pharmacy in the past without a prescription. Albuterol inhalers were taken off the market about two years ago and replaced with three much more expensive alternatives. Because older generic albuterol was taken off the market, READING did not know what to say other than it was likely that someone might have asked for an Albuterol inhaler. Many if not most of their customers come in and ask for their medications by name and if they know their Rx numbers they usually call them in so that the medications will be ready when they come into the pharmacy.

The pharmacy does have a cough syrup that they make up and have sold for years which does contain codeine and every sale is recorded. It is a combination of generic Robitussin AC mixed with plain over the counter generic Benadryl. When they mix this they are diluting the legal codeine concentration of the cough syrup. The cough syrup is labeled appropriately and they do not make it more than one or two liters at a time depending on whether it is cold and allergy season. The pharmacy had a manufacturing license and found that they did not sell enough of anything to justify the license and so they do not make more than one or two

days' supply at a time. The lot number and expiration date is put on the label according to which ingredient has the codeine in it.

MCDONALD stated that he did not know if the other pharmacists violated any statutes but he had thrown them in for good measure. MCDONALD focused on RPT1 and RPT2 because almost everyone knows their names and calls them by name, as they call their customers by name. RPT 1 has been at CANTONMENT PHARMACY for over 40 years.

[INVESTIGATOR'S NOTE: On 6/26/13, Investigator LANIER interviewed READING by telephone. READING stated he was closing CANTONMENT PHARMACY on 7/8/13, for good.]

CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498

Insp # 86062

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
CANTONMENT PHARMACY INC	2748	9/22/2009
DOING BUSINESS AS	DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER JOHN T READING
STREET ADDRESS 433 HIGHWAY 29 S	TELEPHONE # 850-968-2489 EXT.	
CITY CANTONMENT / COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Johnny Reading PTech
3. Karen Bonanno PTech

	SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]		X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]		X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]		X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]		X	
5	Items properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]		X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]		X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]		X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]		X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.		X	
10	Generic drug sign displayed. [465.025(7),F.S.]		X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]		X	
12	Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*	X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]		X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]		X	
15	Adequate patient counseling by Pharmacist when offer is accepted. [64B16-27.820,F.A.C.]		X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]		X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]		X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]		X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]		X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]		X	
21	Medication properly labeled [64B16-27.101,F.A.C.]			X
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]		X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]		X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]		X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]		X	

	SATISFACTORY	N/A	YES	NO
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]		X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]		X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]		X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]		X	
30	Controlled substance records readily retrievable. [893.07,F.S.]		X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]		X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]		X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]		X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]		X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]		X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]		X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]		X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]		X	
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]		X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]		X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*		X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]		X	
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]		X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *		X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *	X		
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *	X		
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *	X		

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Missy Shores PTech. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #21 Two bottles of OTC drug in pharmacy stock without expiration date. #23 Last CQI meeting 9-15-2009. #39 CS inventory 5-1-2009. #44 Logbook. Rx drug purchases from Smith Drug, AmerisourceBergen, Masters, & Top Rx.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

Institutional Representative — 09-22-2009 (Date) — Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

Exhibit 5

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498

Insp # 94915

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

Note: If establishment is engaged in parenteral/enteral compounding, license must so indicate and a separate inspection form should be completed

NAME OF ESTABLISHMENT	PERMIT NUMBER	DATE OF INSPECTION
CANTONMENT PHARMACY INC	2748	10/18/2010
DOING BUSINESS AS	DEA NUMBER AC5573767	PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 433 HIGHWAY 29 S	TELEPHONE # 850-968-2489 EXT.	JOHN T READING
CITY CANTONMENT / COUNTY 27	STATE/ZIP 32533-1401	PRESCRIPTION DEPARTMENT MANAGER LICENSE # 10065

PRESCRIPTION DEPARTMENT HOURS

	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday
Open	9am	9am	9am	9am	9am	9am	closed
Close	6pm	6pm	6pm	6pm	6pm	3pm	

REGISTERED PHARMACIST/INTERN/TECHNICIAN — LICENSE #

1. Benjamin Fenn PS 13028
2. Wilton Glover PS 7751
3. Melissa Shores RPT 21008

		SATISFACTORY	N/A	YES	NO
1	Current pharmacy permit displayed. [465.015(1)(a),F.S.]			X	
2	Board of Pharmacy notified in writing of current Rx department manager. [465.018,F.S.]			X	
3	Current DEA registration. [21CFR 1301.11] [465.023(1)(c),F.S.]			X	
4	Rx department hours open for business are posted and are a minimum of 40 hours per week. [64B16-28.404, F.A.C.]			X	
5	Interns properly registered and supervised. [465.013,F.S.] [64B16-26.400(4),F.A.C.]			X	
6	Pharmacy technicians properly identified and supervised. [64B16-27.410,F.A.C.]			X	
7	Proper pharmacist technician ratio. If 2:1 or 3:1 Pharmacy Manager has Board of Pharmacy approval. [64B16-27.410] [64B16-27.420, F.A.C.]			X	
8	Pharmacist license/renewal certificate displayed. [64B16-27.100(1)F.A.C.]			X	
9	Pharmacist on duty when Rx department open. [64B16-28.109,F.A.C.			X	
10	Generic drug sign displayed. [465.025(7),F.S.]			X	
11	Sign displayed "Rx Dept Closed" if establishment is open and Rx Department closed. [64B16-28.109(1),F.A.C.]			X	
12	Sign with meal break hours of Pharmacist, (no more than half hour), and stating that a pharmacist is available on premises for consultation upon request. [64B16-27.400(6),F.A.C.]*		X		
13	Sign designating the private patient consultation area [64B16-28.1035,F.A.C.]			X	
14	Adequate written and verbal offer to counsel patients. [64B16-27.820,F.A.C.]			X	
15	Adequate patient counseling by pharmacist when offer is accepted. [64B16-27.820,F.A.C.]			X	
16	Rx dept. has sink/running water convenient to Rx dept. [64B16-28.102,F.A.C.]			X	
17	Prescription department has drug refrigeration storage. [64B16-28.104,F.A.C.]			X	
18	Prescription department clean and safe. [64B16-28.105,F.A.C.]			X	
19	Rx balance and weights or electronic balance; counting tray or other suitable counting device; assortment of graduates/spatulas/mortar and pestles. [64B16-28.107(2)(a-d),F.A.C.]			X	
20	Current reference books and current copy of laws and rules in hard copy or in a readily available electronic data format [64B16-28.107(1), F.A.C.]			X	
21	Medication properly labeled [64B16-27.101,F.A.C.]			X	
22	All Rx medication within the Rx department. [64B16-28.120(1),F.A.C.]			X	
23	CQI Policy and Procedures and proof of quarterly meetings (protected under [766.101,F.S.] [64B16-27.300, F.A.C.]			X	
24	Outdated pharmaceuticals removed from active stock. [64B16-28.110, F.A.C.]			X	
25	"Discard after date" on Rx label. [64B16-28.402(1)(h),F.A.C.]			X	

		SATISFACTORY	N/A	YES	NO
26	All medicinal drug Rx's require date dispensed. [64B16-28.140(3)(b)2,F.A.C.]			X	
27	Prescription records identify the responsible dispensing pharmacists. [64B16-28.140(3)(b)7,F.A.C.]			X	
28	Complete pharmacy prescription records. [64B16-28.140,F.A.C.]			X	
29	Pharmacy maintains patient profile records. [64B16-27.800,F.A.C.]			X	
30	Controlled substance records readily retrievable. [893.07,F.S.]			X	
31	Initials of pharmacist filling controlled substance Rx. [893.04(1)(c)6,F.S.]			X	
32	Prescriber's name/address/DEA # on all controlled substance Rx. [893.04(1)(c)2,F.S.]			X	
33	Patient's name/address on controlled substance Rx. [893.04(1)(c)1,F.S.]			X	
34	Date controlled substance Rx was filled on Rx. [893.04(1)(c)6,F.S.]			X	
35	All controlled substance prescriptions must have: drug prescribed, quantity and directions for use. [893.04(1)(c)4,F.S.]			X	
36	Date of refills written on controlled substance Rx or on computer records. [893.04(1)(c)6,F.S.]			X	
37	Pharmacist's initials on controlled substance Rx refills. [893.04(1)(c)6,F.S.]			X	
38	Controlled substance refills limited to 5 within 6 months from date prescription was signed. [893.04(1)(g),F.S.]			X	
39	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a),F.S.]			X	
40	DEA 222 order forms properly completed. [893.07(2),F.S.]			X	
41	Controlled substance Rx information in computer system is retrievable. [CFR 1306.22] [893.07,F.S] [64B16-28.140,F.A.C.]*			X	
42	Controlled substance records maintained for 2 years. [CFR 1304.04 & 1306.22] [893.07(4)(b),F.S.]			X	
43	Schedule V drug records/sales properly kept. [893.08(3)(a),F.S.]			X	
44	Certified daily log OR printout maintained as required by section. [64B16-28.140(3)(c) OR (e),F.A.C.] *			X	
45	Registered pharmacist properly prescribing. [64B16-27.210,F.A.C.] *			X	
46	Compounding records properly maintained [64B16-28.140(4),F.A.C.] *			X	
47	Unit dose records properly maintained [64B16-27.410 (1), F.A.C.] *			X	

** Questions with (*) may be answered n/a (not applicable).*

Remarks: Leslie Johnson RPT 21005; John Reading, Jr. RPT 21007. #3 DEA expires 8-31-2011. #5 NA. #7 Tech ratio letter 6-22-1994. #23 Last CQI meeting #39 CS inventory #43 Book - OK. #44 Logbook. Rx drug purchases from Smith Drug-Valdosta and AmerisourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Benjamin Fenn, RPh

B. Fenn R.P.

Institutional Representative

10-18-2010

Date

J. Q. Wilson

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 01/07 Replaces 12/02

00033

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

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ROUTINE [X] CHANGE LOC [ ] NEW [ ] CURRENTLY NOT OPERATING [ ] CHANGE OWNER [ ]

File # 498

Insp # 103821

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
CANTONMENT PHARMACY INC		2748		1/23/2012
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
		Ac5573767		
STREET ADDRESS		TELEPHONE #	EXT.	JOHN T READING
433 HIGHWAY 29 S		850-968-2489		
CITY	COUNTY	STATE/ZIP		PRESCRIPTION DEPARTMENT MANAGER LICENSE #
CANTONMENT	27	32533-1401		10065

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN	LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday		
Open	9am	9am	9am	9am	9am	9am	closed	1. Joseph Gibson PS 26203	
Close	6pm	6pm	6pm	6pm	6pm	3pm		2. Benjamin Fenn PS 13028	
								3. Melissa Shores RPT 21008	

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			X	
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]			X	
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]			X	
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			X	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			X	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			X	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			X	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			X	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]			X	
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]			X	
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			X	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	X			
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]			X	
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]			X	
15	All controlled substance prescriptions contain information required. [893.04, F.S.]			X	
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].			X	
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]			X	
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]			X	
19	DEA 222 order forms properly completed. [893.07, F.S.]			X	
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]			X	
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]			X	
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]			X	
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]			X	
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	X			
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	X			
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]			X	
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	X			
28	Compounding records properly maintained. [64B16-27.700, F.A.C.]*	X			
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	X			
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]			X	

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: Adam Bass RPT 21001; John Reading RPT 21007; Karin Bonano RPT 21006; Leslie Johnson RPT 21005. DEA expires 8-31-2014. #2 Tech ratio letter 6-22-1994. #11 Last CQI meeting 9-1-2011. #12 Future requirement. #18 CS inventory 5-1-2011. #22 Logbook. #23 One incident - Escambia CSO. #24 None since 7-1-2011.
CII prescription file survey (60Rxs): Local Practitioner - 97%; Local Patient - 100%; Pain Therapy - 78%; Non-pain Therapy - 22%.
No batch compounding. No compounding for practitioner office stock.
Rx drug suppliers: Smith Drug-Valdosta; AmericansourceBergen-Orlando.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge. I have received a copy of the Licensee Bill of Rights.

PRINT NAME OF RECIPIENT Joseph Gibson, RPh

Institutional Representative

01-23-2012
Date

Investigator/Sr. Pharmacist Signature

ID ci20

INV 359 Revised 12/11, 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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Florida HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201212130

BRUCE ROBERT KLINE,
RESPONDENT.

NOTICE

TO: BRUCE ROBERT KLINE
PO BOX 1197
MANSFIELD, MA 02048

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Determination Of Waivers

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

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The purpose of the hearing is to consider a motion for: Settlement Agreement

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

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JL for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201212130

BRUCE ROBERT KLINE,
RESPONDENT.

NOTICE

TO: BRUCE ROBERT KLINE
PO BOX 231098
207 MASS AVE
BOSTON, MA 02123

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The purpose of the hearing is to consider a motion for: Determination Of Waivers

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Casey Cowan, Assistant General Counsel
RE: **Determination of Waiver**
SUBJECT: DOH v. Bruce Robert Kline, R.PH.
DOH Case Number: 2012-12130 CLC
DATE: January 8, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Bruce Robert Kline, R.PH.
Subject's Address of Record:	P.O. Box 1197 Mansfield, MA 02048
Enforcement Address:	12 Giles PL Mansfield, MA 02048
Subject's License No:	46053 **Rank:** PS
Licensure File No:	37952
Initial Licensure Date:	4/8/2010
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	**Count 1:** Violated section 456.072(1)(c), F. S. (2012) **Count 2:** Violated Section 456.072(1)(x), F. S. (2012
Prior Discipline:	None
Probable Cause Panel:	January 31, 2013 Fallon & Risch
Subject's Attorney:	Pro Se

Complainant/Address: Massachusetts Department Of Public Health Board Of Pharmacy
239 Causeway Street
Suite 500 5th Floor
Boston, MA 02114

Materials Submitted:
Memorandum to the Board
Motion for Determination of Waiver
Exhibit A - Administrative Complaint
Exhibit B - Copy of Certified Mail Receipt
Exhibit C - Board Affidavit
Exhibit D - Clerk Affidavit
Defense Attorney/Respondent Documents
Motion to Assess Costs with Attachments
Exhibit A – Affidavit of Fees and Costs Expended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
PCP Memo
Final Investigative Report
Exhibits 1-2

CLC/bhh

Disciplinary Guidelines:
Count I: Section 456.072(1)(x), Florida Statutes (2012)- 1 year suspension, 2 years probation & $5000 Fine to revocation.
Count II: Section 456.072(1)(c), Florida Statutes (2012)- 1 year suspension, 2 years probation & $5000 Fine to revocation.

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

Two count AC alleging violations of Section 456.072(1)(x), Florida Statutes (2012) and Section 456.072(1)(c), Florida Statutes (2012).

On or about September 6, 2012, in the Trial Court of Massachusetts, District Court Department, Respondent entered a plea of guilty to Operating Under the Influence, Third Offense, a felony in violation of M.G.L. ch.90,§1 and One count of the crime of Drug Possession, a misdemeanor violation of M.G.L. ch.94c,§31.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-12130**

BRUCE ROBERT KLINE, R.PH.,

Respondent.
_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

Petitioner, Department of Health, by and through counsel, moves the Board of Pharmacy to find that Respondent has waived his right to elect a method of disposition of the pending Administrative Complaint, to determine that no material facts are in dispute, to conduct a hearing not involving disputed issues of material fact, and to enter a Final Order. As grounds therefore, Petitioner states:

1. An Administrative Complaint was filed against Respondent on January 21, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Explanation of Rights form, and Election of Rights forms were delivered successfully to Respondent at his address of record, via certified US mail, on February 26, 2013, article number 7196-9008-9111-3566-3568. A copy of the certified mail receipt is attached as Petitioner's Exhibit B.

3. Respondent has not filed with either the Department of Health or the Board of Pharmacy, an Election of Rights form or other responsive pleading in this case within the twenty-one (21) day period to dispute the allegations contained in the Administrative Complaint. Copies of affidavits supporting the same are attached hereto as Petitioner's Exhibits C and D.

4. Rule 28-106.111(2), Florida Administrative Code, provides in pertinent part that:

> . . . persons seeking a hearing on an agency decision which does or may determine their substantial interests shall file a petition for hearing with the agency within 21 days of receipt of written notice of the decision.

5. Rule 28.106.111(4), Florida Administrative Code, provides in pertinent part that:

> . . . any person who received written notice of an agency decision and who fails to file a written request for a hearing within 21 days waives the right to request a hearing on such matters.

6. Respondent has been advised, by a copy of this motion sent to his address of record that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

7. The Department has determined that there are no material facts in dispute and has concluded that Respondent has waived his right to elect the method of resolution.

8. The Department requests that this Motion and a hearing be placed on the agenda for the next meeting of the Board of Pharmacy to be held on June 5, 2013, at the Doubletree Miami Airport Convention Center, 711 N. W. 72nd Avenue, Miami, Florida 33126.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived his right to elect a method of resolution of this matter, find that there are no material facts in dispute, hold a hearing not involving material issues of disputed fact based on the information contained in the investigative file, find that Respondent violated Chapters 456 and 464, Florida Statutes, as alleged in the Administrative Complaint, impose discipline in accordance with the disciplinary guidelines, and enter a Final Order.

Respectfully submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Casey L Cowan

CASEY L. COWAN
Assistant General Counsel
Florida Bar No.: **0035536**
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Determination of Waiver and for Final Order by Hearing Not Involving Disputed Issues of Material Fact has been furnished via U.S. mail to: **BRUCE ROBERT KLINE, R.PH., at P.O. BOX 1197, 12 GILES PL, MANSFIELD, MASSACHUSETTS, 02048**, on, this 9th day of January, 2014.

Casey L Cowan

CASEY L. COWAN
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-12130**

BRUCE ROBERT KLINE, R.PH.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Bruce Robert Kline, R.Ph., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a registered pharmacist within the state of Florida, having been issued license number PS 46053.

EXHIBIT
A

3. Respondent's address of record is Post Office Box 1197, 12 Giles Place, Mansfield, Massachusetts.

4. On or about September 6, 2012, in the Trial Court of Massachusetts, District Court Department, in case number 1289CR001230, Respondent entered a plea of guilty to the following:

a. Operating Under the Influence, Third Offense, a felony in violation of M.G.L. ch.90,§1; and

b. One count of the crime of Drug Possession, a misdemeanor violation of M.G.L. ch.94c,§31.

5. Respondent failed to report his entry of a plea to the Board, or the Department if there is no Board, within thirty days of entering the plea.

6. Operating Under the Influence, Third Offense and Drug Possession are crimes that relate to the practice of the licensee's profession as a registered pharmacist.

COUNT ONE

7. Petitioner realleges and incorporates paragraphs one (1) through six (6) as if fully set forth herein.

8. Section 456.072(1)(c), Florida Statutes (2012), provides that being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession, constitutes grounds for discipline.

9. On or about September 6, 2012, in the Trial Court of Massachusetts, District Court Department, in case number 1289CR001230, Respondent entered a pleas of guilty to Operating Under the Influence, Third Offense, a felony in violation of M.G.L. ch.90,§1; and one count of the crime of Drug Possession, a misdemeanor violation of M.G.L. ch.94c,§31., which are crimes that relate to the practice of the licensee's profession as a registered pharmacist.

10. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (2012), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

COUNT TWO

11. Petitioner realleges and incorporates paragraphs one (1) through six(6) as if fully set forth herein.

12. Section 456.072(1)(x), Florida Statutes (2012), provides failing to report to the board, or the department if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction, constitutes grounds for discipline.

13. Respondent failed to timely report to the board in writing the plea in the above-referenced criminal case in paragraph four within thirty (30) days after his pleas were entered by the court.

14. Based on the foregoing, Respondent violated Section 456.072(1)(x), Florida Statutes (2012), failing to report to the board, or the department if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 31 **day of** January, **2013.**

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Casey L. Cowan

CASEY L. COWAN
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Florida Bar Number: 0035536
(850) 245 - 4640 Telephone
(850) 245 – 4683 Facsimile
casey_cowan@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 3 1 2013

/CLC
PCP: 1/31/13
PCP Members: Fallon + Risch

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

Heller-Hutchison, Blondell

From: U.S._Postal_Service_ [U.S._Postal_Service@usps.com]
Sent: Thursday, April 18, 2013 1:55 PM
To: Heller-Hutchison, Blondell
Subject: U.S. Postal Service Track & Confirm email Restoration - 7196 9008 9111 3566 3568

This is a post-only message. Please do not respond.

BLONDELL HELLER-HUTCHISON has requested that you receive this restoration information for Track & Confirm as listed below.

Current Track & Confirm e-mail information provided by the U.S. Postal Service.

Label Number: 7196 9008 9111 3566 3568

Service Type: Certified Mail(TM)

Shipment Activity	Location	Date & Time
Delivered	MANSFIELD MA 02048	02/26/13 1:52pm
Arrival at Unit	MANSFIELD MA 02048	02/15/13 8:29am

USPS has not verified the validity of any email addresses submitted via its online Track & Confirm tool.

For more information, or if you have additional questions on Track & Confirm services and features, please visit the Frequently Asked Questions (FAQs) section of our Track & Confirm site at http://www.usps.com/shipping/trackandconfirmfaqs.htm

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BEGIN-ANTISPAM-VOTING-LINKS

Teach CanIt if this mail (ID 07JptSyHS) is spam:
Spam: https://antispam.doh.ad.state.fl.us/canit/b.php?i=07JptSyHS&m=ae8a81448bfc&t=20130418&c=s
Not spam: https://antispam.doh.ad.state.fl.us/canit/b.php?i=07JptSyHS&m=ae8a81448bfc&t=20130418&c=n
Forget vote: https://antispam.doh.ad.state.fl.us/canit/b.php?i=07JptSyHS&m=ae8a81448bfc&t=20130418&c=f
---
END-ANTISPAM-VOTING-LINKS

7196 9008 9111 3566 3568

TO:

Stip pack
Cassandra/Cowan
Date Mailed 2/11/2013
2012-12130

SENDER:

REFERENCE:

Bruce Robert Kline, R.Ph.
P.O. Box 1197, 12 Giles Place
Mansfield, Massachusetts 02048

PS Form 3800, January 2005

RETURN RECEIPT SERVICE	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

US Postal Service®

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POSTMARK OR DATE

2/26

2. Article Number

7196 9008 9111 3566 3568

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) | B. Date of Delivery

C. Signature

X Theresa Whalen ☐ Agent ☐ Addressee

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type **CERTIFIED MAIL™**

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

Reference Information

1. Article Addressed to:

Bruce Robert Kline, R.Ph.
P.O. Box 1197, 12 Giles Place
Mansfield, Massachusetts 02048

Stip pack 2012-12130
Cassandra/Cowan

PS Form 3811, January 2005 Domestic Return Receipt

EXHIBIT

B

I, Mark Whitten, hereby certify in my official capacity as custodian for the Board of Pharmacy, licensure files that the Board of Pharmacy as of April 18, 2013, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **CASE NAME: BRUCE ROBERT KLINE: R.PH., CASE NUMBER: 2012-12130,** which would affect the Subject's substantial interests or rights.

Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Mark Whitten, whose identity is known to me personally (type of identification) and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed this 18th day of April, 2013.

Lorraine Gail Curry

Notary Public

LORRAINE GAIL CURRY
MY COMMISSION # EE 97687
EXPIRES: May 26, 2015
Bonded Thru Notary Public Underwriters

EXHIBIT
tabbies
C

AFFIDAVIT

I, Angel Sanders, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **CASE NAME:BRUCE ROBERT KLINE, R.PH., CASE NUMBER 2012-12130,** which would affect the Respondent's substantial interests or rights.

Angel Sanders
Custodian of Record
Department Clerk's Office

Before me, personally appeared Angel Sanders, whose identity is known to me by personally known (type of identification) and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 18th day of April, 2013.

Angela Barton
Notary Public

My Commission Expires:

ANGELA BARTON
NOTARY PUBLIC - STATE OF FLORIDA
COMMISSION # DD922154
EXPIRES 9/1/2013
BONDED THRU 1-888-NOTARY1

EXHIBIT
tabbies D

CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2012-12130**

BRUCE ROBERT KLINE, R.PH.,

Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1, 2001, pursuant to this section or discipline imposed through

> final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. . . .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $207.36, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**0.20**	**$11.52**
Investigation:	**1.60**	**$89.48**
Legal:	**1.00**	**$106.36**
Compliance:	**0.00**	**0.00**
Sub Total:	**2.80**	**$207.36**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$207.36**

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $207.36 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for

the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $207.36 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $207.36.

DATED this 9th day of January, 2014.

Respectfully submitted,

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

CASEY L. COWAN
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Fla. Bar No. **0035536**
Telephone: (850) 245-4444
Facsimile: (850) 245-4683

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Cost has been furnished via U.S. mail to: **BRUCE ROBERT KLINE, R.PH., of P.O. BOX 1197, 12 GILES PL, MANSFIELD, MASSACHUSETTS, 02048**, on, this 9th day of January, 2014.

Casey L Cowan

CASEY L. COWAN
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-12130** (Department of Health v. **BRUCE ROBERT KLINE, R.PH.**) are **TWO HUNDRED SEVEN DOLLARS AND THIRTY-SIX CENTS ($207.36).**

6) The costs for DOH case numbers **2012-12130** (Department of Health v. **BRUCE ROBERT KLINE, R.PH.**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2012-12130** (Department of Health v. **BRUCE ROBERT KLINE, R.PH.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators

EXHIBIT
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and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 22 day of April, 2013, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette Carter

Name of Notary Printed

ANTOINETTE F. CARTER
MY COMMISSION EXPIRES
September 26, 2015
#EE 132192
Bonded thru
Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

Stamp Commissioned Name of Notary Public:

Complaint Cost Summary

Complaint Number: 201212130

Subject's Name: KLINE, BRUCE ROBERT

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	0.20	$11.52
Investigation:	1.60	$89.48
Legal:	1.00	$106.36
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	2.80	$207.36
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$207.36

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201212130

Report Date 04/22/2013

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA115	0.20	$57.62	$11.52	08/20/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HA115	0.30	$57.62	$17.29	09/17/2012	77	PREPARATION OF DESK INVESTIGATION SYNOPSIS
HA115	0.30	$57.62	$17.29	10/17/2012	77	PREPARATION OF DESK INVESTIGATION SYNOPSIS
HA115	1.00	$54.90	$54.90	12/10/2012	76	REPORT PREPARATION
Sub Total	**1.80**		**$101.00**			
PROSECUTION SERVICES UNIT						
HLL67B	0.20	$106.35	$21.27	12/18/2012	29	REVIEW ADMINISTRATIVE COMPLAINT
HLL67B	0.10	$106.35	$10.64	12/18/2012	89	PROBABLE CAUSE PREPARATION
HLL67A	0.30	$106.35	$31.91	01/28/2013	25	REVIEW CASE FILE
HLL67A	0.40	$106.35	$42.54	02/05/2013	90	POST PROBABLE CAUSE PROCESSING
Sub Total	**1.00**		**$106.36**			

Total Cost	**$207.36**

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint

Complaint

Report Date: 04/22/2013

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Bruce Robert Kline, R.Ph.**
Case Number: 2012-12130

MEMBERS: **Leo Fallon and Lorena Risch**

DATE OF PCP: **January 31, 2013** **AGENDA ITEM: A-10**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(c), Florida Statutes (2012), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

Section 456.072(1)(x), Florida Statutes (2010), failing to report to the board, or the department if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

___ Upon **reconsideration**, dismiss

___ **other** _____

1/31/2013

Chair, Probable Cause Panel Date
Board of Pharmacy

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201313813

ANNE COLYN MILEY,
RESPONDENT.

NOTICE

TO: ANNE COLYN MILEY
1505 HIGHFIELD DRIVE
JACKSONVILLE, FL 32259

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Determination of Waivers

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201313813

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RESPONDENT.

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615 FRUIT COVE ROAD
JACKSONVILLE, FL 32259

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Louise Wilhite-St. Laurent, Assistant General Counsel
RE: Determination of Waiver
SUBJECT: DOH v. Anne Colyn Miley, R. P.T.
DOH Case Number 2013-13813
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the **April 2, 2014**, agenda for final agency action for the meeting of the board. The following information is provided in this regard.

Subject: Anne Colyn Miley, R.P.T.
Subject's Address of Record: 1505 Highfield Drive
Jacksonville, FL 32259
904-465-2602 Telephone

Enforcement Address: 615 Fruit Cove Road
Jacksonville, FL 32259

Subject's License No: 4163 **Rank:** RPT
Licensure File No: 6967
Initial Licensure Date: 10/27/2009
Board Certification: None
Required to Appear: No
Current IPN/PRN Contract: None

Allegation(s): 465.016(1)(e), Florida Statutes (2012-2013), by violating Section 893.13, Florida Statutes (2012-2013).
Prior Discipline: None

Probable Cause Panel: Lee Fallon, BPharm, Ph.D. and Debra Glass, BPharm
PCP: October 10, 2013

Subject's Attorney: Pro Se

Complainant/Address: Department of Health/Investigative Services Unit-Jacksonville

Materials Submitted: Memorandum to the Board
Motion for Determination of Waiver

Exhibit A - Administrative Complaint
Exhibit B - Copy of Certified Mail Receipt
Exhibit C – Affidavit of Non-Receipt – Board
Exhibit D – Affidavit of Non-Receipt – Clerk
Motion to Assess Costs with Attachments
Exhibit A – Affidavit of Fees & Costs Expended
Exhibit 1 – Complaint Cost Summary
Exhibit 2 – Itemized Cost by Complaint
Probable Cause Panel Memorandum
Emergency Suspension Order
Affidavit of Diligent Search (from investigator)
Certified mail receipt
Administrative weekly
Supplemental Investigative Report dated 10/03/2013
Exhibits S-1 through S-2
Final Investigative Report dated 9/18/2013 with Exhibits 1-4

DISCIPLINARY GUIDELINES:

- Unlawful Possession of Controlled Substance in violation of Section 893.13, Florida Statutes: **Minimum** of $5,000 fine and 2 years probation; **Maximum** of Revocation.

PRELIMINARY CASE REMARKS: DETERMINATION OF WAIVER

- The Respondent in this case was a registered pharmacy technician working for CVS Pharmacy in Jacksonville, Florida. Medication counts performed between April and June 2013 indicated that hydrocodone tablets were being stolen. The pharmacy was short 304 tablets of hydrocodone/APAP, 10/325mg on June 11, 2013; and short 155 tablets of the same medication on June 14, 2013. On June 23, 2013, Respondent was working at CVS. A medication count was performed prior to the opening of the pharmacy and the pharmacy was short 100 tablets of hydrocodone/APAP after the pharmacist used the restroom. On June 25, 2013, Respondent was confronted about the missing medications and admitted that she stole Paxil and Lortab from the pharmacy. A JSO detective found 26 Paxil tablets and 99 hydrocodone tablets in Respondent's possession and an additional 100 tablets in Respondent's vehicle. Respondent admitted to selling the tablets for $5.00 per pill.
- The Department issued an Emergency Suspension Order on October 1, 2013.
- The Department filed an Administrative Complaint on October 10, 2013.

The Administrative Complaint was served on respondent on October 24, 2013, via certified mail as evidenced by the green card received by the Department.

RECOMMENDATION OF THE DEPARTMENT

- **The Department recommends that the Respondent's registration be permanently revoked and that the Board require the Respondent to pay all Department costs incurred in the investigation and prosecution of this case.**

CONSIDERATIONS SUPPORTING THE DEPARTMENT'S RECOMMENDATION

- The Respondent stole at least 200 hydrocodone/APAP tablets from her employer, possibly even more. Respondent further admitted to selling them to acquaintances for money. Respondent is well aware that medications should not be administered or given out without an appropriate prescription. She should also be aware of the harmful effects that prescription drug addiction causes, especially in people obtaining the drugs without a prescription. The Respondent failed to return an Election of Rights to the Department within the required period and is appearing to take no responsibility for her actions in this case.
- The Department recommends revocation because, based on the Respondent's actions, she cannot be trusted in any pharmacy where she will have access to controlled substances. The egregiousness of the thefts in the quantity of the pills stolen, the number of occasions stolen, and her sale of the drugs for personal profit demonstrate that the Respondent should not be permitted to practice in a pharmacy in the future.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-13813**
Anne Colyn Miley, R.P.T.,

Respondent.
_____/

MOTION FOR DETERMINATION OF WAIVER AND FOR FINAL ORDER BY HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT

Petitioner, Department of Health, by and through counsel, moves the Board of Pharmacy to find that Respondent has waived her right to elect a method of disposition of the pending Administrative Complaint, to determine that no material facts are in dispute, to conduct a hearing not involving disputed issues of material face, and to enter a Final Order. As grounds therefore, Petitioner states:

1. An Administrative Complaint was filed against Respondent on October 10, 2013. A copy of said Administrative Complaint is attached hereto as Petitioner's Exhibit A.

2. Copies of the Administrative Complaint, Election of Rights form, and Explanation of Rights form were sent to Respondent, via certified US mail delivery, on October 15, 2013, (article number 7196 9008 9111 5773 9432). A copy of the green card receipt are attached hereto as Petitioner's Exhibit B.

3. Respondent has not filed with either the Department of Health or the Board of Pharmacy, an Election of Rights form or other responsive pleading in this case within the required twenty-one (21) day period to dispute the allegations contained in the Administrative Complaint. Copies of affidavits supporting same are attached hereto as Petitioner's Exhibits C and D.

4. Respondent has been advised, by a copy of this motion sent to her address of record that a copy of the Investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

5. The Department requests that this Motion and a hearing be placed on the agenda for the next meeting of the Board of Pharmacy to be held on April 2, 2014, in Tampa, Florida.

WHEREFORE, Petitioner respectfully requests that the Board find that Respondent has waived her right to elect a method of resolution of this matter, find that there are no material facts in dispute, hold a hearing not involving material issues of disputed fact based on the information contained in the investigative file, find that Respondent violated Chapters 456 and 465, Florida Statutes, as alleged in the Administrative Complaint, impose discipline in accordance with the disciplinary guidelines, and enter a Final Order.

DATED this 5th day of February, 2014.

Respectfully Submitted,

Louise Wilhite-St Laurent, Esq.
Florida Bar No. 0091244
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
(P) 850-245-4444, extension 8331
(F) 850-245-4662
(E) Louise_StLaurent@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion for Determination of Waiver and for Final Order by Hearing not Involving Disputed Issues of Material Fact has been provided by U.S. certified Mail to Respondent, Anne Colyn Miley, R.P.T, 1505 Highfield Drive, Jacksonville, Florida 32259, this 5th day of February, 2014.

Louise Wilhite-St. Laurent
Assistant General Counsel

LSL/mla

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v.

CASE NO.: 2013-13813

ANNE COLYN MILEY, R.P.T.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

Petitioner, Department of Health, by and through the undersigned counsel, files this Administrative Complaint before the Board of Pharmacy against Respondent, Anne Colyn Miley, R.P.T., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy and registered pharmacy technicians, pursuant to Chapters 20.43, Florida Statutes (2012-2013), Chapter 456, Florida Statutes (2012-2013) and Chapter 465, Florida Statutes (2012-2013).

2. At all times material to this Administrative Complaint, Respondent was a registered pharmacy technician, pursuant to Chapter

EXHIBIT
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465, Florida Statutes (2012-2013), having been issued license number RPT 4163.

3. Respondent's address of record is 615 Fruit Cove Road, Jacksonville, Florida 32259. Respondent's current address is 1505 Highfield Drive, Jacksonville, Florida 32259.

4. Respondent worked at CVS Pharmacy located at 9962 Baymeadows Road, Jacksonville, Florida.

5. On or about June 11, 2013, Respondent stole approximately 304 tablets of hydrocodone/APAP 10/325mg from CVS Pharmacy.

6. On or about June 14, 2013, Respondent stole approximately 155 tablets of hydrocodone/APAP 10/325mg from CVS Pharmacy.

7. On or about June 23, 2013, Respondent stole approximately 100 tablets of hydrocodone/APAP 10/325mg from CVS Pharmacy.

8. On or about June 25, 2013, Respondent stole approximately 26 tablets of Paxil and approximately 99 tablets of hydrocodone/APAP from CVS Pharmacy.

9. Hydrocodone/APAP, commonly known by the brand name Lortab, is an opioid-class medication that contains hydrocodone and acetaminophen, or Tylenol. According to Section 893.03(3), Florida

Statutes (2012-2013), hydrocodone, in the dosages found in hydrocodone/APAP, is a Schedule III controlled substance.

10. Paxil is an antidepressant drug. It is a legend drug, but not a controlled substance.

11. On or about June 25, 2013, Respondent had 26 Paxil tablets and 99 hydrocodone/APAP tablets in her possession. Respondent also had 100 hydrocodone/APAP tablets in her vehicle.

12. Respondent obtained and possessed the stolen medication without a valid prescription and outside the course of her professional practice as a registered pharmacy technician.

13. Respondent sold some of the stolen medication to one or more acquaintances. Respondent was aware that the acquaintances to whom she sold the medication did not possess a valid prescription.

14. Section 465.016(1)(e), Florida Statutes (2012-2013), subjects registered pharmacy technicians to discipline for violating Chapter 893, Florida Statutes (2012-2013).

15. Chapter 893.13, Florida Statutes (2012-2013), states in pertinent part:

> (6)(a) It is unlawful for any person to be in actual or constructive possession of a controlled substance

unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as authorized by this chapter....

(7)(a) A person may not:
1. Distribute or dispense a controlled substance in violation of this chapter....
[or]
9. Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge.

16. Respondent violated Section 465.016(1)(e), Florida Statutes (2012-2013), in one or more of the following ways:

a. By possessing hydrocodone and/or hydrocodone/APAP in violation of Chapter 893.13(6)(a), Florida Statutes (2012-2013);

b. By distributing or dispensing hydrocodone and/or hydrocodone/APAP, in violation of Chapter 893.13(7)(a)(1), Florida Statutes (2012-2013); and/or

c. By acquiring possession of hydrocodone and/or hydrocodone/APAP by misrepresentation, fraud, forgery, deception or subterfuge in violation of Chapter 893.13(7)(a)(9), Florida Statutes (2012-2013).

17. Based on the foregoing, Respondent violated Section 465.016(1)(e), Florida Statutes (2012-2013), by violating Chapter 893, Florida Statutes (2012-2013).

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board of Pharmacy deems appropriate.

SIGNED this 10th day of October, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Louise Wilhite-St Laurent
Assistant General Counsel
Florida Bar Number 0091244
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444 x 8331
Facsimile: (850) 245-4662
Email: Louise_StLaurent@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE OCT 10 2013

PCP: October 10, 2013

PCP Members: Leo J. "Lee" Fallon, BPharm, PhD & Debra Glass, BPharm

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

7196 9008 9111 5773 9432

TO:
Anne Colyn Miley, RPT
1505 Highfield Dr.
Jacksonville, FL 32259

SENDER: AC-VR
Miley 2013-13813

REFERENCE:

PS Form 3800, January 2005

RETURN RECEIPT SERVICE	Postage	
	Certified Fee	
	Return Receipt Fee	
	Restricted Delivery	
	Total Postage & Fees	

US Postal Service®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE
10/15/13

2. Article Number
7196 9008 9111 5773 9432

3. Service Type **CERTIFIED MAIL™**
4. Restricted Delivery? *(Extra Fee)* ☐ Yes

1. Article Addressed to:
Anne Colyn Miley, RPT
1505 Highfield Dr.
Jacksonville, FL 32259

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly): Anne Miley
B. Date of Delivery: OCT 24
C. Signature: X [signature] ☐ Agent ☐ Addressee
D. Is delivery address different from item 1? ☐ Yes ☐ No
If YES, enter delivery address below:

2013-13813
St. Laurent

PS Form 3811, January 2005 Domestic Return Receipt

EXHIBIT
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Affidavit of Non-Receipt

I, Tammy Collins, hereby certify in my official capacity as custodian for the Board of Nursing's licensure files that the Board, as of February 27, 2014, has no evidence of an Election of Rights form or other responsive pleading requesting a hearing prior to any agency action regarding **Anne Colyn Miley, R.P.T.; 2013-13813,** which would affect the Subject's substantial interests or rights.

Custodian of Records
Florida Board of Pharmacy

Before me, personally appeared Tammy Collins, whose identity is known to me personally and who, under, oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 27th day of February, 2013.

LORRAINE GAIL CURRY
MY COMMISSION # EE 97887
EXPIRES: May 26, 2015
Bonded Thru Notary Public Underwriters

Lorraine Gail Curry
Notary Public Signature
My commission expires:

AFFIDAVIT

I, Bridget Coates, Deputy Clerk for the Department Clerk's Office, hereby certify in my official capacity as custodian for the Department Clerk's records, that the Department Clerk's Office has not received an Election of Rights form or other responsive pleading, which requests a hearing prior to any Department action regarding **Ann Colyn Miley, R.P.T.; 2013-13813**, which would affect the Respondent's substantial interests or rights.

Bridget Coates
Custodian of Record
Department Clerk's Office

Before me, personally appeared Bridget Coates, whose identity is known to me personally and who, under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed before me this 5th day of February, 2014.

Lawanda Bell
Notary Public

My Commission Expires:

LAWANDA M BELL
MY COMMISSION # EE197051
EXPIRES May 09, 2016
(407) 398-0153 FloridaNotaryService.com

EXHIBIT
letter D

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO. 2013-13813**

Anne Colyn Miley, R.P.T.,

Respondent.
_____/

MOTION TO ASSESS COSTS
IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes (2012). As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes (2012), states, in pertinent part, as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or after July 1,

> 2001, under this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is no board, shall assess costs related to the investigation and prosecution of the case. The costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto....

3. As evidenced in the attached affidavit (Exhibit A), the investigation and prosecution of this case has resulted in costs in the total amount of $1,821.90, based on the following itemized statement of costs:

Complaint Cost Summary

Complaint Number: 201313813

Subject's Name: MILEY, ANNE COLYN

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	1.00	$54.90
Investigation:	21.80	$1,394.75
Legal:	3.50	$372.25
Compliance:	0.10	$0.00
	**********	**********
Sub Total:	26.40	$1,821.90
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,821.90

4. The attached affidavit reflects the Department's costs for attorney time in this case as $372.25 (Exhibit A). The cost of obtaining an affidavit from an outside attorney will be greater than $372.25. Therefore, the Department is not seeking costs for attorney time in this case.

5. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

6. Petitioner requests that the Board grant this motion and assess costs in the amount of $1,821.90 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes (2012).

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $1,821.90.

DATED this 5th day of February, 2014.

Respectfully submitted,

Louise Wilhite-St. Laurent
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, FL 32399-3265
Florida Bar # 0091244
Phone (850) 245-4444 x 8331
Fax (850) 245-4662
Louise_StLaurent@doh.state.fl.us

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 5th day of February, 2014 to Anne Colyn Miley, R.P.T., 1505 Highfield Drive, Jacksonville, Florida 32259.

Louise Wilhite- St. Laurent
Assistant General Counsel

LSL/mla

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2013-13813**(Department of Health v **Anne Colyn Miley, R.P.T.**) are **ONE THOUSAND EIGHT HUNDRED TWENTY ONE DOLLARS AND NINETY CENTS ($1,821.90).**

6) The costs for DOH case **2013-13813** (Department of Health v **Anne Colyn Miley, R.P.T**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case numbers **2013-13813**(Department of Health v. **Anne Colyn Miley, R.P.T.**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators

EXHIBIT
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and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of her knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 5 day of February, 2014, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette F Carter

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

ANTOINETTE F. CARTER
MY COMMISSION EXPIRES
September 26, 2015
#EE 132192
Bonded thru Troy Fain Insurance
NOTARY PUBLIC, STATE OF FLORIDA

Complaint Cost Summary

Complaint Number: 201313813

Subject's Name: MILEY, ANNE COLYN

	***** Cost to Date *****	
	Hours	**Costs**
Complaint:	**1.00**	**$54.90**
Investigation:	**21.80**	**$1,394.75**
Legal:	**3.50**	**$372.25**
Compliance:	**0.10**	**$0.00**
	**********	**********
Sub Total:	**26.40**	**$1,821.90**
Expenses to Date:		**$0.00**
Prior Amount:		**$0.00**
Total Costs to Date:		**$1,821.90**

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201313813

Report Date 02/05/2014

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
JI81	1.50	$63.98	$95.97	10/02/2013	58	TRAVEL TIME
JI81	1.00	$63.98	$63.98	10/03/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**21.80**		**$1,394.75**			

PROSECUTION SERVICES UNIT

HLL101B	0.20	$106.35	$21.27	09/03/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL101B	0.50	$106.35	$53.18	09/24/2013	25	REVIEW CASE FILE
HLL101B	1.00	$106.35	$106.35	09/24/2013	81	ESO/ERO
HLL101B	0.20	$106.35	$21.27	09/25/2013	81	ESO/ERO
HLL101B	0.10	$106.35	$10.64	09/27/2013	81	ESO/ERO
HLL101B	0.60	$106.35	$63.81	10/01/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL101B	0.10	$106.35	$10.64	10/01/2013	74	MEETINGS WITH DEPARTMENT STAFF
HLL101B	0.10	$106.35	$10.64	10/01/2013	115	CONTACT WITH INVESTIGATORS
HLL101B	0.30	$106.35	$31.91	10/03/2013	89	PROBABLE CAUSE PREPARATION
HLL101B	0.20	$106.35	$21.27	10/03/2013	115	CONTACT WITH INVESTIGATORS
HLL101B	0.20	$106.35	$21.27	10/10/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
Sub Total	**3.50**		**$372.25**			

Total Cost	**$1,821.90**

EXHIBIT
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Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201313813

Report Date 02/05/2014

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
COMPLIANCE MANAGEMENT UNIT						
HC00	0.10	$0.00	$0.00	10/01/2013	119	REVIEWING FO/CITATIONS & TERM INPUT
Sub Total	**0.10**		**$0.00**			
CONSUMER SERVICES UNIT						
HA115	1.00	$54.90	$54.90	08/29/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**1.00**		**$54.90**			
INVESTIGATIVE SERVICES UNIT						
JI91	1.50	$63.98	$95.97	08/30/2013	100	SERVICE OF ADMINISTRATIVE COMPLAINTS, SUBPOENAS, NOTICE TO CEASE
JI91	0.30	$63.98	$19.19	08/30/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	2.50	$63.98	$159.95	09/03/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	1.50	$63.98	$95.97	09/03/2013	76	REPORT PREPARATION
JI81	0.30	$63.98	$19.19	09/04/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	0.40	$63.98	$25.59	09/04/2013	76	REPORT PREPARATION
JI81	0.50	$63.98	$31.99	09/11/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	1.00	$63.98	$63.98	09/11/2013	76	REPORT PREPARATION
JI81	1.50	$63.98	$95.97	09/16/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	1.50	$63.98	$95.97	09/16/2013	76	REPORT PREPARATION
JI81	1.50	$63.98	$95.97	09/17/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	1.00	$63.98	$63.98	09/17/2013	58	TRAVEL TIME
JI81	2.00	$63.98	$127.96	09/17/2013	76	REPORT PREPARATION
JI81	0.50	$63.98	$31.99	09/18/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	1.50	$63.98	$95.97	09/18/2013	76	REPORT PREPARATION
JI91	0.30	$63.98	$19.19	10/01/2013	4	ROUTINE INVESTIGATIVE WORK
JI81	0.50	$63.98	$31.99	10/01/2013	6	SUPPLEMENTAL INVESTIGATION
JI81	1.00	$63.98	$63.98	10/02/2013	6	SUPPLEMENTAL INVESTIGATION

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 02/05/2014

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

MEMORANDUM OF FINDING OF PROBABLE CAUSE

TO: DEPARTMENT OF HEALTH

ADMINISTRATION, GENERAL COUNSEL, PHARMACY SECTION

FROM: CHAIRMAN, PROBABLE CAUSE PANEL

RE: **Anne Colyn Miley, R.P.T.** CASE NO. **2013-13813**

DATE OF PROBABLE CAUSE PANEL MEETING: **October 10, 2013**

THIS MATTER WAS BROUGHT BEFORE THE PROBABLE CAUSE PANEL MEMBERSHIP COMPOSED OF **Leo J. "Lee" Fallon, BPharm, PhD & Debra Glass, BPharm** ON THE DATE SET FORTH ABOVE. THE PANEL, HAVING RECEIVED THE COMPLETE INVESTIGATIVE REPORT, HAVING CAREFULLY REVIEWED THAT REPORT, HAVING REVIEWED THE RECOMMENDATION OF THE AGENCY, AND HAVING HAD THE OPPORTUNITY TO INQUIRE OF COUNSEL AND BEING OTHERWISE DULY ADVISED IN THE PREMISES THEREOF, FIND THAT:

_____ PROBABLE CAUSE WAS NOT FOUND IN THIS CASE.

__X__ PROBABLE CAUSE WAS FOUND ON THE FOLLOWING STATUTORY AND REGULATORY GROUNDS, INCLUDING BUT NOT LIMITED TO SECTION(S):

Section 465.016(1)(e), Florida Statutes (2012-2013)

Larry Ellis for Debra Glass

CHAIRPERSON, PROBABLE CAUSE PANEL
BOARD OF PHARMACY

Final Order No. DOH-13-1874-ESD-MQA
FILED DATE OCT 01 2013
Department of Health
By: Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the Registration of
Anne Colyn Miley, R.P.T.
Registration Number RPT 4163
Case Number 2013-13813

ORDER OF EMERGENCY SUSPENSION OF LICENSE

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the emergency suspension of the registration of Anne Colyn Miley, R.P.T., ("Ms. Miley") to practice as a registered pharmacy technician in the State of Florida. Ms. Miley holds registration number RPT 4163. Her address of record is 615 Fruit Cove Road, Jacksonville, FL 32259. Ms. Miley's current address is unknown. The following Findings of Fact and Conclusions of Law support the emergency suspension of Ms. Miley's registration to practice as a pharmacy technician in the State of Florida.

FINDINGS OF FACT

1. The Department of Health ("Department") is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes (2012-2013). Section 456.073(8), Florida Statutes (2012-2013), authorizes the State Surgeon General to summarily

suspend Ms. Miley's registration to practice as a registered pharmacy technician in the State of Florida in accordance with Section 120.60(6), Florida Statutes (2012-2013).

2. At all times material to this order, Ms. Miley was a registered pharmacy technician in the State of Florida, pursuant to Chapter 465, Florida Statutes (2012-2013), and worked as a registered pharmacy technician at CVS Pharmacy located at 9962 Baymeadows Road, Jacksonville, Florida.

3. Pharmacists at CVS Pharmacy routinely perform medication counts in the pharmacy. According to the medication audits performed between the approximate dates of June 2012, and June 2013, CVS could not account for over 2,000 tablets of hydrocodone.

4. Hydrocodone is an opioid-class medication, commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2012-2013), hydrocodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of hydrocodone may lead to severe psychological or physical dependence.

5. A CVS loss-prevention officer, Mr. D.C., began conducting pill

counts at the pharmacy after the hydrocodone losses were detected. Mr. D.C. noted that several incidents of apparent theft occurred between April and June, 2013. Mr. D.C. also noted that the thefts occurred on days when Ms. Miley was working.

6. Specifically, Mr. D.C. found that on or about June 11, 2013, the pharmacy was short 304 tablets of hydrocodone/APAP, 10/325mg and on June 14, 2013, the pharmacy was short 155 tablets of hydrocodone/APAP 10/325mg.

7. Hydrocodone/APAP, commonly known by the brand name Lortab, is an opioid-class medication that contains hydrocodone and acetaminophen, or Tylenol. It is prescribed to treat pain. According to Section 893.03(3), Florida Statutes (2012), hydrocodone, in the dosages found in hydrocodone/APAP, is a Schedule III controlled substance that has a potential for abuse less than the substances

8. On or about June 23, 2013, Ms. Miley was working at CVS as a cashier and Ms. M.B. was the pharmacist on duty. Mr. D.C. directed Ms. M.B. to perform a medication count that morning before Ms. M.B.'s shift. Later in the day, Ms. M.B. left the pharmacy area to go to the restroom. Ms. Miley entered the pharmacy area for a few moments. Upon Ms. M.B.'s

return to the pharmacy, Ms. M.B. noticed that a bottle containing 100 tablets of hydrocodone/APAP 10/325mg was missing.

9. On or about June 25, 2013, Mr. D.C. went to CVS to speak with Ms. Miley regarding the missing medications. Mr. D.C. observed that Ms. Miley became nervous and requested to be permitted a break for lunch. Ms. Miley also tried several times to leave the store. Ms. Miley told Mr. D.C. that she stole Paxil and Lortab from the pharmacy.

10. Paxil is an antidepressant that belongs to a class of drugs called selective serotonin reuptake inhibitors (SSRIs). It is used to treat depression, anxiety disorders and other mental health disorders. Paxil is a legend drug, but not a controlled substance.

11. Mr. D.C. contacted the Jacksonville Sheriff's Office. Detective D.V. and Detective S. responded to the pharmacy to gather evidence.

12. Detective D.V. found 26 Paxil tablets and 99 hydrocodone tablets in Ms. Miley's possession. Detectives also found 100 tablets of hydrocodone in Ms. Miley's vehicle.

13. Ms. Miley told Detective S. that she stole the pills because she needs money and she sells the Lortab to acquaintances for $5.00 per pill.

14. Mr. D.C. received a written statement from Ms. Miley on June

25, 2013. Ms. Miley wrote that she first started taking Lortab and Paxil from the pharmacy two months prior. She admitted that she took the Lortab and Paxil pills from the pharmacy on June 25, 2013, by pouring them out of the bottle, placing them in her pocket and she planned to put them into her car. Ms. Miley wrote that she sells the pills to someone named "Scotty." Ms. Miley admitted that she did not have a valid prescription for the pills that she took and that she took at least 200 pills from the pharmacy. Ms. Miley stated that she regretted taking the pills and that she "will never do it again."

15. Ms. Miley was arrested and charged with two felony counts of Trafficking in Controlled Substances and Theft of Controlled Substances in Duval County Case Number 2013CF5980. The charges are currently pending resolution.

16. Registered pharmacy technicians assist pharmacists in data entry, and the counting, weighing, measuring, pouring and mixing of prescription medication or stock legend drugs and controlled substances, among various other tasks. Because registered pharmacy technicians are entrusted with such important tasks which include the handling, counting, and reporting of the drugs in the pharmacy, it is imperative that a

registered pharmacy technician have good judgment and moral character while working in a pharmacy

17. Ms. Miley's behavior in stealing at least 200 prescription hydrocodone tablets over a period of two months in order to sell them for profit clearly demonstrates that she is lacking the judgment and moral character needed to practice as a registered pharmacy technician.

18. As a result of her employment as a registered pharmacy technician, Mr. Miley was aware that prescription medications and controlled substances may only be dispensed to patients who have valid prescriptions and need the medications for a legitimate health reason. Despite this, Ms. Miley illegally diverted controlled substances for selling to at least one person whom she knew did not have a valid prescription for the drugs.

19. Mr. Miley's lack of good judgment and moral character, her theft of large quantities of controlled substances from her employer, her sale of the controlled substances for personal gain to people who did not have valid prescriptions and her disregard for the laws and rules governing the practice of pharmacy in the State of Florida represent a significant likelihood that Ms. Miley will continue her illegal behavior. This probability

constitutes an immediate serious danger to the health, safety, and welfare of the citizens of the State of Florida. Restricting Ms. Miley's registration would not adequately protect the public because the very nature of practicing as a registered pharmacy technician puts Ms. Miley in contact with legend drugs and controlled substances, which creates the risk for further theft and sale of the controlled substances. As a result, nothing short of the immediate suspension of Ms. Miley's registration to practice as a registered pharmacy technician will protect the public from this danger.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The State Surgeon General of the Department of Health has jurisdiction over this matter pursuant to Sections 20.43 and 456.073(8), Florida Statutes (2012-2013), and Chapter 465, Florida Statutes (2012-2013), as set forth above.

2. Section 465.016(1)(e), Florida Statutes (2012-2013), subjects registered pharmacy technicians to discipline, including suspension, for violating Chapter 893, Florida Statutes (2012-2013).

3. Chapter 893.13, Florida Statutes (2012-2013), states in

pertinent part:

> (6)(a) It is unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as authorized by this chapter....
>
> (7)(a) A person may not:
> 1. Distribute or dispense a controlled substance in violation of this chapter....
> [or]
> 9. Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception or subterfuge.

4. Ms. Miley violated Section 465.016(1)(e), Florida Statutes (2012-2013), in one or more of the following ways:

a. By possessing hydrocodone and/or hydrocodone/APAP in violation of Chapter 893.13(6)(a), Florida Statutes (2012-2013);

b. By distributing or dispensing hydrocodone and/or hydrocodone/APAP, in violation of Chapter 893.13(7)(a)(1), Florida Statutes (2012-2013); and/or

c. By acquiring possession of hydrocodone and/or

hydrocodone/APAP by misrepresentation, fraud, forgery, deception or subterfuge in violation of Chapter 893.13(7)(a)(9), Florida Statutes (2012-2013).

5. Section 120.60(6), Florida Statutes (2013), authorizes the Department to suspend a registered pharmacy technician's registration upon a finding that the registered pharmacy technician presents an immediate, serious danger to the public health, safety or welfare.

6. Ms. Miley's continued ability to practice as a registered pharmacy technician constitutes an immediate serious danger to the health, safety, or welfare of the public and this summary procedure is fair under the circumstances to adequately protect the public.

In accordance with Section 120.60(6), Florida Statutes (2012-2013), it is **ORDERED THAT:**

1. The registration of Anne Colyn Miley, registration number RPT 4163, is immediately suspended.

2. A proceeding seeking formal discipline of the registration of Ms. Miley to practice as a registered pharmacy technician will be promptly instituted and acted upon in compliance with Sections 120.569 and 120.60(6), Florida Statues (2012-2013).

DONE and ORDERED this 30th day of September, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

PREPARED BY:
Louise Wilhite-St Laurent
Assistant General Counsel
Fla. Bar No. 0091244
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4444 x8331
Facsimile: (850) 245-4662
Email: Louise_StLaurent@doh.state.fl.us

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Sections 120.60(6) and 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Review proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the Petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

7196 9008 9111 5772 5459

TO:

Anne Colyn Miley, R.P.T.
1505 Highfield Drive
Jacksonville, FL 32259
ESO/13-13813_L. St. Laurent, Esq.
10/1/13

SENDER:

REFERENCE:

PS Form 3800, January 2005

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MEMORANDUM

TO: Florida Administrative Registry

FROM: Tamia Christopher, Regulatory Specialist I

RE: Anne Colyn Miley, R.P.T., RPT# 4163 (FAW **#13626965)**

CASE NO: 2013-13813

DATE: October 1, 2013

Attached please find notice of the issuance of an **Emergency Suspension** Order for notice in the next issue of the Florida Administrative Register.

On October 1, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Anne Colyn Miley, R.P.T., RPT# 4163. This Emergency Suspension Order was predicated upon the State Surgeon General's findings of an immediate and serious danger to the public health, safety and welfare pursuant to Sections 456.073(8) and 120.60(6) Florida Statutes (2011). The State Surgeon General determined that this summary procedure was fair under the circumstances, in that there was no other method available to adequately protect the public.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Jacksonville	Date of Case: 08/29/13	Case Number: RPT 2013-13813
Subject: **ANNE COLYN MILEY, RPT** 615 Fruit Cove Road Jacksonville, FL 32259 (B) (904) 465-2602	Source: **DOH / JACKSONVILLE ISU**	

Prefix:	License #:	Profession:	Board:	Report Date:
RPT	4163	Registered Pharmacy Technician	Pharmacy	10/03/13

Period of Investigation: 10/01/13—10/03/13	Type of Report: SUPPLEMENTAL

Alleged Violation: F.S. 456.072 "Grounds for discipline; penalties; enforcement.— (1) The following... (k) Failing to perform... (dd) Violating..." and F.S. 465.016 "Disciplinary actions.— (1) The following acts... (d) Being unfit or incompetent to practice pharmacy... (i) Compounding, dispensing, or distributing... (m) Being unable to practice... (r) Violating..."

Synopsis:
This supplemental report is predicated upon the receipt of a request from PSU for this office to hand serve the Emergency Suspension Order and attachments, (Exhibit S-1).

On 10/02/13, this Investigator presented to 1505 Highland Forest Drive, Jacksonville, FL 32259 in attempt of service. A woman who did not identify herself other than as MILEY's twin sister, stated that MILEY did not live there, but was currently in a rehabilitation center. She stated she would be visiting MILEY on 10/03/13, and would provide the ESO to her at that time. She further agreed to have MILEY contact this Investigator to verify receipt, but outside communication is limited, so she did not know how or when MILEY would be able to contact this Investigator.

If MILEY contacts this Investigator, any information obtained will be forwarded to Legal upon receipt.

Attachments:
S-1. Supplemental Request and attachments.....2-13
S-2. Affidavit of Service.....14

RECEIVED-LEGAL
13 OCT 10 AM 8:33

Related Complaint: None

Investigator/Date:	Approved By/Date:
Ryan F. Heal MQA Investigator (JI-81) 10/03/13	Charles C. Coats, III District Manager (JI-15) 10/03/2013

Received Investigative Services

Distribution: HQ/ISU

INV Form 300 7/02

DOH/MQA
Tallahassee HQ

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

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HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201213103

AVALON PARK PHARMACY,
RESPONDENT.

NOTICE

TO: AVALON PARK PHARMACY
457 AVALON PARK SOUTH BLVD STE 300
ORLANDO, FL 32828

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201213103

AVALON PARK PHARMACY,
RESPONDENT.

NOTICE

TO: MARTY R. DIX
106 EAST COLLEGE AVENUE
12TH FLOOR
TALLAHASSSEE, FL 32301

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Mary Miller, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Avalon Park Pharmacy
DOH Case Number 2012-13103
DATE: January 13, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Avalon Park Pharmacy
Subject's Address of Record:	457 Avalon Park South Blvd, Ste 300 Orlando, FL 32828
Enforcement Address:	457 Avalon Park South Blvd, Ste 300 Orlando, FL 32828
Subject's License No:	24071 **Rank:** PH
Licensure File No:	16591
Initial Licensure Date:	5/15/2009
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Ct 1: 465.023(1)(h), FS (2009)(2010)(2011) Ct 2: 465.023(1)(c), FS (2009)(2010)(2011) 64B16-27.813, FAC Ct 3: 465.023(1)(c), FS (2009)(2010)(2011) 465.016(1)(i), FS (2009)(2010)(2011) Ct 4: 465.023(1)(c), FS (2012) 499.005(18), FS (2012) 61N-1.012(1)(a), FAC Ct 5: 465.023(1)(c), FS (2012) 499.005(22), FS (2012) Ct 6: 465.023(1)(c), FS (2012) 499.005(3), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	July 30, 2013; Weizer & Meshad
Subject's Attorney:	Marty R. Dix

	106 East College Avenue, 12th floor Tallahasssee, FL 32301
Complainant/Address:	DOH/ISU-Orlando
Materials Submitted:	Memorandum to the Board
	Voluntary Relinquishment
	Administrative Complaint
	Notification Letter
	Expert Report
	Election of Rights with Attachments
	456 Packet
	Letter of Representation
	Probable Cause Panel Memorandum
	Final Investigative Report with Exhibits 1-14

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JAN 13 2014

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO: 2012-13103**

AVALON PARK PHARMACY,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **AVALON PARK PHARMACY**, Permit No. **PH 24071** hereby voluntarily relinquishes Respondent's Florida pharmacy permit and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's permit pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to voluntarily cease practicing pharmacy immediately upon executing this Voluntary Relinquishment. Respondent

further agrees to refrain from the practice of pharmacy pursuant to its permit until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

3. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

4. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

5. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 7 day of January, year of 2014.

For Avalon Park Pharmacy

STATE OF FLORIDA

COUNTY OF ORANGE

Before me, personally appeared VALENTINE OKONKWO, whose identity is personally known to me or by producing FDL (type of identification) as identification and who acknowledges that her signature appears above.
Sworn to or affirmed by Respondent before me this 7 day of January, 2014.

My Commission Expires

NOTARY PUBLIC - STATE OF FLORIDA

Mary L Sheridan

Type or Print Notary

MARY L. SHERIDAN
Notary Public - State of Florida
My Comm. Expires Nov 12, 2014
Commission # EE 37836
Bonded Through National Notary Assn.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-13103**

AVALON PARK PHARMACY,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Avalon Park Pharmacy, and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent held a permit to operate as community pharmacy pursuant to Chapter 465, Florida Statutes (2012), being issued license number PH 24071.

3. Respondent's address of record is 457 Avalon Park South Boulevard, Suite 300, Orlando, Florida 32828.

4. At all times material to this Complaint, Respondent did not hold a permit to operate as a prescription drug distributor.

5. At all times material to this Complaint, Respondent did not hold a permit to operate as a retail pharmacy wholesale distributor.

6. At all times material to this Complaint, Respondent was owned by Valentine Chike Okonkwo (Mr. Okonkwo), a licensed pharmacist in the State of Florida, having been issued license number PS 40496.

7. Mr. Okonkwo also owns Quality Care Pharmacy Corporation (Quality Care). Quality Care held a permit to operate as a community pharmacy, being issued license number PH 25478.

8. At all times material to this Complaint, Mr. Okonkwo was Respondent's Prescription Department Manager (PDM) and only pharmacist employed by Respondent.

9. Section 465.022(11), Florida Statutes (2012), provides:

> The prescription department manager of a [pharmacy] must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy . . . [t]he prescription department manager must ensure the [pharmacy] permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

10. From on or about February 3, 2012 until on or about November 29, 2012, Jen-Chen Ho, R.Ph (Mr. Ho), was Quality Care's Prescription Department Manager (PDM) and Quality Care's agent. Mr. Ho is a licensed pharmacist in the State of Florida, having been issued license number PS 42218.

Facts Specific to N.C.

11. At all times material to this Complaint, N.C. was not a Florida licensed health care professional.

12. On or about March 2, 2010, N.C. presented two prescriptions to Mr. Okonkwo at Respondent. Both prescriptions were purportedly written by Dr. F.J., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. F.J.'s name. The prescriptions were for 220 oxycodone 30 milligram (mg) tablets and 30 Xanax two mg tablets. Dr. F.J. did not write or authorize the oxycodone and Xanax prescriptions N.C. presented to Mr. Okonkwo on or about March 2, 2010. Mr. Okonkwo dispensed the medications pursuant to each prescription without attempting to verify the prescriptions.

13. Oxycodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes, oxycodone is a Schedule II controlled

substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of oxycodone may lead to severe psychological or physical dependence.

14. Xanax is the brand name for alprazolam and is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes, alprazolam is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of alprazolam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

15. On or about May 12, 2010, N.C. presented three prescriptions to Mr. Okonkwo at Avalon. All three prescriptions were purportedly written by Dr. P.M., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. P.M.'s name. The prescriptions were for 220 oxycodone 30 mg tablets, 120 Soma 350 mg tablets, and 30 Xanax two mg tablets. Dr. P.M. did not write or authorize the oxycodone, Soma, and Xanax prescriptions N.C. presented to Mr. Okonkwo on or about May 12, 2010. Mr. Okonkwo dispensed the

medications pursuant to each prescription without attempting to verify the prescriptions.

16. Soma is the brand name for carisoprodol, a muscle relaxant commonly prescribed to treat muscular pain. According to Section 893.03(4), Florida Statutes, carisoprodol is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of carisoprodol may lead to limited physical or psychological dependence relative to the substances in Schedule III.

17. N.C. and Mr. Okonkwo agreed Mr. Okonkwo would fill the prescription N.C. wrote using Dr. F.J.'s name and presented to Mr. Okonkwo at Respondent on or about March 2, 2010.

18. N.C. and Mr. Okonkwo agreed Mr. Okonkwo would fill the prescription N.C. wrote using Dr. P.W.'s name and presented to Mr. Okonkwo at Respondent on or about May 12, 2010.

19. N.C. only presented prescriptions for controlled substances to Mr. Okonkwo at Respondent.

20. Mr. Okonkwo knew or had reason to believe the prescriptions presented by N.C. to him at Respondent on or about March 2, 2010 and May 12, 2010 were not based upon a valid practitioner-patient relationship.

Facts Specific to K.D.

21. On or about February 24, 2010, K.D. presented a prescription for 210 oxycodone 30 mg tablets to Mr. Okonkwo at Respondent. The prescription was purportedly written by Dr. F.J., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescription using Dr. F.J.'s name. Dr. F.J. did not write or authorize the oxycodone prescription K.D. presented to Mr. Okonkwo on or about February 24, 2010. Mr. Okonkwo dispensed the medication pursuant to the prescription.

22. On or about July 20, 2011, K.D. presented two prescriptions to Mr. Okonkwo at Respondent. The prescriptions were purportedly written by Dr. A.W., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescription using Dr. F.J.'s name. The prescriptions were for 180 oxycodone 30 mg tablets and 20 Xanax two mg tablets. Dr. F.J. did not write or authorize the oxycodone and Xanax prescriptions K.D. presented to Mr. Okonkwo on or about July 20, 2011. Mr. Okonkwo dispensed the mediations pursuant to the prescriptions.

23. Mr. Okonkwo knew or had reason to believe the prescriptions K.D. presented to Respondent at Respondent on or about February 24, 2010 and July 20, 2011 were not based on a valid practitioner-patient relationship.

Facts Specific to T.F.

24. On or about April 19, 2010, T.F. presented a prescription to Mr. Okonkwo at Respondent. The prescription was purportedly written by Dr. P.M., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescription using Dr. P.M.'s name. The prescription was for 30 Xanax, two mg tablets. Dr. P.M. did not write or authorize the Xanax prescription T.F. presented to Mr. Okonkwo on or about April 19, 2010. Mr. Okonkwo dispensed the medication pursuant to the prescription without verifying the prescription.

25. On or about May 12, 2010, T.F. presented a prescription to Mr. Okonkwo at Respondent. The prescription was purportedly written by Dr. P.M., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescription using Dr. P.M.'s name. The prescription was for 30 Xanax two mg tablets. Dr. P.M. did not write or authorize the Xanax prescription T.F. presented to Mr. Okonkwo on or about May 12, 2012. Mr. Okonkwo dispensed the medication pursuant to the prescription without attempting to verify the prescription.

26. T.F. only presented prescriptions for controlled substances to Mr. Okonkwo at Respondent.

27. Mr. Okonkwo knew or had reason to believe the prescriptions T.F. presented to him at Respondent on or about April 19, 2010 and May 12, 2010 were not based upon a valid practitioner-patient relationship.

Facts Specific to K.H.

28. On or about June 3, 2010, K.H. presented a prescription for 240 oxycodone 30 mg tablets to Mr. Okonkwo at Respondent. The prescription was purportedly written by Dr. C.Y., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescription using Dr. C.Y.'s name. Dr. C.Y. did not write or authorize the oxycodone prescription K.H. presented to Mr. Okonkwo on or about June 3, 2010. Mr. Okonkwo dispensed the medication pursuant to the prescription.

29. On or about September 30, 2011, K.H. presented three prescriptions to Mr. Okonkwo at Respondent. The prescriptions were purportedly written by Dr. J.R., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. J.R.'s name. The prescriptions were for 60 Xanax two mg tablets, 30 ibuprofen 800 mg tablets, and 180 oxycodone 30 mg tablets. Dr. J.R. did not write or authorize the Xanax, ibuprofen, and oxycodone prescriptions K.H. presented to Mr. Okonkwo on or about September 30, 2011. Mr. Okonkwo dispensed the medication pursuant to the prescriptions.

30. Dr. J.R.'s name on the prescriptions K.H. presented to Mr. Okonkwo at Respondent on or about September 30, 2011 was misspelled.

31. Mr. Okonkwo knew or had reason to believe the prescriptions K.H. presented to him at Respondent on or about June 3, 2010 and September 30, 2011 were not based on a valid practitioner-patient relationship.

Facts Specific to H.D.

32. On or about June 27, 2011, H.D. presented two prescriptions to Mr. Okonkwo at Respondent. The prescriptions were purportedly written by Dr. A.W., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. A.W.'s name. The prescriptions were for 180 oxycodone 30 mg tablets and 60 Xanax two mg tablets. Dr. A.W. did not write or authorize the oxycodone and Xanax prescriptions H.D. presented to Mr. Okonkwo on or about June 27, 2011. Mr. Okonkwo dispensed the medications pursuant to the prescriptions.

33. On or about July 28, 2011, H.D. presented three prescriptions to Mr. Okonkwo at Respondent. The prescriptions were purportedly written by Dr. J.R., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. J.R.'s name. The prescriptions were for 90 Soma 350 mg tablets, 60 Xanax two mg tablets,

and 180 oxycodone 30 mg tablets. Dr. J.R. did not write or authorize the Soma and Xanax prescriptions H.D. presented to Mr. Okonkwo on or about July 28, 2011. Mr. Okonkwo dispensed the medications pursuant to the prescriptions without attempting to verify the prescriptions.

34. Dr. J.R.'s name on the prescriptions H.D. presented to Mr. Okonkwo on or about July 28, 2011 was misspelled.

35. Patient H.D. only presented prescriptions for controlled substances to Mr. Okonkwo at Respondent.

36. Mr. Okonkwo knew or had reason to believe the prescriptions Patient H.D. presented to him at Respondent on or about June 27 and July 28, 2011 were not based upon a valid practitioner-patient relationship.

Facts Specific to A.R.

37. On or about July 14, 2011, A.R. presented three prescriptions to Mr. Okonkwo at Respondent. The prescriptions were purportedly written by Dr. A.W., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. A.W.'s name. The prescriptions were for 30 ibuprofen 800 mg tablets, 180 oxycodone 30 mg tablets, and 60 Xanax two mg tablets. Dr. A.W. did not write or authorize the ibuprofen, oxycodone, and Xanax prescriptions A.R. presented to Mr.

Okonkwo on or about July 14, 2011. Mr. Okonkwo dispensed the medications pursuant to the prescriptions.

38. Ibuprofen is a non-steroidal anti-inflammatory drug used to reduce fever or inflammation. Some forms and dosages of ibuprofen may be obtained over-the-counter, while other forms and dosages require a prescription.

39. On or about August 10, 2011, A.R. presented three prescriptions to Mr. Okonkwo at Respondent. The prescriptions were purportedly written by Dr. J.R., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. J.R.'s name. The prescriptions were for 180 oxycodone 30 mg tablets, 90 Soma 350 mg tablets, and 60 Xanax two mg tablets. Dr. J.R. did not write or authorize the oxycodone, Soma, and Xanax prescriptions A.R. presented to Mr. Okonkwo on or about August 10, 2011. Mr. Okonkwo dispensed the medications pursuant to the prescriptions.

40. Dr. J.R.'s name on the prescriptions A.R. presented to Mr. Okonkwo on or about August 10, 2011 was misspelled.

41. Mr. Okonkwo knew or had reason to believe the prescriptions A.R. presented to him at Respondent on or about July 14 and August 10, 2011 were not based upon a valid practitioner-patient relationship.

Facts Specific to B.D.

42. On or about August 1, 2011, B.D. presented three prescriptions to Mr. Okonkwo at Respondent. The prescriptions were purportedly written by Dr. J.R., a licensed physician in the State of Florida. However, N.C. prepared and signed the prescriptions using Dr. J.R.'s name. The prescriptions were for 180 oxycodone 30 mg tablets, 60 Xanax two mg tablets, and 30 ibuprofen 800 mg tablets. Dr. J.R. did not write or authorize the oxycodone, Xanax, and ibuprofen prescriptions B.D. presented to Mr. Okonkwo on or about August 1, 2011. Mr. Okonkwo dispensed the medications pursuant to the prescriptions.

43. Dr. J.R.'s name on the prescriptions B.D. presented to Mr. Okonkwo at Respondent on or about August 1, 2011 was misspelled.

44. Mr. Okonkwo knew or had reason to believe the prescriptions B.D. presented to Mr. Okonkwo at Respondent on or about August 1, 2011 were not based upon a valid practitioner-patient relationship.

Facts Specific to Quality Care

45. On or about November 29, 2012, a Department inspector conducted a routine inspection of Quality Care.

46. The Department inspector found Quality Care's inventory to be low and some bottles on Quality Care's shelves were bearing Respondent's labels.

47. From in or about August 2012 until in or about October 2012, Mr. Okonkwo delivered legend drugs from Respondent for use at Quality Care when Quality Care's inventory was low.

48. From in or about August 2012 until in or about October 2012, Mr. Okonkwo and Respondent were not authorized to transfer legend drugs from Respondent to Quality Care.

49. From in or about August 2012 until in or about October 2012, Mr. Okonwko failed to deliver appropriate documentation, such as pedigree papers, to Quality Care documenting the transfer of legend drugs from Respondent to Quality Care.

50. From in or about August 2012 until in or about October 2012, Mr. Okonkwo delivered legend drugs from Respondent to Quality Care so Quality Care could further distribute these legend drugs to internet pharmacies.

51. On or about November 16, 2012, Mr. Okonkwo delivered legend drugs from Respondent for use at Quality Care because Quality Care's inventory was low.

52. On or about November 16, 2012, Mr. Okonkwo and Respondent were not authorized to transfer legend drugs from Respondent to Quality Care.

53. On or about November 16, 2012, Mr. Okonkwo failed to deliver appropriate documentation, such as pedigree papers, to Quality Care documenting the transfer of legend drugs from Respondent to Quality Care.

54. On or about November 16, 2012, Mr. Okonkwo delivered legend drugs from Respondent to Quality Care so Quality Care could further distribute these legend drugs to internet pharmacies.

55. On or about November 20, 2012, Mr. Okonkwo delivered legend drugs from Respondent for use at Quality Care because Quality Care's inventory was low.

56. On or about November 20, 2012, Mr. Okonkwo and Respondent were not authorized to transfer legend drugs from Respondent to Quality Care.

57. On or about November 20, 2012, Mr. Okonkwo failed to deliver appropriate documentation, such as pedigree papers, to Quality Care documenting the transfer of legend drugs from Respondent to Quality Care.

58. On or about November 20, 2012, Mr. Okonkwo delivered legend drugs from Respondent to Quality Care so Quality Care could further distribute these legend drugs to internet pharmacies.

59. On or about November 22, 2012, Mr. Okonkwo delivered legend drugs from Respondent for use at Quality Care because Quality Care's inventory was low.

60. On or about November 22, 2012, Mr. Okonkwo and Respondent were not authorized to transfer legend drugs from Respondent to Quality Care.

61. On or about November 22, 2012, Mr. Okonkwo failed to deliver appropriate documentation, such as pedigree papers, to Quality Care documenting the transfer of legend drugs from Respondent to Quality Care.

62. On or about November 22, 2012, Mr. Okonkwo delivered legend drugs from Respondent to Quality Care so Quality Care could further distribute these legend drugs to internet pharmacies.

63. On or about November 29, 2012, in Orange County, Florida, Mr. Okonkwo was arrested by Florida Highway Patrol troopers on 16 counts of Trafficking in Opium, Four Grams to Under 30 Kilograms, a felony, in violation of Section 893.135(1)(c), Florida Statutes (2009 – 2011) and 17

counts of Conspiring to Deliver or Traffic Opium, a felony, in violation of Section 893.0135(5), Florida Statutes (2009 – 2011).

64. On or about November 30, 2012, in the Circuit Court for the Ninth Judicial Circuit, in and for Orange County, Florida, Mr. Okonkwo was charged with two counts of Trafficking in Illegal Drugs/Controlled Substances, a first degree felony, in violation of Section 893.135(1)(c)1.c., Florida Statutes (2009 – 2011), 14 counts of Controlled Substance Offense, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2009 – 2011), and 15 counts of Conspiracy to Commit a Controlled Substance Offense, a felony, in violation of Section 893.13(6)(a), Florida Statutes (2009 – 2011).

COUNT ONE

65. Petitioner realleges and incorporates paragraphs one (1) through sixty-four (64) as if fully set forth herein.

66. Section 465.023(1)(h), Florida Statutes (2009)(2010)(2011), subjects a permittee to discipline for dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by Section 465.003(14), Florida Statutes (2009)(2010)(2011), or Section 892.02, Florida Statutes (2009)(2010)(2011), when the pharmacist knows

or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

67. Respondent dispensed medicinal drugs based upon a communication that purports to be a prescription as defined by Sections 465.003(14) or 893.02, Florida Statutes when Respondent's agent, Mr. Okonkwo, knew or had reason to believe that the purported prescriptions were not based upon a valid patient-practitioner relationship in one or more of the following ways:

a) by dispensing medicinal drugs to N.C. based on prescriptions Mr. Okonkwo knew or had reason to believe were not based upon a valid practitioner-patient relationship; and/or

b) by dispensing medicinal drugs to K.D. based on prescriptions Mr. Okonkwo knew or had reason to believe were not based upon a valid practitioner-patient relationship; and/or

c) by dispensing medicinal drugs to T.F. based on prescriptions Mr. Okonkwo knew or had reason to believe were not based upon a valid practitioner-patient relationship; and/or

d) by dispensing medicinal drugs to K.H. based on prescriptions Mr. Okonkwo knew or had reason to believe were not based upon a valid practitioner-patient relationship; and/or

e) by dispensing medicinal drugs to H.D. based on prescriptions Mr. Okonkwo knew or had reason to believe were not based upon a valid practitioner-patient relationship; and/or

f) by dispensing medicinal drugs to A.R. based on prescriptions Mr. Okonkwo knew or had reason to believe were not based upon a valid practitioner-patient relationship; and/or

g) by dispensing medicinal drugs to B.D. based on prescriptions Mr. Okonkwo knew or had reason to believer were not based upon a valid practitioner-patient relationship.

68. Based on the foregoing, Respondent violated Section 465.023(1)(h), Florida Statutes (2009)(2010)(2011), by dispensing medicinal drugs based upon communications that purport to be prescriptions as defined by Section 465.003(14), Florida Statutes (2009)(2010)(2011), or Section 892.02, Florida Statutes (2009)(2010)(2011), when the pharmacist knows or has reason to believe the purported prescriptions are not based upon valid practitioner-patient relationships.

COUNT TWO

69. Petitioner realleges and incorporates paragraphs one (1) through sixty-four (64) as if fully set forth herein.

70. Section 465.023(1)(c), Florida Statutes (2009)(2010)(2011), subjects a permittee to discipline if the permittee, or agent of the permittee, violates any of the requirements of Chapter 465; Chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or Chapter 893.

71. Rule 64B16-27.831, Florida Administrative Code sets forth the standards for dispensing controlled substances for the treatment of pain, provides in pertinent part:

> (1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.
>
> (2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:
>
> (a) Frequent loss of controlled substance medications;
>
> (b) Only controlled substance medications are prescribed for a patient;
>
> (c) One person presents controlled substance prescriptions with different patient names;
>
> (d) Same or similar controlled substance medication is prescribed by two or more prescribers at the same time;

(e) Patient always pays cash and always insists on a brand name.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom the medication is dispensed provide a picture identification. . .;

(b) Verify the prescription with the prescriber. . . .

72. Between on or about February 24, 2010 and on or about September 30, 2011, Respondent failed to follow the standards for dispensing controlled substances in one or more of the following ways:

a) when Respondent's agent, Mr. Okonkwo, knowingly filled purported prescriptions for controlled substances for N.C., K.D.,T.F., K.H.,H.D., A.R., and/or B.D. that were not issued for a legitimate medical purpose; and/or

b) when Respondent's agent, Mr. Okonkwo, failed to verify the purported prescriptions for controlled substances for N.C., T.F., and/or H.D. with the purported prescriber.

73. Respondent violated Section 465.023(1)(c), Florida Statutes (2009)(2010)(2011), by violating Rule 64B16-27.831, Florida Administrative Code, when its agent, Mr. Okonkwo failed to follow the standards for dispensing controlled substances.

COUNT THREE

74. Petitioner realleges and incorporates paragraphs one (1) through sixty-four (64) as if fully set forth herein.

75. Section 465.023(1)(c), Florida Statutes (2009)(2010)(2011), subjects a permittee to discipline if the permittee, or agent of the permittee, violates any of the requirements of Chapter 465; Chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or Chapter 893.

76. Section 465.016(1)(i), Florida Statutes (2009)(2010)(2011), provides that compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy, constitutes grounds for discipline.

77. From on or about February 24, 2010 until on or about September 30, 2011, Respondent's agent, Mr. Okonkwo, dispensed legend drugs, including controlled substances, other than in the course of the professional practice of pharmacy, in one or more of the following ways:

a) by failing to verify the purported prescriptions for controlled substances for N.C., T.F., and/or H.D. with the purported prescriber; and/or

b) by dispensing prescriptions to N.C., K.D., T.F., K.H., H.D., A.R., and/or B.D. which were not based on valid physician – patient relationships; and/or

c) by distributing legend drugs to another pharmacy without an appropriate permit; and/or

d) by transferring legend drugs to another pharmacy without appropriate documentation such as pedigree papers documenting the transfer; and/or

e) by providing controlled substances to N.C., K.D., T.F., K.H., H.D., A.R., and/or B.D. without valid prescriptions.

78. Respondent violated Section 465.023(1)(c), Florida Statutes (2009)(2010)(2011), when Respondent's agent, Mr. Okonkwo, violated Section 465.016(1)(i), Florida Statutes (2009)(2010)(2011), by compounding, dispensing, or distributing, a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy by dispensing controlled substances to patients based upon fraudulent prescriptions.

COUNT FOUR

79. Petitioner realleges and incorporates paragraphs one (1) through sixty-four (64) as if fully set forth herein.

80. Section 465.023(1)(c), Florida Statutes (2012), subjects a permittee to discipline if the permittee, or agent of the permittee, violates any of the requirements of Chapter 465; Chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or Chapter 893.

81. Section 499.005(18), Florida Statutes (2012), states that it is unlawful if there is a failure to maintain records as required by this part and rules adopted under this part.

82. Rule 61N-1.012(1)(a), Florida Administrative Code, (formerly Rule 64F-12.012(1)(a), Florida Administrative Code), provides that records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component.

83. As set forth above, Respondent cannot provide documentation to account for delivery of multiple boxes of medications from Respondent to Quality Care between in or about August 2012 and in or about November 2012, by Respondent's agent, Mr. Okonkwo.

84. Based on the foregoing, Respondent violated Section 465.023(1)(c), Florida Statutes (2012), by violating Section 499.005(18),

Florida Statutes (2012), by violating Rule 61N-1.012(1)(a), Florida Administrative Code, which requires that records to document the movement of drugs, devices or cosmetics must provide a complete audit trail from a person's receipt or acquisition to sale or other disposition of the product or component.

COUNT FIVE

85. Petitioner realleges and incorporates paragraphs one (1) through sixty-four (64) as if fully set forth herein.

86. Section 465.023(1)(c), Florida Statutes (2012), subjects a permittee to discipline if the permittee, or agent of the permittee, violates any of the requirements of Chapter 465; Chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or Chapter 893.

87. Section 499.005(22), Florida Statutes (2012), provides that failure to obtain a permit or registration, or operating without a permit when a permit or registration is required by this part for that activity, constitutes grounds for discipline.

88. Section 499.01, Florida Statutes (2012), provides in pertinent part:

(1) Prior to operating, a permit is required for each person and establishment that intends to operate as: . . .

(d) A prescription drug wholesale distributor;

. . .

(f) A retail pharmacy drug wholesale distributor; . . . .

89. Section 499.003(54), Florida Statutes (2012), provides in pertinent part:

"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer of patient. . . .

90. Section 499.003(17), Florida Statutes (2012), provides in pertinent part:

"Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver, or offer to deliver. . . .

91. Mr. Okonkwo, as Respondent's agent, failed to obtain appropriate permits for Respondent to operate in one or more of the following ways:

a) by failing to failing to obtain a permit for Respondent to operate as a prescription drug wholesale distributor before transferring medicinal drugs from Respondent to Quality Care; and/or

b) by failing to obtain a permit for Respondent to operate as a retail pharmacy drug distributor before transferring medicinal drugs from Respondent to Quality Care.

92. Respondent violated Section 465.023(1)(c), Florida Statutes (2012), by violating Section 499.005(22), Florida Statutes (2012), by failing to obtain appropriate permits for Respondent to operate as a prescription drug wholesale distributor and/or as a retail pharmacy drug distributor.

COUNT SIX

93. Petitioner realleges and incorporates paragraphs one (1) through sixty-four (64) as if fully set forth herein.

94. Section 465.023(1)(c), Florida Statutes (2012), subjects a permittee to discipline if the permittee, or agent of the permittee, violates any of the requirements of Chapter 465; Chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or Chapter 893.

95. Section 499.005(3), Florida Statutes (2012), provides it is unlawful for any person to receive any drug, device, or cosmetic that is adulterated or misbranded.

96. Section 499.006(10), Florida Statutes (2012), provides that a drug is adulterated if it has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so.

97. Respondent did not have or obtain appropriate permits to transfer and distribute drugs to or from Quality Care from in about August 2012 until in or about November 2012.

98. Based on the foregoing, Respondent violated Section 465.023(1)(c), Florida Statutes (2012), by violating Section 499.005(3), Florida Statutes (2012), by receiving adulterated drugs, as defined by Section 499.006(10), Florida Statutes (2012).

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 30th day of July, 2013.

John H. Armstrong, MD
Surgeon General and Secretary of Health

Mary S. Miller
Assistant General Counsel
Fla. Bar No. 0780420
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone (850) 245 – 4444, ext. 8104
Facsimile (850) 245 – 4683
E-mail: Mary_Miller2@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUL 30 2013

PCP: July 30, 2013
PCP Members: Weizer + Meshad
MSM/mm

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

January 17, 2014

Martin R. Dix, Esquire
106 E. College Ave., #1200
Tallahassee, FL 32301

Re: DOH vs. Avalon Park Pharmacy
DOH Case Number: 2012-13103

Dear Mr. Dix:

We are in receipt of your client's executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form your client agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against his/her license, pursuant to Section 456.072(1)(f), Florida Statutes;
- Voluntarily relinquishing his/her Florida pharmacy license may have an effect on pharmacy licenses they may hold in other states.

If this is not what you understood, please contact me as soon as possible to discuss, at 850-245-4444. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your client's request for Voluntary Relinquishment of License at their next regularly scheduled meeting. You are not required to attend the meeting.

Sincerely,

Mary S. Miller
Assistant General Counsel

MM/ab

CONFIDENTIAL AND EXEMPT MATERIALS

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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March 6, 2013

Certified Article Number
7196 9008 9111 8826 2985
SENDERS RECORD

Christopher E. Brown, J.D.
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, FL 32714

Re: Complaint No. 2012-13103
Respondent: Avalon Park Pharmacy

Dear Mr. Brown:

Pursuant to section 456.073(10), Florida Statutes, you requested a copy of the Department's investigative file prior to the submission of this matter to the probable cause panel. Section 456.073(10), Florida Statutes, provides in part:

> The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) until 10 days after probable cause has been found to exist by the probable cause panel or by the department, or until the regulated professional or subject of the investigation waives his or her privilege of confidentiality, whichever occurs first. Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057.

Attached for your review is an Acknowledgement of and Agreement to Maintain Patient Confidentiality. Please sign and return the enclosed form to my office as soon as possible. The signed confidentiality agreement will be placed in our file.

Upon receipt of this form, and a determination by the Department to recommend that an Administrative Complaint be filed, a copy of the investigative file, including any expert witness report or patient record, will be forwarded to you for review. Our office will not make duplicates of any x-rays contained within the investigative file unless specifically requested to do so. You will have twenty (20) days from the date of mailing to file your response with the Department, unless an extension is granted by the attorney handling this matter.

However, please note that the Department is only required to provide a copy of the investigative file after the investigation has been completed and only if the Department is recommending an Administrative Complaint. A copy of the file will not be provided if the Department recommends closure of the complaint.

If you have any questions, please give me a call at (850) 245-4444 ext. 8104.

Respectfully,

Mary S. Miller
Assistant General Counsel

MSM/cmn

Enclosure: Confidentiality Agreement

Acknowledgement of and
Agreement to Maintain Patient Confidentiality

I, Valentine Okonkwo, am the Subject of an investigation by the Department of Health. As the Subject of such an investigation, I am entitled to inspect or receive a copy of the investigative report, including any expert witness report or patient records connected with the investigation pursuant to Section 456.073(10), Florida Statutes, if I agree in writing to maintain the confidentiality of any information received under this provision, until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to Section 456.057, Florida Statutes.

I understand the cost associated with duplicating x-rays and I want ( ) do not want (✓) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this 12th day of March, 2013.

Avalon Park Pharmacy
2012-13103

SIGNED this ____ day of _____, 2013 on behalf of Avalon Park Pharmacy.

Christopher E. Brown, J.D.

7196 9008 9111 8826 2985

TO:

456 CA
Cassandra/Miller
Date Mailed 3/5/2013
2012-13103

SENDER:

REFERENCE: Avalon Park Pharmacy

**

Christopher E. Brown, J.D.
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, FL 32714

PS Form 3800, January 2005

RETURN RECEIPT SERVICE	Postage
	Certified Fee
	Return Receipt Fee
	Restricted Delivery
	Total Postage & Fees

USPS®
Receipt for Certified Mail™
No Insurance Coverage Provided
Do Not Use for International Mail

POSTMARK OR DATE

2. Article Number
7196 9008 9111 8826 2985

3. Service Type CERTIFIED MAIL™
4. Restricted Delivery? *(Extra Fee)* ☐ Yes
1. Article Addressed to:

Christopher E. Brown, J.D.
The Health Law Firm
1101 Douglas Avenue
Altamonte Springs, FL 32714

COMPLETE THIS SECTION ON DELIVERY

A. Received by (Please Print Clearly) Janae Gibson
B. Date of Delivery 3/8/13
C. Signature
X
☐ Agent ☐ Addressee
D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

Reference Information

456 CA 2012-13103
Cassandra/Miller

Avalon Park Ph

60

PS Form 3811, January 2005 Domestic Return Receipt

March 6, 2013

Certified Article Number
7196 9008 9111 8826 2985
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Altamonte Springs, FL 32714

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I understand the cost associated with duplicating x-rays and I want ( ) do not want ( ) to receive a copy of any x-rays that are contained within the investigative file.

SIGNED this ____ day of _____, 2013.

_____
Avalon Park Pharmacy
2012-13103

SIGNED this ____ day of _____, 2013 on behalf of Avalon Park Pharmacy.

_____
Christopher E. Brown, J.D.

GEORGE F. INDEST III
LICENSED IN FLORIDA, LOUISIANA AND THE DISTRICT OF COLUMBIA
BOARD CERTIFIED BY THE FLORIDA BAR IN HEALTH LAW

MICHAEL L. SMITH, J.D.
LICENSED IN FLORIDA
REGISTERED RESPIRATORY THERAPIST
BOARD CERTIFIED BY THE FLORIDA BAR IN HEALTH LAW

THE FLORIDA BAR BOARD CERTIFIED HEALTH LAW

THE HEALTH LAW FIRM®
"THE PHYSICIAN'S ADVOCATES"
RESPOND ONLY TO MAIN OFFICE:
1101 DOUGLAS AVENUE
ALTAMONTE SPRINGS, FLORIDA 32714
TELEPHONE: (407) 331-6620
TELEFAX: (407) 331-3030
WWW.THEHEALTHLAWFIRM.COM
BRANCH OFFICE
37 N. ORANGE AVENUE, SUITE 500
ORLANDO, FLORIDA 32801
BRANCH OFFICE
201 E. GOVERNMENT STREET
PENSACOLA, FLORIDA 32501
TELEPHONE: (850) 439-1001

JOANNE KENNA, R.N., J.D.
LICENSED IN FLORIDA
REGISTERED NURSE (ILLINOIS)

CHRISTOPHER E. BROWN, J.D.
LICENSED IN FLORIDA

LANCE O. LEIDER, J.D.
LICENSED IN FLORIDA

DANIELLE M. MURRAY, J.D.
LICENSED IN FLORIDA

MARISSA A. SMEYNE, J.D.
LICENSED IN FLORIDA AND CALIFORNIA
(OF COUNSEL)

MATTHEW R. GROSS, J.D., P.A.
LICENSED IN FLORIDA
(OF COUNSEL)

December 11, 2012

VIA TELEFAX & STANDARD U.S. MAIL

CONFIDENTIAL

MQA-IS-ORLANDO
DEC 12 2012
RECEIVED

Ms. Shelly Simon
Medical Malpractice Investigator
Division of Medical Quality Assurance
Investigative Services Unit - Orlando
400 West Robinson Street, S-827
Orlando, Florida 32801

Re: Department of Health vs. Valentine C. Okonkwo, R.Ph.
DOH Case No.: 2012-13130
Our File No.: 1441/003
NOTICE OF REPRESENTATION/REQUEST FOR COPY OF DOH INVESTIGATION FILE

Dear Ms. Simon:

We have the honor and privilege of having been retained to represent Valentine C. Okonkwo, R.Ph., in the above-referenced matter.

Please do not attempt to contact Mr. Okonkwo, his pharmacy, Avalon Park Pharmacy, or any of its employees except through our office.

In accordance with Chapter 456, Florida Statutes, and the applicable Florida Administrative Code (F.A.C.) rules, we are specifically requesting a copy of the report of investigation and the entire investigation file for this matter. The copy of the file should include, but not be limited to: medical records, summaries of interviews with witnesses, witness statements, receipts, investigator's notes, internal correspondence and memoranda, all notes,

EXHIBIT _____ PAGE _____

expert reviews, external correspondence sent or received, and anything and everything else that may be included in the file. We will, of course, agree to keep the matters contained therein confidential as required by law.

A release/authorization form executed by our client authorizing us to receive information and documents from the Department of Health on this matter is attached. We are also enclosing a DOH Acknowledgment of and Agreement to Maintain Patient Confidentiality signed by our client.

It is Mr. Okonkwo's intention to exercise his statutory right to receive and review a copy of the investigation report and file in this matter after the investigation is complete but before it is forwarded to the Probable Cause Panel.

In addition, Mr. Okonkwo may desire, after he reviews the investigation to provide additional documents and information, if considered necessary, before this matter is considered by the Probable Cause Panel. This is his right under Florida law. He desires to exercise his right.

After we have had an opportunity to consult with our client and review his/her documents, we will decide whether or not he/she will submit a written response to you for inclusion in the investigation.

Again, since you are now aware that the health care provider is represented by counsel, please do not attempt to contact or communicate with the health care provider or any of his employees except through this firm.

Should you desire to discuss this matter further, you may reach me at the numbers indicated above. If I am not available, please feel free to speak with George F. Indest, III, another attorney with this firm, who is also familiar with this case.

Also, once you have completed the investigation and forwarded it to DOH in Tallahassee, could you please call my office and let me know? This way, we will not bother you with further requests. You may leave word with anyone in my office who answers.

Thank you very much for your cooperation in this matter.

Sincerely,

THE HEALTH LAW FIRM, by:

CHRISTOPHER E. BROWN

encls: (1) DOH Agreement to Maintain Confidentiality
(2) Authorization to Represent and For Release of Documents and Information

cc: Valentine C. Okonkwo, R.Ph., Owner (w/out encls)
Avalon Park Pharmacy

CEB/lmw
S:\1441\003\310-Letters-Drafts\DOH Simon-1.wpd

SUPPLEMENTAL 1 EXHIBIT 1 PAGE 47

CONFIDENTIAL AND EXEMPT MATERIALS

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

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MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: **Department of Health, Prosecution Services Unit**
FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy
RE: **Avalon Park Pharmacy (MSM)**
Case Number: 2012-13103
MEMBERS: **Michele Weizer, PharmD and Gavin Meshad**
DATE OF PCP: **May 30, 2013** **AGENDA ITEM: A-6**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(h), Florida Statutes (2009)(2010)(2011), by dispensing medicinal drugs based upon communications that purport to be prescriptions as defined by Section 465.003(14), Florida Statutes (2009)(2010)(2011), or Section 892.02, Florida Statutes (2009)(2010)2011);

Section 465.023(1)(c), Florida Statutes (2009)(2010)(2011), when Respondent's agent, Mr. Okonkwo, violated Section 465.016(1)(i), Florida Statutes (2009)(2010)(2011);

Section 465.023(1)(c), Florida Statutes (2012), by violating Section 499.005(18), Florida Statutes (2012) by violating Rule 61N-1.012(1)(a), Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), by violating Section 499.005(22), Florida Statutes (2012),

Section 465.023(1)(r), Florida Statutes by violating Section 3465.023(1)(r), Florida Statutes (2012), by violating Section 499.005(3), Florida Statutes (2012), by receiving adulterated drugs, as defined by Section 499.006(10), Florida Statutes (2012)

___ Probable Cause was **not** found in this case
____ In lieu of probable cause, issue **letter of guidance**
____ Case requires **expert review**
____ Case needs **further investigation**
a)
b)

___ Upon **reconsideration**, dismiss
___ **other**

Michele Weizer PharmD, BCPS 7/30/13
Chair, Probable Cause Panel Date
Board of Pharmacy

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HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201211172

MEGAN ELIZABETH CRANE,
RESPONDENT.

NOTICE

TO: MEGAN ELIZABETH CRANE
378 W ROSEWOOD LANE
TAVARES, FL 32778

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201211172

MEGAN ELIZABETH CRANE,
RESPONDENT.

NOTICE

TO: MEGAN CRANE - LOWELL CORRECTIONAL INSTITUTE
3700 NW 111 PLACE
OCALA, FL 34482

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Mary Miller, Assistant General Counsel MSM
RE: Voluntary Relinquishment
SUBJECT: DOH v. Megan Elizabeth Crane, R.P.T.
DOH Case Number 2012-11172
DATE: February 3, 2014 AB

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Megan Elizabeth Crane
Subject's Address of Record:	378 W Rosewood Lane Tavares, FL 32778
Enforcement Address:	378 W Rosewood Lane Tavares, FL 32778
Subject's Additional Addresses:	Lowell Correctional Institute 3700 NW 111 Place Ocala, FL 34482 11423 Lake Eustis Drive Leesburg, FL 34788
Subject's License No:	13859 **Rank:** RPT
Licensure File No:	15501
Initial Licensure Date:	12/1/2009
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Ct 1: 456.072(1)(x), FS (2012) Ct 2: 456.072(1)(c), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	July 30, 2013; Weizer & Meshad
Subject's Attorney:	Pro Se
Complainant/Address:	Wal-Mart Stores East, Lp 702 SW 8th Street, Dept 8719 Bentonville, AR 72716-0230
Materials Submitted:	Memorandum to the Board

Voluntary Relinquishment
Administrative Complaint
Supplemental Investigative Report dated 7/2/2013
Election of Rights
Probable Cause Panel Memorandum
Emergency Suspension Order
Order to Compel Evaluation
Final Investigative Report with Exhibits 1-11

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO.: 2012-11172**

MEGAN ELIZABETH CRANE, R.P.T.,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **Megan Elizabeth Crane, R.P.T.**, License No. **RPT 13859** hereby voluntarily relinquishes Respondent's license to practice nursing in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to voluntarily cease practicing pharmacy immediately upon executing this Voluntary Relinquishment. Respondent

further agrees to refrain from the practice of pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

3. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

4. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment

and of the Final Order of the Board incorporating this Voluntary Relinquishment.

5. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

6. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the Board does not accept the terms of this Voluntary Relinquishment.

DATED this 27 day of December, year of 2013.

Megan Crane DC# 156147
MEGAN ELIZABETH CRANE, R.P.T.

STATE OF Florida

COUNTY OF Marion

Before me, personally appeared CRANE, MAGAN, whose identity is personally known to me or by producing DC I56149 (type of identification) as identification and who acknowledges that her signature appears above.
Sworn to or affirmed by Respondent before me this 27 day of DECEMBER, 2013.

Sept 03 2017
My Commission Expires

NOTARY PUBLIC - STATE OF Florida Cynthia Wallace

Cynthia Wallace
Type or Print Notary

CYNTHIA D. WALLACE
MY COMMISSION # FF 050940
EXPIRES: September 3, 2017
Bonded Thru Budget Notary Services

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-11172**

MEGAN ELIZABETH CRANE, R.P.T.,

RESPONDENT.

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Megan Elizabeth Crane, R.P.T., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a registered pharmacy technician (R.P.T.) within the state of Florida, having been issued license number RPT 13859.

3. Respondent's address of record is 378 West Rosewood Lane, Tavares, Florida 32778.

4. During the course of the investigation, the Department developed another address for Respondent at Lowell Correctional Institute, 11120 N.W. Gainesville Road, Ocala, Florida 34482-1479.

5. On July 6, 2012, in Leesburg, Florida, Fruitland Park Police Department police officers arrested Respondent on one count of Obtaining a Prescription by Fraud, a third degree felony, in violation of Section 831.30(1), Florida Statutes (2012); one count of Grand Theft, a third degree felony, in violation of Section 812.014(3), Florida Statutes (2012); two counts of Possession of a Schedule Three Controlled Substance, a third degree felony, in violation of Section 893.13, Florida Statutes, (2012); and two Counts of Possession of a Schedule Four Controlled Substance, a third degree felony, in violation of Section 893.13, Florida Statutes (2012).

6. On May 13, 2013, in the Circuit Court of the Fifth Judicial Circuit, in and for Lake County, Florida, in case no. 2012-CF-001751, Respondent entered pleas of nolo contendere to, and was adjudicated guilty of, one count of Trafficking Hydrocodone, a first degree felony, in violation of Section 893.135(1)(c), Florida Statutes (2012); one count of

Possession of Alprazolam, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012); one count of Possession of Carisoprodol, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012); one count of Unlawful Acquisition or Attempt to Acquire Possession of a Controlled Substance by Fraud, a third degree misdemeanor, in violation of Section 893.13(7)(a)9, Florida Statutes (2012); and one count of Grand Theft, a third degree felony, in violation of Section 812.014(2)(c)1, Florida Statutes (2012).

7. The crimes of Trafficking Hydrocodone, Possession of Alprazolam, Possession of Carisoprodol, Unlawful Acquisition or Attempt to Acquire Possession of a Controlled Substance by Fraud, and Grand Theft, are crimes that relate to the practice of, or the ability to practice Respondent's profession.

8. Respondent failed to report her pleas to the Board, in writing, in a timely manner.

COUNT ONE

9. Petitioner realleges and incorporates paragraphs one (1) through eight (8) as if fully set forth herein.

10. Section 456.072(1)(x), Florida Statutes (2012), provides that failure to report to the board, or department, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction, constitutes grounds for disciplinary action by the Board of Pharmacy.

11. Respondent failed to report her pleas of nolo contendere to the Board of Pharmacy, in writing, in a timely manner.

12. Based on the foregoing, Respondent violated Section 456.072(1)(x), Florida Statutes (2012), by failing to report to the board, or department, in writing within 30 days after the licensee had been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.

COUNT TWO

13. Petitioner realleges and incorporates paragraphs one (1) through eight (8) as if fully set forth herein.

14. Section 456.072(1)(c), Florida Statutes (2012), provides that being convicted or found guilty of, or entering a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the

practice of a licensee's profession, or to the ability to practice a licensee's profession, constitutes grounds for disciplinary action.

15. On May 13, 2013, in the Circuit Court of the Fifth Judicial Circuit, in and for Lake County, Florida, Respondent entered pleas of nolo contendere to one count of Trafficking Hydrocodone, one count of Possession of Alprazolam, one count of Possession of Carisoprodol, one count of Unlawful Acquisition or Attempt to Acquire Possession of a Controlled Substance by Fraud, and one count of Grand Theft, crimes which relate to the practice of, or the ability to practice Respondent's profession.

16. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (2012), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

WHEREFORE, the Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand,

placement of the Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 30th day of July, 2013.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

MARY S. MILLER
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Fla. Bar No. 0780420
(850) 245-4444 phone, ext. 8104
(850) 245-4683 fax
E-mail: Mary_Miller2@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK *Angel Sanders*
DATE JUL 30 2013

PCP: July 30, 2013
PCP Members: Weizer + Meshad

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

February 3, 2014

Megan Crane, DC#156149
Lowell Correctional Institute
3700 NW 111 Place
Ocala, FL 34482

Re: DOH vs. Megan Elizabeth Crane, R.P.T.
DOH Case Number: 2012-11172

Dear. Ms. Crane:

We are in receipt of your executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form you agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- Voluntarily relinquishing your Florida pharmacy license may have an effect on pharmacy licenses you may hold in other states.

If this is not what you understood, please contact me as soon as possible to discuss, at 850-245-4444. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their next regularly scheduled meeting. You are not required to attend the meeting.

Sincerely,

Mary S. Miller
Assistant General Counsel

MM/ab

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Alachua	Date of Case: 08/01/2012	Case Number: RPT 2012-11172

Subject: **MEGAN ELIZABETH CRANE, RPT** 11423 Lake Eustis Drive Leesburg, FL 34788 * 352-406-5042	Source: **WAL-MART STORES EAST, LLP** **ATTN: HEATHER GREGORY** 702 SW 8th Street, Dept. 8719 Bentonville, AR 72716-0230 479-277-7032

Prefix:	License #:	Profession:	Board:	Report Date:
RPT (2208)	13859	Registered Pharmacy Technician	Pharmacy	08/15/2013

Period of Investigation:	Type of Report:
08/07/2012 to 08/15/2013	SUPPLEMENTAL 3

Alleged Violation: F.S. 456.072(1)(z): Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition; **(dd):** Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto; **465.016(1)(d):** Being unfit or incompetent to practice pharmacy by reason of: **2.** The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893; **3.** Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs, or medical supplies or for whom she or he might manufacture, prepare, or package, or supervise the manufacturing, preparation, or packaging of, prescriptions, drugs, or medical supplies; **(m):** Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition; **(r):** Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

Synopsis: This investigation is predicated upon the receipt of a request from the Florida Department of Health Prosecution Services Unit to serve Megan Elizabeth CRANE, RPT with an Emergency Suspension Order.

On 07/19/2013, the Alachua ISU office received a request from the Prosecution Services Unit to serve CRANE with an Emergency Suspension Order. On 08/13/2013, at 1300 hours, I met with CRANE at the Florida Women's Reception Center in Ocala, Florida, where she is currently incarcerated. CRANE was wearing her Florida Department of Corrections photo identification card and I recognized her from our previous meeting. I gave CRANE a copy of the ESO and explained to her that her registered pharmacy technician license has been suspended and it would be a violation of Florida law to work as a registered pharmacy technician until her license is reinstated. CRANE stated that she understood. I asked CRANE if she had any questions about the ESO, and she stated that she did not.

I completed an Affidavit of Service on 08/15/2013. No further investigative action taken.

**CRANE is currently incarcerated in DOC until 04/15/2016.*

Related Case: N/A

Investigator/Date: 8/15/13

Edward Legall, GI-31

Received Investigative Services AUG 16 2013 DOH/MOA Tallahassee, FL

Approved By/Date: 8/15/13

William Schauer, Investigation Manager

Distribution: HQ/ISU

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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

PSU REQUEST FORM

FROM: Tamia Christopher For Mary S. Miller, Esq.	TO: William Schauer, Investigative Supervisor ISU Alachua
Date: 7/19/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC:

Case Number: 2012-11172 Board: Pharmacy
Subject: Megan Elizabeth Crane HL Code: HLL70A Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 11423 Lake Eustis Drive, Leesburg, Florida 34788
Last Known Name & Phone Number: Megan Elizabeth Crane (352) 406-5042
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.

****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☒ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Final Order No. DOH-13-1317-ESO-MQA
FILED DATE: 7-18-13
Department of Health
By: Bridget Coates
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Megan Elizabeth Crane, R.P.T.
License No.: RPT 13859
Case No.: 2012-11172

ORDER OF EMERGENCY SUSPENSION OF LICENSE

John H. Armstrong, MD, FACS, Surgeon General and Secretary of Health, ORDERS the emergency suspension of the license of Megan Elizabeth Crane, R.P.T., to practice as a registered pharmacy technician in the State of Florida. Ms. Crane holds license number RPT 13859. Her address of record is 378 West Rosewood Lane, Tavares, Florida 32778. Another address for Ms. Crane is Lowell Correctional Institute, 11120 N.W. Gainesville Road, Ocala, Florida 34482-1479. The following Findings of Fact and Conclusions of Law support the emergency suspension of Ms. Crane's license to practice as a registered pharmacy technician.

FINDINGS OF FACT

1. The Department of Health (Department) is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes.

2. At all times material to this Order, Ms. Crane was licensed to

practice as a registered pharmacy technician in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On July 6, 2012, in Leesburg, Florida, Fruitland Park Police Department police officers arrested Ms. Crane on one count of Obtaining a Prescription by Fraud, a third degree felony, in violation of Section 831.30(1), Florida Statutes (2012); one count of Grand Theft, a third degree felony, in violation of Section 812.014(3), Florida Statutes (2012); two counts of Possession of a Schedule Three Controlled Substance, a third degree felony, in violation of Section 893.13, Florida Statutes, (2012); and two Counts of Possession of a Schedule Four Controlled Substance, a third degree felony, in violation of Section 893.13, Florida Statutes (2012).

4. On May 13, 2013, in the Circuit Court of the Fifth Judicial Circuit, in and for Lake County, Florida, in case no. 2012-CF-001751, Ms. Crane entered pleas of nolo contendere to, and was adjudicated guilty of, one count of Trafficking Hydrocodone, a first degree felony, in violation of Section 893.135(1)(c), Florida Statutes (2012); one count of Possession of Alprazolam, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012); one count of Possession of Carisoprodol, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012);

one count of Unlawful Acquisition or Attempt to Acquire Possession of a Controlled Substance by Fraud, a third degree misdemeanor, in violation of Section 893.13(7)(a)9, Florida Statutes (2012); and one count of Grand Theft, a third degree felony, in violation of Section 812.014(2)(c)1, Florida Statutes (2012).

5. The Department did not learn of Ms. Crane's nolo contendere pleas until on or about June 11, 2013.

6. Section 456.074(1), Florida Statutes (2012), provides that the Department *shall* issue an emergency order suspending the license of any person licensed under Chapter 465, Florida Statutes, who enters a plea of nolo contendere to a felony under Chapter 893, Florida Statutes, regardless of adjudication.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General and Secretary of Health concludes as follows:

1. The Department has jurisdiction pursuant to Sections 20.43 and 456.074(1), Florida Statutes, and Chapter 465, Florida Statutes (2012).

2. The Department is mandated to summarily suspend Ms. Crane's license to practice as a registered pharmacy technician in accordance with Section 456.074(1), Florida Statutes (2012).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes (2012), it is ORDERED THAT:

1. The license of Megan Elizabeth Crane, R.P.T., license number RPT 13859, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Megan Elizabeth Crane, R.P.T., to practice as a registered pharmacy technician will be promptly instituted and acted upon in compliance with Sections 120.569, Florida Statutes (2012).

DONE and ORDERED this 17th day of July, 2013.

John H. Armstrong, MD, FACS
for Surgeon General and Secretary of Health

PREPARED BY:

Mary S. Miller
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(850)245-4444 Telephone ext. 8104
(850)245-4683 Facsimile
Florida Bar No. 0780420
Mary_Miller2@doh.state.fl.us

8

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Section 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the **Healthiest State** in the Nation

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

FLORIDA DEPARTMENT OF HEALTH
Petitioner
vs

Case No. 2012-11172

MEGAN ELIZABETH CRANE, R.P.T.
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 08/13/2013, Affiant made a diligent effort to locate Respondent, to serve
_____ Administrative Complaint and related papers; _____ Order compelling examination(s);
_____Subpoena(s); _____Final order; _____Notice to cease and desist;
__XX__ ESO/ERO and related papers.

3) Check applicable answer below:

__XX__ Affiant made personal service on MEGAN ELIZABETH CRANE, R.P.T. at the Florida Women's Reception Center located at 3700 NW 111th Place, Ocala, Florida, or on some person at Respondent's usual place of abode over the age of 15 residing there, on 08/13/2013 at 1300 hours. Crane was identified by her Florida Department of Corrections identification card and she is known to me by previous contact.

_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Edward Legall, G1-31
Affiant

State of Florida
County of Alachua

Before me, personally appeared Edward Legall whose identity is known to me by personal knowledge (type of identification) and who, acknowledges that his/her signature appears above.

PAMELA SHARKEY
Commission # EE 178424
Expires April 8, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Sworn to or affirmed by Affiant before me this 15th day of August 2013.

Pamela Sharkey
Notary Public-State of Florida

My Commission Expires

Pamela Sharkey
Type or Print Name

INV FORM 321 Created 9/05

EXHIBIT # S3-3

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Alachua	Date of Case: 08/01/2012	Case Number: RPT 2012-11172
Subject: **MEGAN ELIZABETH CRANE, RPT** 11423 Lake Eustis Drive Leesburg, FL 34788 * 352-406-5042	Source: **WAL-MART STORES EAST, LLP** **ATTN: HEATHER GREGORY** 702 SW 8th Street, Dept. 8719 Bentonville, AR 72716-0230 479-277-7032	

Prefix:	License #:	Profession:	Board:	Report Date:
RPT (2208)	13859	Registered Pharmacy Technician	Pharmacy	07/02/2013

Period of Investigation:	Type of Report:
08/07/2012 to 07/02/2013	SUPPLEMENTAL 2

Alleged Violation: F.S. 456.072(1)(z): Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition; **(dd)**: Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto; **465.016(1)(d)**: Being unfit or incompetent to practice pharmacy by reason of: **2.** The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893; **3.** Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs, or medical supplies or for whom she or he might manufacture, prepare, or package, or supervise the manufacturing, preparation, or packaging of, prescriptions, drugs, or medical supplies; **(m)**: Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition; **(r)**: Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

Synopsis: This investigation is predicated upon the receipt of a request from the Florida Department of Health Prosecution Services Unit for additional information.

On 06/24/2013, at 1440 hours, the Alachua ISU office received a request from the Prosecution Services Unit to obtain additional information concerning CRANE's criminal conviction. CRANE was convicted in Lake County on 05/13/2013 for trafficking in hydrocodone, possession of alprazolam, possession of carisoprodol, unlawful acquisition/attempt to acquire possession of a controlled substance by fraud, and grand theft ($300 or more but less than $20,000.) Crane was sentenced to three years in prison and $25,000 fine.

On 07/02/2013, I obtained the following documents from CCIS:

- A copy of CRANE's judgment and sentencing;
- A copy of the arrest affidavit;
- A copy of the charging documents/information.

The documents are attached to this supplemental report. No further investigative action taken at this time.

**CRANE is currently incarcerated in DOC until 05/05/2016.*

RECEIVED LEGAL
13 JUL -8 AM 10:05

Related Case: N/A

Investigator/Date:	Approved By/Date:
Edward Legall, GI-31	William Schauer, Investigation Manager

7/2/13

7/2/13

Received
Investigative Services
JUL 05 2013
DOH/MQA
Tallahassee HQ

Distribution: HQ/ISU

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***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

PSU REQUEST FORM

FROM: Mary S. Miller, Esq.	TO: ISU William Schauer, Investigation Manager
Date: 6/19/2013	TO: CSU
Phone #: 850-245-4444, Ext. 8104	CC: Edward Legal II, MMI

Case Number: 2012-11172 Board: **Pharmacy**
Subject: **Megan E. Crane, RPT** HL Code:**HLL70A** Status: **67**
Requested Completion Date: **ASAP**

(PSU) TYPE OF REQUEST: (describe details below)

- ☐ Process Service* (**Activity Code 160**)
- ☒ Additional Information Requested (**Activity Code 145**)
- ☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Mary Miller is requesting the following information be obtained: (1) A copy of Megan E. Crane's judgment and sentencing; (2) the arrest report and (3) the charging documents/information.

***The following additional information is needed for each service request:**
Last Known Address 11423 Lake Eustis Drive, Leesburg, FL 34788 Last Known Name & Phone Number: 352-406-5042
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☒ NOTE: All process service requests need to be sent to appropriate field office.
**IF YES, please send a copy of the original Investigative Report without attachments.

(ISU/CSU) RESPONSE:

- ☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)
- ☒ Additional Info Sent to Legal (Activity Code 156)
- ☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to:										
Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

CONFIDENTIAL

EXHIBIT # S2-1

INSTRUMENT#: 2013059164 OR BK 4328 PG 1277 PAGES: 2 5/24/2013 9:57:06 AM
NEIL KELLY, LAKE COUNTY CLERK OF THE CIRCUIT COURT
REC FEES: $0.00

IN THE CIRCUIT COURT OF THE FIFTH JUDICIAL CIRCUIT
IN AND FOR LAKE COUNTY, FLORIDA
FELONY DIVISION

JUDGMENT

☐ **PROBATION VIOLATOR**
☐ **RETRIAL**
☐ **COMMUNITY CONTROL VIOLATOR**
☐ **RESENTENCE**

CASE # 2012 CF 001751

THE STATE OF FLORIDA
VS
MEGAN ELIZABETH CRANE
DEFENDANT

THE DEFENDANT, MEGAN ELIZABETH CRANE BEING PERSONALLY BEFORE THIS COURT REPRESENTED BY JOHN SPIVEY, ESQUIRE, ATTORNEY OF RECORD, AND THE STATE BEING REPRESENTED BY ELIZABETH B. PURDY, ASA, AND HAVING

☐ Been tried and found guilty ☐ Entered a plea of guilty ☐ Entered a plea of not guilty

☒ Entered a plea of nolo contendere ☐ Admitted Violation

as to the following crime(s):

COUNT	CRIME	OFFENSE STATUTE #	DEGREE OF CRIME	OBTS #	CASE #
1	TRAFFICKING IN HYDROCODONE	893.135(1c)	1F	3501136184	2012 CF 001751
2	POSSESSION OF ALPRAZOLAM	893.13(6a)	3F	3501136184	2012 CF 001751
3	POSSESSION OF CARISOPRODOL	893.13(6a)	3F	3501136184	2012 CF 001751
4	UNLAWFUL ACQUISITION/ATTEMPT TO ACQUIRE POSSESSION OF A CONTROLLED SUBSTANCE BY FRAUD	893.13(7a9)	3F	3501136184	2012 CF 001751
5	GRAND THEFT-$300 OR MORE BUT LESS THAN $20 000	812.014(2c1)	3F	3501136184	2012 CF 001751

☒ and no cause being shown why the defendant should not be adjudicated guilty, **IT IS ORDERED THAT** the defendant is hereby **ADJUDICATED GUILTY** of the above crime(s);

☐ and with good cause being shown, **IT IS ORDERED THAT ADJUDICATION OF GUILT BE WITHHELD;**

☒ and having been convicted or found guilty of, or having entered a plea of nolo contendere or guilty, regardless of adjudication, pursuant to section 943.325, Florida Statutes, effective July 1, 2005, any person who is convicted or was previously convicted in this state of any felony offense shall be required to submit two biological specimens to a Florida Department of Law Enforcement designated testing facility for inclusion in the DNA database, the defendant shall submit to the collection of two biological specimens (oral swabs) for DNA testing.

DONE AND ORDERED in open court in LAKE County, Florida this date May 13, 2013.

JUDGE: HONORABLE WILLIAM G LAW

FELONY DIVISION
2013 MAY 16 P 1:14
CLERK OF CIRCUIT
AND COUNTY COURT
LAKE COUNTY
TAVARES FLORIDA

Case: 2012 CF 001751
00087625129
DR1: CFJF

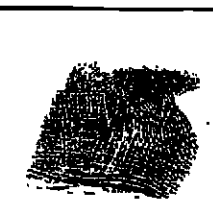
#78

EXHIBIT # S2-2

IN THE CIRCUIT COURT OF
THE FIFTH JUDICIAL CIRCUIT
LAKE COUNTY, FLORIDA
FELONY DIVISION
CASE NO. 2012 CF 001751

STATE OF FLORIDA
VS
MEGAN ELIZABETH CRANE
DEFENDANT

FINGERPRINTS OF DEFENDANT

1. R. THUMB	2. R. INDEX	3. R. MIDDLE	4. R. RING	5. R. LITTLE
				
1. L. THUMB	2. L. INDEX	3. L. MIDDLE	4. L. RING	5. L. LITTLE
				

FINGERPRINTS TAKEN BY
DEPUTY SHERIFF
NAME AND TITLE

DONE AND ORDERED IN OPEN COURT AT TAVARES, LAKE COUNTY, FLORIDA THIS 13th DAY OF May 2013. I HEREBY CERTIFY THAT THE ABOVE AND FOREGOING FINGERPRINTS ARE THE FINGERPRINTS OF THE DEFENDANT MEGAN ELIZABETH CRANE AND THAT THEY WERE PLACED THEREON BY SAID DEFENDANT IN MY PRESENCE IN OPEN COURT THIS DATE.

JUDGE

FILED IN OPEN COURT

May 13, 2013
NEIL KELLY
CLERK OF CIRCUIT COURT

BY
DEPUTY CLERK

OBTS Number 3501136184

Case Number 2012 CF 001751
Defendant MEGAN ELIZABETH CRANE

SENTENCE

As to Count(s) 1

The defendant, being personally before this court, accompanied by the defendant's attorney of record, JOHN SPIVEY, and having been adjudicated guilty herein or having adjudication withheld, and the court having given the defendant an opportunity to be heard and to offer matters in mitigation of sentence, and to show cause why the defendant should not be sentenced as provided by law, and no cause being shown

(Check one if applicable.)

☐ and the Court having on deferred imposition of sentence until this date

☐ and the Court having previously entered a judgment in this case now resentences the defendant

☐ and the Court having placed the defendant on probation/community control and having subsequently revoked the defendant's probation/community control.

It Is The Sentence of The Court that:

☒ The defendant pay a fine of **$250.00**, pursuant to section 775.083, Florida Statutes, plus **$12.50** as the 5% surcharge required by section 938.04, Florida Statues.

☒ The defendant is hereby committed to the custody of the Department of Corrections.

☐ The defendant is hereby committed to the custody of the Sheriff of Lake County, Florida.

☐ The defendant is sentenced as a youthful offender in accordance with section 958.04, Florida Statutes.

FELONY DIVISION
2013 MAY 16 P 1:14
CLERK OF CIRCUIT AND COUNTY COURT LAKE COUNTY TAVARES FLORIDA

To Be Imprisoned (Check one; unmarked sections are inapplicable.):

☐ For a term of natural life.

☒ For a term of **3 YEARS.**

☐ Said SENTENCE SUSPENDED for a period of subject to conditions set forth in this order.

If "split" sentence, complete the appropriate paragraph.

☐ Followed by a period of on probation/community control under the supervision of the Department of Corrections according to the terms and conditions of supervision set forth in a separate order entered herein.

☐ However, after serving a period of imprisonment in , the balance of the sentence shall be suspended and the defendant shall be placed on probation/community control for a period of under supervision of the Department of Correction according to the terms and conditions of probation/community control set forth in a separate order entered herein.

In the event the defendant is ordered to serve additional split sentence, all incarceration portions shall be satisfied before the defendant begins service of the supervision terms.

Case: 2012 CF 001751
DRY: CFSEN

6 #7

Case Number 2012 CF 001751
Defendant MEGAN ELIZABETH CRANE

SPECIAL PROVISIONS

As to Count(s) 1

By appropriate notation, the following provisions apply to the sentence imposed:

Mandatory/Minimum Provisions:

Firearm	☐ It is further ordered that the 3-year minimum imprisonment provision of section 775.087(2), Florida Statutes, is hereby imposed for the sentence specified in this count.
Drug Trafficking	☒ It is further ordered that the3 **YEAR** mandatory minimum imprisonment provision of section 893.135(1), Florida Statues, is hereby imposed for the sentence specified in this count.
Controlled Substance Within 1,000 Feet of School	☐ It is further ordered that the 3-year minimum imprisonment provisions of section 893.13(1)(c)1, Florida Statues, is hereby imposed for the sentence specified in this count
Habitual Felony Offender	☐ The defendant is adjudicated a habitual felony offender and has been sentenced to an extended term in accordance with the provisions of section 775.084(4)(a), Florida Statutes. The requisite findings by the court are set forth in a separate order or stated on the record in open court.
Habitual Violent Felony Offender	☐ The defendant is adjudicated a habitual violent felony offender and has been sentenced to an extended term in accordance with the provisions of section 775.084(4)(b), Florida Statutes. A minimum term of year(s) must be served prior to release. The requisite findings of the court are set forth in a separate order or stated on the record in open court.
Law Enforcement Protection Act	☐ It is further ordered that the defendant shall served a minimum of years before release in accordance with section 775.0823, Florida Statutes. (Offenses committed before January 1, 1994).
Capital Offense	☐ It is further ordered that the defendant shall serve no less than 25 years in accordance with the provisions of section 775.082(1), Florida Statutes. (Offenses committed before October 1, 1995).
Short-Barreled Rifle, Shotgun, Machine Gun	☐ It is further ordered that the 5-year minimum provisions of section 790.221(2), Florida Statutes, are hereby imposed for the sentence specified in this count. (Offenses committed before January 1, 1994).
Continuing Criminal Enterprise	☐ It is further ordered that the 25-year minimum sentence provisions of section 893.20, Florida Statutes, are hereby imposed for the sentence specified in this count. (Offenses committed before January 1, 1994).
Taking a Law Enforcement Officer's Firearm	☐ It is further ordered that the 3 year mandatory minimum imprisonment provision of section 775.0857(1), Florida Statutes, is hereby imposed for the sentence specified in this court. (Offenses committed before January 1, 1994).

Case Number 2012 CF 001751
Defendant MEGAN ELIZABETH CRANE

Sexual Offender/Sexual Predator Determinations:

Sexual Predator	☐ The defendant is adjudicated a sexual predator as set forth in section 775.21, Florida Statutes.
Sexual Offender	☐ The defendant meets the criteria for a sexual offender as set forth in section 943.0435(1)(a)1a.,b.,c., or d.
Age of Victim	The victim was years of age at the time of the offense.
Age of Defendant	The defendant was years of age at the time of the offense.
Relationship to Victim	☐ The defendant is not the victim's parent or guardian
Sexual Activity [F.S. 800.04(4)]	The offense ☐ did ☐ did not involve sexual activity.
Use of Force or Coercion [F.S. 800.04(4)]	The sexual activity described herein ☐ did ☐ did not involve the use of force or coercion.
Use of Force or Coercion/ unclothed Genitals [F.S. 800.04(5)]	The molestation ☐ did ☐ did not involve unclothed genitals or genital area. The molestation ☐ did ☐ did not involve the use of force or coercion.

Other Provisions:

Criminal Gang Activity	☐ The felony conviction is for an offense that was found, pursuant to section 874.04, Florida Statutes, to have been committed for the purpose of benefiting, promoting, or furthering the interests of a criminal gang.
Retention of Jurisdiction	☐ The court retains jurisdiction over the defendant pursuant to section 947.16(4), Florida Statutes (1983).
Jail Credit	☒ It is further ordered that the defendant shall be allowed a total of 0003 days as credit for time incarcerated before imposition of this sentence.

OBTS Number 3501136184

Case Number 2012 CF 001751
Defendant MEGAN ELIZABETH CRANE

SENTENCE

As to Count(s) 2 THROUGH 5

The defendant, being personally before this court, accompanied by the defendant's attorney of record, JOHN SPIVEY, and having been adjudicated guilty herein or having adjudication withheld, and the court having given the defendant an opportunity to be heard and to offer matters in mitigation of sentence, and to show cause why the defendant should not be sentenced as provided by law, and no cause being shown

(Check one if applicable.)

☐ and the Court having on deferred imposition of sentence until this date

☐ and the Court having previously entered a judgment in this case now resentences the defendant

☐ and the Court having placed the defendant on probation/community control and having subsequently revoked the defendant's probation/community control.

It Is The Sentence of The Court that:

☐ The defendant pay a fine of $, pursuant to section 775.083, Florida Statutes, plus $ as the 5% surcharge required by section 938.04, Florida Statues.

☒ The defendant is hereby committed to the custody of the Department of Corrections.

☐ The defendant is hereby committed to the custody of the Sheriff of Lake County, Florida.

☐ The defendant is sentenced as a youthful offender in accordance with section 958.04, Florida Statutes.

To Be Imprisoned (Check one; unmarked sections are inapplicable.):

☐ For a term of natural life.

☒ For a term of **3 YEARS – AS TO EACH COUNT – TO RUN CONCURRENT WITH EACH OTHER.**

☐ Said SENTENCE SUSPENDED for a period of subject to conditions set forth in this order.

If "split" sentence, complete the appropriate paragraph.

☐ Followed by a period of on probation/community control under the supervision of the Department of Corrections according to the terms and conditions of supervision set forth in a separate order entered herein.

☐ However, after serving a period of imprisonment in , the balance of the sentence shall be suspended and the defendant shall be placed on probation/community control for a period of under supervision of the Department of Correction according to the terms and conditions of probation/community control set forth in a separate order entered herein.

In the event the defendant is ordered to serve additional split sentence, all incarceration portions shall be satisfied before the defendant begins service of the supervision terms.

Case Number 2012 CF 001751
Defendant MEGAN ELIZABETH CRANE

SPECIAL PROVISIONS

As to Count(s) 2 THROUGH 5

By appropriate notation, the following provisions apply to the sentence imposed:

Mandatory/Minimum Provisions:

Firearm	☐ It is further ordered that the 3-year minimum imprisonment provision of section 775.087(2), Florida Statutes, is hereby imposed for the sentence specified in this count.
Drug Trafficking	☐ It is further ordered that the mandatory minimum imprisonment provision of section 893.135(1), Florida Statues, is hereby imposed for the sentence specified in this count.
Controlled Substance Within 1,000 Feet of School	☐ It is further ordered that the 3-year minimum imprisonment provisions of section 893.13(1)(c)1, Florida Statues, is hereby imposed for the sentence specified in this count
Habitual Felony Offender	☐ The defendant is adjudicated a habitual felony offender and has been sentenced to an extended term in accordance with the provisions of section 775.084(4)(a), Florida Statutes. The requisite findings by the court are set forth in a separate order or stated on the record in open court.
Habitual Violent Felony Offender	☐ The defendant is adjudicated a habitual violent felony offender and has been sentenced to an extended term in accordance with the provisions of section 775.084(4)(b), Florida Statutes. A minimum term of year(s) must be served prior to release. The requisite findings of the court are set forth in a separate order or stated on the record in open court.
Law Enforcement Protection Act	☐ It is further ordered that the defendant shall served a minimum of years before release in accordance with section 775.0823, Florida Statutes. (Offenses committed before January 1, 1994).
Capital Offense	☐ It is further ordered that the defendant shall serve no less than 25 years in accordance with the provisions of section 775.082(1), Florida Statutes. (Offenses committed before October 1, 1995).
Short-Barreled Rifle, Shotgun, Machine Gun	☐ It is further ordered that the 5-year minimum provisions of section 790.221(2), Florida Statutes, are hereby imposed for the sentence specified in this count. (Offenses committed before January 1, 1994).
Continuing Criminal Enterprise	☐ It is further ordered that the 25-year minimum sentence provisions of section 893.20, Florida Statutes, are hereby imposed for the sentence specified in this count. (Offenses committed before January 1, 1994).
Taking a Law Enforcement Officer's Firearm	☐ It is further ordered that the 3 year mandatory minimum imprisonment provision of section 775.0857(1), Florida Statutes, is hereby imposed for the sentence specified in this court. (Offenses committed before January 1, 1994).

Case Number 2012 CF 001751
Defendant MEGAN ELIZABETH CRANE

Sexual Offender/Sexual Predator Determinations:

Sexual Predator ☐ The defendant is adjudicated a sexual predator as set forth in section 775.21, Florida Statutes.

Sexual Offender ☐ The defendant meets the criteria for a sexual offender as set forth in section 943.0435(1)(a)1a.,b.,c., or d.

Age of Victim The victim was years of age at the time of the offense.

Age of Defendant The defendant was years of age at the time of the offense.

Relationship to Victim ☐ The defendant is not the victim's parent or guardian

Sexual Activity [F.S. 800.04(4)] The offense ☐ did ☐ did not involve sexual activity.

Use of Force or Coercion [F.S. 800.04(4)] The sexual activity described herein ☐ did ☐ did not involve the use of force or coercion.

Use of Force or Coercion/ unclothed Genitals [F.S. 800.04(5)] The molestation ☐ did ☐ did not involve unclothed genitals or genital area.
The molestation ☐ did ☐ did not involve the use of force or coercion.

Other Provisions:

Criminal Gang Activity ☐ The felony conviction is for an offense that was found, pursuant to section 874.04, Florida Statutes, to have been committed for the purpose of benefiting, promoting, or furthering the interests of a criminal gang.

Retention of Jurisdiction ☐ The court retains jurisdiction over the defendant pursuant to section 947.16(4), Florida Statutes (1983).

Jail Credit ☒ It is further ordered that the defendant shall be allowed a total of 0003 days as credit for time incarcerated before imposition of this sentence.

Case Number 2012 CF 001751
Defendant MEGAN ELIZABETH CRANE

Other Provisions Continued:

Credit for Time Served Resentencing after Violation of Probation or Community Control

☐ It is further ordered that the defendant be allowed _____ days time served between date of arrest as a violator following release from prison to the date of resentencing. The Department of Corrections shall apply original jail time credit and shall compute and apply credit for time served and unforfeited gain time previously awarded on case/count _____ . (Offenses committed before October 1, 1989.)

☐ It is further ordered that the defendant be allowed _____ days time served between date of arrest as a violator following release from prison to the date of resentencing. The Department of Corrections shall apply original jail time credit and shall compute and apply credit for time served on case/count _____ . (Offenses committed between October 1, 1989, and December 31, 1993).

☐ The court deems the unforfeited gain time previously awarded on the above case/count forfeited under section 948.06(7).

☐ The Court allows unforfeited gain time previously awarded on the above case/count. (Gain time may be subject to forfeiture by the Department of Corrections under section 944.28(1).

☐ It is further ordered that the defendant be allowed _____ days time served between date of arrest as a violator following release from prison to the date of resentencing. The Department of Corrections shall apply original jail time credit and shall compute and apply credit for time served only pursuant to section 921.0017, Florida Statutes, on case count _____ . (Offenses committed on or after January 1, 1994)

Consecutive/Concurrent As to Other Counts

☒ It is further ordered that the sentence imposed for **COUNTS 2 THROUGH 5** shall run (check one) ☐ consecutive to ☒ concurrent with the sentence set forth in **COUNT 1** of this case.

Consecutive/Concurrent As To Other Convictions

☒ It is further ordered that the composite term of all sentences imposed for the counts specified in this order shall run (check one) ☐ consecutive to ☒ concurrent with the following: (check one)

☒ any active sentence being served.
☐ specific sentences:

In the event the above sentence is to the Department of Corrections, the Sheriff of LAKE County, Florida, is hereby ordered and directed to deliver the defendant to the Department of Corrections at the facility designated by the department together with a copy of this judgment and sentence and any other documents specified by Florida statue.

The defendant in open court was advised of the right to appeal from this sentence by filing notice of appeal within 30 days from this date with clerk of this court and the defendant's right to the assistance of counsel in taking the appeal at the expense of the State on showing of indigency.

In imposing the above sentence, the court further recommends

DONE AND ORDERED in open court at TAVARES, LAKE County, Florida, this day of May 13, 2013.

JUDGE: HONORABLE WILLIAM G LAW

CERTIFICATE OF SERVICE

I HEREBY CERTIFY THAT A COPY OF THE FOREGOING JUDGMENT AND/OR SENTENCE HAS BEEN FURNISHED TO JOHN SPIVEY, COUNSEL FOR THE DEFENDANT, THIS 10th DAY OF MAY, 2013.

DEPUTY CLERK
LAKE COUNTY CLERK'S OFFICE

Rule 3.992(a) Criminal Punishment Code Scoresheet

The Criminal Punishment Code Scoresheet Preparation Manual is available at: *http://www.dc.state.fl.us/pub/sen_cpcm/index.html*

1. DATE OF SENTENCE	2. PREPARER'S NAME	3. COUNTY	4. SENTENCING JUDGE	
5/13/13	LASHLEY	LAKE	LAW	
5. NAME (LAST, FIRST, MI.I.)	6. DOB	8. RACE	10. PRIMARY OFF. DATE	12.
CRANE,MEGAN ELIZABETH	04/19/1979	WHITE	07/06/2012	PLEA ☑
	7. DC #	9. GENDER	11. PRIMARY DOCKET #	TRIAL ☐
		Male	2012CF001751	

I. PRIMARY OFFENSE:

FELONY DEGREE	F.S.#	DESCRIPTION	OFFENSE LEVEL	POINTS
1	893.13	TRAFFICKING IN HYDROCODONE >14GRAMS<28GRAMS	8	

(Level - Points: 1=4, 2=10, 3=16, 4=22, 5=28, 6=36, 7=56, 8=74, 9=92, 10=116)

Prior capital felony triples Primary Offense points ☐

I. 74

II. ADDITIONAL OFFENSE(S): Supplemental page attached ☐

DOCKET #	FEL/MM DEGREE	F.S.#	OFFENSE LEVEL	QUALIFY: A/S/C/R	COUNTS	POINTS	TOTAL
2012CF001751	3	893.13	3		1	2.4	2.4
DESCRIPTION: POSS OF ALPRAZOLAM							
	3	893.13	3		1	2.4	2.4
DESCRIPTION: POSS OF CARISOPRODOL							
	3	893.13	3		1	2.4	2.4
DESCRIPTION: UNLAWFUL AQUISITION CONTROLLED SUBSTANCE							
	3	812.014	2		1	1.2	1.2
DESCRIPTION: GRAND THEFT > $300 < $20,000							

(Level - Points: M=0.2, 1=0.7, 2=1.2, 3=2.4, 4=3.6, 5=5.4, 6=18, 7=28, 8=37, 9=46, 10=58)

Prior capital felony triples Additional Offense points ☐

Supplemental page points 0

II. 8.4

III. VICTIM INJURY:

	Number	Total		Number	Total
2nd Degree Murder	240 X ____ =	0	Slight	4 X ____ =	0
Death	120 X ____ =	0	Sex Penetration	80 X ____ =	0
Severe	40 X ____ =	0	Sex Contact	40 X ____ =	0
Moderate	18 X ____ =	0			

III. 0

IV. PRIOR RECORD: Supplemental page attached ☐

FEL/MM DEGREE	F.S.#	OFFENSE LEVEL	QUALIFY: A/S/C/R	DESCRIPTION	NUMBER		POINTS		TOTAL
M	322.34	M		DWLSR	1	X	0.2	=	0.2
						X		=	
						X		=	
						X		=	
						X		=	
						X		=	
						X		=	
						X		=	
						X		=	

Filed in Open Court
Neil Kelly
Clerk of Circuit Court
MAY 18 2013
Lake County, FL

(Level - Points: M=0.2, 1=0.5, 2=0.8, 3=1.6, 4=2.4, 5=3.2, 6=9, 7=13, 8=19, 9=23, 10=29)

Supplemental page points 0

IV. 0.2

Page 1 Subtotal: 82.6

Case: 2012 CF 001751
DKT: CPSCS

Effective Date: For offenses committed under the Criminal Punishment Code effective for offenses committed on or after October 1, 1998, and subsequent revisions.

w #164

13

NAME (LAST, FIRST, MI)	DOCKET #
CRANE,MEGAN ELIZABETH	2012CF001751

Page 1 Subtotal: 82.6

V. Legal Status Violation = 4 Points

☐ Escape ☐ Fleeing ☐ Failure to Appear ☐ Supersedeas bond ☐ Incarceration ☐ Pretrial intervention or diversion program

☐ Court imposed post prison release community supervision resulting in a conviction V. _____

VI. Community Sanction violation before the court for sentencing VI. _____

☐ Probation ☐ Community Control ☐ Pretrial Intervention or diversion

☐ 6 points for any violation other than new felony conviction x _____ each successive violation OR

☐ New felony conviction = 12 points x _____ each successive violation if new offense results in conviction before or at same time as sentence for violation of probation OR

☐ 12 points x _____ each successive violation for a violent felony offender of special concern when the violation is not based solely on failure to pay costs, fines, or restitution OR

☐ New felony conviction = 24 points x _____ each successive violation for a violent felony offender of special concern if new offense results in a conviction before or at the same time for violation of probation

VII. Firearm/Semi-Automatic or Machine Gun = 18 or 25 points VII. _____

VIII. Prior Serious Felony = 30 points VIII. _____

Subtotal Sentence Points 82.6

IX. Enhancements (only if the primary offense qualifies for enhancement)

Law Enf. Protect.	Drug Trafficker	Motor Vehicle Theft	Criminal Gang Offense	Domestic Violence in the Presence of Related Child (offenses commited on or after 03-12-07)
☐ x 1.5 ☐ x 2.0 ☐ x 2.5	☑ x 1.5	☐ x 1.5	☐ x 1.5	☐ x 1.5

Enhanced Subtotal Sentence Points IX. 123.9

TOTAL SENTENCE POINTS 123.9

SENTENCE COMPUTATION

If total sentence points are less than or equal to 44, the lowest permissible sentence is any non-state prison sanction. If the total sentence points are 22 points or less, see Section 775.082(10), Florida Statutes, to determine if the court must sentence the offender to a non-state prison sanction.

If total sentence points are greater than 44:

123.9 (total sentence points) minus 28 = 96 x .75 = 71.925 (lowest permissible prison sentence in months)

If total sentence points are 60 points or less than and court makes findings pursuant to both Florida Statutes 948.20 and 397.334(3), the court may place the defendant into a treatment-based drug court program.

The maximum sentence is up to the statutory maximum for the primary and any additional offenses as provided in s.775.082, F.S., unless the lowest permissible sentence under the code, exceeds the statutory maximum. Such sentences may be imposed concurrently or consecutively. If the total sentence points are greater than or equal to 363, a life sentence may be imposed.

50 (maximum sentence in years)

TOTAL SENTENCE IMPOSED

		Years	Months	Days
☑ State Prison	☐ Life	3		
☐ County Jail	☐ Time Served			
☐ Community Control				
☐ Probation ☐ Modified				

Please check if sentenced as ☐ habitual offender, ☐ habitual violent offender, ☐ violent career offender, ☐ prison releasee reoffender, or a ☒ mandatory minimum applies.

☐ Mitigated Departure ☐ Plea Bargain ☐ Prison Diversion Program

Other Reason _____

JUDGE'S SIGNATURE	

Effective Date: For offenses committed under the Criminal Punishment Code effective for offenses committed on or after October 1, 1998, and subsequent revisions.

Rule 3.992(b) Supplemental Criminal Punishment Code Scoresheet

NAME (LAST, FIRST, MI)	DOCKET #	Date of Sentence
CRANE,MEGAN ELIZABETH	2012CF001751	

II. ADDITIONAL OFFENSE(S):

DOCKET #	FEL/MM DEGREE	F.S.#	OFFENSE LEVEL	QUALIFY	COUNTS	POINTS	TOTAL

DESCRIPTION: _____

(Level - Points: M=0.2, 1=0.7, 2=1.2, 3=2.4, 4=3.6, 5=5.4, 6=18, 7=28, 8=37, 9=46, 10=58)

II. 0

IV. PRIOR RECORD:

FEL/MM DEGREE	F.S.#	OFFENSE LEVEL	QUALIFY: A/S/C/R	DESCRIPTION	NUMBER	POINTS	TOTAL
						X	=

(Level - Points: M=0.2, 1=0.5, 2=0.8, 3=1.6, 4=2.4, 5=3.6, 6=9, 7=14, 8=19, 9=23, 10=29)

IV. 0

Reasons for Departure - Mitigating Circumstances

(reasons may be checked here or written on the scoresheet)

- ☐ Legitimate, uncoerced plea bargain.
- ☐ The defendant was an accomplice to the offense and was a relatively minor participant in the criminal conduct.
- ☐ The capacity of the defendant to appreciate the criminal nature of the conduct or to conform that conduct to the requirements of law was substantially impaired.
- ☐ The defendant requires specialized treatment for a mental disorder that is unrelated to substance abuse or addiction, or for a physical disability, and the defendant is amenable to treatment.
- ☐ The need for payment of restitution to the victim outweighs the need for a prison sentence.
- ☐ The victim was an initiator, willing participant, aggressor, or provoker of the incident.
- ☐ The defendant acted under extreme duress or under the domination of another person.
- ☐ Before the identity of the defendant was determined, the victim was substantially compensated.
- ☐ The defendant cooperated with the State to resolve the current offense or any other offense.
- ☐ The offense was committed in an unsophisticated manner and was an isolated incident for which the defendant has shown remorse.
- ☐ At the time of the offense the defendant was too young to appreciate the consequences of the offense.
- ☐ The defendant is to be sentenced as a youthful offender.
- ☐ The defendant is amenable to the services of a postadjudicatory treatment-based drug court program and is otherwise qualified to participate in the program.

Pursuant to 921.0026(3) the defendant's substance abuse or addiction does not justify a downward departure from the lowest permissible sentence, except for the provisions of s.921.0026(2)(m).

Effective Date: For offenses committed under the Criminal Punishment Code effective for offenses committed on or after October 1, 1998, and subsequent revisions.

INSTRUMENT#: 2013056830 OR BK 4325 PG 579 PAGES: 1 5/20/2013 4:12:49 PM
NEIL KELLY, LAKE COUNTY CLERK OF THE CIRCUIT COURT
REC FEES: $0.00

IN THE CIRCUIT COURT OF THE FIFTH
JUDICIAL CIRCUIT, CRIMINAL DIVISION,
IN AND FOR LAKE COUNTY

FELONY

CASE NO.: 2012-CF-1751 (12CF1751)
STATE OF FLORIDA
VS.
DEFENDANT: Megan Crane (Megan Crane)
ADDRESS:

SOCIAL SECURITY NO.:
DATE OF BIRTH:
DEFENDANT'S SIGNATURE

The defendant shall report immediately to Room 105, Lake County Judicial Center, to establish a payment plan with the Clerk of Courts if unable to pay in full when sentenced. If incarcerated, the defendant shall report to Room 105 within 5 business days of release from custody to establish a payment plan.

Failure to pay costs, fines, fees in full or as agreed will result in your case being sent to collections with additional fees applied. Your case may be referred to the Florida Department of Highway Safety and Motor Vehicles for the suspension of your driver's license.

FINAL JUDGMENT AND SENTENCE, FINANCIAL ORDER, AND PLEA

The defendant is hereby ordered to pay and a judgment is hereby entered on behalf of Lake County Clerk of the Court, PO Box 7800, Tavares, Florida 32778 and the State of Florida in the following sums (if indicated), for which let execution issue.

MANDATORY

1.	$ 50.00	Indigent Criminal Defense Trust Fund [§27.52] (Public Defender's Application Fee, if not previously paid)
2.	$ 5.00	Recording Fee [§28.24]
3.	$ 50.00	County Crime Prevention Fund [§775.083(2); Lake County Code §9-17] ($50 for felony; $20 for other offenses)
4.	$ 3.00	Additional Court Cost Clearing Trust Fund [§938.01]
5.	$ 50.00	Crimes Compensation Trust Fund [§938.03]
6.	$ 225.00	Local Government Criminal Justice Trust Fund [§938.05]
7.	$ 20.00	Crime Stoppers Trust Fund [§938.06]
8.	$ 2.00	Additional Criminal Justice Education by Municipalities and Counties [§938.15; Lake County Code, §9-11]
9.	$ [illegible]	Public Defender/Appointed Counsel Fees and Costs [§938.29; F.R.Cr.P. 3.720(d)(1)]
10.	$ 65.00	Additional court costs for court system, legal aid, law library, juvenile programs [§939.185; Lake County Code §8]
11.	$ 3.00	Teen Court Fund [§938.19; Lake County Code §9-17]
12.	$	Felony DUI [§316.193(6)]
13.	$ 50.00	State Court Facilities Fund [§318.18(13)(a); Lake County Code §9-12] ($30 for violations listed in §318.17)
14.	$ 5.00	State Agency Law Enforcement Radio System Trust Fund [§318.18(17)] ($3 for violations listed in §318.17).
15.	$ 65.00	Additional Costs to Dept. of Health [§318.18(20)] for violation §316.191, 316.192
16.	$	Criminal Wildlife Violation [§372.7015] ($250 if wildlife offense committed while violating Ch. 810)
17.	$ 12.50	Crimes Compensation Trust Fund [§938.04, §20.21] (5% surcharge on all fines)
18.	$	DUI/BUI Assessment [§938.07] ($115 for any violation of §316.193 or §327.35)
19.	$ 25,000	Trafficking [§893.135] (Mandatory fines $25,000 to $500,000)
20.	$	Additional Cost Domestic Violence [§938.08] ($201 for §784.011 misd, 784.021 agg /misd, 784.03 batt, 784.041 fel batt, 784.045 agg batt, 784.048 stalk, 784.07 misd/batt leo, 784.03 misd/batt 65, 784.081 misd/batt spec offic, 784.082 misd/batt jail, 784.083 misd/batt inspector, 784.085 batt child , 784.011 war batt, 741.28 dv)
21.	$	Additional Cost Rape Crisis Center [§938.085]
22.	$	Additional Cost for Crimes against Minors [§938.10] ($151 for §784.085, ch. 787, 794, §795.05, 800.04, ch. 827, §847.0145, 985.4045)
23.	$	County Alcohol and Other Drug Abuse Trust Fund [§938.13; Lake County Code, §9-14] ($15, mand. use of drugs or alcohol)
24.	$	Investigative Costs [§938.27(7)]
25.	$ 100.00	Prosecution Costs [§938.27(8)] (Not less than $100)
26.	$	Incarceration Costs [§960.293] ($50/day or $250,000 if capital/life felony, upon motion to assess when # days served is known, written to defendant, and hearing)
27.	$	Prostitution/solicitation [§796.07(2)(f)] ($5,000 civil penalty)

DISCRETIONARY

28.	$ 250.00	Fines [§775.083] (Up to $15,000 for life felony; $10,000 for 1st or 2d degree felony; $5,000 for 3rd degree felony; add $5
OR	$ ☐ W/H	for §316.061, 316.192; §775.0835 fine up to $10,000 for injury or death to CCTF)
29.	$	Alcohol and drug abuse programs [§938.21] (Cost up to fine cost: ch. 562, 567, 568, 893, §316.193, 856.011, 856.015.)
30.	$	Assistance Grants for alcohol and drug abuse programs [§938.23] (Up to fine cost; some crimes as in 22 above)
31.	$	Operating Trust Fund of the FDLE [§938.055] ($151 for any criminal violation of §775-835)
32.	$	Other:

Total: $ 25,785.50

DONE AND ORDERED in open court in Lake County, Florida,
this 15th day of May, 2013

CIRCUIT COURT JUDGE

STATE OF FLORIDA, COUNTY OF LAKE
I HEREBY CERTIFY the above and foregoing
is a true copy of the document filed in this office.
Neil Kelly, Clerk of Circuit Court
By: Deputy Clerk
Dated: May 19, 2013
This document may be redacted as required by law.

The quality of this image is equivalent to the quality of the document filed in this office.

Effective January 1, 2013

Case: 2012 CF 001751
DOC: CFFJREC

16

ARREST AFFIDAVIT/FIRST APPEARANCE FORM

LAKE COUNTY, FLORIDA

OBTS # 3501136184			Agency ORI # FL0350400						
Court Case Number: 12CF1751-03	X Felony / Traffic	X Misdemeanor / Juvenile	County or Municipal Ordinance / Warrant/CAPIAS					Agency Case Number: 12-FR-4898	
Defendant's Name: Last First Middle	DOB	SEX	RACE	HGT	WGT	HAIR	EYES		
CRANE, MEGAN ELIZABETH	Mo. 4 Day 19 Yr. 1979	F	W	5'07"	225	BRO	BRO		
Mailing Address: St./P.O. Box / City / State / Zip	Scars-Marks-Tattoos-Amputations (describe each): Tattoo-Left-Breast-NAME "SHANE"								
St. Add. (If different), Street 517 PAULING DRIVE / City Leesburg / State FL / Zip 34748-	Phone: Home (352) 406-5042	Place of Birth: FLORIDA	Social Security No.: 594-09-6038						
Place of Employment: Street 2501 N CITRUS BLVD / City Leesburg / State FL / Zip 34748-	Phone: Business	Occupation: PHARMCY TECH	Alias:						
Driver Lic. No.: C650545796390	Vehicle Towed By:	Hold on Vehicle: Yes ☐ No ☐ Agency:	Arrest Suffix: 1						
Arrest Date: mo 7 day 6 yr 2012	Arrest Time: 16:56	Arrest Location: 2501 N CITRUS BLVD, Leesburg, FL 34748							
U.S. Citizen: Y☐ N☐ U☐	Residence Type: ☐1. City ☐2. County ☐3. Florida ☐4. Out-of-Florida								

CODES

ACTIVITY: A. Fraud; B. Buy; D. Deliver; F. Forgery; K. Dispense / Distribute; M. Manufacture / Produce / Cultivate; N. N/A; O. Counterfeit; P. Possess; R. Smuggle; S. Sell; T. Traffic; U. Use; X. Stolen Property; Z. Other

TYPE: A. Amphetamine; B. Barbiturate; C. Cocaine; E. Heroin; H. Hallucinogen; M. Marijuana; N. N/A; O. Opium/Deriv; P. Paraphernalia/ Equipment; S. Synthetic; U. Unknown; Z. Other

CHARGES

	Description	Counts	Activity	Type	NCIC	CIS	Statute	Bond Amount	In Accordance to Bond Schedule
C	2000-OBTAINING PRESCRIPTION BY FRAUD	1	N	N			831.30(1)	$500.00	Y☐ N☐
H	230G-GRAND THEFT	1					812.014 (3)	$2,000.00	Y☐ N☐
A	350A-POSS. OF CONTROLLED SUBSTANCE - SCH III	2	P	S			893.03(3)(a)	$2,000.00	Y☐ N☐
R	350A-POSS. OF CONTROLLED SUBSTANCE - SCH IV	2	P	S			893.03(4)(a)	$2,000.00	Y☐ N☐
G									Y☐ N☐
E									Y☐ N☐
S									Y☐ N☐
									Y☐ N☐
									Y☐ N☐
									Y☐ N☐

Case: 2012 CF 001751
#0004559605
ORI: CFAPC

CLERK OF CIRCUIT AND COUNTY COURT LAKE COUNTY FLORIDA
2012 JUL -9 P 2:31
FELONY DIVISION

Indication of:
Alcohol Influence Y☐ N☐ Unknown☐
Drug Influence Y☐ N☐ Unknown☒

Weapon Seized: Y☐ N☐

JAIL LOG: (To be completed by Booking Officer) Foster / FPPD / Jail Inmate Number: 107835

Date Booked:	Time Booked:	Booking Officer:	Fingerprinted By:	Photographed By:	Bin Number:
7/6/12	2043 AM PM	Richardson	Breedlove	Carter	

Advised of Rights By:	Check for Warrant(s):	Holds:	Agency of Hold:
	NCIC☑ FCIC☑ Local☑	Yes☐ No☑	

Attorney (If Known):	Religion:	Marital Status:	Telephone Call Logged:	Telephone No:
	J☐ Pr☐ C☐ Other☐	S☐ M☐ D☐ Sep☐	Time: AM PM	

Next of Kin/PARENTS OF JUVENILE for emergency)	Relation:	Address:	Telephone No:

Juvenile Disposition:

___ 1. Handled/Processed Within Dept and Released ___ 2. Turned Over to D.J.J. ___ 3. Incarcerated (County Jail)

NO OF PGS

FAXED ORIGINAL

EXHIBIT # S2-3

17

Complaint/Arrest Affidavit Continuation	Court Case No.	Agency Case No. 12-FR-4698 - 1

Defendant's Name: Last	First	Middle	Date of Birth
CRANE, MEGAN ELIZABETH			04/19/1949

PROBABLE CAUSE AFFIDAVIT:
(specify probable cause for each charge)

Before Me, the undersigned authority personally appeared **Sr. Officer S. M. Foster** who being duly sworn, alleges, on information and belief, that on the **6th** day of **July**, **2012**, in **Lake** County, Florida. the defendant did:

DID COMMIT THE OFFENSE OF GRAND THEFT, OBTAINING PRESCRIPTION BY FRAUD, AND POSS. OF A CONTROLLED SUBSTANCE TO WIT.

ON 07-16-12 AT APPROXIMATELY 1610 HRS I RESPOND TO 2501 N. CITRUS BLVD THE LEESBURG WALMART IN REFERENCE TO A THEFT COMPLAINT.

UPON MY ARRIVAL I MADE CONTACT WITH ASSET PROTECTION ASSOCIATE(APA) LARRY REDDING, WHO ADVISED ME THAT HE HAD BEEN CONTACTED ON 06-28-12 BY APA TYLER MILFORD. MILFORD ADVISED REDDING THAT THERE WAS AN ASSOCIATE STEALING PILLS FROM THE PHARMACY. REDDING ADVISED THAT WHEN HE RETURNED TO WORK ON 07-02-12 HE BEGAN WATCHING WALMART'S CLOSE CIRCUIT TV RECORDINGS. ON THE VIDEO REDDING OBSERVED A W/F ASSOCIATE IDENTIFIED BY THEM AS MEGAN CRANE, ON THREE SEPARATE OCCASSIONS TAKING MEDICATIONS FROM THE PHARMACY WITH OUT PAYING FOR THEM OR HAVING A PROPER PRESCRIPTION.

REDDING ADVISED THAT HE AND THE MANAGEMENT TEAM APPROACHED CRANE ABOUT THE INCIDENTS, CRANE WAS ESCORTED TO THE STORE MANAGERS OFFICES AND QUESTIONED BY MANAGEMENT AND REDDING ABOUT THE INCIDENTS. CRANE ADMITTED MANAGEMENT AND REDDING THAT SHE WAS TAKING THE PILLS, SHE TOLD THEM SHE WAS TAKEN APPROXIMATELY 20 PILLS A DAY.

CRANE ADVISED REDDING THAT SHE ALSO HAD SOME OF THE PILLS IN HER EMPLOYEE LOCKER.

AT THIS TIME REDDING NOTIFIED LAW ENFORCEMENT.

WHILE TALKING TO REDDING, CRANE SPONTANEOUSLY STATED TO ME THAT SHE HAD TAKEN THE PILLS, AND ADVISED ME THAT SHE HAD MORE PILLS IN HER LOCKER. AT THIS TIME I ESCORTED CRANE TO HER LOCKER AND HAD HER OPEN IT FOR ME. CRANE ADVISED ME THAT THE PILLS WERE IN HER PURSE. AT THIS TIME I RETRIEVED CRANE'S PURSE FROM THE LOCKER UPON EXAMINING THE CONTENTS OF THE PURSE I DISCOVER AN ORANGE MEDICINE BOTTLE WITH NO LABEL CONTAIN NUMEROUS WHITE ROUND PILLS WITH THE INSCRIPTION OF IP 145, ALSO IN THE PURSE WAS A WHITE BOTTLE WITH THE WORD SOMA WRITTEN ON IT, IT CONTAINED SEVERAL WHITE ROUND PILLS WITH INSCRIPTION 2410 V, A PINK CONTAINER WAS LOCATED CONTAINING 12 OBLONG WHITE PILLS WITH THE INSCRIPTION M363, AND A GREEN CONTAINER CONTAINING 4 WHITE ROUND PILLS WITH INSCRIPTION BP 633. ALL THE PILLS WERE IDENTIFIED USING DRUGS.COM

SWORN to and SUBSCRIBED before me

this 6 day of July, 2012.

☒ CONTINUED

AFFIANT

DAC David B

Notary Public (Certified Officer)
(circle one)

FRUITLAND PARK POLICE DEPARTMENT
ARRESTING AGENCY

SEAL

Complaint/Arrest Affidavit Continuation	Court Case No.	Agency Case No. 12-FR-4698 - 1

Defendant's Name: Last	First	Middle	Date of Birth
CRANE, MEGAN ELIZABETH			04/19/1949

PROBABLE CAUSE AFFIDAVIT:
(specify probable cause for each charge)

Before Me, the undersigned authority personally appeared **Sr. Officer S. M. Foster** who being duly sworn, alleges, on information and belief, that on the **6th** day of **July**, **2012**, in **Lake** County, Florida. the defendant did:

IP 145 - HYDROCODONE BITARTRATE AND IBUPROFEN 7.5 mg / 200mg SCHD III

2410 V - CARISOPRODOL 350mg SCHD IV

M363 - ACETAMINOPHEN AND HYDROCODONE BITARTRATE 500mg / 10mg SCHD III

BP 633 - ALPRAZOLAM 2mg SCHD IV

AFTER LOCATING THE PILLS IN HER PURSE I ESCORTED HER TO THE ASSET PROTECTION OFFICE, WHILE IN THE OFFICE CRANE SPONTANEOUSLY STATED THAT SHE WOULD FILL PRESCRIPTION BOTTLES MAKING IT APPEAR THAT SHE WAS DOING A LEGIT FILL. SHE STATE THAT SHE WOULD PRINT OFF A FRAUDULENT PRESCRIPTION LABEL FOR THE BOTTLE SHE WOULD THEN HIDE THE PILLS FOR REMOVAL AT A LATER TIME. CRANE ADVISED THAT SHE DID AT ONE TIME HAVE A PRESCRIPTION FOR HYDROCODONE BUT IT IS NO LONGER VALID. CRANE ADVISED THAT SHE HAD A PRESCRIPTION FOR THE CARISOPRODOL BUT WAS UNABLE TO PROVIDE THAT PRESCRIPTION.

AT THIS TIME CRANE WAS PLACED UNDER ARREST AND TRANSPORTED TO THE FRUITLAND PARK POLICE DEPARTMENT.

CRANE WAS THEN TRANSPORTED TO THE LAKE COUNTY JAIL AND HELD ON BOND.

SWORN to and SUBSCRIBED before me

this 6 day of July, 2012.

☐ CONTINUED

AFFIANT

OFC. [signature]
Notary Public (Certified Officer)
(circle one)

FRUITLAND PARK POLICE DEPARTMENT
ARRESTING AGENCY

SEAL

IN THE CIRCUIT COURT OF THE FIFTH JUDICIAL CIRCUIT OF THE STATE OF FLORIDA,
IN AND FOR LAKE COUNTY IN THE YEAR OF OUR LORD, TWO THOUSAND-TWELVE.

THE STATE OF FLORIDA

vs

MEGAN ELIZABETH CRANE

CASE NO. 2012-CF-001751-A-03

INFORMATION

IN THE NAME AND BY THE AUTHORITY OF THE STATE OF FLORIDA:

BRAD KING, State Attorney of the Fifth Judicial Circuit of the State of Florida, in and for Lake County prosecuting for the State of Florida, by and through the undersigned Assistant State Attorney, in the said County, under oath, information makes that: MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve:

COUNT I
POSSESSION OF HYDROCODONE (F3)
893.13(6)(a) AND 893.03(2)(a)(1)(j)

did knowingly and unlawfully have in her actual or constructive possession a controlled substance, to-wit: Hydrocodone, in violation of Florida Statutes 893.13(6)(a) and 893.03(2)(a)(1)(o);

COUNT II
POSSESSION OF ALPRAZOLAM (F3)
893.13(6)(a) AND 893.03(4)(a)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did knowingly and unlawfully have in her actual or constructive possession a controlled substance, to-wit: Alprazolam, in violation of Florida Statutes 893.13(6)(a) and 893.03(4)(a);

COUNT III
POSSESSION OF CARISOPRODOL (F3)
893.13(6)(a) and 893.03(4)(iii)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did knowingly, willfully and feloniously be in the actual or constructive possession of a controlled substance, to-wit: Carisoprodol, in violation of Florida Statutes 893.13(6)(a) and 893.03 (4)(iii);

COUNT IV
UNLAWFUL ACQUISITION/ATTEMPT TO ACQUIRE POSSESSION OF A CONTROLLED SUBSTANCE BY FRAUD (F3)
893.13(7)(a)9 and 893.13(7)(d)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did unlawfully acquire or attempt to acquire possession of a controlled substance, to-wit: Hydrocodone, Alprazolam, Carisoprodol, commercially known as Vicodin, Xanax, Soma, as described in Florida Statute 893.03, and in the course thereof utilized misrepresentation, fraud, deception, or subterfuge, in violation of Florida Statutes 893.13(7)(a)9 and 893.13(7)(c);

COUNT V
GRAND THEFT-$300 OR MORE BUT LESS THAN $20 000 (F3)
812.014(1) AND 812.014(2)(c)1

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did unlawfully and knowingly obtain, use or endeavor to obtain or use the property of WALMART, to-wit: Prescription Drugs, of the value of three hundred dollars ($300.00) or more, but less than twenty thousand dollars ($20,000.00), with the intent to either temporarily or permanently deprive WALMART of a right to the property or a benefit thereof, or did appropriate the said property to her own use or the use of any person not entitled thereto, in violation of Florida Statutes 812.014(1) and 812.014(2)(c)1;

contrary to the form of the statute in such cases made and provided and against the peace and dignity of the State of Florida.

STATE OF FLORIDA, COUNTY OF LAKE

Personally appeared before me, BRAD KING, State Attorney for the Fifth Judicial Circuit, State of Florida, in and for Lake County, State of Florida, or his duly designated Assistant State Attorney, who first being sworn, says that the allegations as set forth in the foregoing information are based upon facts that have been sworn to as true, and which if true, would constitute the offense therein charged. Prosecution instituted in good faith and subscribed under oath, certifying he has received testimony under oath from the material witness or witnesses of the offense.

SHERYL BARNES
Commission # DD 962473
Expires February 17, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

D Gary Lashley Jr, Assistant to BRAD KING State Attorney,
Fifth Judicial Circuit of Florida
Florida Bar No. 86786

Sworn to and subscribed before me this 23 day of July, 2012.

Affiant Personally Known to Notary Public

Presented and filed in the CIRCUIT Court this 25 day of July, 2012.

JJ Neil Kelly
CLERK OF CIRCUIT COURT

BY: _____ D.C.

2012 JUL 25 A 10:00

CLERK OF CIRCUIT COURT
LAKE COUNTY
TAVARES FLORIDA

Case: 2012 CF 001751
00038727432
Drt: CFINF

EXHIBIT # S2-4

20

IN THE CIRCUIT COURT OF THE FIFTH JUDICIAL CIRCUIT OF THE STATE OF FLORIDA,
IN AND FOR LAKE COUNTY IN THE YEAR OF OUR LORD, TWO THOUSAND-TWELVE.

THE STATE OF FLORIDA

CASE NO. 2012-CF-001751-A-03

vs

AMENDED INFORMATION

MEGAN ELIZABETH CRANE

IN THE NAME AND BY THE AUTHORITY OF THE STATE OF FLORIDA:

BRAD KING, State Attorney of the Fifth Judicial Circuit of the State of Florida, in and for Lake County prosecuting for the State of Florida, by and through the undersigned Assistant State Attorney, in the said County, under oath, information makes that: MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve:

COUNT I
TRAFFICKING IN HYDROCODONE (F1)
893.135(1)(c) and 893.03(2)(a)1

did then and there unlawfully and knowingly have in her actual or constructive possession a controlled substance, to-wit: Hydrocodone, or a mixture containing Hydrocodone, in an amount of four (4) grams or more, but less than fourteen (14) gram, in violation of Florida Statutes 893.135(1)(c) and 893.03(2)(a)1;

COUNT II
POSSESSION OF ALPRAZOLAM (F3)
893.13(6)(a) AND 893.03(4)(a)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did knowingly and unlawfully have in her actual or constructive possession a controlled substance, to-wit: Alprazolam, in violation of Florida Statutes 893.13(6)(a) and 893.03(4)(a);

COUNT III
POSSESSION OF CARISOPRODOL (F3)
893.13(6)(a) and 893.03(4)(iii)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did knowingly, willfully and feloniously be in the actual or constructive possession of a controlled substance, to-wit: Carisoprodol, in violation of Florida Statutes 893.13(6)(a) and 893.03 (4)(iii);

COUNT IV
UNLAWFUL ACQUISITION/ATTEMPT TO ACQUIRE POSSESSION OF A CONTROLLED SUBSTANCE BY FRAUD (F3)
893.13(7)(a)9 and 893.13(7)(d)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did unlawfully acquire or attempt to acquire possession of a controlled substance, to-wit: Hydrocodone, Alprazolam, Carisoprodol, commercially known as Vicodin, Xanax, Soma, as described in Florida Statute 893.03, and in the course thereof utilized misrepresentation, fraud, deception, or subterfuge, in violation of Florida Statutes 893.13(7)(a)9 and 893.13(7)(c);

COUNT V
GRAND THEFT-$300 OR MORE BUT LESS THAN $20 000 (F3)
812.014(1) AND 812.014(2)(c)1

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did unlawfully and knowingly obtain, use or endeavor to obtain or use the property of WALMART, to-wit: Prescription Drugs, of the value of three hundred dollars ($300.00) or more, but less than twenty thousand dollars ($20,000.00), with the intent to either temporarily or permanently deprive WALMART of a right to the property or a benefit thereof, or did appropriate the said property to her own use or the use of any person not entitled thereto, in violation of Florida Statutes 812.014(1) and 812.014(2)(c)1;

contrary to the form of the statute in such cases made and provided and against the peace and dignity of the State of Florida.

STATE OF FLORIDA, COUNTY OF LAKE

Personally appeared before me, BRAD KING, State Attorney for the Fifth Judicial Circuit, State of Florida, in and for Lake County, State of Florida, or his duly designated Assistant State Attorney, who first being sworn, says that the allegations as set forth in the foregoing information are based upon facts that have been sworn to as true, and which if true, would constitute the offense therein charged. Prosecution instituted in good faith and subscribed under oath, certifying he has received testimony under oath from the material witness or witnesses of the offense.

MICHELE D. SKIBA
Commission # DD 984349
Expires May 14, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

D Gary Lashley Jr, Assistant to BRAD KING State Attorney,
Fifth Judicial Circuit of Florida
Florida Bar No. 86786

Sworn to and subscribed before me this 21st day of August, 2012.

Affiant Personally Known to Notary Public

Presented and filed in the CIRCUIT Court this 21 day of August, 2012.

Neil Kelly
CLERK OF CIRCUIT COURT
BY: _____ D.C

CLERK OF CIRCUIT AND COUNTY COURT
LAKE COUNTY
TAVARES FLORIDA

2012 AUG 21 A 10:26

CRIMINAL DIVISION

Case: 2012 CF 001751
2012-32458
20037094008
DKT: CFINF

21

IN THE CIRCUIT COURT OF THE FIFTH JUDICIAL CIRCUIT OF THE STATE OF FLORIDA,
IN AND FOR LAKE COUNTY IN THE YEAR OF OUR LORD, TWO THOUSAND-TWELVE.

CLERK OF CIRCUIT AND COUNTY COURTS
LAKE COUNTY
TAVARES FLORIDA

2012 AUG 29 A 10:53

FELONY DIVISION

THE STATE OF FLORIDA

vs

MEGAN ELIZABETH CRANE

CASE NO. 2012-CF-001751-A-03

2nd AMENDED INFORMATION

IN THE NAME AND BY THE AUTHORITY OF THE STATE OF FLORIDA:

BRAD KING, State Attorney of the Fifth Judicial Circuit of the State of Florida, in and for Lake County prosecuting for the State of Florida, by and through the undersigned Assistant State Attorney, in the said County, under oath, information makes that: MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve:

COUNT I
TRAFFICKING IN HYDROCODONE (F1)
893.135(1)(c) and 893.03(2)(a)1

did then and there unlawfully and knowingly have in her actual or constructive possession a controlled substance, to-wit: Hydrocodone, or a mixture containing Hydrocodone, in an amount of fourteen (14) grams or more, but less than twenty-eight (28) grams, in violation of Florida Statutes 893.135(1)(c) and 893.03(2)(a)1;

COUNT II
POSSESSION OF ALPRAZOLAM (F3)
893.13(6)(a) AND 893.03(4)(a)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did knowingly and unlawfully have in her actual or constructive possession a controlled substance, to-wit: Alprazolam, in violation of Florida Statutes 893.13(6)(a) and 893.03(4)(a);

COUNT III
POSSESSION OF CARISOPRODOL (F3)
893.13(6)(a) and 893.03(4)(jjj)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did knowingly, willfully and feloniously be in the actual or constructive possession of a controlled substance, to-wit: Carisoprodol, in violation of Florida Statutes 893.13(6)(a) and 893.03 (4)(jjj);

COUNT IV
UNLAWFUL ACQUISITION/ATTEMPT TO ACQUIRE POSSESSION OF A CONTROLLED SUBSTANCE BY FRAUD (F3)
893.13(7)(a)9 and 893.13(7)(d)

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did unlawfully acquire or attempt to acquire possession of a controlled substance, to-wit: Hydrocodone, Alprazolam, Carisoprodol, commercially known as Vicodin, Xanax, Soma, as described in Florida Statute 893.03, and in the course thereof utilized misrepresentation, fraud, deception, or subterfuge, in violation of Florida Statutes 893.13(7)(a)9 and 893.13(7)(c);

COUNT V
GRAND THEFT-$300 OR MORE BUT LESS THAN $20 000 (F3)
812.014(1) AND 812.014(2)(c)1

and the Assistant State Attorney upon his oath aforesaid, further information makes that MEGAN ELIZABETH CRANE (R/G: W/F, DOB: 04/19/1979) in the County of Lake, and the State of Florida, on or about the 28th day of June in the year of Our Lord, twenty-twelve through the 16th day of July in the year of Our Lord, twenty-twelve, in the County and State aforesaid did unlawfully and knowingly obtain, use or endeavor to obtain or use the property of WALMART, to-wit: Prescription Drugs, of the value of three hundred dollars ($300.00) or more, but less than twenty thousand dollars ($20,000.00), with the intent to either temporarily or permanently deprive WALMART of a right to the property or a benefit thereof, or did appropriate the said property to her own use or the use of any person not entitled thereto, in violation of Florida Statutes 812.014(1) and 812.014(2)(c)1;

contrary to the form of the statute in such cases made and provided and against the peace and dignity of the State of Florida.

STATE OF FLORIDA, COUNTY OF LAKE

Personally appeared before me, BRAD KING, State Attorney for the Fifth Judicial Circuit, State of Florida, in and for Lake County, State of Florida, or his duly designated Assistant State Attorney, who first being sworn, says that the allegations as set forth in the foregoing information are based upon facts that have been sworn to as true, and which if true, would constitute the offense therein charged. Prosecution instituted in good faith and subscribed under oath, certifying he has received testimony under oath from the material witness or witnesses of the offense.

D Gary Lashley Jr, Assistant to BRAD KING State Attorney,
Fifth Judicial Circuit of Florida
Florida Bar No. 86786

Sworn to and subscribed before me this 27 day of August, 2012.

Affiant Personally Known to Notary Public

MICHELE D. SKIBA
Commission # DD 984349
Expires May 14. 2014
Bonded Thru Troy Fain Insurance 800-385-7019

Presented and filed in the CIRCUIT Court this 29 day of August, 2012.

Neil Kelly
CLERK OF CIRCUIT COURT
BY: _____ D.C.

Case: 2012 CF 001751
0006124412B
Dkt: CFINF

L-2012-32458

ABS

22 17

IN THE CIRCUIT COURT OF THE FIFTH JUDICIAL CIRCUIT,
OF THE STATE OF FLORIDA, IN AND FOR LAKE COUNTY

STATE OF FLORIDA

VS.

MEGAN ELIZABETH CRANE/

CASE NO. 2012-CF-001751-A-03
AGENCY #: , FPPD 12FR4698

CHARGE: VI DRUG POSSESSION - GENERAL

ANNOUNCEMENT OF NO INFORMATION

Comes now the State of Florida, by and through its undersigned Assistant State Attorney, and announces that it will file no information in the above entitled cause based on the following grounds:

THIS CHARGE IS CONTAINED IN OTHER CHARGES

DATED this the 23 day of July, 2012.

I HEREBY CERTIFY that a copy of the above has been furnished to Public Defender, Lake County Office Of The Public Defender, 123 N Sinclair Ave - PO Box 7800, Tavares, FL 32778, by hand or mail, and the Lake County Jail (Inmate Records and Warrants Division), by facsimile this 24 day of July, 2012.

BRAD KING
STATE ATTORNEY
FIFTH JUDICIAL CIRCUIT OF FLORIDA

PCM
OBTS
AD

BY _____

D Gary Lashley Jr
Assistant State Attorney
Fla. Bar # 86786
Lake County Judicial Center
550 West Main Street
PO Box 7800
Tavares, FL 32778
(352) 742-4236

Case: 2012 CF 001751
DEFENDANT: CRANE

CLERK OF CIRCUIT AND COUNTY COURTS
LAKE COUNTY
TAVARES FLORIDA
L-2012-002458

2012 JUL 25 A 10:00

CRIMINAL DIVISION

11

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STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: Alachua	Date of Case: 08/01/2012	Case Number: RPT 2012-11172

Subject: **MEGAN ELIZABETH CRANE, RPT** 11423 Lake Eustis Drive Leesburg, FL 34788 * 352-406-5042	Source: **WAL-MART STORES EAST, LLP** **ATTN: HEATHER GREGORY** 702 SW 8th Street, Dept. 8719 Bentonville, AR 72716-0230 479-277-7032

Prefix:	License #:	Profession:	Board:	Report Date:
RPT (2208)	13859	Registered Pharmacy Technician	Pharmacy	01/11/2013

Period of Investigation:	Type of Report:
08/07/2012 to 01/13/2013	SUPPLEMENTAL 1

Alleged Violation: F.S. 456.072(1)(z): Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition; **(dd)**: Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto; **465.016(1)(d)**: Being unfit or incompetent to practice pharmacy by reason of: **2.** The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893; **3.** Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs, or medical supplies or for whom she or he might manufacture, prepare, or package, or supervise the manufacturing, preparation, or packaging of, prescriptions, drugs, or medical supplies; **(m)**: Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition; **(r)**: Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

Synopsis: This investigation is predicated upon the receipt of a request from the Florida Department of Health Prosecution Services Unit to serve an emergency action.

On 01/04/2013, at 1328 hours, the Alachua ISU office received a request from the Prosecution Services Unit requesting that CRANE be served with an Order to Compel Evaluation (OCE). On 01/10/2013, at 1320 hours, I met with CRANE in the employee break room of Goodwill, located at 10601 NW US HWY 441, Suite C-13, Leesburg, Florida. I recognized CRANE from her jail mug shot. I served the OCE to CRANE. The OCE was packaged in a sealed envelope marked "confidential." I was unable to discuss the OCE with CRANE due to the fact that two other employees were in the room with her. I gave my business card to CRANE and advised her to call me if she had any questions about the document that I had delivered to her.

I completed an Affidavit of Service on 01/11/2013. No further investigative action taken at this time.

**Address is different than the address on file with the Department of Health*

Related Case: N/A

Investigator/Date:	Approved By/Date:
Edward Legall, GI-31	William Schauer, Investigations Manager

Distribution: HQ/ISU

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* S1-4. Miscellaneous Correspondence..... 11-13

***EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES**

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

Gwendolyn Swatts, AAII for Candace Rochester, Esq.	TO: William Schauer, Investigation Manager
Date: 1/4/2013	TO: **CSU** ☐
Phone #: 850-245-4640 Ext. 8214	CC: Edward Legal II, MMI

Case Number: 2012-11172
Subject: **Megan E. Crane, RPT**
Requested Completion Date: 1/23/2013

Board: **Registered Pharmacy Tech.**
HLCode: **HLL96A** Status: **60**

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please hands serve the attached Order Compelling Evaluation. Please contact me by January 23, 2013 if you are unable to serve the Subject. Thank you.

*The following additional information is needed for each service request:

Last Known Address: 11423 Lake Eustis Drive, Leesburg, FL 34788; Last Known Name & Phone: Megan E. Crane, RPT (352) 406-5042.
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☒ NOTE: All process service requests need to be sent to appropriate field office.
**IF YES, please send a copy of the original Investigative Report without attachments.

(ISU/CSU) RESPONSE:

☒ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Add'l Info Sent to Legal (Activity Code 156)

☐ Investigative Work Returned to Legal (Activity Code 156)

☐ Cancelled by Legal (Activity Code 157) ☐ Cancelled by ISU/CSU (Activity Code 158)

INV FORM 376, Revised 10/11, 6/10, 06/09. 4/09,11/08 Created 4/05

EXHIBIT # S1-1

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: The Order Compelling Examination of
Megan Elizabeth Crane, RPT
License Number RPT 13859
Case Number 2012-11172

ORDER COMPELLING EXAMINATION

The Department of Health (the "Department") is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes (2011-2012).

For probable cause shown and pursuant to the authority vested in the Department by Chapters 456 and 465, Florida Statutes (2011-2012), you are hereby ordered to report and submit to a mental and physical examination to be conducted by the following named physician at the date, time, and place indicated.

MENTAL AND PHYSICAL EXAMINATION

Stacy Seikel, M.D.
1118 S. Orange Avenue, Ste. 202
Orlando, FL 32806
(407) 592-6371
ON
Wednesday, January 30, 2013 @ 10:00 a.m.

The above-directed physical and mental examination is being conducted for the purpose of obtaining examination reports and expert

EXHIBIT #S1-2

opinion and testimony concerning your ability to practice as a registered pharmacy technician with reasonable skill and safety pursuant to Section 456.072(1)(z), Florida Statutes (2011-2012), and for introduction into evidence at any administrative hearing to be conducted on any administrative complaint filed against you which may allege a violation of Section 456.072(1)(z), Florida Statutes (2011-2012). This Order is predicated upon the following Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. At all times material to this Order, Megan Elizabeth Crane, RPT, ("Ms. Crane"), was licensed to practice as a registered pharmacy technician in the State of Florida, pursuant to Chapter 465, Florida Statutes (2011-2012) and was employed at the Wal-Mart store located at 2501 North Citrus Boulevard, Leesburg, Florida 34748 ("Wal-Mart").

2. Beginning on June 28, 2012, Wal-Mart began an investigation after Wal-Mart surveillance cameras observed Ms. Crane taking prescription bottles from the will-call bin and placing them with her personal and family prescriptions.

3. After completing their internal investigation, Wal-Mart representatives reported Ms. Crane's behavior to Fruitland Park Police Department ("law enforcement") on or about July 6, 2012. When officers spoke with Ms. Crane, she admitted to diverting pills. Law enforcement searched Ms. Crane's purse and found approximately 45 hydrocodone pills, 13 carisoprodol pills, and 4 alprazolam pills.

4. Hydrocodone is commonly prescribed to treat pain. According to Section 893.03(2), Florida Statutes (2011-2012), hydrocodone is a Schedule II controlled substance that has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States. Abuse of hydrocodone may lead to severe psychological or physical dependence.

5. Carisoprodol, commonly known by the brand name Soma, is a muscle relaxant prescribed to treat muscular pain. According to Section 893.03(4), Florida Statutes (2011-2012), carisoprodol is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of carisoprodol may lead to limited

physical or psychological dependence relative to the substances in Schedule III.

6. Alprazolam is prescribed to treat anxiety. According to Section 893.03(4), Florida Statutes (2011-2012), alprazolam is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of alprazolam may lead to limited physical or psychological dependence relative to the substances in Schedule III.

7. In a voluntary statement to Wal-Mart signed by Ms. Crane on July 6, 2012, she admitted to diverting hydrocodone/APAP pills and hydrocodone pills from Wal-Mart for personal use for approximately six months.

8. Hydrocodone/APAP contains hydrocodone and acetaminophen, or Tylenol and is prescribed to treat pain. According to Section 893.03(3), Florida Statutes (2011-2012), hydrocodone, in the dosages found in hydrocodone/APAP is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has

a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

9. On July 6, 2012, Ms. Crane was arrested and charged with: (1) trafficking in hydrocodone; (2) possession of alprazolam; (3) possession of carisoprodol; (4) unlawful acquisition/attempt to acquire possession of a controlled substance; and (5) grand theft $300 or more but less than $20,000.

10. Because Ms. Crane was arrested for diverting hydrocodone pills and admitted to personally consuming them, a thorough and complete mental and physical examination of Ms. Crane is necessary to protect the public and to ensure that she is able to practice as a registered pharmacy technician with reasonable skill and safety.

CONCLUSIONS OF LAW

1. Based on the foregoing Findings of Fact, the State Surgeon General, through his undersigned designee, concludes that probable cause exists to believe Ms. Crane is unable to practice as a registered pharmacy

8

technician with reasonable skill and safety to patients, pursuant to Section 456.072(1)(z), Florida Statutes (2012).

2. In accordance with the authority vested in the Department of Health under Chapters 456 and 465, Florida Statutes (2012), the State Surgeon General, through his undersigned designee, concludes that Section 456.072(1)(z), Florida Statutes (2012), should be enforced.

DONE and ORDERED by the Department of Health on this 5th day of December, 2012.

John H. Armstrong, MD
State Surgeon General and
Secretary of Health

Daniel Hernandez
Deputy General Counsel
Prosecution Services Unit

COUNSEL FOR DEPARTMENT:
Candace A. Rochester, Esq.
Florida Bar No. 0078393
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4662
Candace_Rochester@doh.state.fl.us

Rick Scott
Governor

FLORIDA DEPARTMENT OF HEALTH

John H. Armstrong, MD, FACS
Surgeon General & Secretary

AFFIDAVIT OF SERVICE OR DILIGENT SEARCH

FLORIDA DEPARTMENT OF HEALTH
Petitioner

vs

Case No. RPT 2012-11172

MEGAN ELIZABETH CRANE, RPT
Respondent

COMES NOW, the affiant, who first being duly sworn, deposes and states:

1) Affiant is an Investigator/Inspector employed by the DEPARTMENT OF HEALTH, State of Florida.

2) That on 01/10/2013, Affiant made a diligent effort to locate Respondent, to serve
_____ Administrative Complaint and related papers; __XX__ Order compelling examination(s);
_____Subpoena(s); _____Final order; _____Notice to cease and desist;
_____ ESO/ERO and related papers.

3) Check applicable answer below:

__XX__Affiant made personal service on MEGAN ELIZABETH CRANE, RPT at Goodwill, 10601 NW US HWY 441, Suite C-13, Leesburg, Florida, or on some person at Respondent's usual place of abode over the age of 15 residing there, on 01/10/2013 at 1320 hours.

_____Affiant was unable to make service after searching for Respondent at: (a) all addresses for Respondent shown in the DOH investigation of the case; (b) all official addresses for Respondent shown in his licensing records on the computer terminal or Board office; (c) Local telephone company for the last area Respondent was known to frequent; (d) Division of Drivers Licenses; and (e) Utilities (electric, cable, etc.); any others: _____

Affiant

State Of Florida
County Of ____Alachua_____

Before me, personally appeared _Edward Legall_ whose identity is known to me by personal knowledge (type of identification) and who, acknowledges that his/her signature appears above.

Sworn to or affirmed by Affiant before me this ____11th____ day of January 2013.

Notary Public-State of Florida

My Commission Expires

Pamela Shackey
Type or Print Name

PAMELA SHARKEY
Commission # EE 178424
Expires April 8, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

INV FORM 321 Created 9/05

EXHIBIT # S1-3

Rick Scott
Governor

FLORIDA DEPARTMENT OF HEALTH

John H. Armstrong, MD, FACS
Surgeon General & Secretary

January 7, 2013

CONFIDENTIAL TO:
MEGAN ELIZABETH CRANE
11423 LAKE EUSTIS DRIVE
LEESBURG, FL 34788

RE: DOH Case #RPT 2012-11172

Dear Ms. Crane:

The Florida Department of Health regulates the professional licenses of all health care practitioners practicing in the State of Florida. I have been asked by the Department to deliver some urgent correspondence to you. I have been unable to reach you by telephone. Please contact me at 386-462-3378 as soon as possible so we can arrange a time when I can deliver it to you. If I am not available when you call, please leave a voicemail with the best telephone number and time of day for me to reach you.

Thank you for your assistance in this matter.

Sincerely,

Investigator Edward Legall
Florida Department of Health
Investigative Services Unit

COPY

Florida Department of Health
Investigative Services Unit
14101 NW Highway 441, Suite 700
Alachua, Florida 32615-5669

www.doh.state.fl.us

Division of Medical Quality Assurance
Phone: (386) 418-5330
Fax: (386) 418-5327

EXHIBIT # S1-4

Legall, Edward A

From: Legall, Edward A

Sent: Monday, January 07, 2013 9:29 AM

To: 'meganeliz@ymail.com'

Subject: **Florida Department of Health: Please Contact Me.**

Good Morning, Ms. Crane,

I have an urgent communication for you from the Florida Department of Health. Please contact me as soon as possible at 386-462-3378 to make arrangements for delivery.

Thank you,

Investigator Edward Legall
Florida Department of Health
Investigative Services Unit
14101 NW US HWY 441, Suite 700
Alachua, FL 32615-6387
Tel: (386) 462-3378 Fax: (386) 418-5327
Email: edward_legall@doh.state.fl.us
Visit our website: www.doh.state.fl.us/mga
Customer Satisfaction Survey

Legall, Edward A

From: Legall, Edward A

Sent: Monday, January 07, 2013 3:53 PM

To: Schauer, William

Subject: Request for Accurint search.

Please run an Accurint search on the subject below. I am trying to locate her to serve an OCE. Thank you.

DOH Case #: RPT 2012-11172
Subject: Megan Elizabeth Crane
DOB: 4/19/1979
SSN: 594-09-6038
Last Known Address: 11423 Lake Eustis Drive, Leesburg, FL 34788

Investigator Edward Legall
Florida Department of Health
Investigative Services Unit
14101 NW US HWY 441, Suite 700
Alachua, FL 32615-6387
Tel: (386) 462-3378 Fax: (386) 418-5327
Email: edward_legall@doh.state.fl.us
Visit our website: www.doh.state.fl.us/mqa
Customer Satisfaction Survey

CONFIDENTIAL AND EXEMPT MATERIALS

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MEMORANDUM OF FINDING OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy
RE: **DOH v. Megan E.Crane**
DOH Case Number 2012-11172

MEMBERS: Michele Weizer, PharmD & Gavin W. Meshad

DATE OF PCP: July 30, 2013 **AGENDA ITEM: A2**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative report, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Count I: **Section 456.072(1)(x), Florida Statutes (2012)**

Count II: **Section 456.072(1)(c), Florida Statutes (2012)**

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

Michele Weizer PharmD, BCPS 7/30/2013
Chair, Probable Cause Panel Date
Board of Pharmacy

U.S. Postal Service™
CERTIFIED MAIL™ RECEIPT
(Domestic Mail Only; No Insurance Coverage Provided)

For delivery information visit our website at www.usps.com®

OFFICIAL USE

Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$

Postmark Here

7011 1570 0000 0080 3188

Sent To: Megan Elizabeth Crane
Street, Apt. No.; or PO Box No.: 378 W. Rosewood LN
City, State, ZIP+4: Tavares, FL 32778

PS Form 3800, August 2006 — See Reverse for Instructions

SENDER: *COMPLETE THIS SECTION*

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Megan E. Crane
378 W Rosewood Lane
Tavares, FL 32778

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) Stephanie Crane C. Date of Delivery 7/29/12

D. Is delivery address different from item 1? ☒ Yes
If YES, enter delivery address below: ☐ No
11423 Lake Eustis Dr.
Leesburg, FL 34788

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☒ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? *(Extra Fee)* ☐ Yes

2. Article Number *(Transfer from service label)* 7011 1570 0000 0080 3188

PS Form 3811, February 2004 — Domestic Return Receipt — RR 2 — 102595-02-M-1540

PRACTICE NOTICE OF PETITIONER REQUIRED BY RULE

PSU REQUEST FORM

FROM: Tamia Christopher For Mary S. Miller, Esq.	TO: William Schauer, Investigative Supervisor ISU Alachua
Date: 7/19/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC:

Case Number: **2012-11172** Board: Pharmacy
Subject: Megan Elizabeth Crane HL Code: HLL70A Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 11423 Lake Eustis Drive, Leesburg, Florida 34788
Last Known Name & Phone Number: Megan Elizabeth Crane (352) 406-5042
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.

****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to: Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

July 19, 2013

7011 1570 0000 0080 3188

Megan Elizabeth Crane, RPT
378 W Rosewood Lane
Tavares, FL 32778

RE: Department of Health vs. Megan Elizabeth Crane, RPT
Case Number: 2012-11172

Dear Megan Elizabeth Crane:

Enclosed please find an Order of Emergency **Suspension** of License filed July 18, 2013, against your license to practice as a registered pharmacy technician in the State of Florida. You should immediately cease the practice as a registered pharmacy technician according to the enclosed Order of Emergency **Suspension** of License.

If you have any questions, please do not hesitate to contact Mary Miller, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc
Enclosure

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Megan Elizabeth Crane, R.P.T.
License No.: RPT 13859
Case No.: 2012-11172

ORDER OF EMERGENCY SUSPENSION OF LICENSE

John H. Armstrong, MD, FACS, Surgeon General and Secretary of Health, ORDERS the emergency suspension of the license of Megan Elizabeth Crane, R.P.T., to practice as a registered pharmacy technician in the State of Florida. Ms. Crane holds license number RPT 13859. Her address of record is 378 West Rosewood Lane, Tavares, Florida 32778. Another address for Ms. Crane is Lowell Correctional Institute, 11120 N.W. Gainesville Road, Ocala, Florida 34482-1479. The following Findings of Fact and Conclusions of Law support the emergency suspension of Ms. Crane's license to practice as a registered pharmacy technician.

FINDINGS OF FACT

1. The Department of Health (Department) is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes.

2. At all times material to this Order, Ms. Crane was licensed to

practice as a registered pharmacy technician in the State of Florida pursuant to Chapter 465, Florida Statutes (2012).

3. On July 6, 2012, in Leesburg, Florida, Fruitland Park Police Department police officers arrested Ms. Crane on one count of Obtaining a Prescription by Fraud, a third degree felony, in violation of Section 831.30(1), Florida Statutes (2012); one count of Grand Theft, a third degree felony, in violation of Section 812.014(3), Florida Statutes (2012); two counts of Possession of a Schedule Three Controlled Substance, a third degree felony, in violation of Section 893.13, Florida Statutes, (2012); and two Counts of Possession of a Schedule Four Controlled Substance, a third degree felony, in violation of Section 893.13, Florida Statutes (2012).

4. On May 13, 2013, in the Circuit Court of the Fifth Judicial Circuit, in and for Lake County, Florida, in case no. 2012-CF-001751, Ms. Crane entered pleas of nolo contendere to, and was adjudicated guilty of, one count of Trafficking Hydrocodone, a first degree felony, in violation of Section 893.135(1)(c), Florida Statutes (2012); one count of Possession of Alprazolam, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012); one count of Possession of Carisoprodol, a third degree felony, in violation of Section 893.13(6)(a), Florida Statutes (2012);

one count of Unlawful Acquisition or Attempt to Acquire Possession of a Controlled Substance by Fraud, a third degree misdemeanor, in violation of Section 893.13(7)(a)9, Florida Statutes (2012); and one count of Grand Theft, a third degree felony, in violation of Section 812.014(2)(c)1, Florida Statutes (2012).

5. The Department did not learn of Ms. Crane's nolo contendere pleas until on or about June 11, 2013.

6. Section 456.074(1), Florida Statutes (2012), provides that the Department *shall* issue an emergency order suspending the license of any person licensed under Chapter 465, Florida Statutes, who enters a plea of nolo contendere to a felony under Chapter 893, Florida Statutes, regardless of adjudication.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General and Secretary of Health concludes as follows:

1. The Department has jurisdiction pursuant to Sections 20.43 and 456.074(1), Florida Statutes, and Chapter 465, Florida Statutes (2012).

2. The Department is mandated to summarily suspend Ms. Crane's license to practice as a registered pharmacy technician in accordance with Section 456.074(1), Florida Statutes (2012).

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes (2012), it is ORDERED THAT:

1. The license of Megan Elizabeth Crane, R.P.T., license number RPT 13859, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Megan Elizabeth Crane, R.P.T., to practice as a registered pharmacy technician will be promptly instituted and acted upon in compliance with Sections 120.569, Florida Statutes (2012).

DONE and ORDERED this 17th day of July, 2013.

John H. Armstrong, MD, FACS
for Surgeon General and Secretary of Health

PREPARED BY:

Mary S. Miller
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(850)245-4444 Telephone ext. 8104
(850)245-4683 Facsimile
Florida Bar No. 0780420
Mary_Miller2@doh.state.fl.us

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Section 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

** Transmit Conf. Report **

P.1 Jul 19 2013 03:27pm

Fax/Phone Number	Mode	Start	Time	Page	Result	Note
99216847	Normal	19:03:26pm	0'29"	1	* O K	

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the Healthiest State in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

July 19, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Megan Elizabeth Crane, RPT
Case Number: 2012-11172

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of **Megan Elizabeth Crane** to practice as a registered pharmacy technician in the State of Florida. An Administrative Complaint has not been issued in the above case. Therefore, this is not a request for a formal hearing.

This letter is sent to advise you of the action taken by the Department and to advise you of the possibility that the respondent may request an expedited hearing. The Department shall keep you advised of any developments. If you need additional information, please contact Mary Miller, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc

Florida Department of Health
Office of the General Counsel • Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 • Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 • FAX 850/245-4682

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: floh

July 19, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Megan Elizabeth Crane, RPT
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Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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Florida
HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201306571

MYKEL CHANEY THOMAS,
RESPONDENT.

NOTICE

TO: MYKEL CHANEY THOMAS
391 112TH AVE N #1306
ST.PETERSBURG, FL 33706

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Rick Scott
Governor

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201306571

MYKEL CHANEY THOMAS,
RESPONDENT.

NOTICE

TO: MYKEL CHANEY THOMAS
7201 72ND STREET NORTH, APT C
PINELLAS PARK, FL 33781

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201306571

MYKEL CHANEY THOMAS,
RESPONDENT.

NOTICE

TO: MYKEL CHANEY THOMAS
1768 30TH STREET SOUTH
ST. PETERSBURG, FL 33712

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Ana Gargollo-McDonald, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Mykel Chaney Thomas, R.P.T.
DOH Case Number 2013-06571
DATE: December 27, 2013 AB

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Mykel Chaney Thomas
Subject's Address of Record:	391 112th Ave N #1306 St.Petersburg, FL 33706
Enforcement Address:	391 112th Ave N #1306 St.Petersburg, FL 33706
Subject's Additional Addresses:	7201 72nd Street North, Apt C Pinellas Park, FL 33781 1768 30th Street South St Petersburg, FL 33712
Subject's License No:	12401 **Rank:** RPT
Licensure File No:	11934
Initial Licensure Date:	11/30/2009
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	456.072(1)(c), FS (2012)
Prior Discipline:	None
Probable Cause Panel:	August 8, 2013; Griffin & Mesaros
Subject's Attorney:	Pro Se
Complainant/Address:	DOH/ISU-St Pete
Materials Submitted:	Memorandum to the Board Voluntary Relinquishment Administrative Complaint Notification Letter Supplemental Investigative Reports (3)

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **DOH Case No. 2013-06571**

MYKEL CHANEY THOMAS, R.P.T,

Respondent.

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Mykel Chaney Thomas, R.P.T., license number RPT 12401, hereby voluntarily relinquishes Respondent's license to practice as a licensed registered pharmacy technician in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a pharmacist in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from the practice of pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 4th day of Dec., 20__.

Mykel Chaney Thomas, R.P.T.

STATE OF FLORIDA
COUNTY OF:

Before me, personally appeared MYKEL THOMAS, whose identity is known to me by DRIVERS LICENSE (type of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 4TH day of DECEMBER, 2013.

MAURA J LUCIANO
Notary Public - State of Florida
My Comm. Expires Aug 7, 2017
Commission # FF 043345

NOTARY PUBLIC

My Commission Expires:

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. CASE NO. 2013-06571

MYKEL CHANEY THOMAS, R.P.T.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Mykel Chaney Thomas, R.P.T., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a registered pharmacy technician within the State of Florida, having been issued license number RPT 12401.

3. Respondent's address of record is 391 112th Avenue North, #1306, St. Petersburg, Florida 33706.

4. On or about June 10, 2013, in the Circuit Court for the Sixth Judicial Circuit of Florida in and for Pinellas County, Criminal Division, case number 13-06091CFANO, Respondent pled guilty to the crime of scheme to defraud, a second degree felony, in violation of Section 817.034(4)(a)2, Florida Statutes (2012).

5. Section 456.072(1)(c), Florida Statutes (2012), provides that being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession, constitutes grounds for discipline.

6. As set forth above, on or about June 10, 2013, in the Circuit Court for the Sixth Judicial Circuit of Florida in and for Pinellas County, Criminal Division, case number 13-06091CFANO, Respondent pled guilty to the crime of scheme to defraud, a second degree felony, in violation of Section 817.034(4)(a)2, Florida Statutes (2012), which is a crime that relates to the practice of the licensee's profession as a registered pharmacy technician.

7. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (2012), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of

adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 8th day of August, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel
Florida Bar Number: 0085907
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245 - 4444 Ext. 8133
Facsimile: (850) 245 - 4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE AUG 08 2013

/AGM

PCP: August 8, 2013
PCP Members: Griffin and Mesaros

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

January 14, 2013

Mykel Thomas
391 112th Avenue North #1306
St Petersburg, FL 33706

Re: DOH vs. Mykel Chaney Thomas, R.P.T.
DOH Case Number: 2013-06571

Dear Ms. Thomas:

We are in receipt of your executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form you agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- Voluntarily relinquishing your Florida pharmacy license may have an effect on pharmacy licenses you may hold in other states.

If this is not what you understood, please contact me as soon as possible to discuss. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their next regularly scheduled meeting. You are not required to attend the meeting.

Sincerely,

Ana M. Gargollo-McDonald
Assistant General Counsel

AM/ab

January 14, 2013

Mykel Thomas
7201 72nd Street North #C
Pinellas Park, FL 33781

Re: DOH vs. Mykel Chaney Thomas, R.P.T.
DOH Case Number: 2013-06571

Dear Ms. Thomas:

We are in receipt of your executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form you agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- Voluntarily relinquishing your Florida pharmacy license may have an effect on pharmacy licenses you may hold in other states.

If this is not what you understood, please contact me as soon as possible to discuss. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their next regularly scheduled meeting. You are not required to attend the meeting.

Sincerely,

Ana M. Gargollo McDonald
Assistant General Counsel

AM/ab

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Case:	Case Number:
St. Petersburg	04/25/13	RPT2013-06571

Subject:
MYKEL CHANEY THOMAS, RPT
391 112th Avenue North
1306
St Petersburg, Florida 33706 *
(727) 657-9362

Source:
DOH/INVESTIGATIVE SERVICES/ST PETERSBURG

Prefix:	License No.	Profession:	Board:	Report Date:
RPT	12401	Registered Pharmacy Technician	Pharmacy	11/06/13

Period of Investigation:	Type of Report:
10/28/13 to 11-06-13	SUPPLEMENTAL - 5

Alleged Violation: F.S. 456.072(1)(b)(m)(z)(dd) and 465.016(1)(d) 2,3, (e)(m)(r) and 893.13(6)(a)(7)(a) 9, by engaging in a diversion of drugs, possible impairment and violating a provision of this chapter in the practice of pharmacy.

Synopsis:

This Supplemental Report is predicated on a request (Exh. S5-1) from DOH/LEGAL asking for a hand service of an Administrative Complaint (Exh. S5-2) on THOMAS as soon as possible.

On 11-05-13 at approximately 4:00 pm, this investigator served THOMAS with the documents at THOMAS's home.

An Affidavit of Service is attached as Exh. S5-3.

RECEIVED-LEGAL
13 NOV -7 PM 4:34

***Subject located at: 7201 72nd Street North, Apt C, Pinellas Park, Florida 33781 (727) 657-9362**

Related Cases: RPT2013-06605

Investigator/Date:	Approved By/Date:
11/06/13	11-6-13
Dave Berry, Medical Quality Assurance Investigator (PI-21)	Karen Hanzal, Investigation Supervisor (PI-28)

Distribution: HDQTRS/ISU

Received
Investigative Services
NOV 07 2013

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

FROM: Blondell Heller-Hutchison for Ana M. Gargollo-McDonald, Esq.	TO: ISU Matthew Knispel
Date: 10/28/2013	TO: CSU
Phone #: (850) 245-4444 ext. 8133	CC: Dave Berry, MMI PE-21

Case Number: 2013-06571
Subject: **Mykel Chaney Thomas, RPT**
Requested Completion Date: **11/28/2013**
Board: **Pharmacy**
HL Code: **HLL106a**
Status: **87**

RECEIVED-LEGAL
13 NOV -7 PM 4:34

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please have the attached Administrative Complaint, Election of Rights and Stipulation hand served. The respondent's mail is being returned "unclaimed". If the Subject cannot be located, please have a supplemental prepared within thirty (30) days of receipt of this memo along with an affidavit of diligent service/search. Please check the licensure screen as well for hand service. Please complete an Accurint check on this respondent if she cannot be located at the address above. Please state in the affidavit the type of method you used to identify the respondent.
Thanking you in advance

*The following additional information is needed for each service request:
Last Known Address: **391 112th Avenue, #1306, St. Petersburg, Florida 33706 and 7201 72nd Street North, Apt. #C, Pinellas Park, Florida 33781**
Last Known Name & Phone Number: **(727) 657-9362**
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☒** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
__IF YES, please send a copy of the original Investigative Report without attachments.**__

(ISU/CSU) RESPONSE:
☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

INV FORM 376, Revised 1/12. 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

EXH. 55-1

FLORIDA DEPARTMENT OF
HEALTH

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to:

Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

October 28, 2013

Mykel C. Thomas, RPT
391 112th Avenue North, #1306
St. Petersburg, Florida 33706

RE: DOH v. Mykel Chaney Thomas, RPT
Case Number 2013-06571

Dear Ms. Thomas:

Enclosed is a copy of an Administrative Complaint that has been filed against your license, along with an Explanation of Rights and an Election of Rights form. You have also been provided with a Settlement Agreement containing disciplinary terms I believe will be acceptable in resolving this matter. If you agree with the terms of the Settlement Agreement, please sign it before a notary public and return it to my office.

Please be aware that the Settlement Agreement is subject to final approval by the Board of Pharmacy. A Voluntary Relinquishment form has also been included in this package for your consideration. Voluntarily relinquishing your license is considered disciplinary action. However, signing the Voluntary Relinquishment form will allow you to avoid costs and forgo further disciplinary hearings.

You may also want to read and understand the several provisions of Florida Statutes and administrative rules related to this disciplinary action. For further information, please refer to the following websites: www.leg.state.fl.us and http://www.flrules.org.

If you accept the Settlement Agreement, your case will be scheduled for the next available Board meeting for consideration. Your attendance at this meeting may be required. You will receive details regarding the meeting date, time, and location once the case is scheduled. If the Board accepts the Settlement Agreement, then its terms become the final resolution of the case. Should the Board not accept the Settlement Agreement, then your response on the Election of Rights form will determine how the case will proceed.

PLEASE NOTE the signed and notarized Election of Rights form must be received by the Department of Health within twenty-one (21) days of the date you were served. Failure to file this form within twenty-one (21) days may be considered a waiver of your right to dispute the allegations in this matter.

Sincerely,

Ana M. Gargollo-McDonald
Assistant General Counsel

AGM/bhh
Enclosures: Administrative Complaint, Election of Rights, Explanation of Rights
Settlement Agreement and Voluntary Relinquishment

ELECTION OF RIGHTS
Case Name: Case No.

PLEASE SELECT ONLY 1 OF THE 3 OPTIONS

An Explanation of Rights is attached. If you do not understand these options, please consult with your attorney or contact the attorney for the Prosecution Services Unit at the address/phone number listed at the bottom of this form.

OPTION 1. ____ **I do not dispute the allegations** of fact in the Administrative Complaint, but do wish to be accorded a hearing, pursuant to Section 120.57(2), Florida Statutes, at which time I will be permitted to submit oral and/or written evidence in mitigation of the complaint to the Board.

OPTION 2. ____ **I do not dispute the allegations** of fact contained in the Administrative Complaint and **waive my right** to object or to be heard. I request that the Board enter a final order pursuant to Section 120.57, Florida Statutes.

OPTION 3. ____ **I do dispute the allegations** of fact contained in the Administrative Complaint and request this to be considered a petition for formal hearing, pursuant to Sections 120.569(2)(a) and 120.57(1), Florida Statutes, before an Administrative Law Judge appointed by the Division of Administrative Hearings. **I specifically dispute the following paragraphs of the Administrative Complaint:**

_____

_____

In addition to the above selection, I also elect the following:

( ) I accept the terms of the Settlement Agreement, have signed and am returning the Settlement Agreement **or** I am interested in settling this case.

( ) I do not wish to continue practicing and have signed and returned the Voluntary Relinquishment of licensure form.

Regardless of which option I have selected, I understand that I will be given notice of time, date, and place when this matter is to be considered by the Board for Final Action. Mediation under Section 120.573, Florida Statutes, is not available in this matter.

(Please sign and complete all the information below.)

_____
Respondent's signature
Address: _____

_____

Lic. No. _____

Phone No. _____

Fax No. _____

STATE OF FLORIDA
COUNTY OF _____
Before me personally appeared _____ whose identity is known to be by _____ (type of identification), and who under oath, acknowledges that his/her signature appears above. Sworn to and subscribed by Respondent before me this ____ day of _____, 201__.

_____
Notary Public
My Commission Expires:

PLEASE MAIL AND/OR FAX COMPLETED FORM TO: Ana M. Gargollo-McDonald, Assistant General Counsel, DOH, Prosecution Services Unit, 4052 Bald Cypress Way, Bin C-65, Tallahassee, Florida 32399-3265. Telephone Number: (850) 245-4444 Extension 8133; FAX (850) 245-4683- TDD 1-800-955-8771.

STATE OF FLORIDA
DEPARTMENT OF HEALTH
EXPLANATION OF RIGHTS

In response to the allegations set forth in the Administrative Complaint issued by the Department of Health, you should make **ONE OF THREE** of the following elections within twenty-one (21) days from the date of receipt of the Administrative Complaint. Please make your election on the attached Election of Rights form and return it fully executed to the address listed on the form. **Your Election of Rights must be received by the Department within twenty-one (21) days of the date you were served.**

Option 1 – If you do not dispute any material fact alleged in the Administrative Complaint, you may request a proceeding pursuant to Section 120.57(2), Florida Statutes, before the Board. At this proceeding you will be given an opportunity to present both written and oral evidence in mitigation of the allegations contained in the Administrative Complaint. This request should be directed to the Department by checking the appropriate space, marked as Option 1, on the Election of Rights form.

Option 2 – If you do not dispute any material fact alleged in the Administrative Complaint and you do not desire to participate in the disposition of the case, you may elect Option 2 on the Election of Rights form.

Option 3 – If you do dispute any material fact alleged in the Administrative Complaint, you may request a formal hearing and the appointment of an Administrative Law Judge with the Division of Administrative Hearings pursuant to Section 120.569(2)(a), Florida Statutes, by checking the appropriate space, marked as Option 3, on the Election of Rights form. You must also specifically indicate which paragraphs you dispute in the Administrative Complaint pursuant to Rule 28-106.2015(5)(c), Florida Administrative Code. Failure to do so may be considered a waiver of your right to dispute the allegations at a formal hearing.

Regardless of whether you dispute any material fact alleged in the Administrative Complaint and after choosing one of the three options above, you may also sign the Settlement Agreement or request the opportunity to enter into a Settlement Agreement to resolve this case, pursuant to Section 120.57(4), Florida Statutes. If you accept the Settlement Agreement, it will be presented to the Board for approval. Please be advised that a Final Order approving a Settlement Agreement is considered disciplinary action and will be reported as such.

You may also sign the Voluntary Relinquishment of license, which will be presented to the Board for approval. Please be advised that a Final Order accepting the Voluntary Relinquishment is considered disciplinary action and will be reported as such.

Failure to file the Election of Rights form within twenty-one (21) days may be considered a waiver of your right to dispute the allegations in this matter, pursuant to Rule 28-106.111(4), Florida Administrative Code, and the Board may proceed to hear the case and impose discipline against your license.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-06571**

MYKEL CHANEY THOMAS, R.P.T.,

RESPONDENT.

_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Mykel Chaney Thomas, R.P.T., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a registered pharmacy technician within the State of Florida, having been issued license number RPT 12401.

3. Respondent's address of record is 391 112th Avenue North, #1306, St. Petersburg, Florida 33706.

4. On or about June 10, 2013, in the Circuit Court for the Sixth Judicial Circuit of Florida in and for Pinellas County, Criminal Division, case number 13-06091CFANO, Respondent pled guilty to the crime of scheme to defraud, a second degree felony, in violation of Section 817.034(4)(a)2, Florida Statutes (2012).

5. Section 456.072(1)(c), Florida Statutes (2012), provides that being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession, constitutes grounds for discipline.

6. As set forth above, on or about June 10, 2013, in the Circuit Court for the Sixth Judicial Circuit of Florida in and for Pinellas County, Criminal Division, case number 13-06091CFANO, Respondent pled guilty to the crime of scheme to defraud, a second degree felony, in violation of Section 817.034(4)(a)2, Florida Statutes (2012), which is a crime that relates to the practice of the licensee's profession as a registered pharmacy technician.

7. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (2012), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of

adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 8th day of August, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

Ana M. Gargollo-McDonald
Assistant General Counsel
Florida Bar Number: 0085907
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245 - 4444 Ext. 8133
Facsimile: (850) 245 - 4683

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE AUG 0 8 2013

/AGM

PCP: August 8, 2013
PCP Members: Griffin and Mesaros

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2013-06571**

MYKEL CHANEY THOMAS, R.P.T.,

RESPONDENT.

_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the above named parties hereby offer this Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached hereto as Exhibit "A", in lieu of any other administrative proceedings. The terms herein become effective only if and when a Final Order accepting this Agreement is issued by the Board and filed. In considering this Agreement, the Board may review all investigative materials regarding this case. If this Agreement is rejected, it, and its presentation to the Board, shall not be used against either party.

STIPULATED FACTS

1. Respondent is a registered pharmacy technician (R.P.T.) in the State of Florida holding license number RPT 12401.

2. The Respondent is charged by an Administrative Complaint filed by the Department and properly served upon Respondent with violations of Chapters 456 and/or 464, Florida Statutes. A true and correct copy of the Administrative Complaint is attached hereto and incorporated by reference as Exhibit A.

3. Respondent neither admits nor denies the factual allegations contained in the Administrative Complaint.

STIPULATED LAW

1. Respondent admits that he/she is subject to the provisions of Chapters 456 and 464, Florida Statutes, and the jurisdiction of the Department and the Board.

2. Respondent admits that the stipulated facts, if proven true, constitute violations of laws as alleged in the Administrative Complaint.

3. Respondent admits that the Agreement is a fair, appropriate and reasonable resolution to this pending matter.

PROPOSED DISPOSITION

1. The license of Mykel Chaney Thomas, R.P.T., is revoked. Within 30 days the Respondent shall return her license to DOH-Compliance Management Unit, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3276, Attention: Pharmacy Compliance Officer, or shall surrender the license to an investigator of the Department of Health. The Respondent's employer shall immediately be informed of the revocation in writing from the Respondent with a copy to DOH-Compliance Management Unit, 4052 Bald Cypress Way, Tallahassee, Florida 32399-3276, Attention: Pharmacy Compliance Officer.

2. The Respondent shall not violate Chapter 456 or 464, Florida Statutes, the rules promulgated pursuant thereto, any other state or federal law, rule, or regulation relating to the practice or the ability to practice pharmacy. Violation of an order from another state/jurisdiction shall constitute grounds for violation of the Board Order adopting this Agreement.

3. It is expressly understood that this Agreement is subject to the approval of the Board and Department and has no force and effect until an Order is entered adopting the Agreement.

4. This Agreement is executed by the Respondent for the purpose of avoiding further administrative action by the Board of Pharmacy regarding the acts or omissions specifically set forth in the Administrative Complaint attached hereto. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Agreement. Furthermore, should this joint Agreement not be accepted by the Board, it is agreed that presentation to, and consideration of, this Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration or resolution of these proceedings. Respondent shall offer no evidence, testimony or argument that disputes or contravenes any stipulated fact or conclusion of law.

5. Respondent and the Department fully understand that this joint Agreement and subsequent Final Order incorporating same will in no way preclude additional proceedings by the Board and/or Department against the Respondent for acts or omissions not specifically set forth in the Administrative Complaint attached hereto. This Agreement relates solely to the current disciplinary proceedings arising from the above-mentioned

Administrative Complaint and does not preclude further action by other divisions, departments, and/or sections of the Department, including but not limited to the Agency for Health Care Administration's Medicaid Program Integrity Office.

6. The Respondent waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

7. Respondent waives all rights to appeal and further review of this Agreement and these proceedings.

WHEREFORE, the parties hereto request the Board to enter a Final Order accepting and implementing the terms contained herein.

SIGNED this ____ day of _____, 2013.

_____
Mykel Chaney Thomas, R.P.T.

STATE OF FLORIDA
COUNTY OF _____

Before me personally appeared _____ whose identity is known to be by _____ (type of identification), and who under oath, acknowledges that his/her signature appears above.

Sworn to and subscribed by Respondent before me this ____ day of _____, 2013.

_____
Notary Public
My Commission Expires:

APPROVED this ___day of _____, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

_____

ANA M. GARGOLLO-MCDONALD
Assistant General Counsel
Fla. Bar No. 0085907
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Tel: (850) 245-4444 Fax: (850) 245-4683
email: ana_gargollo-mcdonald@doh.state.fl.us

/AGM

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

v. **DOH Case No. 2013-06571**

MYKEL CHANEY THOMAS, R.P.T,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Mykel Chaney Thomas, R.P.T., license number RPT 12401, hereby voluntarily relinquishes Respondent's license to practice as a licensed registered pharmacy technician in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a pharmacist in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from the practice of pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this _____ day of _____, 20__.

_____
Mykel Chaney Thomas, R.P.T.

STATE OF FLORIDA
COUNTY OF:

Before me, personally appeared _____, whose identity is known to me by _____ (type of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this _____ day of _____, 2013.

_____
NOTARY PUBLIC

My Commission Expires:

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Case:	Case Number:
St. Petersburg	04/25/13	RPT2013-06571

Subject:
MYKEL CHANEY THOMAS, RPT
391 112thAvenue North
1306
St Petersburg, Florida 33706 *
(727) 657-9362

Source:
DOH/INVESTIGATIVE SERVICES/ST PETERSBURG

Prefix:	License No.	Profession:	Board:	Report Date:
RPT	12401	Registered Pharmacy Technician	Pharmacy	07/24/13

Period of Investigation:	Type of Report:
07/23/13 to 07-24-13	SUPPLEMENTAL - 4

Alleged Violation: F.S. 456.072(1)(b)(m)(z)(dd) and 465.016(1)(d) 2,3, (e)(m)(r) and 893.13(6)(a)(7)(a) 9, by engaging in a diversion of drugs, possible Impairment and violating a provision of this chapter in the practice of pharmacy.

Synopsis:

This Supplemental Report is predicated on a request (Exh. S4-1) from DOH/LEGAL asking for a hand service of an Emergency Suspension Order (Exh. S4-2) on THOMAS as soon as possible.

On 07-241-13 at approximately 12:30 pm, this Inspector RONALD DILWORTH served the document at THOMAS's home on THOMAS herself.

Legal was advised of the service approximately thirty minutes later by electronic mail.

An Affidavit of Service is attached as Exhibit S4-3.

RECEIVED-LEGAL
13 JUL 31 PM 4:47

***Subject located at: 7201 72nd Street North, Apt C, Pinellas Park, Florida 33781 (727) 657-9362**

Related Cases: RPT2013-06605

Investigator/Date:	Approved By/Date:
7/24/13	7/24/13
Dave Berry, Medical Quality Assurance Investigator (PI-21)	Karen Hanzal, Investigation Supervisor (PI-28)

Distribution: HDQTRS/ISU

[X] CONFIDENTIAL

Received
Investigative Services
JUL 31 2013
DOH/MQA
Tallahassee HQ

PSU REQUEST FORM

FROM: Tamia Christopher For Ana M. Gargollo-McDonald, Esq.	TO: Dave Berry, (PI-21)Investigative Supervisor ISU St. Petersburg
Date: 7/23/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC: Karen Hanzal

Case Number: 2013-06571 Board: Pharmacy
Subject: Mykel Chaney Thomas HL Code: HLL106A Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

RECEIVED-LEGAL
13 JUL 31 PM 4:47

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 7201 72nd Street North, Apt. C, Pinellas Park, Florida 33781
Last Known Name & Phone Number: Mykel Chaney Thomas (727) 657-9362
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:
☑ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)
☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

PSU REQUEST FORM

FROM: Tamia Christopher For Ana M. Gargollo-McDonald, Esq.	TO: Dave Berry, (PI-21)Investigative Supervisor ISU St. Petersburg
Date: 7/23/13	TO: CSU
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Requested Completion Date: A.S.A.P.

RECEIVED-LEGAL
13 JUL 31 PM 4:47

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 7201 72nd Street North, Apt. C, Pinellas Park, Florida 33781
Last Known Name & Phone Number: Mykel Chaney Thomas (727) 657-9362
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.

****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☑ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

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Postage	$
Certified Fee	
Return Receipt Fee (Endorsement Required)	
Restricted Delivery Fee (Endorsement Required)	
Total Postage & Fees	$

Postmark Here

13-06871

7011 1570 0000 0080 3232

Sent To: Mykel C. Thomas
Street, Apt. No., or PO Box No.: 391 112th Ave, N. #1306
City, State, ZIP+4: St. Petersburg, FL 33704

PS Form 3800, August 2006 — See Reverse for Instructions

SENDER: *COMPLETE THIS SECTION*

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

Mykel C. Thomas
391 112th Ave., N #1306
St. Petersburg, FL 33704

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by (Printed Name) [illegible] C. Date of Delivery 8/10/13

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

7201 72 St #A
PINELLAS PARK FL. 33781

3. Service Type
☒ Certified Mail ☐ Express Mail
☐ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7011 1570 0000 0080 3232

PS Form 3811, February 2004 — Domestic Return Receipt — 102595-02-M-1540

PETITIONER REGARDING REGULATION

July 23, 2013

7011 1570 0000 0080 3232

Mykel Chaney Thomas, R.P.T.
391 112th Avenue N #1306
St. Petersburg, FL 33706

RE: Department of Health vs. Mykel Chaney Thomas, R.P.T.
Case Number: 2013-06571

Dear Mykel Chaney Thomas:

Enclosed please find an Order of Emergency **Suspension** of License filed July 23, 2013, against your license to practice as a registered pharmacy technician in the State of Florida. You should immediately cease the practice as a registered pharmacy technician according to the enclosed Order of Emergency **Suspension** of License.

If you have any questions, please do not hesitate to contact Ana Gargollo-McDonald, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc
Enclosure

** Transmit Conf.Report **

P.1 Jul 23 2013 04:17pm

Fax/Phone Number	Mode	Start	Time	Page	Result	Note
99216847	Normal	23:04:16pm	0'29"	1	* O K	

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Vision: To be the Healthiest State in the Nation

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

July 23, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Mykel Chaney Thomas, R.P.T.
Case Number: 2013-06571

Dear Judge Cohen:

This letter is to advise you that the Department has issued an Emergency Suspension Order concerning the license of **Mykel Chaney Thomas** to practice as a registered pharmacy technician in the State of Florida. An Administrative Complaint has not been issued in the above case. Therefore, this is not a request for a formal hearing.

This letter is sent to advise you of the action taken by the Department and to advise you of the possibility that the respondent may request an expedited hearing. The Department shall keep you advised of any developments. If you need additional information, please contact Ana Gargollo-Mcdonald, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc

Florida Department of Health
Office of the General Counsel - Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65 - Tallahassee, FL 32399-1701
Express mail address: 2585 Merchants Row - Suite 105
PHONE: 850/245-4444 - FAX 850/245-4662

www.FloridasHealth.com
TWITTER:HealthyFLA
FACEBOOK:FLDepartmentofHealth
YOUTUBE: fdoh

July 23, 2013

The Honorable Robert S. Cohen
Chief Administrative Law Judge
Division of Administrative Hearings
1230 Apalachee Parkway
Tallahassee, FL 32301

RE: Department of Health vs. Mykel Chaney Thomas, R.P.T.
Case Number: 2013-06571

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This letter is sent to advise you of the action taken by the Department and to advise you of the possibility that the respondent may request an expedited hearing. The Department shall keep you advised of any developments. If you need additional information, please contact Ana Gargollo-Mcdonald, Assistant General Counsel at (850) 245-4444.

Sincerely,

Tamia Christopher
Regulatory Specialist I
Prosecution Services Unit

/tc

Christopher, Tamia L

From: Christopher, Tamia L
Sent: Tuesday, July 23, 2013 4:07 PM
To: zzzz Feedback, MQA_PSU_Operations
Cc: Pope, Berita
Subject: In Ref: FAW#: 13289211

Attachments: FAR Suspension Memorandum_Mykel Chaney Thomas, RPT.doc

Please find attached for your review and records is the FAW memorandum regarding:
DOH Case: Mykel Chaney Thomas,R.P.T.
DOH Case No.: 2013-06571

FAR Suspension
emorandum_Myke

Thank you.

Tamia L. Christopher, Regulatory Specialist I
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(850) 245-4640 ext. 8200

How am I communicating? Please contact my supervisor.

DOH Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.
Vision: Healthiest State in the Nation
Values: (ICARE)
Innovation: We search for creative solutions and manage resources wisely.
Collaboration: We use teamwork to achieve common goals & solve problems.
Accountability: We perform with integrity & respect.
Responsiveness: We achieve our mission by serving our customers & engaging our partners.
Excellence: We promote quality outcomes through learning & continuous performance improvement.
There have been changes to the license renewal process. Please visit www.CEAtRenewal.com to

MEMORANDUM

TO: Florida Administrative Registry

FROM: Tamia Christopher, Regulatory Specialist I

RE: Mykel Chaney Thomas, R.P.T., License # RPT 12401 (FAW # **13289211**)

CASE NO: 2013-06571

DATE: July 23, 2013

Attached please find notice of the issuance of an **Emergency Suspension** Order for notice in the next issue of the Florida Administrative Register.

On July 23, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Mykel Chaney Thomas, R.P.T., License # RPT 12401. This Emergency Suspension Order was predicated upon the State Surgeon General's findings of an immediate and serious danger to the public health, safety and welfare pursuant to Sections 456.073(8) and 120.60(6) Florida Statutes (2011). The State Surgeon General determined that this summary procedure was fair under the circumstances, in that there was no other method available to adequately protect the public.

Miscellaneous

DEPARTMENT OF HEALTH
Board of Pharmacy

Notice of Emergency Action

On July 23, 2013, the State Surgeon General issued an Order of Emergency Suspension Order with regard to the license of Mykel Chaney Thomas, R.P.T., License # RPT 12401. This Emergency Suspension Order was predicated upon the State Surgeon General's findings of an immediate and serious danger to the public health, safety and welfare pursuant to Sections 456.073(8) and 120.60(6) Florida Statutes (2011). The State Surgeon General determined that this summary procedure was fair under the circumstances, in that there was no other method available to adequately protect the public.

If the above contains all content in this notice, click 'Save to HTML File and Finish'. Otherwise copy/paste this content into a Word file; ONLY edit the FULL TEXT portion if applicable, then upload the Word file from Notice Home.

Save to HTML File and Finish

Back To Notice Home Back To Agency Home

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CONFIDENTIAL

Christopher, Tamia L

From: Christopher, Tamia L
Sent: Tuesday, July 23, 2013 2:29 PM
To: DL MQA Inv Serv Priority Mail Area5 (PI) St.Petersburg
Cc: Pope, Berita
Subject: Request for Hand Serve ESO/Thomas, M 201306571

Attachments: Supplemental Request Form_Mykel Chaney Thomas, RPT.doc; DOH 13-1332 ESO 201306571-1_Mykel Chaney Thomas, RPT.pdf

Please hand serve the attached ESO on the Respondent. Thank you.

Supplemental equest Form_Myke

DOH 13-1332 O 201306571-1_M

Tamia L. Christopher, Regulatory Specialist I
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265
(850) 245-4640 ext. 8200

CONFIDENTIAL

PSU REQUEST FORM

FROM: Tamia Christopher For Ana M. Gargollo-McDonald, Esq.	TO: Dave Berry, (PI-21)Investigative Supervisor ISU St. Petersburg
Date: 7/23/13	TO: CSU
Phone #: 850/245/4444 Ext. 8200	CC: Karen Hanzal

Case Number: 2013-06571 Board: Pharmacy
Subject: Mykel Chaney Thomas HL Code: HLL106A Status: 90
Requested Completion Date: A.S.A.P.

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: **For Hand Service of ESO**
Last Known Address: 7201 72nd Street North, Apt. C, Pinellas Park, Florida 33781
Last Known Name & Phone Number: Mykel Chaney Thomas (727) 657-9362
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent? YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.

****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Final Order No. DOH-13-1332-ESO-MQA
FILED DATE: JUL 23 2013
Department of Health
By: Angela Sanders
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: Emergency Suspension of the License of
Mykel Chaney Thomas, R.P.T.
License No.: RPT 12401
Case No.: 2013-06571

ORDER OF EMERGENCY SUSPENSION OF LICENSE

John H. Armstrong, MD, FACS, State Surgeon General and Secretary of Health, ORDERS the emergency suspension of the license of Mykel Chaney Thomas, R.P.T., to practice as a registered pharmacy technician in the State of Florida. Ms. Thomas holds license number RPT 12401. Her address of record is 391 112th Avenue North, #1306, St. Petersburg, Florida 33706. The following Findings of Fact and Conclusions of Law support the emergency suspension of Ms. Thomas' license to practice as a registered pharmacy technician.

FINDINGS OF FACT

1. The Department of Health (Department) is the state agency charged with regulating the practice of pharmacy pursuant to Chapters 20, 456, and 465, Florida Statutes (2012). Section 456.074(1), Florida Statutes, authorizes the Department to summarily suspend Ms. Thomas' license to practice as a registered pharmacy technician.

EXH. 54-2

2. At all times material to this Order, Ms. Thomas was licensed to practice as a registered pharmacy technician in the State of Florida pursuant to Chapter 465, Florida Statutes.

3. On or about April 9, 2013, the Pinellas County Sheriff's Office arrested Ms. Thomas and charged her with grand theft.

4. On or about June 10, 2013, in the Circuit Court for the Sixth Judicial Circuit of Florida in and for Pinellas County, Criminal Division, case number 13-06091CFANO, Ms. Thomas pled guilty to the crime of scheme to defraud, a violation of Section 817.034(4)(a)2, Florida Statutes (2012), a second degree felony.

5. Section 456.074(1), Florida Statutes, provides that the Department *shall* issue an emergency order suspending the license of any person licensed under Chapter 465, Florida Statutes, who pleads guilty to a felony under Chapter 817, regardless of adjudication.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the State Surgeon General concludes as follows:

1. The Department has jurisdiction pursuant to Sections 20.43 and 456.074(1), Florida Statutes, and Chapter 465, Florida Statutes.

2. The Department is mandated to summarily suspend Ms. Thomas' license to practice as a registered pharmacy technician in accordance with Section 456.074(1), Florida Statutes.

WHEREFORE, in accordance with Section 456.074(1), Florida Statutes, it is ORDERED THAT:

1. The license of Mykel Chaney Thomas, R.P.T., license number RPT 12401, is immediately suspended.

2. A proceeding seeking formal suspension or discipline of the license of Mykel Chaney Thomas, R.P.T., to practice as a registered pharmacy technician will be promptly instituted and acted upon in compliance with Section 120.569, Florida Statutes.

DONE and ORDERED this 23rd day of July, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and Secretary of Health

PREPARED BY:
Ana M. Gargollo-McDonald
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245–4444 ext. 8133
Facsimile: (850) 245–4683
Florida Bar No. 0085907

NOTICE OF RIGHT TO JUDICIAL REVIEW

Pursuant to Section 120.68, Florida Statutes, this Order is judicially reviewable. Review proceedings are governed by the Florida Rules of Appellate Procedure. Proceedings are commenced by filing a Petition for Review, in accordance with Florida Rule of Appellate Procedure 9.100, with the District Court of Appeal, accompanied by a filing fee prescribed by law, and a copy of the petition with the Agency Clerk of the Department within 30 days of the date this Order is filed.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Case:	Case Number:
St. Petersburg	04/25/13	RPT2013-06571

Subject:
MYKEL CHANEY THOMAS, RPT
391 112thAvenue North
1306
St Petersburg, Florida 33706 *
(727) 657-9362

Source:
DOH/INVESTIGATIVE SERVICES/ST PETERSBURG

Prefix:	License No.	Profession:	Board:	Report Date:
RPT	12401	Registered Pharmacy Technician	Pharmacy	07/09/13

Period of Investigation:	Type of Report:
07/01/13 to 07-09-13	SUPPLEMENTAL – 3

Alleged Violation: F.S. 456.072(1)(b)(m)(z)(dd) and 465.016(1)(d) 2,3, (e)(m)(r) and 893.13(6)(a)(7)(a) 9, by engaging in a diversion of drugs, possible impairment and violating a provision of this chapter in the practice of pharmacy.

Synopsis:

This Supplemental Report is predicated on a request (Exh. S3-1) from DOH/LEGAL asking for the Felony Information and Judgment regarding THOMAS's criminal case as soon as possible.

On 07-03-13, this investigator obtained the documents from Pinellas County Circuit Court. The documents revealed THOMAS changed her plea to guilty on 06-10-13 to Scheming to Defraud and was sentenced to 24 months of probation, costs, restitution (final amount to be determined) and cannot work in a pharmacy setting.

RECEIVED-LEGAL
13 JUL 11 PM 2:36

***Subject located at: 7201 72nd Street North, Apt C, Pinellas Park, Florida 33781 (727) 657-9362**

Related Cases: RPT2013-06605

Investigator/Date:	Approved By/Date:
7/9/13	Karen Hanzal 7-9-13
Dave Berry, Medical Quality Assurance Investigator (PI-21)	Karen Hanzal, Investigation Supervisor (PI-28)

Distribution: HDQTRS/ISU

Received
Investigative Services
JUL 11 2013
DOH/MQA
Tallahassee HQ

☐ CONFIDENTIAL

PSU REQUEST FORM

FROM: Chris Byrne for Casie Barnette, Esq.	TO: ISU Dave Berry PI-21
Date: July 1, 2013	TO: CSU
Phone #: 850-245-4640X8118	CC: Karen Hanzal

Case Number: 2013-06571 Board: **Pharmacy**
Subject: **Mykel Chaney Thomas, RPT** HL Code:HLL105b Status: **60**
Requested Completion Date: ASAP

(PSU) TYPE OF REQUEST: (describe details below)

☐ Process Service* (**Activity Code 160**)

☒ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please obtain a copy of the information and judgment in criminal complaint 522013CF006091AXXXNO. The file date was 4/10/2013 and the status is disposed before trial-plea. Thank you.

*The following additional information is needed for each service request:

Last Known Address Last Known Name & Phone Number:
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to: Pensacola	Tallahassee	Alachua	Jacksonville	St. Pete	Tampa	Orlando	Ft. Myers	West Palm	Ft. Lauderdale	Miami
	Consumer Services	ULA								

RECEIVED-LEGAL
13 JUL 11 PM 2:36

INV FORM 376, Revised 1/12. 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

EXH. 53-1

CONFIDENTIAL

PSU REQUEST FORM

FROM: Chris Byrne for Casie Barnette, Esq.	TO: ISU Dave Berry PI-21
Date: July 1, 2013	TO: CSU
Phone #: 850-245-4640X8118	CC: Karen Hanzal

Case Number: 2013-06571
Subject: **Mykel Chaney Thomas, RPT**
Requested Completion Date: ASAP
Board: **Pharmacy**
HL Code:HLL105b
Status: **60**

(PSU) TYPE OF REQUEST: (describe details below)

☐ Process Service* (**Activity Code 160**)

☒ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please obtain a copy of the information and judgment in criminal complaint 522013CF006091AXXXNO. The file date was 4/10/2013 and the status is disposed before trial-plea. Thank you.

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Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No ☐; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☐ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☐ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☑ Additional Info Sent to Legal (Activity Code 156)

☐ Supp. Investigation Request Cancelled (Activity Code 157)

Email to:
Pensacola Tallahassee Alachua Jacksonville St. Pete Tampa Orlando Ft. Myers West Palm Ft. Lauderdale Miami

Consumer Services ULA

RECEIVED-LEGAL
13 JUL 11 PM 2:36

INV FORM 376, Revised 1/12. 10/11, 6/10, 06/09, 4/09, 11/08 Created 4/05

[!] CONFIDENTIAL

IN THE CIRCUIT COURT FOR THE SIXTH JUDICIAL CIRCUIT OF FLORIDA IN AND FOR PINELLAS COUNTY - FALL TERM, 2012

FILED
CRIMINAL JUSTICE CENTER
2013 APR 24 PM 3:33
KEN BURKE
CLERK OF CIRCUIT COURT

STATE OF FLORIDA

VS.

MYKEL THOMAS
SPN 03089137
B/F; DOB: [redacted]

CRC13-06091CFANO-C

FELONY INFORMATION

SCHEME TO DEFRAUD, 2°F

IN THE NAME AND BY THE AUTHORITY FOR THE STATE OF FLORIDA:

BERNIE McCABE, State Attorney for the Sixth Judicial Circuit of Florida, in and for Pinellas County, prosecuting for the State of Florida, in the said County, under oath, Information makes that

MYKEL THOMAS

in the County of Pinellas and State of Florida, on or between the 1st day of October, 2012, and the 27th day of March, in the year of our Lord, two thousand thirteen, did engage in a scheme constituting a systematic, ongoing course of conduct with intent to defraud one or more persons, or with intent to obtain property from one or more persons by false or fraudulent pretenses, representations, or promises, or willful misrepresentations of a future act and obtained property from one or more such persons in an amount between $20,000 and $50,000; contrary to Chapter 817.034(4)(a)2, Florida Statutes, and against the peace and dignity of the State of Florida. [Ø25]/5

STATE OF FLORIDA
PINELLAS COUNTY

Personally appeared before me, BERNIE McCABE, State Attorney for the Sixth Judicial Circuit of Florida, in and for Pinellas County, or his duly designated Assistant State Attorney, who being first duly sworn, says that the allegations as set forth in the foregoing information are based upon facts that have been sworn to as true, and which if true, would constitute the offense therein charged; hence this information is filed in good faith in instituting this prosecution, and that he has received testimony under oath from the material witness or witnesses for the offense.

The foregoing instrument was acknowledged before me this 24th day of April, 2013 by Mark R McCarty, who is personally known to me and who did take an oath.

Marina Farmer
NOTARY PUBLIC

Assistant State Attorney for the Sixth Judicial Circuit of the State of Florida, Prosecuting for said State

SO13-139483 C-RB/0418LW15

MARINA FARMER
Commission # EE 033512
Expires October 10, 2014
Bonded Thru Troy Fain Insurance 800-385-7019

CONFIDENTIAL

EXH. 53-2

IN THE CIRCUIT COURT FOR THE SIXTH JUDICIAL CIRCUIT OF FLORIDA
IN AND FOR PINELLAS COUNTY
CRIMINAL DIVISION

UCN: 52200_____ Reference No.: 13-06091CFANO

STATE OF FLORIDA
Plaintiff
v. Mykel Thomas 03089137
aka_____
Defendant

FILED
KEN BURKE
CLERK OF CIRCUIT COURT
2013 JUN 07 PM 1:
CRIMINAL DIVISION

CHANGE OF PLEA FORM

1. I, Mykel Thomas, Defendant herein, do hereby withdraw my plea of not guilty and enter a plea of (guilty) (nolo contendere no contest) to the charge(s) of Scheme to defraud in the above-referenced case(s).

2. I understand that the plea of "not guilty" denies my guilt; a plea of "guilty" admits my guilt; and a plea of "nolo contendere" or "no contest" means that, while I do not admit guilt, I will not contest the evidence against me. I understand that, if the court accepts my change of plea, I give up (waive) my right to a jury trial, and that I will be sentenced as a felony offender, based upon my plea.

3. I understand the charge(s) which has/have been placed against me and to which I am changing my plea. My lawyer has explained to me the elements of the crime(s), and any defenses I may have as well as the maximum penalty for the crime(s) to which I am pleading guilty or no contest, which is 5 years.

4. I understand that the guideline recommendations (will) (will not) be applied to my sentence.

5. I understand that, depending upon the nature of the offense(s) to which I am changing my plea, and/or upon the nature of any prior convictions, I may NOT be eligible for certain credits which shorten the length of the sentence imposed. The credits to which I may NOT be entitled include, but are not limited to, control release date (CRD) credits, and/or award(s) of gain time while I am in prison. I further understand that I may serve more time on my sentence than I would if I were not convicted of offense(s) of a nature such as these.

6. I understand that, if the court accepts my plea, I am hereby giving up (waiving) my right to a public jury trial, the right to require the State to prove the charge(s) against me beyond a reasonable doubt, and the right to see and hear the witnesses against me and to have my lawyer question them. I am also waiving the right to employ any defenses which I may have, the right to subpoena and the right to present witnesses, or other evidence, and the right to testify or remain silent, as I choose. I am waiving the right to have a jury decide whether I am guilty or not guilty.

7. I further understand that, by pleading guilty or no contest, I am hereby waiving my right to appeal the facts of the case. My lawyer has explained to me the meaning of an appeal. I further understand that I have thirty (30) days from this date to appeal the court's sentence and that, if I cannot afford to hire a lawyer to represent me for the purposes of an appeal, one will be appointed for me.

8. I do not require the State to tell the court the facts upon which the charge or charges are based before the court accepts my change of plea.

9. I am entering this plea because I believe it is in my best interest to do so, and it is what I wish to do of my own free will. No one has pressured me or forced me to enter this plea against my will. No one has promised me anything to entice me to change my plea to "guilty" or "no contest"; however, there has been an understanding that my sentence will consist of std drug conditions wh, fines/costs, 24 mo, rest $22.58, more rest TBD, RL $25, rest paid @ $25/mo, disclose offense to employers, cannot work in pharmacy

10. I am not aware of any physical evidence disclosed by the State for which DNA testing may exonerate me. I am not aware of any other physical evidence containing DNA known to exist that could exonerate me.

11. If I am to be placed on probation or community control, I will pay $50.00 per month towards court costs in the amount of $ 550 as ordered by this Court commencing with the first day of probation or community control until paid in full.

12. I agree to restitution in the amount of $ 222.58, more TBD If the amount of restitution is not decided at this time, I hereby waive any right to notice which I may have before such restitution may be imposed. I also waive any right to attend any hearing for such purposes.

13. My attorney has reviewed with me all statutory costs being assessed by the Court, including all mandatory and discretionary costs. My attorney has further advised me that I have a right to have the amount of each discretionary cost and certain mandatory costs individually announced in open court. I hereby waive my right to such individual announcement. I agree to pay all fines and costs, including the fines and costs checked on the attached sheets.

14. I further agree that there will be lien(s) placed against me and/or my real property for any unpaid fines, Public Defenders' fees, costs of prosecution, and court costs.

15. I hereby waive any right I may have to a Pre-Sentence Investigation (PSI), so that I may proceed directly to sentencing.

16. If I am not a citizen of the United States of America, I understand that this criminal proceeding could cause me to be deported to the country of my origin.

17. If I have ever been convicted of or pled to a sexually violent offense, I understand that I may later be subject to a civil commitment proceeding for sexually violent predators.

18. If I am entering a plea to an offense for which automatic, mandatory driver's license suspension or revocation is required, regardless of whether the suspension or revocation is by the court or by a seperate agency, I understand that this plea may result in the automatic, mandatory suspension or revocation of my driver's license.

19. My education consists of 12 years of school. At this time, I am not under the influence of any alcoholic beverage, or other drug or medicine, nor am I suffering from any mental or emotional problems which affect my understanding of this plea form.

20. I have read every word of this written plea form. All blank spaces have been filled in and there are no blank spaces upon my accepting and signing this plea form. I have discussed, with my lawyer, the contents of the plea form, and I understand this written plea form fully. My lawyer has answered any questions which I have had.

21. I am satisfied with my lawyer's advice and help concerning my decision to change my plea, and in all matters pertaining to the above-referenced case(s).

SWORN TO, SIGNED, AND FILED IN OPEN COURT, in the presence of the presiding judge and defense counsel of record, this 10 day of June, 2015.

Defendant

I hereby certify that I am counsel for the above-named Defendant in the above-referenced case(s), that I have explained to my client the elements, evidence, defenses, and rights related to the charge(s) against him/ her. I have further reviewed with my client all statutory fines and costs being assessed against him/her, including all mandatory and discretionary costs. I have reviewed the discovery disclosed by the State, including a listing or a description of physical evidence. I reviewed with my client the nature of the evidence disclosed through discovery. I am personally unaware of any physical evidence for which DNA testing may exonerate my client. I believe that my client understands the contents and the meaning of this plea form, his/her rights, and the consequences of his/her change of plea, and that he/she is entering this plea freely, voluntarily, and knowingly.

Counsel for Defendant

I hereby certify that I am personally unaware of any physical evidence for which DNA testing may exonerate the above-named Defendant.

Assistant State Attorney/Statewide Prosecutor

I hereby find that the above-named Defendant did, on this date, freely, voluntarily, and knowingly change his/her plea in the above-referenced case(s).

Presiding Judge

JUDGE: CYNTHIA NEWTON

STATE OF FLORIDA
-VS-.
MYKEL THOMAS
SPN :03089137

IN THE SIXTH JUDICIAL CIRCUIT COURT, IN AND FOR PINELLAS COUNTY
UCN: 522013CF006091XXXXNO - C
REF No.: CRC 13-06091CFANO - C
DC NUMBER: _____

ORDER OF PROBATION

This cause coming before the Court to be heard, and you, the defendant, MYKEL THOMAS being now present before me with counsel SARA MIECZKOWSKI, Assistant Public Defender, and you having:

ENTERED A PLEA OF GUILTY TO

Count 01 SCHEME TO DEFRAUD

SECTION 2: ORDER WITHHOLDING ADJUDICATION

Now, therefore, it is ordered and adjudged that the adjudication of guilt is hereby withheld and that you be placed on PROBATION for a period of 24 Months under the supervision of the Department of Corrections, subject to Florida law.

IT IS FURTHER ORDERED that you shall comply with the following standard conditions of supervision as provided by Florida law:

1. You will report to the probation office as directed.
2. You will pay the State of Florida the amount of $50.00 (fifty dollars) per month, as well as 4% surcharge, toward the cost of your supervision in accordance with s. 948.09, F.S., unless otherwise exempted in compliance with Florida Statutes.
3. You will remain in a specified place. You will not change your residence or employment or leave the county of your residence without first procuring the consent of your officer.
4. You will not possess, carry or own any firearm. You will not possess, carry, or own any weapons without first procuring the consent of your officer.
5. You will live without violating the law. A conviction in a court of law shall not be necessary for such a violation to constitute a violation of your probation/community control.
6. You will not associate with any person engaged in any criminal activity.
7. You will not use intoxicants to excess or possess any drugs or narcotics unless prescribed by a physician. Nor will you visit places where intoxicants, drugs or other dangerous substances are unlawfully sold, dispensed or used.
8. You will work diligently at a lawful occupation, advise your employer of your probation status, and support any dependents to the best of your ability, as directed by your officer.
9. You will promptly and truthfully answer all inquiries directed to you by the court or the officer, and allow your officer to visit in your home, at your employment site or elsewhere, and you will comply with all instructions your officer may give you.
10. You will pay restitution, court costs, and/or fees in accordance with special conditions imposed or in accordance with the attached orders.
11. You will submit to random testing as directed by your officer or the professional staff of the treatment center where you are receiving treatment to determine the presence or use of alcohol or controlled substances.
12. You will submit a DNA sample, as directed by your officer, for DNA analysis as prescribed in ss. 943.325 and 948.014, F.S.
13. You will submit to taking of a digitized photograph by the department. The photograph may be displayed on the department's website while you are on supervision, unless exempt from disclosure due to requirements of s. 119.07, F.S.
14. You will report in person within 72 hours of your release from incarceration to the probation office in Pinellas County, Florida, unless otherwise instructed by the court or department. (This condition applies only if section 3 is indicated above.) Otherwise, you must report immediately to the probation office located at the Criminal Justice Center, 14250 49th Street North, Room 1930 (FIRST FLOOR), Clearwater, Florida.

SPECIAL CONDITIONS:

15. You will make restitution to the following victim(s), as directed by the court, until the obligation is paid in full:
Name: WALGREENS Total Amount: $222.58 Additional instructions ordered, including specific monthly amount, begin date, due date or joint & several: This assessment is payable at the rate of $25.00 per month. Payment of this restitution amount is a condition of Probation. Name: VICTIM Total Amount: To be determined Additional instructions ordered, including specific monthly amount, begin date, due date or joint & several: Payment of this restitution amount is a condition of Probation.
16. Other: Exemptions for cost of supervision are hereby ordered for those months while participating in treatment programs or incarcerated without benefit of income. If exemptions do not apply, failure to make monthly payments for cost of supervision will result in a violation of probation. Cost of supervision is to be suspended until such time that the offender has satisfied all restitution and costs as stated on the supervision order.
17. Other: You will not reside in another state without authorization of the Court and contingent upon the approval of the receiving state.

Return to:
Criminal Court Records Department

DMC

18. Other: If electronic monitoring is imposed, you will pay the costs of electronic monitoring.
19. Other: Probation/community control may not be transferred out of state without express Court approval until all Court ordered and assessed monetary obligations are satisfied.
20. Other: You may apply for early termination after 1/2 of term completed.
21. Other: You will comply with standard drug conditions set forth below.
    a. You will receive a Drug Evaluation, and if drug counseling/treatment is deemed necessary, complete counseling/treatment, including aftercare and assume all reasonable costs for such counseling/treatment. If treatment is recommended, you only have one (1) opportunity to complete this treatment. You must call to arrange for the treatment within five (5) days of receipt of the recommendation for treatment. You must also schedule your treatment to begin at the first available opening.
    b. You will submit to urinalysis, breathalyzer, or blood tests at any time as requested by any professional staff of any treatment center where you are receiving treatment, to determine possible use of alcohol, drugs, or controlled substances.
    c. You shall submit to a search of your person, vehicle, and residence by your probation/community control officer without a warrant.
22. Other: A status check is set as follows: **June 25, 2013 at 8:30 AM for ADD'L RESTITUTION.**
23. Other: You shall not work in any pharmacy.
24. You shall disclose to any employer that you are on probation for this case.

Effective for offenders whose crime was committed on or after September 1, 2005, there is hereby imposed, in additional to any other provision in this section, mandatory electronic monitoring as a condition of supervision for those who:

- Are placed on supervision for a violation of chapter 794, s. 800.04(4), (5), or (6), s. 827.071, or s. 847.0145 and the unlawful sexual activity involved a victim 15 years of age or younger and the offender is 18 years of age or older; or
- Are designated as a sexual predator pursuant to s. 775.21; or
- Has previously been convicted of a violation of chapter 794, s. 800.04(4), (5), or (6), s. 827.071, or s. 847.0145 and the unlawful sexual activity involved a victim 15 years of age or younger and the offender is 18 years of age or older.

You are hereby placed on notice that should you violate your probation or community control, and the conditions set forth in s. 948.063(1) or (2) are satisfied, whether your probation or community control is revoked or not revoked, you shall be placed on electronic monitoring in accordance with F.S. 948.063.

Effective for offenders who are subject to supervision for a crime that was committed on or after May 26, 2010, and who has been convicted at any time of committing, or attempting, soliciting, or conspiring to commit, any of the criminal offenses listed in s.943.0435(1)(a)1.a.(I), or similar offense in another jurisdiction, against a victim who was under the age of 18 at the time of the offense: the following conditions are imposed in addition to all other conditions:

(a) A prohibition on visiting schools, child care facilities, parks, and playgrounds, without prior approval from the offender's supervising officer. The prohibition ordered under this paragraph does not prohibit the offender from visiting a school, child care facility, park, or playground for the sole purpose of attending a religious service as defined in s. 775.0861 or picking up or dropping off the offender's children or grandchildren at a child care facility or school.

(b) A prohibition on distributing candy or other items to children on Halloween; wearing a Santa Claus costume, or other costume to appeal to children, on or preceding Christmas; wearing an Easter Bunny costume, or other costume to appeal to children, on or preceding Easter; entertaining at children's parties; or wearing a clown costume; without prior approval from the court.

YOU ARE HEREBY PLACED ON NOTICE that the court may at any time rescind or modify any of the conditions of your probation, or may extend the period of probation as authorized by law, or may discharge you from further supervision. If you violate any of the conditions of your probation, you may be arrested and the court may revoke your probation, adjudicate you guilty if adjudication of guilt was withheld, and impose any sentence that it might have imposed before placing you on probation or require you to serve the balance of the sentence.

IT IS FURTHER ORDERED that when you have been instructed as to the conditions of probation, you shall be released from custody if you are in custody, and if you are at liberty on bond, the sureties thereon shall stand discharged from liability. (This paragraph applies only if section 1 or section 2 is checked.)

IT IS FURTHER ORDERED that you pay the following charges/costs/fees indicated on the last page of this order entitled Court Ordered Payments.

IT IS FURTHER ORDERED that the clerk of this court file this order in the clerk's office and provide certified copies of same to the officer for use in compliance with the requirements of law.

DONE AND ORDERED on June 10, 2013 in Clearwater, Florida.

Cynthia Newton

CYNTHIA NEWTON, JUDGE

I acknowledge receipt of a certified copy of this Order. The conditions have been explained to me and I agree to abide by them.

Date: _____ _____
Probationer

Instructed by: _____

DAF

MYKEL THOMAS UCN: 522013CF006091XXXXNO REF No.CRC 13-06091CFANO

COURT ORDERED PAYMENTS

CHECK ALL THAT ARE ORDERED:

FINES

[X]	$130.48	Total of fines assessed in sentence, pursuant to s. 775.083 (1)(a) through (g) or Chapter 316, F.S.
[X]	$6.52	Statutorily mandated 5% surcharge/cost if fine assessed (on first line) pursuant to s. 938.04, F.S.

MANDATORY COSTS IN ALL CASES

[X]	$225.00	Additional court cost for felony offense, pursuant to s. 938.05(1)(a), F.S.
[ ]	$60.00	Additional court cost for misdemeanor or criminal traffic offense, pursuant to s. 938.05(1)(b) or (e), F.S.
[X]	$50.00	Crimes Compensation Trust Fund pursuant to s. 938.03(1), F.S.
[X]	$50.00	County Crime Prevention Fund pursuant to s. 775.083(2), F.S.
[ ]	$3.00	Additional Court Costs Clearing Trust Fund pursuant to s. 938.01(1), F.S.
[ ]	$2.00	Per month for each month of supervision for Training Trust Fund Surcharge, pursuant to s. 948.09, F.S.
[X]	$100.00	Prosecution Costs, pursuant to s. 938.27, F.S. (Minimum of $100 Felony/$50 Misdemeanor).
[X]	$25.00	Investigative Costs, pursuant to s. 938.27, F.S. (if applicable and requested).
[X]	$20.00	Crime Stoppers Trust Fund, pursuant to s. 938.06(1), F.S.

MANDATORY COURT COSTS FOR COURT-APPOINTED COUNSEL CASES

[X]	$50.00	Public Defender/Appointed Counsel Application Fee, if not previously collected, pursuant to ss. 27.52 and s. 938.29, F.S.
[X]	$100.00	Public Defender/Appointed Counsel Fees and Costs, pursuant to s. 938.29, F.S. as determined locally (Minimum of $100 Felony/$50 Misdemeanor).

MANDATORY COSTS IN SPECIFIC TYPES OF CASES

[ ]	$151.00	Rape Crisis Program Trust Fund, pursuant to s. 938.085, F.S. for any violations of ss. 775.21(6), 775.21(10)(a), 775.21(10)(b), 775.21(10)(g), 784.011, 784.021, 784.03, 784.041, 784.045, 784.048, 784.07, 784.08, 784.081, 784.082, 784.083, 784.085, 787.01(3), 787.02(3), 787.025, 787.06, 787.07, 794.011, 794.05, 794.08, 796.03, 796.035, 796.04, 796.045, 796.05, 796.06, 796.07(2)(a)-(d) & (i), 800.03, 800.04, 810.14, 810.145, 812.135, 817.025, 825.102, 825.1025, 827.071, 836.10, 847.0133, 847.0135(2), 847.0137, 847.0145, 943.0435(4)(c), 943.0435(7), 943.0435(8), 943.0435(9)(a), 943.0435(13), 943.0435(14)(c), or 985.701, F.S.
[ ]	$201.00	Domestic Violence Trust Fund, pursuant to s. 938.08, F.S. for any violations of ss. 784.011, 784.021, 784.03, 784.041, 784.045, 784.048, 784.07, 784.08, 784.081, 784.082, 784.083, 784.085, 794.011, or any offense of Domestic Violence described in s. 741.28, F.S.
[ ]	$151.00	Certain Crimes Against Minors, pursuant to s. 938.10(1), F.S. for any violations of s. 784.085, chapter 787, chapter 794, s. 796.03, s. 796.035, s. 800.04, chapter 827, s. 847.012, s. 847.0133, s. 847.0135(5), s. 847.0138, s. 847.0145, s. 893.147(3), or s. 985.701, or any offense in violation of s. 775.21, s. 823.07, s. 847.0125, s. 847.0134, or s. 943.0435, F.S.
[ ]	$135.00	DUI Court Costs, pursuant to s. 938.07, F.S. for any violations of ss. 316.193 or 327.35, F.S.
[ ]	$3.00	State Agency Law Enforcement Radio System Trust Fund, pursuant to s. 318.18(17), F.S. for any violations of offenses listed in s. 318.17 including ss. 316.1935, 316.027, 316.061, 877.111, chapter 893, ss. 316.193, 316.192, 316.067, 316.072(3), 316.545(1), or any other offense in chapter 316 which is classified as a criminal violation.
[ ]	$2.00	Pinellas Police Standards, pursuant to chapter 97-333.

MANDATORY COURT COSTS AUTHORIZED BY LOCAL GOVERNMENTAL ENTITIES

[ ]	$2.00	Criminal Justice Education by Municipalities and Counties, pursuant to s. 938.15, F.S. and Pinellas County Code s.46-27.
[X]	$65.00	Additional court costs for local requirements and other county funded programs pursuant to s. 939.185(1)(a), F.S. and Pinellas County Code s. 46-32.
[X]	$3.00	Teen Court pursuant to s. 938.19(2), F.S. and Pinellas County Code s. 46-34

DISCRETIONARY

[X]	$1.00	Per month during the term of supervision to the following nonprofit organization established for the sole purpose of supplementing the rehabilitative efforts of the Department of Corrections, pursuant to s. 948.039(2), F.S. FIRST STEP
[X]	$7.00	Pasco/Pinellas County Sheriff's Office fee for DNA testing, if the DNA specimen is taken by the County Sheriff's Office.

DISCRETIONARY COSTS FOR SPECIFIC TYPES OF CASES

[ ]	$ ____	County Alcohol and Other Drug Abuse Trust Fund, pursuant to s. 938.21 and s. 938.23, F.S. for violations of s. 316.193, s.856.011, s. 856.015, or chapter 562, chapter 567, or chapter 568, F.S.
[ ]	$100.00	Operating Trust Fund of the FDLE, pursuant to s. 938.25, F.S. for violations of s. 893.13 offenses

PAYMENT IS TO BE MADE THROUGH AND PAYABLE TO: [ ] Department of Corrections or [X] Clerk of Court

(If collected by the Department of Corrections, a surcharge of 4% will be added to all payments ordered by the court, pursuant to s. 945.31, F.S.)

[ ] Court Costs/Fines Waived.

[ ] Court Costs/Fines in the amount of _____ converted to _____ community service hours.

[ ] Court Costs/Fines in the amount of _____ reduced to civil judgment.

SPECIFIC INSTRUCTIONS FOR PAYMENT:

You will pay all fines and court costs specified in this order of probation/community control in full. You will first pay restitution in full and after restitution is satisfied, pay at least $100 per month toward the fine and court cost. If the Court determines that you have the ability to pay, failure to pay all fines and court costs in full within 12 months after restitution is satisfied but no later than three months prior to the end of the term of probation, will result in a violation of probation or community control, may become a lien against anything you own now or in the future and will accrue interest at the statutory rate, may result in the suspension of your driver's license, and may also result in collections efforts by the Clerk of the Court or its assignee.

DONE AND ORDERED on June 10, 2013 in Clearwater, Florida.

Cynthia Newton

CYNTHIA NEWTON, JUDGE

CIRCUIT/COUNTY COURT, PINELLAS COUNTY, FLORIDA
CRIMINAL DIVISION

UCN: 522013CF006091XXXXNO REF No. : CRC 13-06091CFANO - C
SPN. : 03089137

Left Four Fingers	Left Thumb	Right Thumb	Right Four Fingers
			

Impressions made by:

Deputy Sheriff

I hereby certify that the above and foregoing fingerprints on this Judgment are the fingerprints of the defendant, **MYKEL THOMAS**, and that they were placed thereon by said in my presence in open court, this **June 10, 2013**.

Judge

(ICD-FINGERPRINTONDEMAND-III 48249905))

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Case:	Case Number:
St. Petersburg	04/25/13	RPT2013-06571

Subject:
MYKEL CHANEY THOMAS, RPT
391 112thAvenue North
1306
St Petersburg, Florida 33706 *
(727) 657-9362

Source:
DOH/INVESTIGATIVE SERVICES/ST PETERSBURG

Prefix:	License No.	Profession:	Board:	Report Date:
RPT	12401	Registered Pharmacy Technician	Pharmacy	06/04/13

Period of Investigation:	Type of Report:
05/31/13 to 06-04-13	SUPPLEMENTAL - 2

Alleged Violation: F.S. 456.072(1)(b)(m)(z)(dd) and 465.016(1)(d) 2,3, (e)(m)(r) and 893.13(6)(a)(7)(a) 9, by engaging in a diversion of drugs, possible impairment and violating a provision of this chapter in the practice of pharmacy.

Synopsis:

This Supplemental Report is predicated on a request (Exh. S2-1) from DOH/LEGAL asking for a hand service of an Order to Compel (Exh. S2-2) on THOMAS as soon as possible.

On 05-31-13 at approximately 5 pm, this investigator served the document at THOMAS's home on a male over the age of 15 years old. The male stated THOMAS would not be home until later that night and accepted service of the sealed envelope.

Legal was advised of the service approximately five minutes later by telephone.

An Affidavit of Service is attached as Exhibit S2-3.

RECEIVED-LEGAL
13 JUN 11 AM 8:20

***Subject located at: 7201 72nd Street North, Apt C, Pinellas Park, Florida 33781 (727) 657-9362**

Related Cases: RPT2013-06605

Investigator/Date:	Approved By/Date:
6/4/13	6-4-13
Dave Berry, Medical Malpractice Investigator (PI-21)	Karen Hanzal, Investigation Supervisor (PI-28)

Distribution: HDQTRS/ISU

Received
Investigative Services
JUN 10 2013

FLORIDA DEPARTMENT OF HEALTH

PSU REQUEST FORM

Gwendolyn Swatts, AAII for Casie Barnett, AGC	TO: Karen Hanzal, Investigation Supervisor
Date: 5/31/2013	TO: **CSU** ☐
Phone #: 850-245-4444 Ext. 8214	CC: Dave Berry, PI-21

Case Number: 2013-06571
Subject: **Mykel C. Thomas, RPT**
Requested Completion Date: 6/10/2013

Board: Registered Pharmacy Technician
HLCode: **HLL105B** Status: **60**

RECEIVED-LEGAL
13 JUN 11 AM 8:20

(PSU) TYPE OF REQUEST: (describe details below)

☒ Process Service* (**Activity Code 160**)

☐ Additional Information Requested (**Activity Code 145**)

☐ Deficiency in Investigative Work (**Activity Code 150**)

Details: Please hand serve the attached Order Compelling Evaluation. Please contact Gwen Swatts at 850-245-4444, Ext 8214 with an update before June 10, 2013 if you are unable to serve the Subject. Thank you.

*The following additional information is needed for each service request:

Last Known Address: 7201 72nd Street North, Apt. C, Pinellas Park, FL 33781; Last Known Name & Phone: Mykel Chaney Thomas, RPT, (727)657-9362
Last Known Place of Employment & Address if Known:
Has Contact Been Made With This Individual? YES ☐ No☒; If Yes, When?

Was this case originally worked by CSU or in an area office different from where this service request is being sent?
YES ☐** No ☒ NOTE: All process service requests need to be sent to appropriate field office.
****IF YES, please send a copy of the original Investigative Report without attachments.**

(ISU/CSU) RESPONSE:

☑ Process Service Completed (Activity Code 161) ☐ Process Service NOT Completed (Activity Code 162)

☐ Add'l Info Sent to Legal (Activity Code 156)

☐ Investigative Work Returned to Legal (Activity Code 156)

☐ Cancelled by Legal (Activity Code 157) ☐ Cancelled by ISU/CSU (Activity Code 158)

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STATE OF FLORIDA
DEPARTMENT OF HEALTH

In Re: The Order Compelling Examination of
Mykel Chaney Thomas, RPT
License No: RPT 12401
Case No: 2013-06571

ORDER COMPELLING AN EXAMINATION

The Department of Health (Department) is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes (2012); Chapter 456, Florida Statutes (2012); and Chapter 465, Florida Statutes (2012).

For probable cause shown and pursuant to the authority vested in the Department by Chapters 456 and 465, Florida Statutes (2012), you are hereby ordered to report and submit to a mental and physical examination to be conducted by the following named physician at the date, time and place indicated.

David Myers, M.D.
825 West Linebaugh Avenue
Tampa, FL 33612
(813) 931-5560
ON
Monday, June 17, 2013
9:00 a.m. – 2:00 p.m.

The above-directed mental and physical examination is for the purpose of obtaining examination reports and expert opinion and testimony concerning

EXH 52-2

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your ability to practice as a registered pharmacy technician with reasonable skill and safety pursuant to Sections 456.072(1)(z) and 465.016(1)(m), Florida Statutes (2012), and for introduction into evidence at any administrative hearing to be conducted on any administrative complaint filed against you which may allege a violation of Section 456.072(1)(z) and/or 465.016(1)(m), Florida Statutes (2012). This Order is predicated upon the following Findings of Fact and Conclusions of Law.

FINDINGS OF FACT

1. At all times material to this Order, Mykel Chaney Thomas, RPT (Ms. Thomas), was a registered pharmacy technician within the state of Florida, having been issued registration number RPT 12401.

2. At all times material to this Order, Ms. Thomas was employed by Walgreens Pharmacy ("Walgreens") at 337 75th Avenue, St. Petersburg Beach, Florida 33706.

3. From approximately October 2012 to March 2013, Ms. Thomas diverted an estimated 1,500 tablets of controlled substances from Walgreens. The medications included, but were not limited to, alprazolam and hydrocodone with acetaminophen.

4. Alprazolam is prescribed to treat anxiety. According to Section

893.03(4), Florida Statutes (2012), alprazolam is a Schedule IV controlled substance that has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III.

5. Hydrocodone with acetaminophen contains hydrocodone and acetaminophen, or Tylenol, and is prescribed to treat pain. According to Section 893.03(3), Florida Statutes (2012), hydrocodone, in the dosages found in hydrocodone with acetaminophen is a Schedule III controlled substance that has a potential for abuse less than the substances in Schedules I and II and has a currently accepted medical use in treatment in the United States. Abuse of the substance may lead to moderate or low physical dependence or high psychological dependence.

6. On or about April 9, 2013, Deputy W.S. of Pinellas County Sheriff's Office was dispatched to Walgreens regarding a theft.

7. Upon arrival at Walgreens, the Walgreens Manager and the Loss Prevention Manager advised Deputy W.S. that they had confronted Ms. Thomas regarding the theft of prescription medication and had obtained a written voluntary statement ("voluntary statement") from Ms. Thomas.

8. In the voluntary statement, Ms. Thomas admitted to committing the thefts while working as a pharmacy technician. She stated that she had diverted over 1,000 alprazolam 2mg tablets and an estimated 500 hydrocodone with acetaminophen tablets by using patient profiles and insurance information to fraudulently bill the patients' insurance companies for prescriptions not dispensed to the patients. Ms. Thomas indicated that she had diverted a total of 300 alprazolam 2mg tablets and 100 hydrocodone with acetaminophen 500mg tablets without the use of patient profiles or insurance.

9. The Walgreens Loss Prevention Manager showed Deputy W.S. copies of inventory pricing worksheets indicating the following inventory stolen by Ms. Thomas:

a. 1,300 alprazolam 2mg tablets; and

b. 200 hydrocodone with acetaminophen 500mg tablets.

10. Deputy W.S. interviewed Ms. Thomas regarding the thefts. Ms. Thomas provided Deputy W.S. with a written statement, in which she admitted to stealing alprazolam and hydrocodone with acetaminophen tablets from Walgreens by:

a. taking prescription bottles directly from the pharmacy inventory; and

b. using her access to patient information and patient insurance to fill prescriptions for alprazolam and hydrocodone with acetaminophen and fraudulently bill the patients' insurance company.

11. The Walgreens Manager informed Deputy W.S. that Walgreens wished to press charges against Ms. Thomas. Deputy W.S. arrested Ms. Thomas for grand theft.

12. Section 456.072(1)(z), Florida Statutes (2012), states, in pertinent part, "the department shall have, upon a finding of the State Surgeon General or the State Surgeon General's designee that probable cause exists to believe that the licensee is unable to practice because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department."

CONCLUSIONS OF LAW

1. The Department of Health, by and through the State Surgeon General, has jurisdiction over this matter pursuant to Chapters 456 and 465, Florida Statutes (2012).

2. Ms. Thomas' diversion of more than one thousand tablets of controlled medications over approximately a five month time period gives cause to believe

that Ms. Thomas is impaired. Therefore, the State Surgeon General, through his undersigned designee, concludes that probable cause exists to believe Ms. Thomas is unable to practice as a registered pharmacy technician with reasonable skill and safety, pursuant to Sections 456.072(1)(z) and 465.016(1)(m), Florida Statutes (2012). A thorough and complete mental and physical examination of Ms. Thomas is necessary to protect the public and ensure that she is able to practice with reasonable skill and safety.

3. In accordance with the authority vested in the Department of Health under Chapters 456 and 465, Florida Statutes, the State Surgeon General, through his undersigned designee, concludes that 456.072(1)(z), Florida Statutes (2012), should be enforced.

Mykel Chaney Thomas, RPT.
License Number RPT 12401
Case Number 2013-06571

DONE and ORDERED by the Department of Health on this 9th day of May, 2013.

John H. Armstrong, MD, FACS
State Surgeon General and
Secretary of Health

Daniel Hernandez
Deputy General Counsel
Prosecution Services Unit

COUNSEL FOR DEPARTMENT:
Casie Barnette, Esq.
Florida Bar No. 100159
Assistant General Counsel
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
(P) 850-245-4444, extension 8102
(F) 850-245-4662
(E) casie_barnette@doh.state.fl.us

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office:	Date of Case:	Case Number:
St. Petersburg	04/25/13	RPT2013-06571

Subject:
MYKEL CHANEY THOMAS, RPT
391 112thAvenue North
1306
St Petersburg, Florida 33706 *
(727) 657-9362

Source:
DOH/INVESTIGATIVE SERVICES/ST PETERSBURG

Prefix:	License No.	Profession:	Board:	Report Date:
RPT	12401	Registered Pharmacy Technician	Pharmacy	05/16/13

Period of Investigation:	Type of Report:
05/16/13	SUPPLEMENTAL - 1

Alleged Violation: F.S. 456.072(1)(b)(m)(z)(dd) and 465.016(1)(d) 2,3, (e)(m)(r) and 893.13(6)(a)(7)(a) 9, by engaging in a diversion of drugs, possible impairment and violating a provision of this chapter in the practice of pharmacy.

Synopsis:

This Supplemental Report is predicated with on an interview conducted on this date with THOMAS in the St Petersburg ISU office. THOMAS admitted to the thefts and stated she had a pre-trial meeting on May 6, 2013 with another court date scheduled for June 10, 2013 at 8:30 am.

This investigator read back Deputy SNYDER'S account of the incidents and THOMAS agreed with the report. She stated her mother had been recently diagnosed with cancer and took the medications to aid her family financially. She admitted to taking the pills directly from inventory and using patient information to order pills through their insurance then making the copayments herself.

THOMAS stated she realized that what she did was very wrong. This investigator gave THOMAS an overview of the Professional's Resource Network and provided her with their number. She was asked to contact this investigator immediately if she decided to enroll in their program. This investigator also gave her an overview of the complaint process from intake to final resolution and also explained the function of a Voluntary Relinquishment of Licensure form.

RECEIVED-LEGAL
13 MAY 21 PM 4:27

***Subject located at: 7201 72nd Street North, Apt C, Pinellas Park, Florida 33781 (727) 657-9362**

Related Cases: RPT2013-06605

Investigator/Date:	Approved By/Date:
Dave Berry, Medical Malpractice Investigator (PI-21)	Karen Hanzal, Investigation Supervisor (PI-28)

Received
Investigative Services
MAY 21 2013

Distribution: HDQTRS/ISU

MEMORANDUM OF FINDING OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy
RE: **DOH v. Mykel Chaney Thomas, RPT**
DOH Case Number 2013-06571

MEMBERS: Cynthia R. Griffin, PharmD & Jeffrey J. Mesaros, R.Ph

DATE OF PCP: August 08, 2013 AGENDA ITEM: A-1 (AGM)

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative report, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 456.072(1)(c), Florida Statutes (2012)

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration**, dismiss

____ **Other** _____

Cynthia R. Griffin, Pharm.D 8/8/13
Chair, Probable Cause Panel Date
Board of Pharmacy

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STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201120030

KISKEYA INVESTMENT GROUP, LLC,
RESPONDENT.

NOTICE

TO: KISKEYA INVESTMENT GROUP, LLC
3880 W BROWARD BLVD STE 7
PLANTATION, FL 33312

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is not required to be presentat this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201120030

KISKEYA INVESTMENT GROUP, LLC,
RESPONDENT.

NOTICE

TO: ROBERT NICHOLSON
707 N.E. THIRD AVENUE, SUITE 301
FT. LAUDERDALE, FL 33304

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. The Respondent is not required to be present at this meeting. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Voluntary Relinquishment

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Kiskeya Investment Group, L.L.C.
DOH Case Number 2011-20030
DATE: February 5, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Kiskeya Investment Group, L.L.C.
Subject's Address of Record:	3880 W Broward Blvd. Suite 7 Plantation, FL 33312
Enforcement Address:	3880 W Broward Blvd. Suite 7 Plantation, FL 33312
Subject's License No:	24086 **Rank:** PH
Licensure File No:	16730
Initial Licensure Date:	5/27/2009
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No
Allegations:	Section 465.23(1)(c), F.S. (2011, 2012), Rule 64B16-28.110, F.A.C.
Prior Discipline:	None
Probable Cause Panel:	January 23, 2014 Glass and Risch

Subject's Attorney:	Robert Nicholson 707 N.E. Third Avenue, Suite 301 Ft. Lauderdale, FL 33304
Complainant/Address:	DOH/ISU – Ft. Lauderdale
Materials Submitted:	Memorandum to the Board Voluntary Relinquishment – filed Administrative Complaint Board Notification Letter Expert Opinion Expert Opinion – Amended Expert Curriculum Vitae Defense Attorney Document dated 06-22-12 PCP Memorandum Final Investigative Report Exhibits 1 thru 9

DEPARTMENT OF HEALTH
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,

Petitioner,

v. **CASE NO: 2011-20030**

Kiskeya Investment Group, L.L.C.,

Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, **Kiskeya Investment Group, L.L.C.,** license No. PH 24086, hereby voluntarily relinquishes Respondent's license to practice as a registered pharmacy in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a registered pharmacy in the State of Florida.

3. Respondent agrees to voluntarily cease operating as a pharmacy immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from operating as a pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the Board does not accept the terms of this Voluntary Relinquishment.

DATED this 31 day of January year of 2014

Price Jean-Gilles, Manager
Kiskeya Investment Group, L.L.C.

STATE OF Florida

COUNTY OF Broward

Before me, personally appeared Price Jean-Gilles, whose identity is (personally known) to me or by producing _____ (type of identification) as identification and who acknowledges that her signature appears above.
Sworn to or affirmed by Respondent before me this 31 day of January, 2014.

April 26, 2014
My Commission Expires

NOTARY PUBLIC-STATE OF FLORIDA
Erin Michelle Bengele
Commission # DD985963
Expires: APR. 26, 2014
BONDED THRU ATLANTIC BONDING CO., INC.

NOTARY PUBLIC - STATE OF Florida

Erin Bengele (Erin Bengele)
Type or Print Notary

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-20030**

KISKEYA INVESTMENT GROUP, L.L.C,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Kiskeya Investment Group, L.L.C., and in support thereof alleges:

1. Petitioner is the state agency charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Administrative Complaint, Respondent was a licensed pharmacy within the State of Florida, having been issued license number PH 24086.

3. Respondent's address of record is 3880 W. Broward Blvd., Suite 7, Plantation, Florida 33312.

4. On or about December 21, 2012, a Department inspector conducted an inspection of Respondent.

5. On or about December 21, 2012, the Department's inspector found expired medications not removed from the shelves.

6. The following chart illustrates the expired medications found during the inspection on or about December 21, 2012:

Medication	Lot Number	Expiration Date
1 bottle of Furosemide 40mg, 1000 tablets	CAB0229AC	November 2012
1 bottle of Metoprolol Tartrate 100mg	GKJ1157	November 2012
1 bottle of Simvastatin 20mg, 1000 tablets	MK9521	November 2012
1 bottle of Fluconzaole 50mg, 30 tablets	Y02708	September 2012
1 bottle of Topiramate 100mg, 60 tablets	BF710015	June 2012
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension, 600mg/42.9mg/5ml	BF3605	November 2012
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension 400mg/57mg/5m	BD0131	October 2012
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension	BC7440	September 2012

125mg/5ml		
1 bottle of Amoxicillin and Cluvulanate Potassium for oral suspension 400mg/5ml	BA4010122-A	July 2012
1 box of Adapalene Cream, 0.1% Net WT 45 grams	264J	October 2012
1 box of Fluconazole 10mg/ml	0848902	December 1, 2012
1 bottle of Indomethacin 25mg, 100 capsules	TE09048	September 2012
2 boxes of Sumatriptan Succinate 25mg, 9 tablets each box	2135549	February 2012
1 box of Clotrimazole Cream USP 1%	1BT0067	November 2012
1 box of Fluconazole for oral suspension 40mg/ml	0843803	December 1, 2012

7. Section 465.023(1)(c), Florida Statutes (2011), provides that violating any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893 is grounds for disciplinary action.

8. Rule 64B16-28.110, Florida Administrative Code, states persons qualified to do so shall examine the stock of the prescription department of

each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

9. As set forth above, during the course of a routine inspection outdated pharmaceuticals were found within the Respondent's active stock.

10. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2011, 2012), Rule 64B16-28.110, Florida Administrative Code, by failing to ensure that outdated pharmaceuticals were removed from active stock.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 23 **day of** January, **2014.**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and
Secretary of Health

Matthew G. Witters
Assistant General Counsel
Fla. Bar No. 0091245
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: matthew.witters@flhealth.gov

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK ANGEL SANDERS
DATE JAN 23 2014

PCP: January 23, 2014
PCP Members: Glass and Risch

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

February 6, 2014

VIA U.S. MAIL

Robert Nicholson, Esquire
707 N.E. Third Avenue
Suite 301
Ft. Lauderdale, Florida 33304

Re: DOH vs. Kiskeya Investment Group, L.L.C.
DOH Case Number: 2011-20030

Dear Mr. Nicholson:

We are in receipt of your client's executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form, your client agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against your license, pursuant to Section 456.072(1)(f), Florida Statutes;
- you would never reapply for licensure as a Pharmacist in the State of Florida; and
- Voluntarily relinquishing the Pharmacist license may have an effect on Pharmacy licenses that you may hold in other states.

If this is not what you understand, please contact me as soon as possible to discuss, at 850-245-4444, ext. 8172. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your request for Voluntary Relinquishment of License at their meeting scheduled for April 2, 2014 in Orlando, Florida. You are not required to attend the meeting.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

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11/12

PRACTITIONER REGULATION
LEGAL
11 MAY 27 AM 9:45

CV

Stephen G. Reeder, RPh, CPh, MSP
2000 Lake Ariana Blvd
Auburndale, FL 33823
863-965-7510 home; 863-224-1052 cell
rgi@tampabay.rr.com

Graduate of the University of Florida:
- B.S. Zoology, 1969
- B.S. Pharmacy, 1972
- M.S. Pharmacy Administration, 2008, Specialty in Pharmacy Policy & Regulatory Affairs

Mr. Reeder is a licensed Pharmacist in the State of Florida; Licensed Consultant Pharmacist in the State of Florida, specializing in Modified II-B pharmacy permits in Hospice In Patient Units; Advanced Pain & Palliative Care Specialist.

Mr. Reeder is currently employed by Hospice Pharmacia, a service of excelleRx, Inc., an Omnicare Company, as their Director, In Patient Services and Client Relations Liaison, Florida Region. Hospice Pharmacia manages the medication for over 80,000 hospice patients nationally in over 850 hospices. Mr. Reeder is an Advanced Pain and Palliative Care Specialist and has been employed by Hospice Pharmacia for the past 12 years.

Prior to employment with HP, Mr. Reeder was the General Manager of a division of a home healthcare agency for five years, with responsibility for 3 pharmacies including an infusion pharmacy and 5 HME centers.

Mr. Reeder has twenty-five years experience in the retail drug store industry, beginning as a pharmacist and advancing on to Vice President of Marketing and Operations with a national retail chain.

Currently the Past Chairman of the National Advisory Board of the University of Florida, College of Pharmacy and a past member of the University of Florida Foundation.

Mr. Reeder is a past Executive Board Member of the Florida Pharmacy Association.

Mr. Reeder was the Recipient of the Distinguished Pharmacy Service Award in 1997 from the University of Florida, College of Pharmacy.

Past member of the Purdue Pharma Speakers Bureau

NICHOLSON & EASTIN, LLP

ATTORNEYS AND COUNSELORS AT LAW
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SUITE 301
FORT LAUDERDALE, FLORIDA 33304
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FACSIMILE: 954.634.4418
www.nicholsonlawgroup.com

ROBERT N. NICHOLSON, ESQ.
PARKER D. EASTIN, ESQ.
ERIN M. BENGELE, ESQ.

ROBERT N. NICHOLSON, ESQ.
EMAIL: Robert@NicholsonLawGroup.com

June 22, 2012

VIA CERTIFIED U.S. MAIL

Ms. Alicia Adams, Esq.
Office of the General Counsel
Prosecution Services Unit
Florida Department of Health
4052 Bald Cypress Way, Bin #C-65
Tallahassee, FL 32399-3265

Re: [redacted]

Complaint Number PH 2011-20030
Kiskeya Investment Group

Dear Ms. Adams:

I write to inform you that Nicholson & Eastin, LLP has been retained by [redacted] Kiskeya Investment Group to represent them in connection with the above referenced investigations. I received your name from the investigator today.

Please also accept this letter as [redacted] Kiskeya's request for a complete copy of any investigative file upon completion of the investigation and prior to any of the matters being submitted to a probable cause panel. We reserve the right to submit rebuttal materials upon receipt of the file(s). My clients are aware that they will be required to execute a confidentiality agreement in connection with the receipt of the investigative file(s).

Please also contact me at your earliest convenience to discuss these cases.

Sincerely,

Nicholson & Eastin, LLP

Robert N. Nicholson, P.A.

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Kiskeya Investment Group, LLC (MGW)**
Case No. 2011-20030

MEMBERS: **Debra Glass and Lorena Risch**

DATE OF PCP: **January 23, 2014** **AGENDA ITEM: A-3**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2011, 2012), Rule 64B16-28.110, Florida Administrative Code

____ Probable Cause was **not** found in this case

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)
c)

____ Upon **reconsideration,** dismiss

____ **other** _____

Tony Collins for Debra Glass 29 Jan 14
Chair, Probable Cause Panel Date
Board of Pharm

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MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Matthew G. Witters, Assistant General Counsel
RE: Voluntary Relinquishment
SUBJECT: DOH v. Delmer H. Parrish, R.Ph.
DOH Case Number 2013-10756
DATE: March 14, 2014

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014** meeting of the board. The following information is provided in this regard.

Subject:	Delmer H. Parrish, R.Ph.
Subject's Address of Record:	390 Hawser Lane Naples, FL 34102
Enforcement Address:	390 Hawser Lane Naples, FL 34102
Subject's License No:	28206 **Rank:** PS
Licensure File No:	17233
Initial Licensure Date:	3/4/1993
Board Certification:	No
Required to Appear:	No
Current PRN Contract:	No
Allegations:	Waived Probable Cause
Prior Discipline:	None
Probable Cause Panel:	Waived Probable Cause
Subject's Attorney:	Monica Rodriguez 9100 South Dadeland Blvd. One Datran Center, Suite 1610 Miami, FL 33156

Complainant/Address: Department Of Health/Consumer Services Unit

Materials Submitted:
Memorandum to the Board
Motion for Voluntary Relinquishment
Voluntary Relinquishment – filed
Notification Letter
Final Investigative Report
Exhibit 1-2

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

CASE NO. 2013-10756

V.

Delmer H. Parrish, R.Ph.,

Respondent.
_____/

MOTION FOR FINAL ORDER
BASED UPON A VOLUNTARY RELINQUISHMENT OF LICENSE

COMES NOW, the Petitioner, by and through its undersigned counsel, and moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore, the Petitioner would state the following:

1. On or about **July 9, 2013 and November 21, 2013**, a Uniform Consumer Complaint was filed with the Department of Health, alleging that the Subject violated the provisions of Chapter 456 or Chapter 465, Florida Statutes.

2. In lieu of undergoing further disciplinary proceedings, the Respondent returned an executed Voluntary Relinquishment of his/her license.

3. Respondent has been advised, by a copy of this Motion, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the **Uniform Consumer Complaint**.

WHEREFORE, the parties respectfully request the Board Pharmacy of enter a Final Order incorporating the terms of the Voluntary Relinquishment of Licensure.

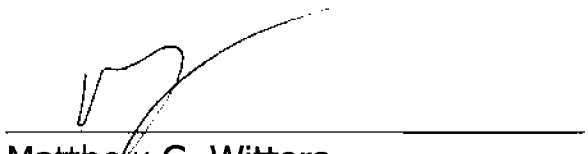
Respectfully Submitted,

John H. Armstrong, MD
State Surgeon General and Secretary of Health

Matthew G. Witters
Assistant General Counsel
DOH Prosecution Services Unit
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Florida Bar No. **091245**
Telephone: (850) 245-4444, ext. 8172
Facsimile: (850) 245-4683
Email: Matthew.Witters@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 14th day of March, 2014, to: Delmer H. Parrish c/o Monica L. Felder Rodriguez, Dresnick, Rodriguez & Perry, P.A., One Datran Center, Suite 1610, 9100 South Dadeland Blvd., Miami, Florida 33156-7817.



Matthew G. Witters
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. DOH Case No. 2013-10756

DELMER H. PARRISH, R.Ph.,
Respondent.
_____/

VOLUNTARY RELINQUISHMENT OF LICENSE

Respondent, Delmer H. Parrish, R.Ph., license No. PS 28206, hereby voluntarily relinquishes Respondent's license to pharmacy in the State of Florida and states as follows:

1. Respondent's purpose in executing this Voluntary Relinquishment is to avoid further administrative action with respect to this cause. Respondent understands that acceptance by the Board of Pharmacy (hereinafter the Board) of this Voluntary Relinquishment shall be construed as disciplinary action against Respondent's license pursuant to Section 456.072(1)(f), Florida Statutes.

2. Respondent agrees to never reapply for licensure as a pharmacist in the State of Florida.

3. Respondent agrees to voluntarily cease practicing pharmacy immediately upon executing this Voluntary Relinquishment. Respondent further agrees to refrain from the practice of pharmacy until such time as this Voluntary Relinquishment is presented to the Board and the Board issues a written final order in this matter.

4. In order to expedite consideration and resolution of this action by the Board in a public meeting, Respondent, being fully advised of the consequences of so doing, hereby waives the statutory privilege of confidentiality of Section 456.073(10), Florida Statutes, and waives a determination of probable cause, by the Probable Cause Panel, or the Department when appropriate, pursuant to Section 456.073(4), Florida Statutes, regarding the complaint, the investigative report of the Department of Health, and all other information obtained pursuant to the Department's

investigation in the above-styled action. By signing this waiver, Respondent understands that the record and complaint become public record and remain public record and that information is immediately accessible to the public. Section 456.073(10) Florida Statutes.

5. Upon the Board's acceptance of this Voluntary Relinquishment, Respondent agrees to waive all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Voluntary Relinquishment and of the Final Order of the Board incorporating this Voluntary Relinquishment.

6. Petitioner and Respondent hereby agree that upon the Board's acceptance of this Voluntary Relinquishment, each party shall bear its own attorney's fees and costs related to the prosecution or defense of this matter.

7. Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent in connection with the Board's consideration of this Voluntary Relinquishment. Respondent agrees that consideration of this Voluntary Relinquishment and other related materials by the Board shall not prejudice or preclude the Board, or any of its members, from further participation, consideration, or resolution of these proceedings if the terms of this Voluntary Relinquishment are not accepted by the Board.

DATED this 29th day of October, 2013.

Delmer H. Parrish, R.Ph.

STATE OF FLORIDA
COUNTY OF:

Before me, personally appeared Delmer H Parrish, whose identity is known to me by ✓ (type of identification) and who, under oath, acknowledges that his signature appears above. Sworn to and subscribed before me this 29 day of October ✓, 2013.

NOTARY PUBLIC

My Commission Expires:

YALE T. FREEMAN
MY COMMISSION # EE 850058
EXPIRES: November 11, 2016
Bonded Thru Budget Notary Services

March 14, 2014

VIA CERTIFIED MAIL

Monica L. Felder Rodriguez, Esquire
Dresnick, Rodriguez & Perry, P.A.
One Datran Center
Suite 1610
9100 South Dadeland Blvd.
Miami, Florida 33156-7817

Re: DOH vs. Delmer H. Parrish, R.Ph.
DOH Case Number: 2013-10756

Dear Ms. Rodriguez:

We are in receipt of your client's executed Voluntary Relinquishment form. As you are aware by signing the Voluntary Relinquishment of License form your client agreed to the following:

- the Voluntary Relinquishment would be considered disciplinary action against their license, pursuant to Section 456.072(1)(f), Florida Statutes;
- he/she would never reapply for licensure as a Pharmacist in the State of Florida; and
- Voluntarily relinquishing his/her Florida Pharmacist license may have an effect on Pharmacist licenses they may hold in other states.

If this is not what your client understood, please contact me as soon as possible to discuss, at 850-245-4640. Otherwise, this case will proceed as planned, and the Florida Board of Pharmacy will take up your client's request for Voluntary Relinquishment of License at their meeting scheduled for April 2, 2014, at the Marriott Westshore, 1001 N. Westshore Blvd., Tampa, Florida 33607. Your client is not required to attend the meeting.

Sincerely,

Matthew G. Witters
Assistant General Counsel

MGW/crl

Florida
HEALTH

INVESTIGATIVE REPORT

Office:	Date of Complaint:	Case Number:
CONSUMER SERVICES	November 19, 2013	201310756

Subject:	Source:
DELMER H PARRISH 390 Hawser lane Naples, FL 34102	**DEPARTMENT OF HEALTH, CONSUMER SERVICES UNIT**

Prefix:	License # :	Profession:	Board:	Report Date:
PH	28206	Pharmacist	Pharmacy	1/16/14

Period of Investigation:	Type of Report:
11/21/13 through 1/16/14	FINAL

Alleged Violation: SS. 456.072(1)(c)(dd); 465.016(1)(f)(r), FS; Having been convicted or found guilty in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice of pharmacy

Synopsis: This investigation is predicated on the receipt of information from the DEPARTMENT OF HEALTH pertaining to the 11/6/13 conviction of PARRISH in the United States District Court, Middle District of Florida, fort Myers Division, for Healthcare Fraud [18:1347 and 1349]. (EXHIBIT #1)

PARRISH was notified of this complaint by letter, dated 11/21/13. The notification was sent to the address of record. Forwarded with this letter were copies of the UCF and the initiating documents. (EXHIBIT #2)

DOH licensure information was reviewed on 1/16/14. It reflects PARRISH'S license is in CLEAR/ACTIVE status.

No patient(s) was/were identified, thus patient notification was not required.

PARRISH does not appear to be represented by counsel in this matter as of the date of this report.

PARRISH has not responded as of the date of this report.

Related Case:

Investigator/Date:	Approved By/Date:
Leo Paulson (HA107) 1/16/14	Shane Walters, OMC Manager JAN 21 2014

Distribution: Prosecution Services Unit/Consumer Services Unit

RECEIVED JAN 14

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INVESTIGATIVE DETAILS

SUMMARY OF RECORDS

There were no authorizations, medical records, or Verification of Completeness of Record forms at issue in this matter.

Exhibit #1 contains the following:

- Court Documents pertaining to the 11/6/13 conviction of PARRISH in the United States District Court, Middle District of Florida, fort Myers Division, for Healthcare Fraud [18:1347 and 1349]. .

INTERVIEW/STATEMENT OF THE FLORIDA DEPARTMENT OF HEALTH - Source

No further information has been received from the source.

INTERVIEW/STATEMENT OF DELMER PARRISH - Subject

PARRISH has not responded as of the date of this report.

CASE SUMMARY

CONFIDENTIAL

Case No: 201310756
Please use this number in all correspondence with the Department concerning this matter.

RESPONDENT INFORMATION

License No: 28206 Profession: 2201 Pharmacist
Name: DELMER H PARRISH
Address: 390 HAWSER LANE
NAPLES, FL 34102
Home Phone:

SOURCE OF INFORMATION

Name: Department Of Health/Consumer Services Unit
Address:
Home Phone:

REPORTED INFORMATION

Receive Date: 11/19/2013 Source Code: 5 Form Code: 1
Responsible Party: ha107 Status Code: 10 Priority: 5
Classification Code: Incident Date: 11/06/2013

Patient Name:

Possible Code(s): 15, 12

Summary:
Possible violation of SS. 456.072(1)(c)(dd); 465.016(1)(f)(r), F.S

On 11/6/13 (PS 28206) , owner of Collier County Sunshine Pharmacy, was convicted in United States District Court, Middle District of Florida, Fort Myers Division with Healthcare Fraud (18:1347and 1349).

Leo Paulson 11/19/13

CONFIDENTIAL

DOH-Form200

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AO (Rev. 5/85) Criminal Complaint

UNITED STATES DISTRICT COURT

MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

UNITED STATES OF AMERICA

v.

DELMER HOLMES PARRISH and
PATRICIA PARRISH

CRIMINAL COMPLAINT

CASE NUMBER: 2:13-mj-1070-DNF

I, the undersigned complainant, being duly sworn, state the following is true and correct to the best of my knowledge and belief. From at least in or about February, 2009, and continuing through in or about July, 2012, in Collier County, in the Middle District of Florida, the defendants did,

knowingly, intentionally, and willfully combine, conspire, confederate, and agree with each other and with other persons known and unknown, to commit certain offenses against the United States, that is, to knowingly and willfully execute, and attempt to execute, a scheme and artifice: (a) to defraud health care benefit programs, that is Medicare, Medicaid, and Tricare; and (b) to obtain money and property owned by and under the custody and control of health care benefit programs, that is Medicare, Medicaid, and Tricare, by means of materially false and fraudulent pretenses, representations, and premises, in connection with payments for health care benefits, items and services, namely drug prescriptions.

in violation of Title 18, United States Code, Sections 1347 and 1349.

I further state that I am a Special Agent with the Department of Health and Human Services, Office of the Inspector General (HHS-OIG), and that this Complaint is based on the following facts:

SEE ATTACHED AFFIDAVIT

Continued on the attached sheet and made a part hereof: ☒ Yes ☐ No

Signature of Complainant
Brian D. Harris, Special Agent
U.S. Department of Health & Human Serv.
Office of Inspector General

Sworn to before me and subscribed in my presence,

May 8, 2013 at Fort Myers, Florida

DOUGLAS N. FRAZIER
United States Magistrate Judge
Name & Title of Judicial Officer

Signature of Judicial Officer

AFFIDAVIT

I, Brian D. Harris, being duly sworn, state and affirm as follows:

I. INTRODUCTION

1. I am a Special Agent with the U.S. Department of Health and Human Services, Office of the Inspector General (HHS-OIG) and have been employed as a Special Agent of HHS-OIG for over two years. I am presently assigned to the Tampa Field Office. Prior to my employment as a Special Agent with HHS-OIG, I was employed with the Diplomatic Security Service of the U.S. Department of State as a Criminal Intelligence Analyst for three years. In my capacity as a Special Agent and Criminal Intelligence Analyst, I have led, conducted, and/or participated in criminal investigations of violations of Federal laws involving fraud, in particular, health care fraud.

2. The facts set forth in this affidavit were gathered in the course of an investigation by HHS-OIG, the Defense Criminal Investigative Service (DCIS), and the Drug Enforcement Administration with the assistance of the Collier County Sheriff's Office (CCSO), and the Naples Police Department (NPD). The facts set forth herein are either personally known to me or have been provided to me by other investigators and/or law enforcement officers. Also, some information has been provided to me by witnesses either formally employed by the subject of the investigation, or affiliated with the target in a professional setting. The purpose of this affidavit is to establish probable cause in support of a request for arrest warrants for Delmer Holmes Parrish and Patricia

Parrish. Accordingly, I have not attempted to set forth all facts known to me or other persons associated with the investigation.

3. I am currently conducting an investigation of potential Medicare, Medicaid, and TRICARE fraud-related offenses pertaining to SUNSHINE PHARMACY, INC ("SUNSHINE PHARMACY "), located at 5482 Rattlesnake Hammock Road, in Naples, in the Middle District of Florida; SUNSHINE SOLUTIONS PHARMACY, INC ("SUNSHINE SOLUTIONS"), located at 5480 Rattlesnake Hammock Road, in Naples; Delmer Holmes Parrish ("PARRISH"), a pharmacist and owner of SUNSHINE and SUNSHINE SOLUTIONS; and Patricia Parrish.

4. This affidavit is submitted in support of an application for an arrest warrant for PARRISH and Patricia Parrish. Based upon evidence gathered to date by your affiant and others, your affiant submits that there is probable cause to believe that beginning on a date unknown, but at least by in or about February 2009 and continuing through in or about July 2012, PARRISH and Patricia Parrish did knowingly, intentionally, and willfully combine, conspire, confederate, and agree with each other and with other persons known and unknown, to commit certain offenses against the United States, that is, to knowingly and willfully execute, and attempt to execute, a scheme and artifice: (a) to defraud health care benefit programs, that is, Medicare, Medicaid, and TRICARE; and (b) to obtain money and property owned by and under the custody and control of health care benefit programs, that is, Medicare, Medicaid, and TRICARE, by means of materially false and fraudulent pretenses, representations, and promises, in connection with payments for health care benefits, items and services, namely drug prescriptions, in violation of Title 18, United States Code, Section § 1347

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and pursuant to Title 18, United States Code, Section § 1349. Pursuant to this conspiracy, PARRISH and Patricia Parrish submitted claims for payment to Medicare, Medicaid, and TRICARE for prescription medications and services without dispensing the medication or providing the services, in violation of United States Code, Section 1349, Conspiracy to Commit Health Care Fraud.

II. PROBABLE CAUSE

A. SUNSHINE PHARMACY Corporate Information

5. SUNSHINE PHARMACY registered with the State of Florida on June 4, 1998. The principal address listed for the corporation is 5482 Rattlesnake Hammock Road., Naples, Florida 34113. SUNSHINE PHARMACY has been assigned Florida License Number PH16358. Records with the Florida Secretary of State, Division of Corporations, list PARRISH as the registered agent and President of SUNSHINE PHARMACY.

B. SUNSHINE SOLUTIONS PHARMACY Corporate Information

6. SUNSHINE SOLUTIONS PHARMACY registered with the State of Florida on August 22, 2007. The principal address listed for the corporation is 5480 Rattlesnake Hammock Road, Naples, Florida 34113. SUNSHINE SOLUTIONS PHARMACY has been assigned Florida License Number PH17844. Records with the Florida Secretary of State, Division of Corporations, list PARRISH as the registered agent and President of SUNSHINE SOLUTIONS PHARMACY.

C. Federally Funded Insurance Affected

(i) The Medicare Program

7. The Medicare Program ("Medicare") is a federally funded health insurance program created by the Social Security Act of 1965 that provides coverage for people 65 and older and for certain disabled persons (hereinafter "beneficiaries"). The United States Department of Health and Human Services (HHS) is responsible for the administration of the Medicare program. The Centers for Medicare and Medicaid Services (CMS) is the component agency of HHS that administers and supervises Medicare.

8. In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding Part D under Title XVIII. The MMA allows Medicare payments to insurance plans that contract with CMS to provide qualified Part D prescription coverage to Medicare beneficiaries, as described in 42 C.F.R. § 423.401. For simplicity in this affidavit, the term "Plans" will refer to entities that provide Part D benefits (i.e., prescription coverage) to Medicare beneficiaries.

9. Plans must submit a summary record- called the Prescription Drug Event (PDE) record-to CMS every time a beneficiary fills a prescription covered under Part D. The PDE record contains prescription drug cost and payment data that enables CMS to make payments to Plans and otherwise administer the Part D benefit. As a matter of process, when prescriptions are filled, pharmacies submit claims to the Plans. These claims are submitted electronically to the Plans. Once these claims are adjudicated, the Plans pay the pharmacies for providing the Part D benefits to qualified Medicare beneficiaries. The Plans then reconcile with (or seek reimbursement from) CMS through the submission of the PDE records.

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(ii) The Medicaid Program

10. The Medicaid Program ("Medicaid") is a federally subsidized health insurance program under Title XIX of the Social Security Act, which pays for medical assistance for certain disabled persons and those with low income and minimal resources (hereinafter "recipients"). Medicaid became law in 1965 as a cooperative venture jointly funded by the Federal and State government to assist States in furnishing medical assistance to eligible needy persons. In Florida, Medicaid receives approximately 57% of its funding from the Federal government. The Florida Agency for Healthcare Administration (AHCA) is responsible for the administration of Medicaid in the state of Florida.

11. On July 29, 1999, SUNSHINE PHARMACY, and on October 18, 2005, SUNSHINE SOLUTIONS PHARMACY, submitted Medicaid Provider agreements to AHCA, bearing the apparent signature of PARRISH and his wife. SUNSHINE PHARMACY was subsequently assigned Medicaid Provider number 021438800 with a registered location of 5482 Rattlesnake Hammock Road, Naples, Florida 34113. SUNSHINE SOLUTIONS PHARMACY was subsequently assigned Medicaid Provider number 031077800 with a registered location of 5480 Rattlesnake Hammock Road, Naples, Florida 34113.

(iii) TRICARE

12. TRICARE is a triple option benefit Plan established by Congress and funded through federal funds allocated through the annual Department of Defense

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Appropriation Acts. Eligible beneficiaries include all seven branches of the Uniformed Services: Army, Air Force, Navy, Marine Corps, National Oceanic Atmospheric Administration, Coast Guard, and the commissioned corps of the Public Health Service.

13. TRICARE benefits are authorized by Congressional legislation incorporated in Chapter 55 of Title 10, United States Code, and implemented by the Secretary of Defense and the Secretary of HHS in Title 32, Code of Federal Regulations, Part 199. According to 32 C.F.R. § 199.4, and subject to all applicable definitions, conditions, limitations, or exclusions specified in this part, TRICARE will only pay for medically-necessary services and supplies required in the diagnosis and treatment of illness or injury. This includes the cost sharing of pharmaceuticals.

14. TRICARE contracts with Express Scripts, Inc ("ESI") to manage the TRICARE prescriptions benefit program. ESI has entered into contracts with individual providers including SUNSHINE PHARMACY and SUNSHINE SOLUTIONS PHARMACY.

(iii) Medicare, Medicaid and TRICARE are Federal Health Care Benefit Programs

15. Medicare, Medicaid, and TRICARE (hereafter collectively " healthcare benefit programs") each qualify as a federal "health care benefit program," as defined by Title 18, United States Code, Section 24(b), in that all of these programs are public plans, affecting commerce, under which medical benefits, items and services are provided to certain individuals.

III. Investigation

16. HHS OIG began its participation in this investigation on or about July 6, 2012, following a referral from another Federal agency. A summary of relevant portions of the investigation is included to establish probable cause in support of the instant applications.

A. Interview of FE1

17. Former Employee #1 ("FE1"), whose true identity is known to me and others involved in this investigation, is a former Pharmacy Technician for SUNSHINE PHARMACY. FE1 was employed at SUNSHINE PHARMACY from approximately May 2010 until June 2012. While employed at SUNSHINE PHARMACY, FE1 had direct access to SUNSHINE PHARMACY records and had thorough knowledge of SUNSHINE PHARMACY operations.

18. On August 30, 2012, I interviewed FE1. FE1 advised that during his/her employment at SUNSHINE PHARMACY, fraudulent claims were submitted to federal healthcare benefit programs for prescription medications that were never provided to individual beneficiaries/recipients. FE1 explained that SUNSHINE PHARMACY intentionally submitted claims for medications not dispensed nor prescribed.

B. Claims for Medication Not Prescribed

19. FE1 further stated that while employed at SUNSHINE PHARMACY, he/she identified claims for medications that were never stocked in the pharmacy,

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therefore not dispensed. FE1 further advised that PARRISH falsified prescriptions from physicians, including those relating to a specific physician, Physician #1 ("P1") of a local hospice[1] facility. FE1 advised that SUNSHINE PHARMACY most often fraudulently billed for the prescription drug Megace[2]. FE1 further advised that P1 typically prescribed Megace at a dosage of 40mg; however SUNSHINE PHARMACY submitted claims to federal healthcare benefit programs at a dosage of 625mg which he/she believed to be neither in stock nor prescribed to the patient.

20. During the course of this investigation, I identified through data analysis of Medicare/Medicaid claims submitted by SUNSHINE PHARMACY and SUNSHINE SOLUTIONS, several high cost medications including 625mg of Megace purportedly prescribed by P1 as stated by FE1.

C. Interview of P1

21. Physician #1 ("P1"), whose true identity is known to me and others involved in this investigation, is a senior medical staff member at a local hospice care facility in Naples, Florida. I interviewed P1 on or about November 15, 2012. After being informed of the nature of the interview and being presented with the claims submitted by SUNSHINE PHARMACY and SUNSHINE SOLUTIONS, P1 identified claims that he/she did not prescribe. These claims include, but are not limited to, 625mg of Megace as

[1] Hospice is a type of care and philosophy of care that focuses on the palliation of a terminally ill or seriously ill patient's symptoms. These symptoms can be physical, emotional, or psychosocial in nature. Hospice care focuses on bringing comfort to patients in their final stages of physical life.

[2] Megestrol acetate ("Megace") is used mainly as an appetite stimulant in a variety of conditions. It can substantially increase appetite in most individuals, even those with advanced cancer, and is often used to boost appetite and induce weight gain in patients with cancer or HIV/AIDS.

stated by FE1 and identified through data analysis. A summary of those claims P1 identified as NOT written by P1 follow:

Patient ID Number	Rx Number	Dispensed Date	Drug Label
XXXXXX048A	842079	12/12/2009	LEVAQUIN TAB 750MG
XXXXXX681A	852238	1/26/2010	ABILIFY TAB 30MG
XXXXXX681A	852250	1/26/2010	DETROL TAB 2MG
XXXXXX018A	784021	2/26/2009	SEROQUEL TAB 400MG
XXXXXXX25D6	853548	2/2/2010	LEVAQUIN TAB 750MG
XXXXXX096A	801999	6/3/2009	LIDODERM DIS 5%
XXXXXX879A	791199	4/6/2009	ABILIFY TAB 30MG
XXXXXX147A	847163	1/5/2010	LEVAQUIN TAB 750MG
XXXXXX075D	868044	4/26/2010	LEVAQUIN TAB 750MG
XXXXXX075D	868043	4/26/2010	LIDODERM DIS 5%
XXXXXX977D	826941	9/28/2009	LEVAQUIN TAB 750MG
XXXXXX006A	897070	1/22/2011	MEGACE ES SUS
XXXXXX641A	789054	3/25/2009	DETROL LA CAP 2MG
XXXXXX825A	897263	1/29/2011	LIDODERM DIS 5%
XXXXXX825A	880644	8/23/2010	LIDODERM DIS 5%
XXXXXX825A	891267	12/15/2010	LEVAQUIN TAB 500MG
XXXXXX108A	731762	4/2/2008	LEVAQUIN TAB 750MG
XXXXXX316B	811467	5/30/2009	LEVAQUIN TAB 750MG
XXXXXX942D	888027	11/20/2010	LEVAQUIN TAB 750MG
XXXXXX942D	888032	11/20/2010	LIDODERM DIS 5%
XXXXXX969A	823841	8/18/2009	LEVAQUIN TAB 750MG
XXXXXX654A	850170	1/16/2010	LEVAQUIN TAB 750MG
XXXXXX659B	871500	5/17/2010	LEVAQUIN TAB 750MG
XXXXXX391A	818277	8/13/2009	LEVAQUIN TAB 750MG
XXXXXX119A	841778	12/10/2009	LEVAQUIN TAB 750MG
XXXXXX971A	792320	4/11/2009	LIDODERM DIS 5%
XXXXXX250B	820652	8/25/2009	LIDODERM DIS 5%
XXXXXX250B	794394	4/22/2009	LIDODERM DIS 5%
XXXXXX431D	808810	6/30/2009	LIDODERM DIS 5%
XXXXXX172A	784019	2/26/2009	SEROQUEL TAB 400MG

D. Additional Former Employees Identifying Delmer and Patricia Parrish

(i). Interview of FE2

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22. Former Employee #2 ("FE2"), whose true identity is known to me and others involved in the investigation, is a former Office Manager for SUNSHINE PHARMACY from approximately June 2002 until approximately May 2012. While employed at SUNSHINE PHARMACY, FE2 had direct access to SUNSHINE PHARMACY records and had thorough knowledge of SUNSHINE PHARMACY operations.

23. FE2 was interviewed and provided information relating to this investigation. FE2 advised that during his/her employment with SUNSHINE PHARMACY, PARRISH and SUNSHINE PHARMACY began to lose contracts with the various Assisted Living Facilities in the area due to a lack of inventory of medications needed. Additionally, there were times when medications were billed to federal healthcare benefit programs but not dispensed. FE2 stated that PARRISH submitted claims to federal healthcare benefit programs for the following medications that were not dispensed:

- Megace (625mg)
- Seroquel
- Levaquin (750mg)
- Abilify
- Plavix (occasionally)

24. FE2 stated that customers complained about billing because they, or the person for whom they were responsible, had received an Explanation of Benefits (EOB) with medications on it that were not correct. Additionally, FE2 recalled that at times when he/she worked at the pharmacy, "random" and unexplained prescriptions would come off the printer as though they needed to be filled. FE2 indicated that these unexplained prescriptions were printed by Patricia Parrish. FE2 further explained that

these prescriptions would be printed by the computer automatically as part of the claim billing process unless an individual remembered to manually tell the computer not to print the billed-for prescription. FE2 explained that that no customer was actually seeking to have those specific prescriptions filled.

25. FE2 saw Patricia Parrish and others submit claims for payment, and advised that Patricia Parrish was responsible for the fraudulent claims submitted to federal healthcare benefit programs to obtain funds to keep the pharmacy in operation. FE2 personally engaged in a conversation with Patricia Parrish regarding the fraudulent activity in which she (Patricia Parrish) was engaged. FE2 advised that Patricia Parrish's response was that she would cease, however she continued in the activity.

26. FE2 also engaged in a personal conversation with PARRISH regarding the purported fraudulent billing practices, in which he responded to FE2 that he would cease.

(ii). Interview of FE3

27. Former Employee #3 ("FE3"), whose true identity is known to me and others involved in this investigation, is a former Pharmacist for SUNSHINE PHARMACY. FE3 was employed at SUNSHINE PHARMACY from approximately April 2011 until approximately April 2012. While employed at SUNSHINE PHARMACY, FE3 had direct access to SUNSHINE PHARMACY records and had thorough knowledge of SUNSHINE PHARMACY operations.

28. On August 30, 2012, I interviewed FE3. FE3 advised that during his/her employment at SUNSHINE PHARMACY, PARRISH submitted claims for refills for

patients for expensive medications, but the medications were not in stock. Additionally, PARRISH would submit claims for "50-60" prescriptions for an expensive medication, but only have "2-4" prescriptions worth of the medication in stock.

29. FE3 advised that Patricia Parrish knew that the claims she was submitting were fraudulent, however she needed to generate revenue for the pharmacy. FE3 personally expressed his/her concerns to PARRISH about the issues that were occurring at the pharmacy, and PARRISH responded that he would "take care of it".

(iii). Interview of FE4

30. Former Employee #4 ("FE4"), whose true identity is known to me and others involved in the investigation, is a former Pharmacy Technician and Billing Specialist for SUNSHINE PHARMACY from approximately 2008 until approximately the summer of 2010. While employed at SUNSHINE PHARMACY, FE4 had direct access to SUNSHINE PHARMACY records and had thorough knowledge of SUNSHINE PHARMACY operations.

31. FE4 was interviewed and provided information relating to this investigation. FE4 advised that during his/her employment with SUNSHINE PHARMACY, he/she found the biggest fraud was with the hospice patient prescriptions, because the pharmacy has the patients' social security numbers, and the pharmacy would run prescriptions for a medication called Megace. Additionally, FE4 stated that Patricia Parrish possessed a book containing the credit card information of hospice patients, and in the back of the book were instructions from PARRISH as to which medications Patricia Parrish should bill for.

32. FE4 advised that PARRISH changed prescriptions to reflect other medications; and justified his actions by stating that the change in prescription was authorized by the prescribing physician. FE4 did not believe those changes were authorized by the prescribing physician. FE4 recalled a specific patient who complained about the medication she was provided. It was determined that the patient was provided medication to which they were allergic, and was not the medication specifically prescribed by their physician. The physician of the patient also complained to PARRISH telephonically about this unauthorized change, and when the prescription was pulled at the pharmacy, it had "ok per doctor" affixed.

33. FE4 advised that in addition to herself/himself, there were approximately three (3) other persons working in the billing office including Patricia Parrish. However, PARRISH was responsible for the false claims that were submitted. FE4 further stated that PARRISH often submitted claims to federal healthcare benefit programs for prescription refills before a refill of that medication was requested by a patient, and if the medication was not requested or received by that patient, he would not reverse[3] the claim. Additionally, PARRISH reprimanded others for not engaging in the scheme.

IV. Conclusion

34. Based upon the investigation to date, your affiant respectfully submits that there is probable cause to believe that Delmer Holmes Parrish and Patricia Parrish, did knowingly, intentionally, and willfully combine, conspire, confederate, and agree with each other and with other persons known and unknown, to commit certain offenses

[3] A claim reversal is the process in which a healthcare provider, including a pharmacy, can refund insurance plans for payment(s) received.

against the United States, that is, to knowingly and willfully execute, and attempt to execute, a scheme and artifice: (a) to defraud health care benefit programs, that is, Medicare, Medicaid, and TRICARE; and (b) to obtain money and property owned by and under the custody and control of health care benefit programs, that is, Medicare, Medicaid, and TRICARE, by means of materially false and fraudulent pretenses, representations, and promises, in connection with payments for health care benefits, items and services, namely drug prescriptions, in violation of Title 18, United States Code, Section 1347. All pursuant to Title 18, United States Code, Section 1349.

WHEREFORE, your affiant requests this Court issue arrest warrants for both Delmer Holmes Parrish and Patricia Parrish, for a violation of Title 18, United States Code, Section 1349.

FURTHER AFFIANT SAYETH NAUGHT.

Brian Harris, Special Agent
U.S. Department of Health and Human Services
Office of the Inspector General
Office of Investigations

Subscribed and sworn to before me
this 8th day of May 2013.

DOUGLAS N. FRAZIER
UNITED STATES MAGISTRATE JUDGE

REPORT
EXHIBIT# 1
PAGE# 19

Paulson, Leo

From: Howell, Donna L
Sent: Tuesday, November 05, 2013 8:04 AM
To: Paulson, Leo
Subject: Ref 2013-10756

Sunshine Pharmacy owners plead guilty to health care fraud charges

By LIZ FREEMAN

Monday, November 4, 2013

FORT MYERS — Sunshine Pharmacy owner Del Parrish and his mother, Patricia Parrish, entered a guilty plea Monday in federal court to conspiracy to commit health care fraud in connection to their family-owned Sunshine Pharmacy in Collier County.

Each could face a maximum penalty of 10 years in prison and fine each of $250,000. They also have agreed to pay joint restitution to the federal government of $351,358, according to the deal.

U.S. Magistrate Douglas Frazier ordered a pre-sentencing investigation before handing down a sentence, which could reduce the amount of time they spend in prison.

Parrish, 44, and his mother, who is 74, were arrested May 14, on charges that they conspired to commit Medicare and Medicaid fraud through false billings, according to an affidavit. They also conspired to defraud the Tricare insurance for members of the military.

Both admitted in open court to the charge.

"I was aware of all of the information of what was going on," Del Parrish said.

Patricia Parrish told the judge that some people did not pay their bills and the pharmacy needed money.

The U.S. Department of Health and Human Services began an investigation of Sunshine Pharmacy in Collier County and, on Jan. 17, raided the Sunshine Pharmacy located on Rattlesnake Hammock Road in East Naples. Federal authorities carted off boxes of documents and computers, and the pharmacy remained closed for several days afterward. A week after the raid, Del Parrish relinquished his license to fill certain controlled substances, including pain pills.

A second pharmacy on Davis Boulevard closed a few months later.

Donna L. Howell

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Consumer Services Ombudsman
Government Analyst II
Florida Department of Health
4052 Bald Cypress Way, Bin C75
Tallahassee, FL 32399
850-245-4444 x*8330 Work
850-488-0796 Fax
Donna.Howell@flhealth.gov

Customer Satisfaction Survey

Mission: To protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts.

Vision: To be the **Healthiest State** in the Nation!

There have been changes to the license renewal process. Please visit www.CEAtRenewal.com to learn more.

****

Please note: Florida has a very broad public records law. Most written communications to or from state officials regarding state business are public records available to the public and media upon request. Your e-mail communications may therefore be subject to public disclosure.

UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

UNITED STATES OF AMERICA

VS. CASE NO: 2:13-cr-68-FtM-29UAM

DELMER HOLMES PARRISH

ACCEPTANCE OF GUILTY PLEA AND ADJUDICATION OF GUILT

Pursuant to the Report and Recommendation of the United States Magistrate Judge (Doc. 59) to which the parties have waived the 14 day objection period, the plea of guilty of the defendant is now accepted and the defendant is adjudged guilty of Count One of the Indictment. A sentencing hearing has been scheduled for **February 10, 2014 at 2:00 PM.**

DONE AND ORDERED at Fort Myers, Florida, this 6th day of November, 2013.

John E. Steele

JOHN E. STEELE
UNITED STATES DISTRICT JUDGE

Copies:

All Parties of Record

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EXHIBIT# 1
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UNITED STATES DISTRICT COURT
MIDDLE DISTRICT OF FLORIDA
FORT MYERS DIVISION

UNITED STATES OF AMERICA

v.

Case No. 2:13-cr-68-FtM-29SPC

DELMER HOLMES PARRISH,
PATRICIA PARRISH,

18 U.S.C. § 1347
18 U.S.C. § 1349
18 U.S.C. § 981(a)(1)(c)(forfeiture)
28 U.S.C. § 2461(c)(forfeiture)

Defendants

INDICTMENT

Count One
(Conspiracy to Commit Health Care Fraud - 18 U.S.C. §§ 1347, 1349)

A. Introduction

At all times material to this Indictment:

i. The Defendants

1. DELMER HOLMES PARRISH was a pharmacist licensed in the State of Florida and was the co-owner and operator of Sunshine Pharmacy, Inc. (SUNSHINE PHARMACY) and Sunshine Solutions Pharmacy, Inc. (SUNSHINE SOLUTIONS PHARMACY), located in Naples, in the Middle District of Florida.

2. PATRICIA PARRISH worked in a billing and management position at SUNSHINE PHARMACY and SUNSHINE SOLUTIONS PHARMACY.

ii. The Companies

3. SUNSHINE PHARMACY, located at 5482 Rattlesnake Hammock Road, in Naples, in the Middle District of Florida, registered with the State of Florida on or about

June 4, 1998. DELMER HOLMES PARRISH was the registered agent and President of SUNSHINE PHARMACY.

4. SUNSHINE SOLUTIONS PHARMACY, located at 5480 Rattlesnake Hammock Road, in Naples, in the Middle District of Florida, registered with the State of Florida on or about August 22, 2007. DELMER HOLMES PARRISH was the registered agent and President of SUNSHINE SOLUTIONS PHARMACY.

5. SUNSHINE PHARMACY received Medicaid Provider number 021438800 on or about July 29, 1999. SUNSHINE SOLUTIONS PHARMACY received Medicaid Provider number 031077800 on or about October 18, 2005.

6. SUNSHINE PHARMACY and SUNSHINE SOLUTIONS PHARMACY occupied, and operated from, the same building with separate entrances in Naples, Florida.

iii. The Programs

7. The Medicare Program ("Medicare") was a federally funded health care benefit program created by the Social Security Act of 1965 that provided coverage for people of 65 and older and for certain disabled persons (hereinafter "beneficiaries"). The Medicare program was funded through federal tax revenue. The United States Department of Health and Human Services (HHS) was responsible for the administration of the Medicare program. The Centers for Medicare and Medicaid Services (CMS) was the component agency of HHS that administered and supervised Medicare.

8. In December 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act (MMA), amending the Social Security Act by adding

Part D under Title XVIII. The MMA allowed Medicare payments to insurance plans that contract with CMS to provide qualified Part D prescription coverage to Medicare beneficiaries, as described in 42 C.F.R. § 423.401. The term "Plans" refers to entities that provide Part D benefits (i.e., prescription coverage) to Medicare beneficiaries.

9. Plans must submit a summary record, called the Prescription Drug Event (PDE) record, to CMS every time a beneficiary fills a prescription covered under Part D. The PDE record contains prescription drug cost and payment data that enables CMS to make payments to Plans and otherwise administer the Part D benefit. To receive payment from Medicare when prescriptions are filled, pharmacies submit claims to the Plans. These claims are submitted electronically to the Plans. Once these claims are adjudicated, the Plans pay the pharmacies for providing the Part D benefits to qualified Medicare beneficiaries. The Plans then reconcile with (or seek reimbursement from) CMS through the submission of the PDE records. Each claim form from a pharmacy requires certain important information, including: (a) the Medicare beneficiary's name and identification number; (b) the identification number of the doctor or other qualified health care provider who ordered the health care benefit, item, or service that was the subject of the claim; (c) the health care benefit, item, or service that was provided or supplied to the beneficiary; (d) the billing codes for the benefit, item, or service; and (e) the date upon which the benefit, item, or service was provided or supplied to the beneficiary.

10. The Medicaid Program ("Medicaid") is a federally subsidized health care benefit program under Title XIX of the Social Security Act, which pays for medical assistance for certain disabled persons and those with low income and minimal resources

(hereinafter "recipients"). The Medicaid program is funded through federal and state tax revenue. The Florida Agency for Healthcare Administration is responsible for the administration of Medicaid in the state of Florida.

11. TRICARE is a federal health care benefit program established by Congress and funded through federal funds allocated through the annual Department of Defense Appropriation Acts. Eligible beneficiaries include current and retired members of all seven branches of the Uniformed Services: Army, Air Force, Navy, Marine Corps, National Oceanic Atmospheric Administration, Coast Guard, and the commissioned corps of the Public Health Service. TRICARE contracts with Express Scripts, Inc. ("ESI") to manage the TRICARE prescriptions benefit program. ESI enters into contracts with individual providers, including pharmacies to fill and distribute prescriptions for eligible beneficiaries.

12. Medicare, Medicaid, and TRICARE each qualify as a federal "health care benefit program," as defined by Title 18, United States Code, Section 24(b).

B. The Conspiracy

13. From at least in or about February, 2009, and continuing through in or about July, 2012, in the Middle District of Florida, and elsewhere,

DELMER HOLMES PARRISH, and
PATRICIA PARRISH,

defendants herein, did knowingly, intentionally, and willfully combine, conspire, confederate, and agree with each other and with other persons known and unknown to the Grand Jury, to commit certain offenses against the United States, that is, to knowingly

and willfully execute, and attempt to execute, a scheme and artifice: (a) to defraud health care benefit programs, that is, Medicare, Medicaid, and TRICARE; and (b) to obtain money and property owned by and under the custody and control of health care benefit programs, that is, Medicare, Medicaid, and TRICARE, by means of materially false and fraudulent pretenses, representations, and promises, in connection with payments for health care benefits, items and services, namely drug prescriptions, in violation of Title 18, United States Code, Section § 1347.

C. Purpose and Object of the Conspiracy

14. It was the purpose and object of the conspiracy for the defendants and their coconspirators to unlawfully enrich themselves by defrauding federal health care benefit programs by fraudulently submitting claims for payment for benefits, items and services that were not authorized and had not been rendered and by fraudulently submitting claims for payments for benefits, items and services for deceased beneficiaries and recipients.

D. Manner and Means

15. The manner and means by which the defendants sought to accomplish the scheme and artifice included, among others, the following:

(a) It was part of the conspiracy that DELMER PARRISH would and did own and operate SUNSHINE PHARMACY and SUNSHINE SOLUTIONS PHARMACY in Naples, Florida, as facilities that provided prescription medication benefits, items and services to patients, including beneficiaries and recipients covered by Medicaid, Medicare, and TRICARE.

(b) It was further part of the scheme and artifice that PATRICIA PARRISH would and did maintain employment and assist in the billing and management of SUNSHINE PHARMACY and SUNSHINE SOLUTIONS PHARMACY.

(c) It was further part of the scheme and artifice that DELMER PARRISH applied for and maintained Medicare, Medicaid, and TRICARE participant numbers for SUNSHINE PHARMACY and SUNSHINE SOLUTIONS PHARMACY.

(d) It was further part of the scheme and artifice that DELMER HOLMES PARRISH and PATRICIA PARRISH, and others known and unknown to the Grand Jury, would and did systematically submit and cause to be submitted claims for reimbursement from the Medicaid, Medicare, and TRICARE programs for prescriptions not filled or provided to beneficiaries and recipients, including prescriptions for patients that had not been written or authorized by any duly licensed physician.

(e) It was further part of the scheme and artifice that DELMER HOLMES PARRISH and PATRICIA PARRISH, and others known and unknown to the Grand Jury, would and did systematically submit and cause to be submitted claims for reimbursement from the Medicaid, Medicare, and TRICARE programs for prescriptions for beneficiaries and recipients who were deceased.

(f) It was further part of the scheme and artifice that DELMER HOLMES PARRISH and PATRICIA PARRISH, and others known and unknown to the Grand Jury, would and did systematically submit and cause to be submitted claims for reimbursement from the Medicaid, Medicare, and TRICARE programs for prescriptions using the means of identification of individuals who were enrolled in the Medicaid, Medicare, or TRICARE

programs without their knowledge or consent.

(g) It was further part of the scheme and artifice that DELMER HOLMES PARRISH and PATRICIA PARRISH, and others known and unknown to the Grand Jury, would and did perform acts and make statements to hide and conceal and to cause to be hidden and concealed the purpose of the scheme to defraud and the acts committed in furtherance thereof.

All in violation of Title 18, United States Code, Section 1349.

FORFEITURE

1. The allegations contained in Count One of this Indictment are hereby realleged and incorporated by reference for the purpose of alleging forfeitures pursuant to Title 18, United States Code, Section 981(a)(1)(c), and Title 28, United States Code, Section 2461(c).

2. From their engagement in the offense conduct charged in Count One of this Indictment, in violation of Title 18, United States Code, Section 1349,

DELMER HOLMES PARRISH, and
PATRICIA PARRISH,

defendants herein shall forfeit to the United States of America, pursuant to Title 18, United States Code, Section 981(a)(1)(c), and Title 28, United States Code, Section 2461(c), any property, real or personal, that constitutes or is derived, directly or indirectly, from gross proceeds traceable to the commission of the offenses. The property to be forfeited includes, but is not limited to a forfeiture money judgment in the amount of proceeds the defendants received as a result of the conspiracy to commit health care fraud as charged in Count One of the Indictment.

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EXHIBIT# 1
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3. If any of the property described above, as a result of any act or omission of the defendants:

(a) cannot be located upon the exercise of due diligence;

(b) has been transferred or sold to, or deposited with, a third party;

(c) has been placed beyond the jurisdiction of the court;

(d) has been substantially diminished in value; or

(e) has been commingled with other property which cannot be divided without difficulty,

the United States of America shall be entitled to forfeiture of substitute property pursuant to Title 21, United States Code, Section 853(p), as incorporated by Title 18, United States Code, Section 982(b)(1) and Title 28, United States Code, Section 2461(c).

Date: 5-15-13

A TRUE BILL,

Foreperson

ROBERT E. O'NEILL
United States Attorney

By:
DAVID G. LAZARUS
Assistant United States Attorney

By:
NICOLE H. WALL
Assistant United States Attorney
Chief, Fort Myers Division

1
30

FORM OBD-34
APR 1991

No.

UNITED STATES DISTRICT COURT

Middle District of Florida
Fort Myers Division

THE UNITED STATES OF AMERICA

vs.

DELMER HOLMES PARRISH and
PATRICIA PARRISH

INDICTMENT

Violations:

18 U.S.C. § 1347
18 U.S.C. § 1349
18 U.S.C. § 981 (a)(1)(c)(Forfeiture)
18 U.S.C. § 2461(c)(Forfeiture)

A true bill,

Foreperson

Filed in open court this 15th day

of May, A.D. 2013.

Clerk

Bail $

GPO 863 525

November 21, 2013

CONFIDENTIAL
Delmer H. Parrish, PS
390 Hawser Lane
Naples, FL 34102

Complaint #: 201310756

Dear Mr. Parrish:

The Consumer Services Unit has received the enclosed complaint against you. We reviewed the complaint or report and determined that you may have violated the practice act that regulates your profession. Therefore, we have opened an investigation into this matter. Please submit a written response to this complaint within 20 days of receipt of this letter.

You may make a written request for a copy of the investigative file. This complaint and all investigative information will remain confidential until 10 days after the probable cause panel has determined that a violation has occurred or you give up the right to confidentiality.

The mission of the Department of Health is to protect, promote & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please call the Consumer Services Unit at (850) 245-4339. In addition, if you have any concerns or suggestions about our complaint process, please fill out our *Customer Concerns or Suggestions* form at www.floridashealth.com/mqa/survey.html.

Sincerely,

Leo W. Paulson
Government Analyst I

LWP/tb
Enclosure

CONFIDENTIAL

DOH-Form300

HEALTH

Rick Scott
Governor

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201218422

WELLS PHARMACY NETWORK LLC,
RESPONDENT.

NOTICE

TO: WELLS PHARMACY NETWORK LLC
11120 S CROWN WAY STE 11
WELLINGTON, FL 33414

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Hearing - No Disputed Material Facts

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201218422

WELLS PHARMACY NETWORK LLC,
RESPONDENT.

NOTICE

AND: EDWIN BAYO
2022-2 RAYMOND DIEHL ROAD
GORSSMAN, FURLOW & BAYO, LLC
TALLAHASSEE, FL 32308

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for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Judson Searcy, Assistant General Counsel JS
RE: **Hearing - No Disputed Material Facts**
SUBJECT: DOH v. Wells Pharmacy Network LLC
DOH Case Number 2012-18422
DATE: February 13, 2014 AB

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014**, meeting of the board. The following information is provided in this regard.

Subject:	Wells Pharmacy Network LLC
Subject's Address of Record:	11120 S. Crown Way, Ste 11 Wellington, FL 33414
Enforcement Address:	11120 S. Crown Way, Ste 11 Wellington, FL 33414
Subject's License No:	25799 **Rank:** PH
Licensure File No:	18677
Initial Licensure Date:	11/29/2011
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Ct 1: 465.023(1)(c), FS (2012) 64B16-27.300(3)(a), FAC Ct 2: 465.023(1)(c), FS (2012) 64B16-27.797(1)(4), FAC Ct 3: 465.023(1)(c), FS (2012) 64B16-27.797 (1)(i)7, FAC
Prior Discipline:	None
Probable Cause Panel:	March 28, 2013; Weizer & Meshad
Subject's Attorney:	Edwin Bayo 2022-2 Raymond Diehl Road Tallahassee, FL 32308
Complainant/Address:	Department Of Health
Materials Submitted:	Memorandum to the Board Motion for Final Order

Administrative Complaint
Motion to Assess Costs
Exhibit A – Affidavit of Fees & Costs Expended
Exhibit 1 – Complain Cost Summary
Exhibit 2 – Itemized Costs by Complaint
Notification Letter
Respondent Documents
Probable Cause Panel Memorandum
Final Investigative Report with Exhibits 1-4

DISCIPLINARY GUIDELINES:

64B16-27.797: $500 fine, 12 hour Laws & Rules course, and course governing sterile compounds, to $2,000 fine and one year probation; to $2,500 to $10,000 fine and one year suspension followed by two years probation to revocation

PRELIMINARY CASE REMARKS: SECTION 120.57(2) HEARING (INFORMAL)

This is a three count AC alleging violations of Section 465.023(1)(c), Florida Statutes, for violations of 64B16-27.300 and 64B16-27.797 for CQI and compounding violations.

On or about December 12, 2012, a Department inspector conducted an inspection of Respondent and observed one or more of the following deficiencies:

a. No documentation of a review of "Quality-Related Events" (QRE) for the months of May and June of 2012;

b. Sterilized high-risk preparations did not pass sterility test or preparations were not properly stored, prior to administration, by exceeding time periods specified in rule; and/or

c. Personnel authorized to compound high-risk compounding sterile preparations (CSP) had not completed a media-filled test within past six (6) months.

Respondent returned a Petition for Hearing Not Involving Disputed Issues of Material Fact electing an informal hearing.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-18422

WELLS PHARMACY NETWORK, LLC
Respondent.
_____/

MOTION FOR FINAL ORDER AFTER HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACTS

COMES NOW, the Petitioner, by and through its undersigned counsel, and moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore, the Petitioner would state the following:

1. Petitioner previously filed an Administrative Complaint against Respondent alleging that Respondent had violated the provisions of Florida Statutes, as set forth therein. The Department, by filing the Administrative Complaint, is seeking to discipline the Respondent's license to practice as a pharmacy, thereby affecting the Respondent's substantial interests.

2. On or about April 10, 2013, Petitioner served Respondent with the Administrative Complaint via Respondent's address of record with the

Department of Health. The Department, by serving the Respondent with the Administrative Complaint, provided the Respondent written notice of its decision to seek discipline of the Respondent's license to practice as a pharmacy.

3. The Respondent has filed an Election of Rights Form or other responsive pleading evincing, or has otherwise indicated, that Respondent does not dispute the material facts alleged in the Administrative Complaint.

4. There are no disputed issues of material fact to be resolved by the Board.

5. Respondent has been advised, by a copy of this Motion, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

WHEREFORE the parties respectfully request the Board of Pharmacy, after allowing the Respondent the opportunity to present oral and/or written evidence in mitigation of the Administrative Complaint, enter a Final Order imposing whatever discipline upon the Respondent's license that the Board deems appropriate.

Respectfully Submitted,

Judson Searcy
Assistant General Counsel
Fla. Bar No. 98772
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Judson.searcy@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 5th day of February, 2014, to Edwin Bayo, Esq., 2022-2 Raymond Diehl Road, Tallahassee, FL 32308.

Judson Searcy
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-18422**

WELLS PHARMACY NETWORK LLC,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Wells Pharmacy Network LLC, Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a permitted community pharmacy within the state of Florida, having been issued permit number PH 25799.

3. Respondent's address of record is 11120 South Crown Way, Suite 11, Wellington, Florida 33414.

4. On or about December 12, 2012, a Department inspector conducted an inspection of Respondent at 11120 South Crown Way, Suite 11, Wellington, Florida 33414, and observed one or more of the following deficiencies:

a. No documentation of a review of "Quality-Related Events" (QRE) for the months of May and June of 2012;

b. Sterilized high-risk preparations did not pass sterility test or preparations were not properly stored, prior to administration, by exceeding time periods specified in rule; and/or

c. Personnel authorized to compound high-risk compounding sterile preparations (CSP) had not completed a media-filled test within past six (6) months.

COUNT I

5. Petitioner realleges and incorporates paragraphs one (1) through four (4) as if fully set forth herein.

6. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

7. Rule 64B16-27.300(3)(a), Florida Administrative Code, provides in pertinent part that each pharmacy shall establish a Continuous Quality Improvement (CQI) Program which shall conduct a review of QREs at least every three months.

8. On or about December 12, 2012, Respondent's CQI records did not contain documentation as to QREs for the months of May and June of 2012.

9. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.300(3)(a), Florida Administrative Code, which requires a review of QREs at least every three months.

COUNT II

10. Petitioner realleges and incorporates paragraphs one (1) through four (4) as if fully set forth herein.

11. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

12. Rule 64B16-27.797(1)(l)4., Florida Administrative Code, provides that for properly stored sterilized high-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and exposed for not more than 24 hours at controlled room temperature, and for not more than 3 days at a cold temperature (2-8 degrees Celsius) and for not more than 45 days in solid frozen state at -20 degrees celsius or colder.

13. On or about December 12, 2012, the Department inspector found sterilized high-risk preparations prepared by Respondent's employees did not pass sterility test or preparations were not properly stored, prior to administration, by exceeding time periods specified in rule.

14. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-

27.797(1)(i)4., Florida Administrative Code, which requires that high-risk preparations are stored at certain temperatures for no more than certain time periods.

COUNT III

15. Petitioner realleges and incorporates paragraphs one (1) through four (4) as if fully set forth herein.

16. Section 465.023(1)(c), Florida Statutes (2012), provides that the board may revoke or suspend the permit of any pharmacy permittee and may fine, place on probation, or otherwise discipline any pharmacy permittee who has violated any of the requirements of Chapter 465, Florida Statutes or any of the rules of the Board of Pharmacy.

17. Rule 64B16-27.797(1)(i)7., Florida Administrative Code, provides that each person authorized to compound high-risk level CSPs demonstrates competency by completing a media-filled test that represents high-level compounding semiannually.

18. On or about December 12, 2012, the Department inspector found personnel, employed by Respondent, authorized to compound high-risk compounding sterile preparations had not completed a media-filled test within past six (6) months.

19. Based on the foregoing, Respondent has violated Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.797(1)(i)7., Florida Administrative Code, which requires each person authorized to compound high-risk level CSPs demonstrates competency by completing a media-filled test that represents high-level compounding semiannually.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, Imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 28th **day of** March, **2013**.

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

JUDSON SEARCY
Assistant General Counsel
Fla. Bar No. 0098772
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444 ex. 8100
Facsimile: (850) 245-4683
Email: judson_searcy@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE MAR 28 2013

PCP: 3-28-13
PCP Members: Weizer + Meshad

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-18422

WELLS PHARMACY NETWORK, LLC
Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or

after July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $1,174.07, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.00	$54.90
Investigation:	2.60	$166.35
Legal:	9.00	$952.82
Compliance:	0.00	$0.00
Sub Total:	12.60	$1,174.07
Expenses to Date:		$0.00
Prior		$0.00

Amount:		
Total Costs to Date:		$1,174.07

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $221.25 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $221.25 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $221.25.

DATED this 5th day of February, 2014.

Judson Searcy
Assistant General Counsel
Fla. Bar No. 98772
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Judson.searcy@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 5th day of February, 2014, to Edwin Bayo, Esq., 2022-2 Raymond Diehl Road, Tallahassee, FL 32308.

Judson Searcy
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

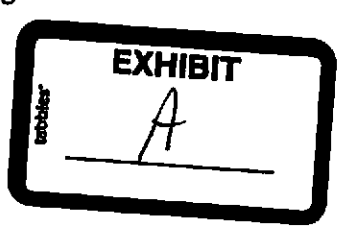
4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-18422** (Department of Health v. **WELLS PHARMACY NETWORK**) are **ONE THOUSAND ONE HUNDRED SEVENTY-FOUR DOLLARS AND SEVEN CENTS ($1,174.07).**

6) The costs for DOH case number(s) **2012-18422** (Department of Health v. **WELLS PHARMACY NETWORK**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case number(s) **2012-18422** (Department of Health v. **WELLS PHARMACY NETWORK**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators



and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of his knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

Sworn to and subscribed before me this 30th day of January, 2014, by Shane Walters, who is personally known to me.

Bernadette Lawanda Hayes

Notary Signature

Bernadette Lawanda Hayes

Name of Notary Printed

Stamp Commissioned Name of Notary Public:

BERNADETTE LAWANDA HAYES
Commission # EE 838344
Expires September 25, 2016
Bonded Thru Troy Fain Insurance 800-385-7019

Complaint Cost Summary

Complaint Number: 201218422

Subject's Name: WELLS PHARMACY NETWORK LLC

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.00	$54.90
Investigation:	2.60	$166.35
Legal:	9.00	$952.82
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	12.60	$1,174.07
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$1,174.07

EXHIBIT 1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201218422

Report Date 01/30/2014

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA107	1.00	$54.90	$54.90	12/17/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**1.00**		**$54.90**			
INVESTIGATIVE SERVICES UNIT						
WI101	0.40	$63.98	$25.59	01/15/2013	4	ROUTINE INVESTIGATIVE WORK
WI101	0.70	$63.98	$44.79	01/28/2013	76	REPORT PREPARATION
WI101	0.20	$63.98	$12.80	01/28/2013	4	ROUTINE INVESTIGATIVE WORK
WI101	0.40	$63.98	$25.59	02/01/2013	76	REPORT PREPARATION
WI101	0.40	$63.98	$25.59	02/06/2013	76	REPORT PREPARATION
WI101	0.50	$63.98	$31.99	02/07/2013	76	REPORT PREPARATION
Sub Total	**2.60**		**$166.35**			
PROSECUTION SERVICES UNIT						
HLL96B	0.30	$106.35	$31.91	02/14/2013	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
HLL96B	0.60	$106.35	$63.81	02/15/2013	25	REVIEW CASE FILE
HLL96B	0.70	$106.35	$74.45	02/15/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.20	$106.35	$21.27	02/15/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFFI
HLL96B	0.30	$106.35	$31.91	02/18/2013	25	REVIEW CASE FILE
HLL96B	0.30	$106.35	$31.91	02/18/2013	64	LEGAL ADVICE/DISCUSSION - BOARD OFFICE,DEPT STAFF OR ATTY GEN OFFI
HLL96B	0.50	$106.35	$53.18	02/18/2013	46	LEGAL RESEARCH
HLL96B	1.20	$106.35	$127.62	02/18/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.50	$106.35	$53.18	02/19/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.40	$106.35	$42.54	02/19/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.60	$106.35	$63.81	02/26/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.10	$106.35	$10.64	03/28/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL96B	0.80	$106.35	$85.08	03/28/2013	79	STIPULATION

EXHIBIT
letter 2

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint

Complaint

Report Date: 01/30/2014

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

February 4, 2014

Edwin Bayo, Esquire
2022-2 Raymond Diehl Road
Tallahassee, FL 32308

Re: DOH vs. Wells Pharmacy Network, LLC
DOH Case Number: 2012-18422

Dear Mr. Bayo:

I am in receipt of your correspondence requesting a hearing not involving disputed issues of material fact concerning the above referenced case. This means that the facts alleged in the Administrative Complaint are uncontested. This is an important distinction because, by law, the Board cannot resolve disputes of material fact in this case or any disciplinary case. Since your client is requesting a hearing not involving disputed issues of material fact, he/she is not admitting the facts alleged in the Administrative Complaint, however, your client is agreeing not to contest these facts and to limit presentation to legal argument, if any, and to matters in mitigation or extenuation.

Our office is now preparing this case to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. Please be advised your client's case will be set at the convenience of the Department and/or the Board and your office will receive notification of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Judson Searcy
Assistant General Counsel

JS/ab

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Wells Pharmacy Network, LLC**
Case Number: 2012-18422

MEMBERS: **Gavin Meshad and Michele Weizer**

DATE OF PCP: **March 28, 2013** **AGENDA ITEM: A-11**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.300(1)(c), Florida Statutes (2012), by violating Rule 64b16-27.300(3)(a), Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.797(1)(i)(4), Florida Administrative Code;

Section 465.023(1)(c), Florida Statutes (2012), by violating Rule 64B16-27.797(1)(i)7, Florida Administrative Code;

____ Probable Cause was **not** found in this case.

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

____ Upon **reconsideration**, dismiss

____ **other** _____

Michele Weizer, PharmD, BCPS 3/28/13
Chair, Probable Cause Panel Date
Board of Pharmacy

STATE OF FLORIDA

DEPARTMENT OF HEALTH

INVESTIGATIVE REPORT

Office: West Palm Beach	Date of Case: 12/12/12	Case Number: 2012 -18422

Subject:	Source:
WELLS PHARMACY NETWORK, LLC 11120 Crown Way S-11 Wellington, FL 33414 O: (561) 955-0920	**DOH / ISU / West Palm Beach** 900 S. US Highway 1, Suite 207 Jupiter, FL 33477 O: (561) 741-4580

Prefix:	License #:	Profession:	Board:	Report Date:
PH	25799	Pharmacy	Pharmacy	2/7/13

Period of Investigation:	Type of Report:
12/20/12 – 2/7/13	FINAL

Possible Violations: F.S. 465.023 (1)(c); 465.022(4); 465.016(1)(e)(r); 456.072(1)(j)(k)(dd); 893.04; FAC 64B16-27.300, 64B16-27.820(1); 64B16-28.108; 64B16-28.140(4): non-compliance with the "Florida Drug and Cosmetic Act"; violating any provision of this chapter or chapter 456; and, non-compliance with the Standards of Practice for Compounding Sterile Preparations.

Synopsis: This investigation is predicated upon receipt of an internally generated complaint (EX 1) submitted by the DOH as a result of a routine community and compounding pharmacy inspection (#112412) at WELLS PHARMACY NETWORK, LLC (WELLS) located in Wellington, FL on 12/12/12. It is alleged that during the course of the routine inspection violations were identified, as noted in the inspection reports (EX 1) including but not limited to: high and low risk sterile compounds are compounded and dispensed without having sterility tests for these compounds in which the beyond use date is being extended past the allowable limits including batches greater than 25 units; controlled substance prescriptions are not completed with patient information; missing CQI meeting minutes; and compounded HCG sterile injected products are shipped directly to physicians to be dispensed to patients, which is not allowed per pharmacy rule.

WELLS owner was notified of the investigation in a letter dated 12/20/12 (EX 2) with a copy of the case summary and the DOH's inspection #112412.

A check of the Department computer records revealed that WELLS PHARMACY NETWORK, LLC is currently licensed as a COMMUNITY PHARMACY.

There is no patient involvement; therefore a patient notification letter was not required.

WELLS PHARMACY NETWORK is not known to be currently represented by an attorney.

On 1/9/13, SCOTT CERAMI, R.Ph and PDM at WELLS PHARMACY, submitted a written response (EX 4) with supporting documents addressing the violations noted in the inspection and corrective actions taken.

Related Case(s): 2012-18423

Investigator/Date:	Approved By/Date:
2/7/13 JACQUELINE MANNING, Investigator WI101	2/7/13 MICHELLE MILLER, Investigations Manager

Distribution: HQ/ISU

Received
Investigative Services
FEB 08 2013
DOH/MQA
Tallahassee HQ

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SCOTT CERAMI, R.Ph. (Witness).....4

IV. EXHIBITS

1. Case Summary, complaint form, copy of DOH pharmacy inspection #112412.....5-11
2. Copy of Subject Notification letter dated 12/20/12.....12
3. Copies of all previous pharmacy inspections at WELLS PHARMACY.....13-14
4. WELL'S response packet.....15-24

*** EXHIBITS CONTAIN INFORMATION WHICH IDENTIFIES PATIENT(S) BY NAME AND ARE SEALED PURSUANT TO SECTION 456.057(10)(a), FLORIDA STATUTES.**

INVESTIGATIVE DETAILS

On 12/20/12 and subsequent dates, this investigator met with DOH Inspector and Sr. Pharmacist, ROBERT DIFIORE, WI 95, to discuss community and compounding pharmacy inspection #112412 (EX1) which DIFIORE performed on 12/12/12 and which generated this complaint. DIFIORE found the following:

- This facility has no supportive documentation of any sterility testing for high and low risk compounded product
- Unacceptable beyond use dating without sterility testing is indicated in the compound records.
- Patient receipt for medications lacks written offer to counsel.
- CQI quarterly meetings and documentation was inconsistent and incomplete.
- No Policy & Procedure available addressing the dispensing of controlled substances.
- Prescriptions for controlled substances were lacking the required information.

SUMMARY OF EXHIBITS/RECORDS/DOCUMENTS

Exhibit 1 contains copies of the completed routine community and compounding pharmacy inspection #112412 on WELLS PHARMACY NETWORK on 12/12/12. Included are DIFIORE's complaint forms and remarks.

Exhibit 3 includes the previous pharmacy inspection performed by DOH Inspector DIFIORE at WELLS. Inspection #111828 done on 11/22/11, which was a new community and compounding inspection that passed with guidance noted since there were no medications on the premises.

Exhibit 4 includes submissions by SCOTT CERAMI, R.Ph, Pharmacy Manager at WELLS PHARMACY in Wellington, FL. The packet contains correspondence, a sample copy of patient's receipt, CQI quarterly meetings and summarization chart documentation form, quality related event form, and copy of controlled substance prescription personnel training

STATEMENT OF ROBERT DIFIORE (SOURCE)
DOH / ISU / West Palm Beach
900 S. US Highway 1, Suite 207
Jupiter, FL 33477
O: (561) 741-4589

On 12/20/12 and subsequent dates, this investigator met with DOH Inspector and Sr. Pharmacist ROBERT DIFIORE, WI 95, to discuss compounding pharmacy inspection #112412 (EX1) which DIFIORE performed on 12/12/12 and which generated this complaint. All communications with DIFIORE are detailed within the INVESTIGATIVE DETAILS section.

STATEMENT OF SCOTT A. CERAMI, R. Ph. (WITNESS)
Business:
11120 Crown Way S-11
Wellington, FL 33414
O: (561) 955-0920

On 1/9/13 a response (EX 4) written by CERAMI, who is the PDM at WELLS PHARMACY, with supports (EX 4) addressing the complaint and corrective actions taken; he essentially stated:

- He received his Pharmacist degree from Long Island University in 2000.
- He is the Pharmacy Manager at WELLS PHARMACY in Wellington since 9/2012.
- WELLS specializes in the compounding of veterinary and equine products.
- Language has been added to the patient's receipt that reads "if you have any questions regarding your medication please call 800-622-4510." A copy was provided (EX 4).
- CQI quarterly meetings and documentation are met. Meetings were held in March and September of 2012. As of 12/28/12, CQI meetings will have written agendas and summarizations.
- WELLS did have a policy and procedure available at the time of the inspections, however addressing concerns regarding controlled substances has been updated. A sample was provided (EX 4)
- All employees have been retrained on the requirements for controlled substance prescriptions (EX 4).
- Sterility testing requirements for batches of over 25 have been reiterated and compounds have been sent for sterility testing.
- A review is underway to address beyond use dating and the formulas used. Compounding records will be changed to follow USP 797 guidelines.

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH

WWW.DOH.STATE.FL.US

ROUTINE ☐ CHANGE LOC ☐ NEW ☒ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

File # 18677

Insp # 111828

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT WELLS PHARMACY NETWORK LLC		PERMIT NUMBER		DATE OF INSPECTION 11/22/2011
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 11120 S CROWN WAY STE 11		TELEPHONE # 561-515-8991	EXT.	ROBERT L WILBUR
CITY WELLINGTON	COUNTY 60	STATE/ZIP 33414		PRESCRIPTION DEPARTMENT MANAGER LICENSE #

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	
Open	9	9	9	9	9	9	x	1. Holly Neary PS45865 (PDM)....Lee Wayne Waits PS36095 (Staff rph)
Close	6	6	6	6	6	12	x	2. Tania Leilani McCabe RPT37710, .. Ashley Hudson RPT 29685
								3. Amy Arthur RPT 364

		SATISFACTORY N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]	☐	☒	☐
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]	☒	☐	☐
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	☒	☐	☐
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]	☐	☒	☐
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	☐	☒	☐
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]	☐	☒	☐
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]	☐	☒	☐
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]	☐	☒	☐
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]	☒	☐	☐
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]	☒	☐	☐
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]	☐	☒	☐
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	☒	☐	☐
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]	☒	☐	☐
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	☒	☐	☐
15	All controlled substance prescriptions contain information required. [893.04, F.S.]	☒	☐	☐
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	☒	☐	☐
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]	☒	☐	☐
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]	☒	☐	☐
19	DEA 222 order forms properly completed. [893.07, F.S.]	☒	☐	☐
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]	☒	☐	☐
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]	☒	☐	☐
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]	☒	☐	☐
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	☒	☐	☐
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]	☒	☐	☐
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]	☒	☐	☐
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]	☒	☐	☐
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]	☒	☐	☐
28	Compounding records properly maintained. [64B16-27.797, F.A.C.]*	☒	☐	☐
29	Unit dose records properly maintained. [465.016(1)(l), F.S.] [64B16-28.118, F.A.C.]	☒	☐	☐
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]	☒	☐	☐

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: New Opening Community/Special P/E Pharmacy inspection conducted with Holly Neary PDM.
No medications currently on site.
Those areas marked as "n/a" are currently not applicable to the new opening inspection.

Reviewed P&P for fraudulent dispensing on controls. Advised must have in place by Dec 2012
Reviewed CQI's, DEA 222's, compounding logs, PDMP reporting,Pedigrees, Unit Dosing, Counterproof Rx pads, biennial inventory, laws and rules.

See CSP inspection form.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Holly Neary PDM

Institutional Representative

11-22-2011
Date

Investigator/Sr. Pharmacist Signature

ID wl95

INV 359 Revised 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

EXHIBIT# 3

00013

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

Standards of Practice for Compounding Sterile Preparations (CSPs)

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

File # 18677
Insp # 111828

ROUTINE ☐ CHANGE LOC ☐ NEW ☒ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

NAME OF ESTABLISHMENT WELLS PHARMACY NETWORK LLC		PERMIT NUMBER		DATE OF INSPECTION 11/22/2011
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 11120 S CROWN WAY STE 11		TELEPHONE # 561-515-8991	EXT.	ROBERT L WILBUR
CITY WELLINGTON	COUNTY 60	STATE/ZIP 33414		PRESCRIPTION DEPARTMENT MANAGER LICENSE #

		SATISFACTORY	N/A	YES	NO
1	Types of sterile compounding prepared (or expected to prepare) per [64B16-27.797, F.A.C.]. Undersigned pharmacist attests:				
	a) High-Risk Level CSPs (If yes, must complete items 5 & 6 - may not answer N/A)				☒
	b) Immediate Use CSPs (If yes, must complete items 7 & 8 - may not answer N/A)				☒
	c) Low-Risk Level CSPs (If yes, must complete items 9 & 10 - may not answer N/A)			☒	
	d) Medium-Risk CSPs				☒
	e) Antineoplastic Drugs (Cytotoxins) (If yes, must complete items 18, 19, 20 & 22 - may not answer N/A)				☒
2	All sterile compounds prepared in barrier isolator? If yes, may answer NA to 3b, 3c, 3d, 4, & 21. [64B16-27.797(5)(e), F.A.C.]	☒			
3	Compounding environment appropriate for Risk Level (certification by independent qualified organization).				
	a) Barrier Isolator?				☒
	b) Anteroom/Ante area?		☒		
	c) Buffer Area (Clean Room)?		☒		
	d) Laminar Air Flow Hood(s)?		☒		
4	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]		☒		
5	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i), F.A.C.]	☒			
6	Personnel authorized to compound high-risk-level CSPs completed a media-filled test within the past 6 months (semiannually). [64B16-27.797(1)(i),F.A.C.]	☒			
7	Preparation time does not exceed 1 hour when preparing immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]	☒			
8	Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]	☒			
9	Storage recommendations in rules are not exceeded when preparing low-risk CSPs. [64B16-27.797(1)(n), F.A.C.]			☒	
10	Personnel authorized to compound low-risk level CSPs completed a media-filled test within the past 12 months. [64B16-27.797(1)(n), F.A.C.]			☒	
11	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]			☒	
12	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]			☒	
13	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]			☒	
14	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]			☒	
15	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]			☒	
16	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]			☒	
17	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation. [64B16-27.797(5), F.A.C.]			☒	
18	Spill kits for antineoplastic agent spills if required. [64B16-27.797(5), F.A.C.]			☒	
19	Current reference material (hard-copy or on-line). [64B16-27.797(5); and 64B16-27.797(1)(2), F.A.C.]	☒			
20	All preparations are compounded in a vertical flow, Class II or biological safety cabinet. [64B16-27.797(6), F.A.C.]			☒	
21	Protective apparel requirements are met. [64B16-27.797(6), F.A.C.]			☒	
22	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]			☒	
23	Documented on-going quality assurance. [64B16-27.797(7), F.A.C.]	☒			
24	Quality assurance audits at regular planned intervals. [64B16-27.797(7), F.A.C]	☒			
25	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]	☒			

Remarks: Holly Neary PS45865 is the PDM of record.
Robert Wilbur RPh was present for inspection (President) as well as Lee Wayne Waits PS36095 staff pharmacist.

Anticipated compounding to be low risk per PDM and to include Hormone therapy, veterinary , Possible HCG compounding. NO HGH compounding expected to be compounded.
Compounds to be patient specific.
Suppliers include Medisca and Letco.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Holly Neary PDM

H Neary
Institutional Representative

11-22-2011
Date

Investigator/Sr. Pharmacist Signature

ID wi95

INV 797 Created 8/11

0001 4

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201218423

SCOTT ANTHONY CERAMI,
RESPONDENT.

NOTICE

TO: SCOTT ANTHONY CERAMI
4859 PINEMORE LANE
LAKE WORTH, FL 33463

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

The purpose of the hearing is to consider a motion for: Hearing - No Disputed Material Facts

Note: Cases shown on the agenda as "timed" items may be heard in a different order or may be heard earlier if all parties are present. Cases are scheduled beginning at 9 a.m.; therefore, it is imperative that you arrive promptly at 9 a.m. and be prepared to be at the meeting for several hours until your case is heard.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

Florida HEALTH

Mission:
To protect, promote & improve the health of all people in Florida through integrated state, county & community efforts.

Rick Scott
Governor

John H. Armstrong, MD, FACS
Surgeon General & Sec

Vision: To be the **Healthiest State** in the Nation

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
PETITIONER,

VS. CASE NO. 201218423

SCOTT ANTHONY CERAMI,
RESPONDENT.

NOTICE

TO: EDWIN A. BAYO
2022-2 RAYMOND DIEHL ROAD
TALLAHASSEE, FL 32308

PLEASE TAKE NOTICE that a disciplinary hearing will be heard before the BOARD OF PHARMACY on Wednesday, April 2, 2014, commencing at 9 a.m. Although the Respondent is not required to be present, it is in their best interest to attend. This hearing will be held at 1001 N. Westshore Boulevard, Tampa, FL 33607, (800) 627-7468.

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CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing Notice of Hearing has been sent by U.S. Mail to the above address(es) this 26th day of February, 2014.

for Tammy Collins
Board Executive Director
BOARD OF PHARMACY
Florida Department of Health
4052 Bald Cypress Way, Bin #
Tallahassee, FL 32399 -

MEMORANDUM

TO: Tammy Collins, Acting Executive Director, Board of Pharmacy
FROM: Judson Searcy, Assistant General Counsel JS
RE: Hearing - No Disputed Material Facts
SUBJECT: DOH v. Scott Anthony Cerami, R.Ph.
DOH Case Number 2012-18423
DATE: January 28, 2014 AB

Enclosed you will find materials in the above-referenced case to be placed on the agenda for final agency action for the **April 2, 2014**, meeting of the board. The following information is provided in this regard.

Subject:	Scott Anthony Cerami
Subject's Address of Record:	4859 Pinemore Lane Lake Worth, FL 33463
Enforcement Address:	4859 Pinemore Lane Lake Worth, FL 33463
Subject's License No:	35168 **Rank:** PS
Licensure File No:	25402
Initial Licensure Date:	9/7/2000
Board Certification:	No
Required to Appear:	No
Current IPN/PRN Contract:	No
Allegation(s):	Ct 1: 465.016(1)(r), FS (2012) 465.022(11)(a), FS (2012) 64B16-27.300(3)(a), FAC Ct 2: 465.016(1)(r), FS (2012) 465.022(11)(a), FS (2012) 64B16-27.797(1)(l)4, FAC Ct 3: 465.016(1)(r), FS (2012) 465.022(11)(a), FS (2012) 64B16-27.797(1)(l)7, FAC
Prior Discipline:	None
Probable Cause Panel:	March 28, 2013; Meshad & Weizer
Subject's Attorney:	Edwin A. Bayo, Esquire 2022-2 Raymond Diehl Road Tallahassee, FL 32308

Complainant/Address:	Department Of Health
Materials Submitted:	Memorandum to the Board
	Motion for Final Order
	Administrative Complaint
	Motion to Assess Costs
	Exhibit A – Affidavit of Fees and Costs Expended
	Exhibit 1 – Complaint Cost Summary
	Exhibit 2 – Itemized Costs by Complaint
	Notification Letter
	Respondent Documents
	Probable Cause Panel Memorandum
	Final Investigative Report with Exhibits 1-4

DISCIPLINARY GUIDELINES:

64B16-27.797: $500 fine, 12 hour Laws & Rules course, and course governing sterile compounds, to $2,000 fine and one year probation; to $2,500 to $10,000 fine and one year suspension followed by two years probation to revocation

PRELIMINARY CASE REMARKS: SECTION 120.57(2) HEARING (INFORMAL)

This is a three count AC alleging violations of Section 465.016(1)(r), Florida Statutes, and 465.022(11)(a), for violations of 64B16-27.300 and 64B16-27.797 for CQI and compounding violations.

On or about December 12, 2012, a Department inspector conducted an inspection of Respondent and observed one or more of the following deficiencies:

a. No documentation of a review of "Quality-Related Events" (QRE) for the months of May and June of 2012;

b. Sterilized high-risk preparations did not pass sterility test or preparations were not properly stored, prior to administration, by exceeding time periods specified in rule; and/or

c. Personnel authorized to compound high-risk compounding sterile preparations (CSP) had not completed a media-filled test within past six (6) months.

Respondent returned a Petition for Hearing Not Involving Disputed Issues of Material Fact electing an informal hearing.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-18423

SCOTT ANTHONY CERAMI, R.PH.,
Respondent.
_____/

MOTION FOR FINAL ORDER AFTER HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACTS

COMES NOW, the Petitioner, by and through its undersigned counsel, and moves the Board of Pharmacy for entry of a Final Order in the above-styled cause on a date and time that has been determined and noticed by the Board. As grounds therefore, the Petitioner would state the following:

1. Petitioner previously filed an Administrative Complaint against Respondent alleging that Respondent had violated the provisions of Florida Statutes, as set forth therein. The Department, by filing the Administrative Complaint, is seeking to discipline the Respondent's license to practice as a pharmacist, thereby affecting the Respondent's substantial interests.

2. On or about April 15, 2013, Petitioner served Respondent with the Administrative Complaint via Respondent's address of record with the

Department of Health. The Department, by serving the Respondent with the Administrative Complaint, provided the Respondent written notice of its decision to seek discipline of the Respondent's license to practice as a pharmacist.

3. The Respondent has filed an Election of Rights Form or other responsive pleading evincing, or has otherwise indicated, that Respondent does not dispute the material facts alleged in the Administrative Complaint.

4. There are no disputed issues of material fact to be resolved by the Board.

5. Respondent has been advised, by a copy of this Motion, that a copy of the investigative file in this case shall be furnished to the Board to establish a prima facie case regarding the violations as set forth in the Administrative Complaint.

WHEREFORE the parties respectfully request the Board of Pharmacy, after allowing the Respondent the opportunity to present oral and/or written evidence in mitigation of the Administrative Complaint, enter a Final Order imposing whatever discipline upon the Respondent's license that the Board deems appropriate.

Respectfully Submitted,

Judson Searcy
Assistant General Counsel
Fla. Bar No. 98772
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Judson.searcy@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the above and foregoing has been provided by U.S. mail this 5th day of February, 2014, to Edwin Bayo, Esquire, 2022-2 Raymond Diehl Road, Tallahassee, FL 32308.

Judson Searcy
Assistant General Counsel

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2012-18423**

SCOTT ANTHONY CERAMI, RPH,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health, by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Scott Anthony Cerami, RPh., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 35168.

3. Respondent's address of record is 4859 Pinemore Lane, Lake Worth, Florida 33463.

4. At all times material to this Administrative Complaint, Respondent was prescription department manager (PDM) of Wells Pharmacy Network, LLC (permittee).

5. On or about December 12, 2012, a Department inspector conducted an inspection of permittee at 11120 South Crown Way, Suite 11, Wellington, Florida 33414, and observed one or more of the following deficiencies:

a. No documentation of a review of "Quality-Related Events" (QRE) for the months of May and June of 2012;

b. Sterilized high-risk preparations did not pass sterility test or preparations were not properly stored, prior to administration, by exceeding time periods specified in rule; and/or

c. Personnel authorized to compound high-risk compounding sterile preparations (CSP) had not completed a media-filled test within past six (6) months.

COUNT I

6. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

7. Section 465.016(1)(r), Florida Statutes (2012), provides that violating any provision of Chapter 465 or Chapter 456, Florida Statutes, or any rules adopted pursuant thereto, constitutes grounds for discipline.

8. Section 465.022(11)(a), Florida Statutes (2012), requires a prescription department manager of a permittee to obtain and maintain all drug records, required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under Chapter 465, Chapter 499, or Chapter 893. The prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

9. Rule 64B16-27.300(3)(a), Florida Administrative Code, provides in pertinent part that each pharmacy shall establish a Continuous Quality Improvement (CQI) Program which shall conduct a review of QREs at least every three months.

10. On or about December 12, 2012, permittee's CQI records did not contain documentation as to QREs for the months of May and June of 2012.

11. Based on the foregoing, Respondent has violated Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by not ensuring permittee's compliance with Rule 64B16-27.300(3)(a), Florida Administrative Code, which requires a review of QREs at least every three months.

COUNT II

12. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

13. Section 465.016(1)(r), Florida Statutes (2012), provides that violating any provision of Chapter 465 or Chapter 456, Florida Statutes, or any rules adopted pursuant thereto, constitutes grounds for discipline.

14. Section 465.022(11)(a), Florida Statutes (2012), requires a prescription department manager of a permittee to obtain and maintain all drug records, required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under Chapter 465, Chapter 499, or Chapter 893. The prescription department

manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

15. Rule 64B16-27.797(1)(i)4., Florida Administrative Code, provides that for properly stored sterilized high-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and exposed for not more than 24 hours at controlled room temperature, and for not more than 3 days at a cold temperature (2-8 degrees Celsius) and for not more than 45 days in solid frozen state at -20 degrees celsius or colder.

16. On or about December 12, 2012, the Department inspector found sterilized high-risk preparations did not pass sterility test or preparations were not properly stored, prior to administration, by exceeding time periods specified in rule at permittee.

17. Based on the foregoing, Respondent has violated Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by not ensuring permittee's compliance with Rule 64B16-27.797(1)(i)4., Florida Administrative Code,

which requires that high-risk preparations are stored at certain temperatures for no more than certain time periods.

COUNT III

18. Petitioner realleges and incorporates paragraphs one (1) through five (5) as if fully set forth herein.

19. Section 465.016(1)(r), Florida Statutes (2012), provides that violating any provision of Chapter 465 or Chapter 456, Florida Statutes, or any rules adopted pursuant thereto, constitutes grounds for discipline.

20. Section 465.022(11)(a), Florida Statutes (2012), requires a prescription department manager of a permittee to obtain and maintain all drug records, required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under Chapter 465, Chapter 499, or Chapter 893. The prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

21. Rule 64B16-27.797(1)(l)7., Florida Administrative Code, provides that each person authorized to compound high-risk level CSPs

demonstrates competency by completing a media-filled test that represents high-level compounding semiannually.

18. On or about December 12, 2012, the Department inspector found permittee personnel authorized to compound high-risk compounding sterile preparations had not completed a media-filled test within past six (6) months.

19. Based on the foregoing, Respondent has violated Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by not ensuring permittee's compliance with Rule 64B16-27.797(1)(i)7., Florida Administrative Code, which requires each person authorized to compound high-risk level CSPs demonstrates competency by completing a media-filled test that represents high-level compounding semiannually.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 28th **day of** March, **2013**

JOHN H. ARMSTRONG, MD, FACS
State Surgeon General and Secretary of Health

JUDSON SEARCY
Assistant General Counsel
Fla. Bar No. 0098772
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444 ex. 8100
Facsimile: (850) 245-4683
Email: judson_searcy@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE MAR 28 2013

PCP: 3-28-13
PCP Members: Weizer + Meshad

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,
Petitioner,

v. CASE NO. 2012-18423

SCOTT ANTHONY CERAMI, R.PH.,
Respondent.
_____/

MOTION TO ASSESS COSTS IN ACCORDANCE WITH SECTION 456.072(4)

COMES NOW the Department of Health, by and through undersigned counsel, and moves the Board of Pharmacy for the entry of a Final Order assessing costs against the Respondent for the investigation and prosecution of this case in accordance with Section 456.072(4), Florida Statutes. As grounds therefore, the Petitioner states the following:

1. At its next regularly scheduled meeting, the Board of Pharmacy will take up for consideration the above-styled disciplinary action and will enter a Final Order therein.

2. Section 456.072(4), Florida Statutes, states as follows:

> In addition to any other discipline imposed through final order, or citation, entered on or

after July 1, 2001, pursuant to this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is not board, shall assess costs related to the investigation and prosecution of the case. Such costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. .

3. The investigation and prosecution of this case has resulted in costs in the total amount of $584.59, based on the following itemized statement of costs:

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.00	$54.90
Investigation:	2.80	$179.14
Legal:	3.30	$350.55
Compliance:	0.00	$0.00
Sub Total:	7.10	$584.59
Expenses to Date:		$0.00
Prior		$0.00

Amount:		
Total Costs to Date:		$584.59

Therefore, the Petitioner seeks an assessment of costs against the Respondent in the amount of $234.04 as evidenced in the attached affidavit. (Exhibit A).

4. Should the Respondent file written objections to the assessment of costs, within ten (10) days of the date of this motion, specifying the grounds for the objections and the specific elements of the costs to which the objections are made, the Petitioner requests that the Board determine the amount of costs to be assessed based upon its consideration of the affidavit attached as Exhibit A and any timely-filed written objections.

5. Petitioner requests that the Board grant this motion and assess costs in the amount of $234.04 as supported by competent, substantial evidence. This assessment of costs is in addition to any other discipline imposed by the Board and is in accordance with Section 456.072(4), Florida Statutes.

WHEREFORE, the Department of Health requests that the Board of Pharmacy enter a Final Order assessing costs against the Respondent in the amount of $234.04.

DATED this 5th day of February, 2014.

Judson Searcy
Assistant General Counsel
Fla. Bar No. 98772
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin #C65
Tallahassee, FL 32399-3265
Telephone: (850) 245-4444
Facsimile: (850) 245-4683
Email: Judson.searcy@flhealth.gov

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Motion to Assess Costs has been provided by U.S. Mail this 5th day of February, 2014, to Edwin Bayo, 2022-2 Raymond Diehl Rd., Tallahassee, FL 32308.

Judson Searcy
Assistant General Counsel

AFFIDAVIT OF FEES AND COSTS EXPENDED

STATE OF FLORIDA
COUNTY OF LEON:

BEFORE ME, the undersigned authority, personally appeared **SHANE WALTERS** who was sworn and states as follows:

1) My name is Shane Walters.

2) I am over the age of 18, competent to testify, and make this affidavit upon my own personal knowledge and after review of the records at the Florida Department of Health (DOH).

3) I am the Operations and Management Consultant Manager (OMCM) for the Consumer Services and Compliance Management Unit for DOH. The Consumer Services Unit is where all complaints against Florida health care licensees (e.g., medical doctors, dentists, nurses, respiratory therapists) are officially filed. I have been in my current job position for more than one year. My business address is 4052 Bald Cypress Way, Bin C-75 Tallahassee, Florida 32399-3275.

4) As OMCM of the Consumer Services and Compliance Management Unit, my job duties include reviewing data in the Time Tracking System and verifying that the amounts correspond. The Time Tracking System is a computer program which records and tracks DOH's costs regarding the investigation and prosecution of cases against Florida health care licensees.

5) As of today, DOH's total costs for investigating and prosecuting DOH case number(s) **2012-18423** (Department of Health v. **SCOTT ANTHONY CERAMI**) are **FIVE HUNDRED EIGHTY-FOUR DOLLARS AND FIFTY-NINE CENTS ($584.59).**

6) The costs for DOH case number(s) **2012-18423** (Department of Health v. **SCOTT ANTHONY CERAMI**) are summarized in Exhibit 1 (Cost Summary Report), which is attached to this document.

7) The itemized costs and expenses for DOH case number(s) **2012-18423** (Department of Health v. **SCOTT ANTHONY CERAMI**) are detailed in Exhibit 2 (Itemized Cost Report and Itemized Expense Report and receipts), which is attached to this document.

8) The itemized costs as reflected in Exhibit 2 are determined by the following method: DOH employees who work on cases daily are to keep track of their time in six-minute increments (e.g., investigators

EXHIBIT
tabbies
A

and lawyers). A designated DOH employee in the Consumer Services Unit, Legal Department, and in each area office, inputs the time worked and expenses spent into the Time Tracking System. Time and expenses are charged against a state health care Board (e.g., Florida Board of Medicine, Florida Board of Dentistry, Florida Board of Osteopathic Medicine), and/or a case. If no Board or case can be charged, then the time and expenses are charged as administrative time. The hourly rate of each employee is calculated by formulas established by the Department. (See the Itemized Cost Report)

9) Shane Walters, first being duly sworn, states that she has read the foregoing Affidavit and its attachments and the statements contained therein are true and correct to the best of his knowledge and belief.

FURTHER AFFIANT SAYETH NOT.

Shane Walters

Shane Walters, Affiant

State of Florida
County of Leon

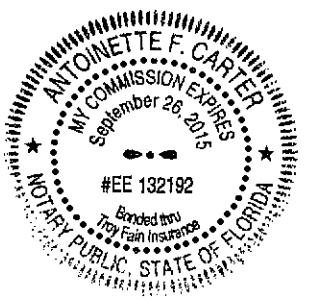
Sworn to and subscribed before me this 3 day of February, 2014, by Shane Walters, who is personally known to me.

Notary Signature

Antoinette F Carter

Name of Notary Printed

Stamp Commissioned Name of Notary Public:



Complaint Cost Summary

Complaint Number: 201218423

Subject's Name: CERAMI, SCOTT ANTHONY

	***** Cost to Date *****	
	Hours	Costs
Complaint:	1.00	$54.90
Investigation:	2.80	$179.14
Legal:	3.30	$350.55
Compliance:	0.00	$0.00
	**********	**********
Sub Total:	7.10	$584.59
Expenses to Date:		$0.00
Prior Amount:		$0.00
Total Costs to Date:		$584.59

EXHIBIT

1

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201218423

Report Date 01/31/2014

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description
CONSUMER SERVICES UNIT						
HA107	1.00	$54.90	$54.90	12/17/2012	78	INITIAL REVIEW AND ANALYSIS OF COMPLAINT
Sub Total	**1.00**		**$54.90**			
INVESTIGATIVE SERVICES UNIT						
WI101	0.40	$63.98	$25.59	12/20/2012	4	ROUTINE INVESTIGATIVE WORK
WI101	0.50	$63.98	$31.99	01/07/2013	4	ROUTINE INVESTIGATIVE WORK
WI101	0.70	$63.98	$44.79	01/28/2013	76	REPORT PREPARATION
WI101	0.30	$63.98	$19.19	02/01/2013	76	REPORT PREPARATION
WI101	0.50	$63.98	$31.99	02/07/2013	76	REPORT PREPARATION
WI101	0.40	$63.98	$25.59	02/26/2013	6	SUPPLEMENTAL INVESTIGATION
Sub Total	**2.80**		**$179.14**			
PROSECUTION SERVICES UNIT						
HLL96B	0.50	$106.35	$53.18	02/15/2013	25	REVIEW CASE FILE
HLL96B	0.30	$106.35	$31.91	02/18/2013	25	REVIEW CASE FILE
HLL96B	0.90	$106.35	$95.72	02/18/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.70	$106.35	$74.45	02/26/2013	28	PREPARE OR REVISE ADMINISTRATIVE COMPLAINT
HLL96B	0.10	$106.35	$10.64	03/28/2013	63	PRESENTATION OF CASES TO PROBABLE CAUSE PANEL
HLL96B	0.70	$106.35	$74.45	03/28/2013	79	STIPULATION
HLL96B	0.10	$101.95	$10.20	01/23/2014	91	BOARD MEETING PREPARATION
Sub Total	**3.30**		**$350.55**			

Total Cost **$584.59**

EXHIBIT
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2

-- FOR INTERNAL USE ONLY --

*** CONFIDENTIAL ***

Time Tracking System
Itemized Cost by Complaint

Complaint 201218423

Report Date 01/31/2014

Staff Code	Activity Hours	Staff Rate	Cost	Activity Date	Activity Code	Activity Description

Division of
Medical Quality Assurance

MQA

*** CONFIDENTIAL ***

Time Tracking System
Itemized Expense by Complaint
Complaint

Report Date: 01/31/2014

Staff Code	Expense Date	Expense Amount	Expense Code	Expense Code Description

SubTotal

Total Expenses

February 5, 2014

Edwin A. Bayo, Esquire
2022-2 Raymond Diehl Road
Tallahassee, FL 32308

Re: DOH vs. Scott Anthony Cerami, R.Ph.
DOH Case Number: 2012-18423

Dear Mr. Bayo:

I am in receipt of your client's petition requesting a hearing not involving disputed issues of material fact concerning the above referenced case. This means that the facts alleged in the Administrative Complaint are uncontested. This is an important distinction because, by law, the Board cannot resolve disputes of material fact in this case or any disciplinary case. Since your client is requesting a hearing not involving disputed issues of material fact, he/she is not admitting the facts alleged in the Administrative Complaint, however, your client is agreeing not to contest these facts and to limit presentation to legal argument, if any, and to matters in mitigation or extenuation.

Our office is now preparing this case to be presented at the next regularly scheduled meeting of the Florida Board of Pharmacy. Please be advised your client's case will be set at the convenience of the Department and/or the Board and your office will receive notification of the date and time approximately two weeks prior to the meeting.

Thank for your attention and cooperation in this matter. Should you have any questions, please feel free to contact this office.

Sincerely,

Judson Searcy
Assistant General Counsel

JS/ab

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SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

JC

MEMORANDUM OF PROBABLE CAUSE DETERMINATION

TO: Department of Health, Prosecution Services Unit

FROM: Chair, Probable Cause Panel, Florida Board of Pharmacy

RE: **Scott Anthony Cerami, R.Ph.**
Case Number: 2012-18423

MEMBERS: **Gavin Meshad and Michele Weizer**

DATE OF PCP: **March 28, 2013** **AGENDA ITEM: A-13**

This matter came before the Probable Cause Panel on the above date. Having reviewed the complete investigative file, recommendations of the Department, and any information submitted by the Subject, and being otherwise fully advised in the premises, the panel finds that:

__X__ **Probable cause exists** and a formal complaint shall be filed for violation of statutes and rules, including but not limited to:

Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022(11)(a), Florida Statutes (2012), by not insuring permittee's compliance with Rule 64B16-27.797(1)(i)4, Florida Administrative Code;

Section 465.016(1)(r), Florida Statutes (2012), by violating Section 465.022 (11)(a), Florida Statutes (2012), by not ensuring permittee's compliance with Rule 64B16-27.797(1)(i)7, Florida Administrative Code;

____ Probable Cause was **not** found in this case.

____ In lieu of probable cause, issue **letter of guidance**

____ Case requires **expert review**

____ Case needs **further investigation**
a)
b)

____ Upon **reconsideration**, dismiss

____ **other** _____

Michele Weizer, PharmD BCPS 3/28/13
Chair, Probable Cause Panel Date
Board of Pharmacy

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STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

FLORIDA DEPARTMENT OF HEALTH
WWW.DOH.STATE.FL.US

Standards of Practice for Compounding Sterile Preparations (CSPs)

ROUTINE ☐ CHANGE LOC ☐ NEW ☒ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

File # 18677
Insp # 111828

NAME OF ESTABLISHMENT		PERMIT NUMBER		DATE OF INSPECTION
WELLS PHARMACY NETWORK LLC				11/22/2011
DOING BUSINESS AS		DEA NUMBER		PRESCRIPTION DEPARTMENT MANAGER
STREET ADDRESS 11120 S CROWN WAY STE 11		TELEPHONE # 561-515-8991	EXT.	ROBERT L WILBUR
CITY WELLINGTON	COUNTY 60	STATE/ZIP 33414		PRESCRIPTION DEPARTMENT MANAGER LICENSE #

		SATISFACTORY	N/A	YES	NO
1	Types of sterile compounding prepared (or expected to prepare) per [64B16-27.797, F.A.C.]. Undersigned pharmacist attests:				
	a) High-Risk Level CSPs (If yes, must complete items 5 & 6 - may not answer N/A)				☒
	b) Immediate Use CSPs (If yes, must complete items 7 & 8 - may not answer N/A)				☒
	c) Low-Risk Level CSPs (If yes, must complete items 9 & 10 - may not answer N/A)			☒	
	d) Medium-Risk CSPs				☒
	e) Antineoplastic Drugs (Cytotoxins) (If yes, must complete items 18, 19, 20 & 22 - may not answer N/A)				☒
2	All sterile compounds prepared in barrier isolator? If yes, may answer NA to 3b, 3c, 3d, 4, & 21. [64B16-27.797(5)(e), F.A.C.]	☒			
3	Compounding environment appropriate for Risk Level (certification by independent qualified organization).				
	a) Barrier Isolator?				☒
	b) Anteroom/Ante area?			☒	
	c) Buffer Area (Clean Room)?			☒	
	d) Laminar Air Flow Hood(s)?			☒	
4	Buffer area does not contain sinks and drains. [64B16-27.797(1)(f), F.A.C.]			☒	
5	Sterilized high-risk preparations pass sterility test OR preparations are properly stored, prior to administration, not exceeding time periods specified in rule. [64B16-27.797(1)(i), F.A.C.]	☒			
6	Personnel authorized to compound high-risk-level CSPs completed a media-filled test within the past 6 months (semiannually). [64B16-27.797(1)(i),F.A.C.]	☒			
7	Preparation time does not exceed 1 hour when preparing immediate use CSPs. [64B16-27.797(1)(j), F.A.C.]	☒			
8	Preparation is properly labeled if preparer does not administer or witness administration when preparing immediate-use CSPs. [64B16-27.797(1) (j), F.A.C.]	☒			
9	Storage recommendations in rules are not exceeded when preparing low-risk CSPs. [64B16-27.797(1)(n), F.A.C.]			☒	
10	Personnel authorized to compound low-risk level CSPs completed a media-filled test within the past 12 months. [64B16-27.797(1)(n), F.A.C.]			☒	
11	P & P includes use of single/multidose containers not to exceed 797 guidelines. [64B16.27-797(4), F.A.C.]			☒	
12	P & P includes verification of compounding accuracy and sterility. [64B16-27.797(4), F.A.C.]			☒	
13	P & P includes personnel training and evaluation in aseptic manipulation skills. [64B16-27.797(4), F.A.C.]			☒	
14	P & P includes environmental quality and control. [64B16-27.797(4), F.A.C.]			☒	
15	Appropriate disposal containers. [64B16-27.797(5), F.A.C.]			☒	
16	Appropriate temperature and transport devices. [64B16-27.797(5), F.A.C.]			☒	
17	Adequate supplies (gloves, mask, etc.) to preserve a suitable environment for aseptic preparation. [64B16-27.797(5), F.A.C.]			☒	
18	Spill kits for antineoplastic agent spills if required. [64B16-27.797(5), F.A.C.]	☒			
19	Current reference material (hard-copy or on-line). [64B16-27.797(5); and 64B16-27.797(1)(2), F.A.C.]			☒	
20	All preparations are compounded in a vertical flow, Class II or biological safety cabinet. [64B16-27.797(6), F.A.C.]			☒	
21	Protective apparel requirements are met. [64B16-27.797(6), F.A.C.]			☒	
22	Disposal of antineoplastic waste meets all applicable requirements. [64B16-27.797(6), F.A.C.]	☒			
23	Documented on-going quality assurance. [64B16-27.797(7), F.A.C.]	☒			
24	Quality assurance audits at regular planned intervals. [64B16-27.797(7), F.A.C]	☒			
25	Compounding personnel skilled and trained based on observation. [64B16-27.797(7), F.A.C]	☒			

Remarks: Holly Neary PS45865 is the PDM of record.
Robert Wilbur RPh was present for inspection (President) as well as Lee Wayne Waits PS36095 staff pharmacist.

Anticipated compounding to be low risk per PDM and to include Hormone therapy, veterinary , Possible HCG compounding. NO HGH compounding expected to be compounded.
Compounds to be patient specific.
Suppliers include Medisca and Letco.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Holly Neary PDM

H Neary
Institutional Representative

11-22-2011
Date

Investigator/Sr. Pharmacist Signature

ID wi95

INV 797 Created 8/11

EXHIBIT# 2

: 00012

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES

COMMUNITY PHARMACY

FLORIDA DEPARTMENT OF HEALTH
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ROUTINE ☐ CHANGE LOC ☐ NEW ☒ CURRENTLY NOT OPERATING ☐ CHANGE OWNER ☐

File # 18677
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INSPECTION AUTHORITY - CHAPTER 465.017, CHAPTER 893.09 AND CHAPTER 456, FLORIDA STATUTES

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CITY WELLINGTON	COUNTY 60	STATE/ZIP 33414		PRESCRIPTION DEPARTMENT MANAGER LICENSE #

PRESCRIPTION DEPARTMENT HOURS								REGISTERED PHARMACIST/INTERN/TECHNICIAN LICENSE #
	Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday	
Open	9	9	9	9	9	9	x	1. Holly Neary PS45865 (PDM)....Lee Wayne Waits PS36095 (Staff rph)
Close	6	6	6	6	6	12	x	2. Tania Leilani McCabe RPT37710, .. Ashley Hudson RPT 29685
								3. Amy Arthur RPT 364

		SATISFACTORY	N/A	YES	NO
1	Rx department hours open 5 days for 40 hours per week. [64B16-28.1081, F.A.C.]			☒	
2	Pharmacy technicians properly identified and supervised. [64B16-27.410, F.A.C.]		☒		
3	Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]		☒		
4	Proper signs displayed. [465.025(7), F.S.] [64B16-28.109(1), F.A.C.] [64B16-28.1081, F.A.C.] [64B16-28.1035, F.A.C.] [64B16-27.1001, F.A.C.]			☒	
5	A verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]			☒	
6	Prescription department has convenient sink/running water. [64B16-28.102(1), F.A.C.]			☒	
7	Prescription department clean and safe. [64B16-28.102(4), F.A.C.]			☒	
8	Proper equipment and references as required. [64B16-28.102(5)(a), F.A.C.]			☒	
9	Medication properly labeled. [465.0255, F.S.] [64B16-28.108, F.A.C.]		☒		
10	Expired medications removed from the shelves. [64B16-28.110, F.A.C.]		☒		
11	CQI Policy and Procedures and quarterly meetings. [766.101, F.S.] [64B16-27.300, F.A.C.]			☒	
12	Board-approved Policy and Procedure implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]		☒		
13	Prescriptions have the date dispensed and dispensing pharmacists. [893.04(1)(c) 6, F.S.] [64B16-28.140(3)(b), F.A.C.]		☒		
14	Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]		☒		
15	All controlled substance prescriptions contain information required. [893.04, F.S.]		☒		
16	Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a Department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].		☒		
17	Prescriptions may not be filled in excess of one year or six months for controls from the date written. [893.04(1)(g), F.S.] [64B16-27.211, F.A.C.]		☒		
18	Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.]		☒		
19	DEA 222 order forms properly completed. [893.07, F.S.]		☒		
20	Controlled substance records and Rx information in computer system is retrievable. [21CFR 1306.22] [64B16-28.140, F.A.C.]		☒		
21	Controlled substance records maintained for 4 years. [465.022(12)(b), F.S.]		☒		
22	Certified daily log OR printout maintained. [21CFR 1306.22(b)(3)] [64B16-28.140(3)(b), F.A.C.]		☒		
23	Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]		☒		
24	Record of theft or significant loss of all controlled substances is being maintained and is being reported to the sheriff within 24 hours of discovery. [893.07(5), F.S.] [465.015, F.S.]		☒		
25	Pharmacy is reporting to the PDMP within 7 days of dispensing controlled substance. [893.055(4), F.S.]		☒		
26	Pharmacy with a retail pharmacy wholesaler permit is reporting sales to the Controlled Substance Reporting system monthly by the 20th of the following month. [499.0121(14), F.S.]		☒		
27	Registered pharmacist properly prescribing. [64B16-27.210, F.A.C.]		☒		
28	Compounding records properly maintained. [64B16-27.797, F.A.C.]*		☒		
29	Unit dose records properly maintained. [465.016(1)(i), F.S.] [64B16-28.118, F.A.C.]		☒		
30	Pedigree records retrievable. [64F-12.012(3)(a)2., (d), F.A.C.]		☒		

* Note: If establishment is engaged in parenteral/enteral compounding, a separate inspection form should be completed.

Remarks: New Opening Community/Special P/E Pharmacy inspection conducted with Holly Neary PDM.
No medications currently on site.
Those areas marked as "n/a" are currently not applicable to the new opening inspection.

Reviewed P&P for fraudulent dispensing on controls. Advised must have in place by Dec 2012
Reviewed CQI's, DEA 222's, compounding logs, PDMP reporting,Pedigrees, Unit Dosing, Counterproof Rx pads, biennial Inventory, laws and rules.

See CSP inspection form.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

PRINT NAME OF RECIPIENT Holly Neary PDM

Institutional Representative

11-22-2011
Date

Investigator/Sr. Pharmacist Signature

ID wi95

INV 359 Revised 10/11, 9/11, 10/10, 10/09, 5/06, 12/02, 12/00

: 00013

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March 14, 2014

John Major
19811 Gulf Blvd #401
Indian Shores, FL 33785

RE: Pharmacist Examination Application

Dear Mr. Major,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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July 25, 2013

John Major
19811 Gulf Blvd #401
Indian Shores, FL 33785

RE: Pharmacist Examination Application

Dear Mr. Major:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, August 14, 2013. The meeting is being held at the Rosen Plaza Hotel, 9700 International Drive, Orlando, FL 32819, (407) 996-9700. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2201-43928✓

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

06/19/2013 295.00
ID: 43928 Type: F
BT: 3023406
VL: 912068367

ITEM #2 –PHARMACIST EXAMINATION APPLICATION FOR U.S. AND PUERTO RICO GRADUATES
FEE: $295.00

Please print or type legibly.

1. Biographical data

Last name	First name	Middle name
MAJOR	JOHN	STEPHEN

Street address (ML – Mailing Address)	City	State	Zip
19811 Gulf Blvd. #401	Indian Shores	FL	33785

Work address (PL – Practice Location)	City	State	Zip
N/A			

Home phone number	Business phone number	E-mail address
(303) 789-0417		johnmajor11@hotmail.com

Date of birth	Place of birth
07/27/1959	Washington, D.C.

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☒ Male ☐ Female
RACE: ☒ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. *Use a separate sheet, if necessary.*

Yes _____ No X

Name	Date

4. Name of University, College or School of Pharmacy attended

University of Colorado

5. Date of graduation	6. Type of degree earned	7. Have you ever been licensed as an intern in Florida?
5/1982	B.S., Pharmacy	Yes _____ No X Intern License number: _____

WL

8. Are you planning to transfer your NAPLEX® score to Florida? If yes, please indicate approximate date of transfer.	9. Did you transfer your NAPLEX® score to Florida within the past three (3) years?
Yes ____ Date of transfer: ____ No X	Yes ____ Date of exam: ____ No X

10. Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?

Yes X No ____

11. Have you ever applied to take the Florida Pharmacist Examination? If yes, please indicate the date.

Yes ____ No X Date ____

12. List all experience earned as an intern. If you have been a registered pharmacist for at least one (1) year, list only your pharmacist experience. If you graduated after January 1, 2001 with a Pharm.D. Degree, it is not necessary to complete this section. Note: you must submit one (1) Internship or Work Experience Form - Form B (Item #4) for each employer listed below. *Use a separate sheet, if necessary.*

Dates	Employer	Location	Intern or pharmacy experience	Total hours
9/1998 - 9/2000	Rocky Mtn. Drug Consultation	Denver, CO	2 yrs R.Ph	
2/1997 - 10/1998	Kenneth Pharm.	Denver, CO	1.5 yrs R.Ph	
4/1987 - 6/1990	Safeway Pharm.	Denver CO	3 yr. R.Ph.	

13. List all state(s) in which you have held or currently hold a pharmacist license. Note: you must submit one (1) Licensure Verification Form (Item #5) for each state listed below. *Use a separate sheet, if necessary.*

State	License number	Date issued
CO	11495	7/82

14. Special testing accommodations – please indicate if you require special testing accommodations due to a disability, or if you have a religious conflict with the scheduled examination date. **If yes, complete the "Application for Candidates Requesting Special Testing Accommodations in Accordance with the Americans with Disabilities Act," form DH-MQA 4000, 6/08, which may be downloaded from the Department's website at http://www.doh.state.fl.us/mqa/exam/spectest.htm, or you may contact Testing Services by phone at (850) 245-4252 for detailed information and an application. All requests must be in writing and include supporting documents.**

Yes ____ No X

15. Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes X No ____

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

20. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state?
Yes X No _____
21. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No X
22. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No X
23. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If no, go to question #25.)
Yes X No _____
24. If "yes" to 23, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes N/A No _____
24a. If "yes" to 23, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6) (a), Florida Statutes).
Yes N/A No _____
24b. If "yes" to 23, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes X No _____
24c. If "yes" to 23, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes X No _____
25. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes _____ No X
25a. If "yes" to 25, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes _____ No _____
26. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 27.)

Yes _____ No X
27. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No _____ N/A
28. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 28a and 28b.) Yes _____ No X
28a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____ N/A
28b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____ N/A
29. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes_____ No X (If yes, provide supporting documentation)
30. If "yes" to any of the questions 23 through 29 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.) Yes X No _____
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 16-29, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Applicant Signature _____ Date 6/9/2013

NOTE: Please check to be sure that you have answered all of the questions above.

Attn: Beth Ranne 8506176438

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #3 - CERTIFICATE OF PHARMACY EDUCATION (FORM A)

Please print or type legibly.

Part I. – To be completed by applicant and forwarded to the College of Pharmacy for completion of Part II below.

Last Name	First Name	Middle Name
Major	John	S.

Maiden Name/Surname	Date of Graduation
	May 21, 1982

Mailing Address	City	State	Zip
19811 Gulf Blvd #401	Indian Shores	FL	33785

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy

University of Colorado School of Pharmacy

Mailing Address	City	State	Zip
12850 E. Montview Blvd	Aurora	CO	80045

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
Bachelor of Science Pharmacy	May 21, 1982	From: 8/1/79 To: 5/21/82

The information recorded above is true and correct according to the official records of this institution. Failure to include the school seal may result in a delay in processing the applicant's application.

Beverly Brunson
Print Name

Signature

Director of Student Services
Title

7/17/13
Date

(SCHOOL SEAL)

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

Ms. Elizabeth Ranne
850 617 6438

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #4 – INTERNSHIP OR WORK EXPERIENCE FORM (FORM B)

Please print or type legibly.

1. Biographical information

Applicant name	Intern/pharmacist license number	Phone number
JOHN S. MAJOR	CO # 11495	303 859-9607

Street address	City	State	Zip
19811 Gulf Blvd #401	Indian Shores	FL	33785

2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.

Yes X No _____ Date 6/15/13

I HEREBY APPLY FOR INTERNSHIP OR WORK EXPERIENCE CREDIT AS OUTLINED BELOW UNDER THE SUPERVISION OF:

3. Pharmacy information

Supervising Pharmacist's name	License number
Debra Devereaux, R.Ph.	CO # 0010501
Pharmacy name	**Permit number**
University Hospital Inpatient Pharmacy	

Street address	City	State	Zip
4200 E. 9th Ave	Denver	CO	80203

Phone number	4. Dates of experience
303-493-8337	From: 6/1/1980 To: 5/1/1982

5. Average number of hours per week	6. Total hours of experience
30	2084

(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)

Applicant's Signature _____ Date 7/14/13

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and are available for inspection by the Board of Pharmacy.

c/o John Devereaux
Preceptor/Supervisor's Signature _____ Date 7/12/13

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

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STATE OF FLORIDA
BOARD OF PHARMACY

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Vicki R. Kenon
DATE 8/28/02

IN RE: THE APPLICATION FOR
LICENSURE OF

JOHN STEPHEN MAJOR
_____/

ORDER OF INTENT TO DENY

THIS MATTER came before the Board of Pharmacy pursuant to Section 120.60 and Section 465.007, Florida Statutes on August 13, 2002, in Orlando, Florida. The Board considered the application for licensure and voted to DENY said application. The Board hereby states as grounds for this decision that the applicant has had prior disciplinary actions against licenses to practice dentistry and pharmacy in the State of Colorado, including the revocation of said licenses. Furthermore, the applicant has a history of impairment. The applicant is therefore ineligible for licensure pursuant to §§456.072(1)(f); 465.016(1)(h), and 465.016(1)(d), Florida Statutes.

This Order serves as notice to the applicant of the Board's intended action on the application for licensure. Furthermore, notice is hereby provided that the applicant has the right to request an administrative hearing to review the intended action of the Board of Pharmacy. Any such hearing would be conducted in accordance with the provisions of Sections 120.569 and 120.57, Florida Statutes, and Rule Chapter 28-106, Florida Administrative Code. The applicant may request a formal hearing pursuant to Sections 120.569 and 120.57(2), Florida Statutes. If a formal hearing is desired, the applicant must file with the Board a petition that substantially complies with the requirements of Rule Section 28-106.201, Florida Administrative Code, including a statement of the material facts in dispute. At any hearing the parties will have the right to be represented by an attorney or other qualified representative, to take testimony, to

call or cross-examine witnesses, to have subpoena and subpoena duces tecum issued, and to present written evidence or argument. Pursuant to the provisions of Rule Section 28-106.111, Florida Administrative Code, the applicant must affirmatively request a hearing on this matter within twenty-one (21) days of service of this Order. Unless a written request for a hearing is received on or before the above stated deadline, the Order of the Board shall in accordance with the provisions of Section 120.59, Florida Statutes, and Rule Section 28-106.111, Florida Administrative Code, become final. Petitions may be filed with the Executive Director of the Board of Pharmacy, 4052 Bald Cypress Way, BIN # C-04, Tallahassee, Florida 32314-6330.

MEDIATION

MEDIATION IS NOT AVAILABLE IN THIS MATTER.

DONE and ORDERED this 26th day of August, 2002, by the Florida Board of Pharmacy.

JOHN D. TAYLOR, R.Ph.
EXECUTIVE DIRECTOR

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Order has been provided by United States Mail to: John Stephen Major, R.Ph., 12923 Arbor Isle Drive, Tampa, FL 33637, this 28th day of August, 2002.

Marci Boyett

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2/14/2014

To the Florida Board of Pharmacy:

I am requesting to be placed on the agenda for the upcoming meeting in April. In early November, I completed and successfully passed the Naplex, Florida MPJE and continuing education requirements for licensure as a pharmacist. In December, 2013, I submitted to an evaluation through PRN which fulfills the Board's directive for licensure. I can and will demonstrate that I am beyond reproach in adhering to my sobriety and have currently tested negative with UDS, hair follicle and Peth testing. I have attempted to comply with the requests made upon me from PRN and am willing to sign a contract with them immediately. They have suggested that I complete a residential rehabilitation program, which for me at this time is extremely cost prohibitive at over $14,000 per month. I am asking the Board to grant licensure based on completion of their requirements and sign a contract with PRN stating that I will complete an outpatient program and submit to all testing required. I am asking the Board for licensure contingent upon signing a contract with PRN. It is my intent to demonstrate my commitment to sobriety and prove my abilities to execute my duties as a pharmacist as outlined by the Florida Board of Pharmacy. I would appreciate the opportunity to complete an intensive outpatient program while permitted to practice pharmacy, even if I must do so provisionally.

It is my humble request that I be permitted to plead my case before the Board of Pharmacy, as requested, on April 1, 2014, supplying adequate evidence that I am deemed worthy of your consideration to act in the capacity of performing the duties of a pharmacist in the state of Florida. Thank you in advance for your consideration.

Sincerely,

John Major

STATE OF FLORIDA
BOARD OF PHARMACY

IN RE: THE APPLICATION OF

JOHN MAJOR
_____/

NOTICE OF INTENT TO APPROVE LICENSE WITH CONDITIONS

This matter appeared before the Board of Pharmacy at a duly-noticed public meeting held on August 14, 2013, in Orlando, Florida, for consideration of an application for a license as a pharmacist by examination. The applicant was present. Upon consideration of the information provided, and being otherwise advised in the premises, the Board has determined that the application for a license as a pharmacist by examination is conditionally approved with the following conditions and restrictions on licensure:

1. The applicant may sit for the licensure examination.
2. Prior to the issuance of a license, the applicant shall obtain an evaluation from the Professionals' Resource Network (PRN) and comply with any recommendation made by PRN within 90 days from the date of entry of this order.
3. If PRN does not recommend a contract, then the license shall issue unencumbered, upon notification of same to the Chair of the Board.
4. If PRN recommends a contract, then the license shall issue upon PRN's notification to the Chair of the Board that the applicant is in compliance with a recommended contract and the applicant is able to practice with reasonable skill and safety.
5. The Board delegates the authority to assess compliance with this Notice and authorizes issuance of the license when its Chair finds the applicant has met the above listed condition.

6. The Board proposes these restrictions for the following reasons:

a. Applicant's file establishes that applicant has a history of substance abuse and that the applicant has prior discipline in Colorado and the Board has previously denied the application for licensure as a pharmacist in Florida.

b. Pursuant to Section 456.072(1)(z), Florida Statutes, the Board may deny a license, grant with restrictions or conditions if the applicant is unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals or other type of material, or as a result of any mental or physical condition. Pursuant to 456.072(1)(f), Florida Statutes, the Board may deny a license, issue with restrictions or conditions, if the applicant has had "a license or authority to practice any regulated profession revoked, suspended, or otherwise acted against, including the denial of a license [.].. ."

c. Pursuant to Section 456.072(2), Florida Statutes the Board is authorized to deny a license application or issue a license with conditions or restrictions for any violations under Section 456.072(1) or the Florida Pharmacy Act.

This Notice shall become effective upon filing with the Clerk of the Department of Health; and will become a Final Order if no further action is taken within the time period stated below.

DONE AND ORDERED this 9 day of September, 2013.

BOARD OF PHARMACY

Mark Whitten, Executive Director *for*
Albert Garcia, BPharm, Chair

NOTICE OF RIGHT TO HEARING

THIS NOTICE CONSTITUTES A FINAL ORDER AND FINAL AGENCY ACTION IF NO REQUEST FOR A HEARING IS RECEIVED BY THE BOARD ON OR BEFORE THE TWENTY-FIRST DAY AFTER THE APPLICANT'S RECEIPT OF THE NOTICE. THE APPLICANT MAY REQUEST A HEARING BY FILING AN APPROPRIATE PETITION WITH THE EXECUTIVE DIRECTOR OF THE BOARD AT 4052 BALD CYPRESS WAY, BIN # C-04, TALLAHASSEE, FLORIDA 32399-3256. THE APPLICANT MAY PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT BEFORE AN ADMINISTRATIVE LAW JUDGE PURSUANT TO SECTION 120.57 (1), FLORIDA STATUTES, OR FOR A HEARING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT PURSUANT TO SECTION 120.57 (2) FLORIDA STATUTES.

A PETITION FOR A HEARING INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28-106.201, FLORIDA ADMINISTRATIVE CODE, INCLUDING A STATEMENT OF ALL DISPUTED ISSUES OF MATERIAL FACT. THE BOARD MAY REFER A PETITION TO THE DIVISION OF ADMINISTRATIVE HEARINGS FOR ASSIGNMENT OF AN ADMINISTRATIVE LAW JUDGE ONLY IF THE PETITION IS IN SUBSTANTIAL COMPLIANCE WITH THE RULE REQUIREMENTS. A PETITION FOR A PROCEEDING NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT MUST CONTAIN INFORMATION REQUIRED BY RULE 28.106.301 FLORIDA ADMINISTRATIVE CODE, INCLUDING A CONCISE STATEMENT OF THE ULTIMATE FACTS ALLEGED, AS WELL AS THE RULES AND STATUTES WHICH ENTITLE PETITIONER TO RELIEF.

IN ACCORDANCE WITH SECTION 120.573, FLORIDA STATUTES MEDIATION IS NOT AVAILABLE.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing has been furnished by Certified Mail to John Major at 19811 Gulf Boulevard, # 401, Indian Shores, Florida 33785; by electronic mail to David D. Flynn, Assistant Attorney General, david.flynn@myfloridalegal.com ; this 10th day of September, 2013.

Angel Sanders

7012 3050 0001 9149 2981

Deputy Agency Clerk

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Collins, Tammy

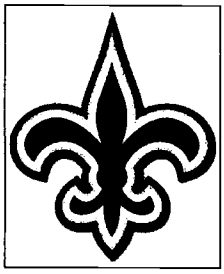
From: Marty Landry MD FACR [doclandry1@yahoo.com]
Sent: Thursday, February 27, 2014 1:17 PM
To: Collins, Tammy; johnmajor11@hotmail.com
Subject: John Major DDS

Dear Ms. Collins,

I have know Dr Major since the day he walked in to my AA home group 3 or so months ago and, shortly thereafter, he asked me to be his sponsor. He has attacked the 12 steps like few people I have worked with and he has once again embraced sobriety. I know that he has had long-term sobriety in the past. After what is hopefully his last short term venture into "mission impossible", he seems poised to re-acquire long term success, a day at a time. He is a terrific young man and someone that I would be very comfortable referring my patients to!

Abner Martin "Marty" Landry III, MD

Medical Aesthetic Arts
727-586-0545



Jay,

Please let Mr. Major know the day and location of the meeting where he will appear.

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Thursday, March 06, 2014 10:25 PM
To: Collins, Tammy
Subject: RE: Dr. Landry's letter and Patient placement criteria
Importance: High

Dear Ms. Collins,

There is no option but to appear before the Board unless PRN relents somewhat on their recommendation. I am
only trying to sign a long-term contract with PRN and am doing the best that I can possibly do. I have fulfilled all of
the obligations of the August Board Order.
Am I scheduled to appear on the morning of April 1? Please let me know what time I am scheduled for so I can make arrangements.

Best Regards,
John Major

From: Collins, Tammy
Sent: Thursday, March 06, 2014 6:54 PM
To: 'john major'
Subject: RE: Dr. Landry's letter and Patient placement criteria

Mr. Major,

Because you are seeking an alteration to the official Order of the Board, and/or that the Board review your request for consideration on your issues with PRN, the absolute only alternative you have available is to attend the meeting with all board members present. I do not need any other documentation from you at this time other than, do you want to appear before the Board or not? If you choose not to appear, the official filed Order of the Board will stand as is and you will not be able to obtain a license until you have complied with all terms including the recommendations of PRN.

Please let me know immediately if you would like to move forward with your request to appear before the Board or if you would like to pull your case from the agenda. That is the only information I need, and the only options you have available.

Sincerely,

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Thursday, March 06, 2014 2:00 PM
To: Collins, Tammy
Subject: RE: Dr. Landry's letter and Patient placement criteria

Dear Ms. Collins,

I have truly tried very hard to accommodate PRN with their wishes; at this point, I would like someone to intervene in this process without having to go before the Board. I can't afford the residential treatment
they want, and they have wavered between requiring residential treatment for health professionals or Salvation Army residential, which would not benefit anyone and doesn't make sense.

PRN has a loan fund which they will not share with me. I do not need a loan if they will allow me to complete outpatient treatment, and I certainly meet the criteria for outpatient instead of residential. Can the Board member intervene before the meeting as was planned? I will submit any drug testing to the Board ASAP.

Thank you kindly for your help,
John Major

Subject: RE: Dr. Landry's letter and Patient placement criteria
Date: Fri, 28 Feb 2014 11:24:09 -0500
From: Tammy.Collins@flhealth.gov
To: johnmajor11@hotmail.com

Mr. Major,

I will add your statement below and a copy of the information from the link you emailed to your documents in the agenda.

Sincerely,

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Friday, February 28, 2014 7:45 AM
To: Collins, Tammy
Subject: Dr. Landry's letter and Patient placement criteria
Importance: High

Dear Ms. Collins,

Dr. Landry's letter yesterday makes reference to my other profession as a dentist. Although I haven't practiced dentistry in a number of years, Dr. Landry knows that I am both a pharmacist and dentist, and he can reference pharmacy in the letter if the Board requires it.

Again, I am willing to submit to any drug test at any time the Board wants prior to and after the Board meeting. I would make an appointment today for additional testing if the Board requests it, and I wish I had known I had to have all testing completed by today (2/28).

Finally, I am emailing you a copy of the patient placement criteria crosswalk issued by the American Society of Addiction Medicine. This is the criteria used to determine whether a patient should be placed in inpatient, residential or outpatient treatment for substance abuse. A certified addictionologist, Dr. Dave Duresky, stated I do not require residential treatment at all, and outpatient treatment is the only placement for me. I can fax this separately to add to the agenda if you would like. However, Dave can't have a statement prepared for the agenda by today.

Kind Regards,
John Major

From: Collins, Tammy
Sent: Thursday, February 27, 2014 12:12 PM
To: 'john major'
Subject: RE: Board evaluation

Your sponsor may email it directly to me, I will provide the information to the Board on the agenda with your file. You sponsor may provide any information they have personal knowledge of about yourself, and your recovery process.

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy

Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Thursday, February 27, 2014 11:53 AM
To: Collins, Tammy
Subject: Re: Board evaluation

Thank you very much, Ms. Collins. My sponsor will email a copy of his statement to me and directly to the Board if you would like. What details would you like him to include?
Thanks
John

Sent from my iPhone

On Feb 27, 2014, at 11:39 AM, Tammy.Collins@flhealth.gov wrote:

Mr. Major,
It is outside of my authority to intervene with this process, and you would need to get a copy of your evaluation directly from PRN. The copy provided to our office is considered confidential material, and may not be shared by us with anyone but the Board.
My final statement is for you to appear at the April meeting and discuss this in its entirety with the Board. PRN will be present, and the Board would have the authority to discuss your situation with all parties at that time.

Sincerely,

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Thursday, February 27, 2014 11:24 AM
To: Collins, Tammy
Subject: Re: Board evaluation

I'll see if I can get that. I can get the evaluation. I've been qualified to be licensed since early November and will wait for the Board to take additional labs. Can I encourage you to discuss this now with PRN? I could use your help and am willing to sign up for outpatient if I am licensed. At that point, I will have health insurance.
Kind Regards,

John Zmajor

Sent from my iPhone

On Feb 27, 2014, at 11:13 AM, Tammy.Collins@flhealth.gov wrote:

Mr. Major,

We already have the report from PRN and we have your personal statement. This information will be presented to the Board for their review and consideration at the April meeting. I do not recommend anything further outside of the Order of the Board. No person or entity outside of the Board can suggest alternatives to the Order that they imposed and doing so would not necessarily be helpful. The only recommendation I do have is that you appear at the meeting to discuss your case directly with the Board in April.

If you like, you may provide a statement from your sponsor. I would need that document sent by noon tomorrow.

Sincerely,

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Thursday, February 27, 2014 10:42 AM
To: Collins, Tammy
Subject: Re: Board evaluation

Dear Ms. Collins
I have only taken one test and one needs to be scheduled by appointment. I don't necessarily want to ask the Board to do this, but I don't have health insurance and can't afford the 20000 fee that Florida Recovery would charge. The only other option they gave me is Salvation Army, and they require a six month stay. My urinalysis for my evaluation in December was 100 percent clean. I am deeply involved in AA, have a physician sponsor in AA who doesn't understand why I would need inpatient if I'm willing to sign a contract with PRN, and I haven't been offered that yet.
I'm doing everything I can. I even offered another less expensive program last month but was refused. I want to work with PRN but PRN does not want to work with me. If you have other suggestions, please let me know. PRN, for whatever reason, has threatened to close my file even before I've had a contract. Have you received the evaluation?
Thanks
John

Sent from my iPhone

On Feb 27, 2014, at 10:27 AM, Tammy.Collins@flhealth.gov wrote:

Mr. Major,

Information will not be presented to the Board that is not on this agenda. The Board will be receiving a few thousand pages of information all together, and they are required to receive all information well in advance of the actual Board meeting in order to enable them to make well informed decisions on each case.

Frankly, I am not recommending that you take a step that the Board has not requested that you take as there is absolutely no guarantee they will accept or consider the information unless it is supported by PRN as per their Order; however, that is up to you to decide. Can you tell me when you are expecting to have documents available? Have you already taken the tests you are referring to?

Sincerely,

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Thursday, February 27, 2014 10:14 AM
To: Collins, Tammy
Subject: Re: Board evaluation

Dear Ms. Collins,
These are lab test results which won't be ready by tomorrow. I was hoping the Board will accept them since it won't take long to peruse them. I'm really trying to work with everyone. I have not heard back from PRN in 3 weeks regarding this issue.

Kind Regards
John Major

Sent from my iPhone

On Feb 27, 2014, at 10:06 AM, Tammy.Collins@flhealth.gov wrote:

Mr. Major,

If you have anything you want the Board to see, you need to send it to this office now so it can be added to the agenda materials. You may fax documents directly to Elizabeth Ranne at (850) 617-6438.

The deadline to provide materials for Board review was February 14, and I will not accept any additional documents after 12:00 p.m. tomorrow, February 28, 2014. The Board can only deliberate on information that has been presented to them on the agenda, in advance of the meeting date.

Sincerely,

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614
Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Thursday, February 27, 2014 9:47 AM
To: Collins, Tammy
Subject: Re: Board evaluation

Thank you, Ms. Collins. I can submit lab results directly to the Board thus week if needed. I am asking to complete an outpatient program and sign a contract with PRN. I'm not asking to attend inpatient.....it is not necessary now nor will it be in the future. Please let me know where to submit test results. I am doing the best and am completely sober. I'll report directly to the Board if necessary,
Best Regards
John Major

Sent from my iPhone

On Feb 27, 2014, at 9:14 AM, Tammy.Collins@flhealth.gov wrote:

Dear Mr. Major,

Your request is being added to the April 2014 Pharmacy Board meeting agenda. You will receive a notice detailing the meeting location, date and time within the next few weeks. This office does not have authority to recommend a treatment center. You will have to make your appeal directly to the Board during the meeting.

Sincerely,

Tammy Collins, CPM
Acting Executive Director
Florida Department of Health
Board of Pharmacy
Direct line (850) 245-4614

Reception area (850) 245-4292
Direct Fax (850) 413-6982

From: john major [mailto:johnmajor11@hotmail.com]
Sent: Wednesday, February 26, 2014 8:42 AM
To: Ranne, Elizabeth
Subject: Fwd: Board evaluation

Dear Ms. Ranne,
I can't afford Florida Recovery Center (where the evaluator has his office), and the only other option in Florida that PRN offered is Salvation Army, which requires a 6 month stay.
I can afford intensive outpatient and have told PRN this. I cannot afford nearly 20 thousand (or more) for the only center in Florida they will accept.
I pray that I'm on the agenda. I will send you all results if you designate a center where the Board prefers that I test. That is
All that I can do, and I am doing the best that I can.
Kind Regards,
John Major

Sent from my iPhone

Begin forwarded message:

From: john major <johnmajor11@hotmail.com>
Date: February 25, 2014 at 10:03:11 AM EST
To: Elizabeth.Ranne@flhealth.gov
Subject: Board evaluation

Dear Ms. Ranne,
I will submit totally negative recent results of hair, urinalysis and peth testing to the Board. If there is a certain testing agency the Board prefers, please apprise me. I have done everything possible to work with PRN, including suggesting an inpatient program which they dismissed. Their suggestion of Salvation Army is not possible; it requires a 6 month stay! I will call later to discuss.

Best Regards
John Major

Sent from my iPhone

March 14, 2014

Samford Jones
245 Inverrary Drive
Destin, FL 32541

RE: Pharmacist Endorsement Application

Dear Mr. Jones,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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2201

F -44243

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FEB 13 2014

Florida Board of Pharmacy

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 245-4292
www.doh.state.fl.us/mqa/pharmacy

ITEM #2 – PHARMACIST ENDORSEMENT APPLICATION
FEE: $295.00

Please print or type legibly.

1. Biographical Data			
Last Name	**First Name**	**Middle Name**	
JONES	SANFORD	CHARLES	
Street Address (ML – Mailing Address)	**City**	**State**	**Zip**
245 INVERRARY DR.	DESTIN	FL	32541
Work Address (PL – Practice Location)	**City**	**State**	**Zip**
60 S. HOLIDAY RD.	MIRAMAR BEACH	FL	32550
Home Phone Number	**Business Phone Number**	**E-Mail Address**	
770-548-9640	850-375-0368	SCJONESRPH@GMAIL.COM	
Date of Birth	**Place of Birth**		
9/25/58	NEW HAVEN, CT.		

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☒ Male ☐ Female
RACE: ☒ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the changes below. *Use a separate sheet, if necessary.* ~~SA~~

Yes X No _____

NAME	**DATE**
SANDY C. JONES	(NICKNAME)

4. Name of university, college or school of pharmacy attended:
MASSACHUSETTS COLLEGE OF PHARMACY

5. Date Of Graduation	**6. Type Of Degree Earned**	**7. Have you ever been licensed as an intern in Florida?**
5/2/1981	B.S. PHARM	Yes _____ No X Intern License Number: —

8. Please indicate the date you successfully completed the NAPLEX examination.

Date 9/1981

9. Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?

Yes Y No _____

10. Method of application - Please select one of the methods of application listed below; you must submit proof that the requirement you choose has been met.

X A. Two years of active practice within two (2) of the last five (5) years.

_____ B. Successful completion of an internship within the immediately preceding two (2) years.

PLEASE NOTE: If you have been licensed in another state in excess of 2 years from the date of your application you must choose A and have completed 30 hours of continuing education in the previous two (2) calendar years. If you choose "B" your internship date will be determined by the Board based on your graduation date, unless the state board of pharmacy where your hours were earned submits the certification of intern hours earned in that state within the preceding two (2) years.

11. List two years work experience if you are applying under 10A Note: you must submit one (1) Internship or Work Experience Form – Form B (Item #4) for each employer listed below. ***Use a separate sheet, if necessary.*** **List internship experience if you are applying under 10B.**

Dates	Employer	Location	Intern Or Pharmacy Experience	Total Hours
2/10-PRESENT	CVS/PHARMACY	MIRAMAR BEACH FLORIDA	R+ EXP	7940

12. List all jurisdictions in which you have been licensed as a pharmacist. Note: you must submit one (1) Licensure Verification Form (Item #5) for each listed below. ***Use a separate sheet, if necessary.***

State or U.S. Jurisdiction	License Number	Date Issued
CT.	PCT.0005839	9/1981
GEORGIA	RPH018975	10/23/1996
SOUTH CAROLINA	9268	2/6/1997

13. Special Testing Accommodations – please indicate if you require special testing accommodations due to a disability, or if you have a religious conflict with the scheduled examination date. **If yes, complete the Request for an Application for Testing Accommodations (item #6) and submit it to Testing Services. You may also contact Testing Services by telephone (850) 245-4252 for detailed information and an application. All requests must be made in writing and include supporting documents.**

Yes _____ No X

14. Have you ever been convicted of, or entered a plea of guilty, nolo contendre, or no contest, to a crime in any jurisdiction other than a minor traffic offense?

Yes _____ No X

(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)

19. Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state or U.S. jurisdiction?
Yes X No _____ SEE ATTACHED
20. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?
Yes _____ No X
21. Are you presently being investigated or is any disciplinary action pending against you?
Yes _____ No X
22. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If no, do not answer 23 A-C.)
Yes _____ No X
23. If "yes" to 22, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No X N/A
23a. If "yes" to 22, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No X N/A
23b. If "yes" to 22, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No X N/A
23c. If "yes" to 22, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No X N/A
24. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes _____ No X
24a. If "yes" to 24, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes _____ No X N/A

25. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 25b.)
Yes _____ No X
25b. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?
Yes _____ No X
26. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 26a and 26b.)
Yes _____ No X
26a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No X
26b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No X N/A
27. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities? (If "yes", please provide official documentation)
Yes_____ No X
28. If "yes" to any of the questions 22 through 26 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No X N/A

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 16-26, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacist's license may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other document, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

_____ 11/18/13

Applicant Signature Date

NOTE: Please check to be sure that you have answered all of the questions above.

F44243

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DEC 09 2013 | 95926

Florida Board of Pharmacy

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #3 - CERTIFICATE OF PHARMACY EDUCATION (FORM A)

Please print or type legibly.

Part I. – To be completed by applicant and forwarded to the College of Pharmacy for completion of Part II below.

Last Name	First Name	Middle Name
JONES	SANFORD	CHARLES

Maiden Name/Surname	Date of Graduation
–	5/1981

Mailing Address	City	State	Zip
245 INVERRARY DR.	DESTIN	FL	32541

Part II. – To be completed by an official of the university

Name of School/College of Pharmacy			
MCPHS UNIVERSITY			
Mailing Address	**City**	**State**	**Zip**
179 LONGWOOD AVE.	BOSTON	MA	02115

Type of Degree Awarded	Date Degree Awarded	Dates of Attendance
B.S. IN PHARMACY	06/14/1981	From: 09/12/1977 To: 02/15/1981

The information recorded above is true and correct according to the official records of this institution. Failure to include the school seal may result in a delay in processing the applicant's application.

GREGORY TILTON
Print Name

Signature

(SCHOOL SEAL)

ASSOCIATE REGISTRAR
Title

12/03/2013
Date

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

RECEIVED 1948037
NOV 21 2013
Florida Board of Pharmacy

FLORIDA BOARD OF PHARMACY
4052 Bald Cypress Way, Bin C-04 • Tallahassee, FL 32399-3254
Phone: (850) 245-4292 • www.doh.state.fl.us/mqa/pharmacy

ITEM #4 – INTERNSHIP OR WORK EXPERIENCE FORM (FORM B)

Please print or type legibly.

1. Biographical Information			
Applicant Name	Intern/Pharmacist License Number	Phone Number	
SANFORD JONES	N/A	770-548-9640	
Street Address	City	State	Zip
245 INVERRARY DR.	DESTIN	FL	32541

2. Have you submitted an application for the Florida Pharmacist Examination? If yes, please indicate date.

Yes X No _____ Date 9/18/13

I HEREBY APPLY FOR INTERNSHIP OR WORK EXPERIENCE CREDIT AS OUTLINED BELOW UNDER THE SUPERVISION OF: LEIGH BROWN - DISTRICT MANAGER

3. Pharmacy information			
Supervising Pharmacist's Name		License Number	
LEIGH BROWN - DISTRICT MANAGER		-	
Pharmacy Name		Permit Number	
CVS PHARMACY #7113		PH21196	
Street Address	City	State	Zip
60 S. HOLIDAY RD	MIRAMAR BEACH	FL	32550
Phone Number	4. Dates of Experience		
850-866-1768	From: 2/1/10 To: 11/18/13 PRESENT		
5. Average number of hours per week	6. Total hours of experience		
40	7940		

(No more than 50 hours per week if you are a student and no more than 60 after graduation is allowed)

Applicant's Signature PHARMACY SUPERVISOR Date 11/18/13

This report is a correct statement of fact. The above information was taken from the records of the above named pharmacy and are available for inspection by the Board of Pharmacy.

Preceptor/Supervisor's Signature Date 11/18/13

NOTE: Please check to be sure that you have answered all of the questions above.

PLEASE RETURN THIS FORM TO THE BOARD OFFICE:

FLORIDA BOARD OF PHARMACY
4052 BALD CYPRESS WAY
BIN #C-04
TALLAHASSEE, FL 32399-3254

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

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Ranne, Elizabeth

From: Hearn, Taylor <thearn@dch.ga.gov>
Sent: Wednesday, March 05, 2014 3:43 PM
To: Ranne, Elizabeth
Subject: License verification for Sanford Jones
Attachments: RPH018975_LICVFCN.pdf

Here is the license verification you requested. Please let me know if you need anything else. Thanks.

Taylor Hearn
Information & Referral Specialist II
Georgia Boards of Dentistry & Pharmacy
Division of the Department of Community Health
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
404-651-8000

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GEORGIA DEPARTMENT
OF COMMUNITY HEALTH

BOARD OF PHARMACY

Date Mailed: March 5, 2014

Date Issued: 10 23 1996
License # RPH018975
Expiration Date: 12 31 2014

Profession: Pharmacy

VERIFICATION OF LICENSURE

...ts the certification information provided by this Division. If other ...ested from the above-named individual or the agency or institution ... this certification indicates that a board order exists, please ... to obtain a copy of

Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

... • Atlanta, Georgia 30303 • (404) 651-8000 • (678) 717-6694 FAX
www.gbp.georgia.gov

Jack W. Campbell, IV
Executive Director

Mailing Address:
PO Box 4560
Chapel Hill, NC 27515-4560

919-246-1050
FAX: 919-246-1056
www.ncbop.org

Clinton R. Pinyan
Brooks, Pierce, McLendon,
Humphrey & Leonard, LLP
Legal Counsel
336-373-8850

NORTH CAROLINA

BOARD OF PHARMACY

February 21, 2007

Mr. Sandy C. Jones
1004 Pelican Drive
New Bern, North Carolina 28560

Dear Mr. Jones:

As you know, the Board of Pharmacy reviewed your application to reciprocate your license to practice pharmacy at its month meeting on February 20, 2007. That review has raised a number of concerns.

Foremost, Question number 7 on the Reciprocity Data Questionnaire that you signed asked: "Have you ever been charged by any Board of Pharmacy on matters which could have produced an action on your license?" You answered "No" to that question. In fact, in 1990, you were charged with violating several Connecticut statutes as a result of your diverting controlled substances. Your license was suspended for three years, suspended with numerous conditions. Under North Carolina law, making "false representations or with[holding] material information in connection with securing a license or permit" is grounds for "refus[ing] to grant . . . a license to practice pharmacy." N.C.G.S. § 90-95.28(a)(1).

As a result of this and other concerns, the Board took no action on your application. As a condition of further review of your application, the Board has stated that you must receive an evaluation by the North Carolina Pharmacist Recovery Network or its designee. Further, you must submit records of all substance abuse treatment that you have undergone, whether by order or voluntarily, for the Board's review.

Once I have received the NCPRN evaluation report and the requested materials, I will present them to the Board for its review

Sincerely yours,

Jay Campbell
Executive Director

JC/cls
cc: Jones file
Wendy Watson
Paul Peterson

Located at I-40 & 54
6015 Farrington Road, Suite 201
Chapel Hill, NC 27517-8822

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PHARMACEUTICAL EDUCATION CONSULTANTS

STATEMENT OF CREDIT

Sandy Jones

CPE Monitor ID: 267599

Medication Error Prevention: A Guide for Pharmacists -FL APPROVED LAW-

Accreditation Number: **0798-0000-13-195-H03-T**
Activity Type: **Knowledge**
Date Completed: **Tuesday, October 22, 2013**

This activity has been approved for 2 contact hour(s) of continuing education for Pharmacy Technicians.

ACPE PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **10/22/2013**

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STATEMENT OF CREDIT

Sandy Jones

CPE Monitor ID: 267599

Medication Errors and Public Safety Update: A Game Show Approach -LAW/FL APPROVED-

Accreditation Number: **0798-0000-11-078-L03-P**
Activity Type: **Knowledge**
Date Completed: **Monday, September 23, 2013**

This activity has been approved for 2 contact hour(s) of continuing education for Pharmacists.

ACPE PharmCon, Inc. is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

Kevin McCarthy, RPh
Continuing Education Administrator

Signed and issued on: **9/23/2013**

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!-- You Are Registered For an Online Event Today --!

Live Online - Acetaminophen Toxicity: The Pharmacist's Role in Prevention and Treatment

Monday, November 18, 2013 Start: 10:30 AM ET End: 11:30 AM ET Status: Closed for Entry

Sandy Jones

Username: scjones
Status: Member
Expiration: 1/2/2014

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> FreeCE > My CE Activity

What is CPE Monitor?

CPE Monitor is a national, collaborative effort by NABP and the Accreditation Council for Pharmacy Education (ACPE) to provide an electronic system for pharmacists and pharmacy technicians to track their completed continuing pharmacy education (CPE) credits. Click here for more information and to learn what you need to do to get started.

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License Overview:

All requirements listed are subject to change and not guaranteed to be 100% accurate. These should be used as a guide only. Our system will update your due dates based on the information you provided and the guidelines we retrieved from the different state boards. Please check with your State's Board of Pharmacy to find requirements for your license.

Pharmacist FL Pharmacist - CT: 05839

Begin Date: 01/01/2011 End Date: 11/18/2013 Display

FL State Requirements: Pharmacist Terms: Annual General CE Credits: 30 Live CE Credits: 10

Pharmacists must complete thirty (30) hours of approved courses of CPE every two (2) years as a condition of relicensure. Ten (10) of those hours must be from an approved live program. Two (2) of those hours must be a Board-approved course on medication errors. A Board-approved one hour course on AIDS/HIV is required prior to first renewal of licensure. In addition, twenty-four (24) hours of consultant pharmacist coursework is required for biennial renewal of a consultant license. Additionally, twenty-four (24) hours of nuclear pharmacist coursework is required for biennial renewal of a nuclear license. No carry over of credit is allowed.

Total Credits: 53.75 General CE Credits: 10 Live CE Credits: 43.75

View	Program Title	Contact Hours	Date
View	Buyer Beware: The Dangers of Synthetic Drugs of Abuse Pharmacist 0798-0000-13-233-L05-P	1 Live	11/11/2013
View	Prostate Cancer: Facts, Controversy and Treatment Options Pharmacist 0798-0000-13-228-L01-P	1 Live	11/5/2013
View	Rheumatoid Arthritis: Primarily an Autoimmune Disease Pharmacist 0798-0000-13-252-L01-P	1 Live	10/29/2013
View	Providing Practical Pediatric Practice Points for Pharmacists Pharmacist 0798-0000-12-052-L01-P	1.25 Live	10/28/2013
View	Closing the Chasm: The Potential Role of the Pharmacist in Addressing Disparities in Healthcare Pharmacist 0798-0000-13-209-L01-P	1 Live	10/24/2013
View	Methadone: An Opioid with Unplumbed Depths Pharmacist 0798-0000-13-148-L01-P	1 Live	10/23/2013
View	Goldilocks and Bipolar Disorder - Getting Treatment Just Right Pharmacist 0798-0000-13-236-L01-P	1 Live	10/22/2013
View	Prescription Opioids: Are Our Pain Killers Killing Our Patients? Pharmacist 0798-0000-13-251-L05-P	1.25 Live	10/21/2013
View	Introduction to Veterinary Dispensing Pharmacist 0798-0000-13-235-L04-P	1 Live	10/17/2013
View	What's New in Familial Hypercholesterolemia Pharmacist 0798-0000-13-173-L01-P	1 Live	10/16/2013
View	Living with Hemophilia Pharmacist 0798-0000-13-232-L01-P	1 Live	10/10/2013
View	Medical Marijuana: Real Medication or Just Recreation? Pharmacist 0798-0000-12-099-L01-P	1 Live	10/9/2013
View	Understanding and Managing Epilepsy Pharmacist 0798-0000-12-097-L01-P	1 Live	10/7/2013
View	Better Living Through Bacteria: Probiotics for the Gut and Beyond Pharmacist 0798-0000-13-176-L01-P	1 Live	9/28/2013
View	HIV: Fact vs Fiction -FL APPROVED- Pharmacist 0798-0000-12-070-L02-P	1 Live	9/28/2013
View	Medication Errors Prevention Update -FL APPROVED/LAW- Pharmacist 0798-0000-12-089-L03-P	2 Live	9/28/2013
View	High Cholesterol: Natural and Pharmaceutical Management Pharmacist 0798-0000-13-172-L01-P	1 Live	9/24/2013
View	Medication Errors and Public Safety Update: A Game Show Approach -LAW/FL APPROVED- Pharmacist 0798-0000-11-078-L03-P	2 Live	9/23/2013
View	New Drugs and Drug News from 2012 Pharmacist 0798-0000-13-085-L01-P	1 Live	9/23/2013

View	Best Practices in Lipid Management and Cardiovascular Risk Reduction Pharmacist 0798-0000-12-008-L01-P	1 Live	10/11/2012
View	Current Issues in Pharmacy: MTM, CPOE and ACA -LAW- Pharmacist 0798-0000-12-067-L03-P	1 Live	10/11/2012
View	Diabetes: The Basics Pharmacist 0798-0000-12-013-L01-P	1 Live	10/10/2012
View	From Here to Timbuktu: Immunizations and Prophylactic Medications to Consider When Planning an International Adventure Pharmacist 0798-0000-12-058-L01-P	1 Live	10/8/2012
View	Head Lice: Diagnosis, Treatment, and Prevention Pharmacist 0798-0000-12-055-L01-P	1 Live	10/8/2012
View	Calming the Flames of Menopause Pharmacist 0798-0000-11-084-L01-P	1 Live	10/5/2012
View	Drug Nutrient Depletion: Which Medications are Robbing Your Body of Essential Nutrients and Natural Ways to Restore Them Pharmacist 0798-0000-12-065-L01-P	1 Live	10/4/2012
View	The State of Obesity in the United States Pharmacist 0798-0000-12-026-L01-P	1 Live	10/3/2012
View	New Drugs and Drug News from 2011 Pharmacist 0798-0000-12-018-L01-P	1 Live	10/3/2012
View	The Cardiovascular Disease Patient: It Only Takes a Minute to Improve Medication Adherance Pharmacist 0798-0000-12-028-L01-P	1 Live	10/2/2012
View	Oral Chemotherapy and the Pharmacist's Role: Providing Pharmaceutical Care for Cancer Patients Pharmacist 0798-0000-12-063-L01-P	1 Live	10/1/2012
View	Opioids and Opioid Rotation - What Pharmacists Need to Know Pharmacist 0798-0000-11-031-L01-P	1 Live	1/2/2012
View	Prostate Cancer: Managing Associated Pain Pharmacist 0798-0000-10-035-L01-P	1 Live	9/29/2011
View	Taking the Mystery Out of Fibromyalgia Pharmacist 0798-0000-11-023-L01-P	1 Live	9/14/2011
View	Hepatitis C: New Frontiers for Treatment Pharmacist 0798-0000-11-036-L01-P	1.25 Live	9/12/2011
View	Understanding and Treating Bipolar Disorder Pharmacist 0798-0000-10-034-L01-P	1 Live	9/1/2011
View	Medication Errors 2011: Impact on the Pharmacist and Public Safety -LAW- Pharmacist 0798-0000-11-002-L03-P	2 Live	8/31/2011
View	A Tale of Two Patients - A Pharmacist's Role in the Treatment of HIV - FL Approved Pharmacist 0798-0000-11-029-L02-P	1 Live	8/29/2011
View	Emily's Law Revisited: the Pharmacist, the Family and the Medication Error that Changed Their Lives - LAW- Pharmacist 0798-0000-11-038-L03-P	1 Live	8/26/2011
View	ADHD. A Guide to Diagnosis, Treatment and Common Misconceptions Pharmacist 0798-0000-11-007-L01-P	1 Live	8/22/2011
View	New Drugs and Drug News of 2010 Pharmacist 0798-0000-11-006-L01-P	1 Live	8/18/2011
View	Medication Error Prevention: A Guide for Pharmacists -FL APPROVED LAW- Pharmacist 0798-0000-13-195-H03-P	2 Homestudy	10/22/2013
View	Medication Errors and Public Safety: Tragic Consequences When the System Breaks Down -FL APPROVED/LAW Pharmacist 0798-0000-11-030-H03-P	2 Homestudy	10/19/2013
View	HIV: Fact vs Fiction - FL APPROVED- Pharmacist 0798-0000-12-070-H02-P	1 Homestudy	10/26/2013
View	But I Don't Want to Take My Medicine! Pharmacist 0798-9999-12-075-H01-P	1 Homestudy	10/19/2013
View	A Pharmacist's Role in the Management of Prescription Drug Abuse Pharmacist 0798-0000-11-095-H01-P	2 Homestudy	10/19/2013
View	Review of Federal and Controlled Substance Laws: Part 2 Pharmacist 0798-0000-13-125-H03-P	1 Homestudy	9/28/2013
View	Review of Federal and Controlled Substance Laws: Part 1 Pharmacist 0798-0000-13-123-H03-P	1 Homestudy	9/28/2013

2201

File # 43276

PHARMACIST'S LETTER

Published by Therapeutic Research Center, Jeff M. Jellin, Pharm.D., Editor
3120 W. March Lane, Stockton, CA 95219
www.pharmacistsletter.com, Email: CE@PLetter.com
Ph (209) 472-2240, Fax (209) 472-2249

Statement of Credit

Pharmacist's Letter/Therapeutic Research Center confirms that

Lemuel Phipps

on February 12, 2014 successfully completed the
Pharmacist's Letter knowledge-based Continuing Education Course
Volume 13, No. 310

Medication Safety: Strategies for Preventing Medication Errors **on 2/12/2014.**
CE Broker #20-401847

ACPE Universal Program #0422-0000-13-310-H05-P and is awarded:
2.00 contact hours of credit or (0.2 CEU's).

ACPE

Tammie Armeni, RPh, PharmD February 12, 2014

This course is sponsored by
Pharmacist's Letter, Stockton CA 95219
TEL: 209/472-2240 FAX: 209/472-2249
CE Broker Provider # 50-2973

Statement of Credit for:
Lemuel Phipps
Rx Remote Solutions
17714 W Biehl Rd Ste 300
Naperville, IL 60563

March 3, 2014

Dana M. Fassbinder
1712 Ocean Shore Blvd. #2
Ormond Beach, FL 32176

RE: Registered Pharmacy Technician Application

Dear Ms. Fassbinder,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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2208
f-55101

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FEB 07 2014
Florida Board of Pharmacy

02/05/2014 105.00
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BT: 3014759
VL: 913040791

Florida HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone 850-245-4292
http://www.doh.state.fl.us/mqa/pharmacy

ITEM #2 - Pharmacy Technician Registration Application
FEE: $105.00
Please print or type legibly

1. Biographical data

Last name	First name	Middle name	
Fassbinder	Dana	michelle	
Street address (ML – Mailing Location)	**City**	**State**	**Zip**
1712 Ocean Shore Blvd #2	Ormond Beach	FL	32176
Work address (PL – Practice Location) (If you are not employed, please list your mailing address below). If you have multiple practice locations, please submit on an additional sheet, attach with application.	**City**	**State**	**Zip**
	Ormond Beach	FL	32176
Home phone number	**Business phone number**	**Date of birth**	
303-944-8835			
E-mail address	**Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?**		
d_fassbinder@yahoo.com	Yes ↘	No _____	

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☐ Male ☒ Female

RACE: ☒ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☐ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. *Use a separate sheet, if necessary.*

Yes ↘ No _____

Name	Date
Dana Fassbinder from Dana Gulley	3/8/1992

DH-MQA PH1183, 09/09
Rule 64B16-26.350, F.A.C.

4. Have you completed a board approved training course according to Rule 64B16-26.351 (3), FA.C.?	
Yes ↘ No _____	**If yes, include a copy of your completed course certificate.**
5. Have you ever been convicted of, or entered a plea of guilty, nolo contendre, or no contest, to a crime in any jurisdiction other than a minor traffic offense?	
Yes ↘ No _____ **(You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)**	
6. Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	
Yes _____ No ↘	
7. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	
Yes _____ No ↘	
8. Are you presently under investigation or is any disciplinary action pending against you?	
Yes _____ No ↘	

13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction? (If you responded "no", skip to #14.)
Yes _____ No ↘
13a. If "yes" to 13, for the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?
Yes _____ No _____
13b. If "yes" to 13, for the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).
Yes _____ No _____
13c. If "yes" to 13, for the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?
Yes_____ No _____
13d. If "yes" to 13, have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed? (If "yes", please provide supporting documentation).
Yes _____ No_____
14. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?
Yes_____ No↘
14a. If "yes" to 14, has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?
Yes_____ No_____
15. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 15a.)
Yes _____ No ↘
15a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No _____
16. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 16a and 16b.)
Yes _____ No ________
16a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?
Yes _____ No _____
16b. Did the termination occur at least 20 years prior to the date of this application?
Yes _____ No _____
17. Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?
Yes_____ No________
18. If "yes" to any of the questions 13through 17 above, on or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health? (If "yes", please provide official documentation verifying your enrollment status.)
Yes_____ No_____
All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-16b, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all if applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Dora M. Fassbender
Applicant Signature

1-30-2014
Date

The Florida Board of Pharmacy 01/27/14

To whom it may concern,

This letter is to provide information in regards to two incidences requested in the enclosed application to become a registered Pharmacy Technician.

#5

In November of 2001 I was arrested for Driving While Ability impaired. This was a result of a long awaited night on the town. We were visiting our parents and took advantage of the opportunity to have a babysitter for the evening. We met friends and enjoyed a night of dancing. Upon leaving the club I could tell that my husband was inebriated so I offered to drive as I felt fine. After a few minutes I realized I did not have all my faculties and was turning into a grocery store parking lot to call our parents to pick us up when an officer showed up and I was charged.

That being said, I have not ever gotten behind the wheel after any alcohol consumption. I did all of the classes and community service. It was a very humbling experience and I try to pass this lesson on to others. I am so very blessed that nobody got hurt.

#10

In November of 2011. I was admitted to the hospital for observation. I had not been able to sleep for days even though I was exhausted and tired. I had been having cry spells which were exhausting yet every time I tried to sleep my mind would race. I finally decided to take a couple of Tylenol PM's. An hour or so later I was still wide awake so I took three. I finally fell asleep. When my husband arrived home he tried to wake me and I was incoherent. I was then taken to the hospital

and was on observation for liver function since Depakote can affect your liver. When I finally could speak intelligably I explained the situation an immediately diagnosed a bipolar 2 and having a mixed episode. It was mentioned that I had been misdiagnosed for many years with depression and that the Zoloft I was on may have contributed to the mania.

After I was released, I immediately sought out help. I started with a psychiatrist whom diagnosed me with Bipolar 2 as well. I then found a phenomenal psychologist whom taught me so much about my disease and how to take care of myself. i.e. plenty of sleep, eating right and having a stable environment. I then switched psychiatrists to the one in my psychologists office.

With the amazing care that I receive, my moods are stable, my life has changed. I feel very good and continue to work

with everyone to maintain a happy healthy life. I do well on the financial and Trazedone. We seem to have found a good combination after some trial and error.

I am a hard, devoted and ethical employee and worker.

I truly appreciate your time and consideration.

Sincerely,

Dana M. Fassbinder

CNT STS STATUTE NUMBER CHARGE DESCRIPTION CLASS

Plea.....: Plea of Guilty Date: 01/17/2002
Disposition.....: Guilty Date: 01/17/2002

1 (A) 42-4-1301(1)(a) Driving Under the Influence M
Offense Date: From: 11/25/2001 To: Time: BAC: .000
Arrest Date.....: Time: Ticket #: 1713547

SNT DATE SENTENCE DESCRIPTION STATUS
01/17/2002 Sentence by Court Active
Judicial Officer.....: ARTHUR R SMITH JR.
Driving Und Influ/Abil Imp: $100.00
Victim Compensation Fund..: $25.00
Victims Assistance Fund...: $37.00
Court Costs.....: $18.00
Alcohol Eval Fee.....: $156.00
Breath/Blood Test Cost....: $10.28
Jail.....: 30.00 DAY(S) SP
Community Service.....: 36.00 HOUR(S)

COMMUNITY SERVICE TO BE COMPLETED BY 4/20/02 /WAL

2 (D) 42-4-1301(2)(a) DUI per se M
Offense Date: From: 11/25/2001 To: Time: BAC: .000
Arrest Date.....: Time: Ticket #: 1713547
Disposition.....: Dism by DA Date: 01/17/2002

3 (D) 42-4-1007(1)(a) Lane Usage Violation TIA
Offense Date: From: 11/25/2001 To: Time: BAC: .000
Arrest Date.....: Time: Ticket #: 1713547
Disposition.....: Dism by DA Date: 01/17/2002

FILE DATE EVENT DESCRIPTION

11/27/2001 Summons and Complaint Filed Event ID: 000001 E-Filed: N
/DFM

OREOLT 6650

FILE DATE SCHEDULED EVENT DESCRIPTION SCHD DATE TIME ROOM PRI

11/27/2001 Arraignment 01/16/2002 08:15 AM 100 01
Officer: ARTHUR R SMITH JR. Length: 1.00 Hour(s)
Status.: HELD-Hearing Held

12/04/2001 Entry of Appearance Event ID: 000002 E-Filed: N
APPEAR; PETERSEN / REQ FOR NAMES OF ALL CO-DEF / REQ DISCOVERY - /LUC

01/15/2002 Motion Event ID: 000003 E-Filed: N
PLEAD GUILTY; PETERSEN /LUC

01/17/2002 Case Closed Event ID: 000004 E-Filed: N

02/04/2002 Reopened Event ID: 000005 E-Filed: N

02/04/2002 Alcohol Eval Ordered Event ID: 000006 E-Filed: N

02/04/2002 Closed after post jdg activity Event ID: 000007 E-Filed: N

04/04/2002 Report Event ID: 000008 E-Filed: N
DRUG/ALCOHOL EVAL /LUC

04/09/2002 Motion Event ID: 000009 E-Filed: N
EXTENSION OF TIME TO COMPLETE COMM SERV & ALCOHOL CLASSES; DDA /LUC

04/10/2002 Order Event ID: 000010 E-Filed: N
MOTIN FOR EXTENSION OF TIME TO COMPLETE COMMUNITY SERVICE AND ALCOHOL CLASSES
GRANTED UNTIL 6/15/02 /WAL

04/10/2002 Review 06/20/2002 08:00 AM 2
Officer: ARTHUR R SMITH JR. Length: 1.00 Hour(s)
Status.: HELD-Hearing Held Note..: TO CONNIE

04/29/2002 Filing Other Event ID: 000011 E-Filed: N
DEF/ FASSBINDER, DANA MICHELLE
/CSU

UPS COMPLETION

07/15/2002 Notice Filed Event ID: 000012 E-Filed: N

FILE DATE SCHEDULED EVENT DESCRIPTION SCHD DATE TIME ROOM PRI
SUCCESSFUL COMPLETION OF ALCOHOL TREATMENT /LUC

BOND INFORMATION

Bond Id Number.....: 1 Bond Status....: BRLD
Set Date.....: Set Amount.....: $750.00 Type:
Post Date.....: 11/26/2001 Post Amount....: $750.00 Type: CASH
Surety.....: DONALD GULLEY
Bond Instructions:
May use for Fines and Costs:
May be released to Defendant:
Conditions:
MAY NOT USE//REF TO SURETY

End of Case: 2001 T 003692

INTEGRATED COLORADO ONLINE NETWORK (ICON)

Status: CLSD County Court, Mesa County
Case #: 2001 T 003692 Div/Room: 2 Type: Driving Under the Influenc
The People of Colorado vs FASSBINDER, DANA MICHELLE

DV STATUS:
Case File Date: 11/27/2001 Case Close Date: 2/04/2002 Appealed: N
Confidential Intermediary.....:

	Bar #	Name
Judicial Off...:	004709	ARTHUR R SMITH JR.
Alt Jud Officer:	000000	

	Description	Stat Date	Time	Rm/D
Trial.....:			0:00	
Next Schd Event:			0:00	
Last Schd Event:	Review	HELD 6/20/2002	8:00	A
Last Event.....:	Notice Filed	n/a 7/15/2002		

Attorney(s)....: Y

Agency: Mesa Troop-A CSP-Retired Agency Case #:
Ticket/Summons Number(s): 1713547 Arrest#:

Warrant.....: Warrant Date: Expired Date:
Party on Warrant:
Change of Venue.: Agency:

Bond(s).....: Y

Sentence Date.....: SCRT 1/17/2002
Detention Location.....:
Supervising Agency.....:
Probation Officer.....:

----- PARTIES -----

PARTY	ROL	STS	NAME	ATTORNEY	ROL
PTF	1		The People of Colorado		
DEF	1		FASSBINDER, DANA MICHELLE	PETERSEN, CHERYL D	PRV

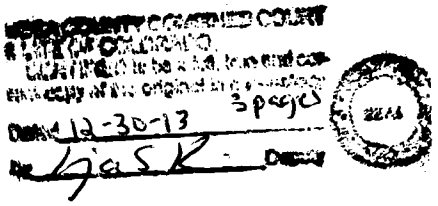
Date of Birth.....: 04/29/1972
Sex.....: Female
Race.....: Caucasian
Height.....: 507
Weight.....: 120
Hair Color.....: Blonde
Eye Color.....: Green
Marital Status.....: Married
Home Address.....: 3276 ROSEWALK COURT
: HIGHLANDS RANCH, CO 80129

----- OTHER PEOPLE -----

ROLE	NAME
IMP 1 SUR	DONALD GULLEY

CNT	STS	STATUTE NUMBER	CHARGE DESCRIPTION	CLASS
1	( )	42-4-1301(1)(b)	Driving While Ability Impaired	M

Offense Date: From: 11/25/2001 To: Time: BAC: .000
Arrest Date.....: Time: Ticket #: 1713547



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PUBLIX

PHARMACY

Feeling well. Living better.

presents

Certificate of Completion

to

Dana Fassbinder

for satisfactory completion of the

Publix Pharmacy Technician Basics

Date completed : 10/21/2013

Fred Ottolino, VP of Pharmacy Operations

RTTP15

March 3, 2014

Seaon Hardeen
3912 Flowering Orchid Lane
Kissimmee, FL 34744

RE: Registered Pharmacy Technician Application

Dear Mr. Hardeen,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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FLORIDA DEPARTMENT OF HEALTH

FLORIDA BOARD OF PHARMACY
P.O. Box 6320 • Tallahassee, FL 32314-6320
Phone: (850) 488-0595
http://www.doh.state.fl.us/mqa/pharmacy

ITEM #2 - Pharmacy Technician Registration Application

FEE: $105.00

Please print or type legibly

1. Biographical data

Last name	First name	Middle name	
Hawdeen	Seaon	Trevor	
Street address (ML – Mailing Location)	**City**	**State**	**Zip**
3917 Flowering orchid LN	Kissimmee	FL	34744
Work address (PL – Practice Location) (If you are not employed, please list your mailing address below). If you have multiple practice locations, please submit on an additional sheet, attach with application.	**City**	**State**	**Zip**
Home phone number	**Business phone number**	**Date of birth**	
(407) 348-2388	—	07/27/1990	
E-mail address	**Would you be willing to provide health services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disasters?**		
Shawdeen1@gmail.com	Yes _____	No ✓	

2. Equal Opportunity Data – We are required to ask that you furnish the following information as part of your voluntary compliance with Section 2, Uniform Guidelines on Employee Selection Procedure (1978) 43FR38295 (August 25, 1978). The information is gathered for statistical and reporting purposes only and does not in any way affect your candidacy for licensure.

SEX: ☑ Male ☐ Female

RACE: ☐ Caucasian ☐ Black ☐ Hispanic ☐ Asian ☐ Native American ☑ Other

3. Have you ever changed your name through marriage or through action of a court or have you ever been known by any other name? If yes, list name(s) and date(s) of the change(s) below. *Use a separate sheet, if necessary.*

Yes _____ No ✓

Name	Date

4. Have you completed a board approved training course according to Rule 64B16-26.351 (3), F.A.C.?	
Yes ✓ No _____	**If yes, include a copy of your completed course certificate.**
5. Have you ever been convicted of, or entered a plea of guilty, nolo contendre, or no contest, to a crime in any jurisdiction other than a minor traffic offense?	
Yes ✓ No _____ (You must include all misdemeanors and felonies, even if adjudication was withheld by the court, so that you would not have a record of conviction. Driving under the influence or driving while impaired is NOT a minor traffic offense for the purposes of this question.)	
6. Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	
Yes _____ No ✓	
7. Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	
Yes _____ No ✓	
8. Are you presently under investigation or is any disciplinary action pending against you?	
Yes _____ No ✓	

13. Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapters 409, Chapter 817, or Chapter 893, Florida Statutes; or 21 U.S.C. ss 801-970 or 42 U.S.C. ss. 1395-1396? (If no, do not answer 13a.)

Yes ✓ No _____

13a. Has it been more than 15 years prior to the date of this application since the sentence and completion of any subsequent period of probation for such conviction?

Yes _____ No ✓

14. Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes? (If no, do not answer 14a.)

Yes _____ No ✓

14a. If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?

Yes _____ No ✓

15. Have you ever been terminated for cause, pursuant to the appeals procedures established by the state or federal government, from any other state Medicaid program or the federal Medicare program? (If no, do not answer 15a and 15b.)

Yes _____ No ✓

15a. Have you been in good standing with a state Medicaid program or the federal Medicare program for the most recent five years?

Yes ✓ E.H. No _____

15b. Did the termination occur at least 20 years prior to the date of this application?

Yes _____ No _____

All of the above questions must be answered or your application will be returned for completion. If you answer "yes" to any questions in 5-16b, explain on a sheet providing accurate details, and submit a certified official copy of the order of the court or state board of pharmacy, supporting documents or all applicable.

Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Applicant Signature

04/11/2015
Date

Seaon Hardeen
3912 Flowering Orchid Ln.
Kissimmee, FL 34744

Florida Board of Pharmacy
P.O. Box 6320
Tallahassee, Fl. 32314-6320

July 10, 2013

To whom it may Concern,

My name is Seaon Hardeen, I am applying for a pharmacy technician's registration and license in the state of Florida. I completed the program through Anthem College on July 10, 2013.

The only thing which is keeping me from attaining this goal is my past of unfortunate choices. I have a felony on my record for possession of counterfeit money. The people I had chosen to consider friends, were not positive influences in my life nor were they honest as I had been led to believe. We set out on a weekend trip as a group where I was one of the passengers and stopped at a rest area to refuel the vehicle and ourselves. These "friends" paid for the purchases unbeknownst to me with counterfeit money. The counterfeit money was discovered at the rest area and we were being detained until the arrival of the police. When the police arrived, they took all the people including myself to the state trooper's precinct. Upon the arrival of the investigator, he informed all of us that were being charged with possession of counterfeit money.

The attorney advised me as to how to plead in this case. Originally he suggested I plead innocent and as the case unraveled he then had me change to plead guilty because I would only have to serve a short probationary period as opposed to the higher punishment which I potentially could have received of imprisonment 5-10 years. I have had nothing but regret or remorse from the moment I associated myself with these so called friends. My life was turned upside down and I nearly lost everything I had worked so hard to attain for my family.

I was a pillar of my community prior to this incident and everyday continue to strive towards that goal. I am still putting my life together after this whole unfortunate circumstance by joining the medical profession as a pharmacy technician, so I can better serve my community. I decided to relocate to Florida in hopes of making a better life for myself as well as for my family.

By obtaining a position as a certified and registered PhT in the state of Florida, my future can continue to change, as I have a vision to further my education towards becoming a pharmacist. I truly believe in new beginnings and hope my application will be considered.

Warmest regards,

Seaon Hardeen

LAW OFFICE OF JARED ALTMAN

RIVER VALLEY CORPORATE CENTER
2125 ALBANY POST ROAD, SUITE ONE NORTH
MONTROSE, NEW YORK 10548-1447
Phone: (914) 737-0200 • Fax: (914) 737-5504
Email: JaredAltman@AltmanLawOffices.com

November 6, 2013

Quality Division of Medical Assurance
Board of Pharmacy

Re: Seaon Hardeen
DOB: 7/27/1980

To Whom It May Concern:

I represented the above referenced individual in connection with charges brought by the Westchester County District Attorney in the New York State Criminal Justice Courts.

On October 11, 2011 Mr. Hardeen was charged together with three close family members with Criminal Possession of a Forged Instrument in the First Degree under NYS Penal Law Sections 170.30 and 170.15. That offense is a class C felony.

On March 14, 2012 Mr. Hardeen plead guilty to the Class D felony of Criminal Possession of a Forged Instrument in the Second Degree under NYS Penal Law Section 170.25.

On June 7, 2012 Mr. Hardeen was sentenced to five (5) years' probation.

Thank you.

Very truly yours,

JARED ALTMAN, ESQ.

JA:o

Additional offices by appointment:
202 Mamaroneck Avenue, White Plains, NY 10601
42 East Tilden Place, Hopewell Junction, NY 12533

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Anthem College

Upon the recommendation of the faculty
and through the authority vested in us by the State,
we hereby confer upon

Seaon T. Hardeen

Diploma

In

Pharmacy Technician

In recognition of the satisfactory fulfillment of the requirements for graduation
Awarded in Orlando, Florida, July 10, 2013

David Champlin
Executive Director

ANTHEM COLLEGE

Jay Bratnick
Director of Education

March 3, 2014

Nicole Bolen
6901 SW 6th Street
Pembroke Pines, FL 33023

RE: Registered Pharmacy Technician Application

Dear Ms. Bolen,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

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If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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Mission:
To protect, promote, & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

Initial Application for Licensure
Florida Board of Pharmacy
Florida Department of Health

Basic Data

Profession:	REGISTERED PHARMACY TECHNICIAN
Application Type:	REGISTERED PHARMACY TECHNICIAN INITIAL APPLICATION
Name:	MS. NICOLE BOLEN
Date of Birth:	09/30/1985
Place of Birth:	MIAMI, FLORIDA
Email Address:	NICOLEBOLEN@YMAIL.COM

Mailing Address

6901 SW 6 ST
PEMBROKE PINES, FL 33023

Physical Location or Address of Employment

4599 SHERIDAN ST
HOLLYWOOD, FL 33024

Phone Numbers

Home:	954-966-8104
Business:	954-961-3720

Equal Opportunity Data

Gender:	FEMALE
Race:	WHITE

Education History

Course Provider:	CVS CAREMARK
Course Approved By:	FLORIDA BOARD OF PHARMACY APPROVED
Course Competion Date:	12/14/2013

Other Name History

Name:	NICOLE LUPISELL

Secondary Work Location

Other State Licenses

License Number:	License Number:
License Type:	License Type:
Licensure Date:	Licensure Date:
Date of Expiration:	Date of Expiration:
Country:	Country:
State:	State:

Criminal History

Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest to a crime in any jurisdiction other than a minor traffic offense? Your answer: **NO**

Discipline History

Has disciplinary action ever been taken against your pharmacist or any other professional license in this state or any other state or U.S. jurisdiction? Your answer: **NO**

Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending? Your answer: **NO**

Are you presently being investigated or is any disciplinary action pending against you?	Your answer: **NO**

Questions related to Section 456.0635(2), Florida Statutes

Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction?	Your answer: **NO**
For the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
For the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).	Your answer: **N/A**
For the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
Have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?	Your answer: **N/A**
Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?	Your answer: **NO**
Has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?	Your answer: **N/A**
Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes?	Your answer: **NO**
If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?	Your answer: **N/A**
Have you ever been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program?	Your answer: **NO**
Have you been in good standing with a state Medicaid program for the most recent five years?	Your answer: **N/A**
Did the termination occur at least 20 years before the date of this application?	Your answer: **N/A**
Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?	Your answer: **NO**
On or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health?	Your answer: **N/A**

Additional Information

Availability for Disaster: Will you be available to provide health care services in special needs shelters or help staff disaster medical assistance teams during times of emergency or major disaster?	Your answer: **NO**

Military Veteran Fee Waiver

Date of Discharge:	Your answer: **N/A**

Application Statement

☒ Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

Nicole Bolen
6751 Branch Street
Hollywood, Fl 33024

February 13, 2014
State Board of Pharmacy

To Representatives of the State Board of Pharmacy:

The intent of this letter is to provide additional details and insights into my health history that was provided to you at my request by Dr. Milana Kaplan. In January of 2012, I was diagnosed with depression and anxiety after a brief hospitalization due to extreme financial stressors and the anxiety over how those stressors would impact my ability to continue to make timely mortgage payments and my overall financial future. With the support of my family and medical professionals (psychiatrist and psychologist), I began a daily regimen of medication and learned techniques through the recommended reading materials from my psychologist that enabled me to cope with the repurcussions of my diagnosis in my daily life. I continue to comply with all of the prescribed medication and appointment dates and maintain a great relationship with my psychologist and psychiatrist to this day.

In June of 2013, I was also briefly hospitalized due to the extreme stressors stemming from my struggles with infertility and the emotional and physical toll the situation was putting on myself and my husband. At the recommendation of my doctors, my husband joined me in some sessions with the psychologist and we learned better ways to cope and communicate in regards to the situation and explored additional options that we could utilize if we were unable to conceive a child of our own.

I hope this letter provides you with enough insight and information into my health history to enable you to successfully make a decision regarding my application to become a registered pharmacy technician in the state of Florida. I would be happy to provide additional details if needed and have authorized Dr. Kaplan to answer any and all questions you may have regarding my diagnosis, medications and treatment. Thank you for your kind attention to this matter.

Sincerely,

Nicole Bolen

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1550418

CVS/pharmacy

Proof of Completion

This document verifies that, in accordance with Florida Board of Pharmacy requirements,

Nicole Bolen

(employee name)

has completed the

Florida Board of Pharmacy Approved CVS/pharmacy® LearnRx Training Program

(CVS/Caremark License Number: RPPT8)

as of

December 14, 2013

(completion date)

Rudy Feldo, Pharm. D.

Pharmacy Trainer/Pharmacist In-Charge signature

RECEIVED
FEB 05 2014
Florida Board of Pharmacy

1/9/2014

Date

March 3, 2014

Kayla M. Cerritos
1420 Drew Street
Clearwater, FL 33755

RE: Registered Pharmacy Technician Application

Dear Ms. Cerritos,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

January 21, 2014

Kayla Cerritos
1420 Drew Street
Clearwater, FL 33755

RE: Pharmacist Technician Application

Dear Ms. Cerritos:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, February 12, 2014. The meeting is being held at the Florida Hotel & Conference Center, 1500 Sand Lake Road, Orlando, FL 32809, (407) 859-1500. The meeting will begin at 9:00 a.m.

You are not required to appear; however, it is encouraged that you do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

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HEALTH

Initial Application for Licensure
Florida Board of Pharmacy

Division of Medical Quality Assurance
MQA

Basic Data

Profession:	REGISTERED PHARMACY TECHNICIAN
Application Type:	REGISTERED PHARMACY TECHNICIAN INITIAL APPLICATION
Name:	KAYLA M CERRITOS
Date of Birth:	05/25/1994
Place of Birth:	SEMINOLE, FL
Email Address:	SACERTIFICATIONS@ULTIMATEMEDICAL.EDU

Mailing Address

1420 DREW STREET
CLEARWATER, FL 33755

Physical Location or Address of Employment

1420 DREW STREET
CLEARWATER, FL 33755

Phone Numbers

Home:	727-953-5225
Business:	727-953-5225

Equal Opportunity Data

Gender:	FEMALE
Race:	HISPANIC

Education History

Course Provider:	OTHER
Course Approved By:	FLORIDA BOARD OF PHARMACY APPROVED
Course Competion Date:	03/26/2013

Other Name History

No Other Name History data entered.

Secondary Work Location

Other State Licenses

License Number:	License Number:
License Type:	License Type:
Licensure Date:	Licensure Date:
Date of Expiration:	Date of Expiration:
Country:	Country:
State:	State:

Mandatory Continue Education

Prevention of Medical Errors

I have completed the Prevention of Medical Errors education required by Florida Statutes, as defined by Rule 64B7-25.001(1)(f), F.A.C.

Provider Number:	
Provider/School Name:	ULTIMATE MEDICAL ACADEMY
Course Name/Title:	PHARMACY TECHNICIAN
Date Completed:	03/26/2013

Criminal History

Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest to, a crime in any jurisdiction other than a minor traffic offense? Your answer: **NO**

HEALTH

Initial Application for Licensure
Florida Board of Pharmacy

Division of Medical Quality Assurance
MQA

Discipline History

Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	Your answer: **NO**
Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	Your answer: **NO**
Are you presently under investigation or is any disciplinary action pending against you?	Your answer: **NO**

Questions related to Section 456.0635(2), Florida Statutes

Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction?	Your answer: **NO**
For the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
For the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).	Your answer: **N/A**
For the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
Have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?	Your answer: **N/A**
Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?	Your answer: **NO**
Has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?	Your answer: **N/A**
Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes?	Your answer: **NO**
If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?	Your answer: **N/A**
Have you ever been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program?	Your answer: **NO**
Have you been in good standing with a state Medicaid program for the most recent five years?	Your answer: **N/A**
Did the termination occur at least 20 years before the date of this application?	Your answer: **N/A**
Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?	Your answer: **NO**
On or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health?	Your answer: **N/A**

Additional Information

Availability for Disaster: Will you be available to provide health care services in special needs shelters or help staff disaster medical assistance teams during times of emergency or major disaster?	Your answer: **YES**

HEALTH

Initial Application for Licensure
Florida Board of Pharmacy

Division of Medical Quality Assurance
MQA

Application Statement

☒ Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

RE: Personal History for Registered Pharmacy Techician

I, Kayla Cerritos, was hospitalized in September of 2011 as well as December of 2011 while I was under 18 into a Pediatric's Pyschiatric Ward. I was diagnosed with Major Depressive Disorder. I was prescribed two antidepressants to treat my depression. The only documents I was able to find were from that time. I am currently still taking the two antidepressants and am in better health. I have not been admitted to any psychiatric facility since then. I am not currently seeing a licensed professional for the depression, so I am not able to get a letter summarizing my diagnosis. I have enclosed to only documents I was able to obtain. If there are any questions feel free to contact me at 727-225-1751.

Thank You,
Kayla Cerritos
File Number 51118

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March 3, 2014

Harry G. Horodeck
3831 NW 44th Place
Cape Coral, FL 33993

RE: Petition for Termination of Probation

Dear Mr. Horodeck,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

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If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

March 3, 2014

Harry G. Horodeck
2636 NW 8th Terrace
Cape Coral, FL 33993

RE: Petition for Termination of Probation

Dear Mr. Horodeck,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

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Jay Cumbie,
Regulatory Specialist II

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Nelson, Sondra

From: Bayo Edwin [e.bayo@gfblawfirm.com]
Sent: Monday, January 06, 2014 5:00 PM
To: Nelson, Sondra
Subject: RE: 2011-13626 Horodeck

go ahead and set it for April then. Thanks.

Edwin A. Bayó
Board Certified in State & Federal Government
and Administrative Practice
Grossman, Furlow
& Bayó, LLC
Grossman, Furlow, & Bayó
2022-2 Raymond Diehl Road
Tallahassee, FL 32308
Phone: (850)385-1314
Fax: (850)385-4240

From: Sondra.Nelson@flhealth.gov [mailto:Sondra.Nelson@flhealth.gov]
Sent: Friday, December 27, 2013 4:28 PM
To: Bayo Edwin
Subject: RE: 2011-13626 Horodeck

Hi Ed,

I'm sorry but the deadline for the February 4-5, 2014 Board meeting agenda was December 20, 2013. I can schedule you guys for the April 1-2, 2014 Board meeting. Just let me know if that is acceptable for you and Mr. Horodeck.

Happy New Year!

From: Bayo Edwin [mailto:e.bayo@gfblawfirm.com]
Sent: Monday, December 23, 2013 11:31 AM
To: Nelson, Sondra
Subject: RE: 2011-13626 Horodeck

Dear Ms. Nelson:

Can you please ensure that Mr. Horodek is on the next BOP agenda (February 4-5 in Orlando) so he can comply with his required appearance?

Edwin A. Bayó
Board Certified in State & Federal Government
and Administrative Practice
Grossman, Furlow
& Bayó, LLC
Grossman, Furlow, & Bayó
2022-2 Raymond Diehl Road
Tallahassee, FL 32308
Phone: (850)385-1314
Fax: (850)385-4240

From: Sondra.Nelson@flhealth.gov [mailto:Sondra.Nelson@flhealth.gov]
Sent: Monday, November 04, 2013 10:50 AM
To: Bayo Edwin
Subject: RE: 2011-13626 Horodeck

Hi Ed,

The Board has not established the 2014 meeting schedule. Please resubmit your request at that time. Thank you.

From: Bayo Edwin [mailto:e.bayo@gfblawfirm.com]
Sent: Monday, November 04, 2013 10:20 AM
To: Nelson, Sondra
Cc: JEAN ETTE HORODECK (jfhgh52@centurylink.net)
Subject: 2011-13626 Horodeck

Dear Ms. Nelson:

The Settlement Agreement we negotiated on behalf of Mr. Horodek specifically did not contain a tolling provision, so that probation would run even if he is not practicing. The reason we did that was because he was already retired and we did not envision that he would be practicing. In exchange for that concession, the Board required him to make an appearance before the end of probation, which we will accomplish on the first meeting in 2014.

Please let me know if you have any questions. I will also apprecviate if you can confirm that he has complied with all his other requirements.

Edwin A. Bayó
Board Certified in State & Federal Government and Administrative Practice
Grossman, Furlow & Bayó, LLC
Grossman, Furlow, & Bayó
2022-2 Raymond Diehl Road
Tallahassee, FL 32308
Phone: (850)385-1314
Fax: (850)385-4240

Disclaimer under Circular 230: Any statements regarding tax matters made herein, including any attachments, are not formal tax opinions by this firm, cannot be relied upon or used by any person to avoid tax penalties, and are not intended to be used or referred to in any marketing or promotional materials.

Final Order No. DOH- 13-0022- S -MQA

FILED DATE - JAN 07 2013
Department of Health
By: Angel Sanders
Deputy Agency Clerk

STATE OF FLORIDA
BOARD OF PHARMACY

DEPARTMENT OF HEALTH,
Petitioner,

vs.

CASE NO.: 2011-13626
LICENSE NO.: PS 12646

HARRY G. HORODECK, RPH
Respondent.

_____/

FINAL ORDER APPROVING SETTLEMENT AGREEMENT

THIS CAUSE came before the Board of Pharmacy (hereinafter the "Board") pursuant to Section 120.57(4), Florida Statutes, on December 12, 2012 in Tallahassee, Florida, for consideration of a Settlement Agreement (attached hereto as Exhibit A) entered into between the parties in the above-styled cause. Upon consideration of the Settlement Agreement, the documents submitted in support thereof, and being otherwise advised in the premises, it is hereby ordered and adjudged:

The Settlement Agreement as submitted is hereby approved, adopted and incorporated herein by reference. Accordingly, the parties shall adhere to and abide by all the terms of the Settlement Agreement. As authorized by the Settlement Agreement the Board finds that the costs of investigation and prosecution are **$3,556.67**.

This Final Order shall take effect upon being filed with the Clerk of the Department of Health.

DONE AND ORDERED this 7th day of January, 2013

BOARD OF PHARMACY

Mark Whitten, Executive Director *for*
Cynthia Griffin, PharmD, Chair

NOTICE OF RIGHT TO JUDICIAL REVIEW UNLESS WAIVED

A PARTY WHO IS ADVERSELY AFFECTED BY THIS ORDER IS ENTITLED TO JUDICIAL REVIEW, UNLESS WAIVED, PURSUANT TO SECTION 120.68, FLORIDA STATUTES. PROCEEDINGS ARE GOVERNED BY THE FLORIDA RULES OF APPELLATE PROCEDURE. SUCH PROCEEDINGS ARE COMMENCED BY FILING ONE COPY OF THE NOTICE OF APPEAL WITH THE AGENCY CLERK OF THE DEPARTMENT OF HEALTH AND A SECOND COPY, ACCOMPANIED BY FILING FEES PRESCRIBED BY LAW, WITH THE DISTRICT COURT OF APPEALS, FIRST DISTRICT, OR WITH THE DISTRICT COURT OF APPEAL IN THE APPELLATE DISTRICT WHERE THE PARTY RESIDES. THE NOTICE OF APPEAL MUST BE FILED WITHIN THIRTY (30) DAYS OF RENDITION OF THE ORDER TO BE REVIEWED.

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been provided by electronic mail to **Harry G. Horodeck, RPH, c/o Edwin Bayó, Esquire** at e.bayo@gfblawfirm.com ; to **John Truitt**, Assistant General Counsel, Department of Health, at john_truitt@doh.state.fl.us , and to **David D. Flynn**, Assistant Attorney General, Department of Legal Affairs, at david.flynn@myfloridalegal.com this 7th day of January, 2013

Angel Sanders

Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-13626**

HARRY G. HORODECK, R.Ph.,

RESPONDENT.
_____/

SETTLEMENT AGREEMENT

Pursuant to Section 120.57(4), Florida Statutes, the parties offer this Settlement Agreement to the Board of Pharmacy (Board) as disposition of the Administrative Complaint, attached as Exhibit A, in lieu of further administrative proceedings.

STIPULATED FACTS

1. At all times material to this matter, Harry G. Horodeck, RPh, was a licensed pharmacist in the state of Florida, having been issued license number PS 12646. Respondent's mailing address of record is 2636 NW 8th Terrace, Cape Coral, Florida 33993.

2. Respondent was charged by an Administrative Complaint, filed by the Department of Health (Department) and properly served upon Respondent, with violations of Chapters 456 and 465, Florida Statutes.

STIPULATED LAW

1. Respondent admits that he is subject to the provisions of Chapters 456 and 465, Florida Statutes, and the jurisdiction of the Department.

2. Respondent admits that the allegations in the Administrative Complaint, if proven true, constitute violations of law and cause the Respondent to be subject to discipline by the Board of Pharmacy.

PROPOSED DISPOSITION

1. **Appearance**- Respondent, Harry G. Horodeck, RPh, shall be present when this Settlement Agreement is presented to the Board and under oath shall answer all questions asked by the Board concerning this case and its disposition.

2. **Fine**- The Board of Pharmacy shall impose an administrative fine of **TWO THOUSAND DOLLARS** ($2,000.00). The fine shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee,**

Florida 32314-6320, within 90 days from the date the Final Order approving and incorporating this Settlement Agreement (Final Order) is filed with the Department Clerk.

3. **Costs**- The Board of Pharmacy shall impose the total, administrative costs associated with the investigation and prosecution of this matter in an amount not to exceed **FOUR-THOUSAND, FIVE-HUNDRED DOLLARS AND NO CENTS** ($4,500.00). Total costs shall be assessed when the Settlement Agreement is presented to the Board. The costs shall be paid by Respondent to the **Department of Health, Compliance Management Unit, Bin C76, Post Office Box 6320, Tallahassee, Florida 32314-6320,** within 90 days from the date the Final Order is filed with the Department Clerk. **Payment must be made by cashier's check or money order ONLY.** Personal Checks shall **NOT** be accepted.

4. **CE Course**- Respondent shall successfully complete a Continuing Education Course on the subject of Laws and Rules consisting of 12 hours of credit, which has approved by the Florida Board of Pharmacy, within one (1) year of the filing of a Final Order accepting and incorporating this Settlement Agreement. These continuing education

hours shall be in addition to the hours required for license renewal. Within ten (10) days of completion of the course and/or receipt of the certificate of completion, Respondent shall mail a copy of the continuing education certificate of completion to the Pharmacy Compliance Officer at the address listed in paragraph two (2) above.

5. **Probation-** Respondent shall be placed on 1 year probation. During the period of probation, Respondent shall be subject to the following terms and conditions:

a. Respodent shall submit written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall include Respondent's license number, current address, and phone number; current name, address, and phone number of each pharmacy in which Respondent is engaged in the practice of pharmacy; the names of all pharmacists, pharmacy interns, pharmacy technicians, relief pharmacists, and prescription department managers working with Respondent. These reports

shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer;

b. Respondent shall ensure that his employer submits written reports to the Compliance Officer for the Medical Quality Assurance/Compliance Management Unit, Compliance Officer, 4052 Bald Cypress Way, Bin C-01, 32399-3251. These reports shall contain the name, address, license number, and phone number of each pharmacy intern, pharmacy technician, relief pharmacist, and prescription department manager working in the prescription department where Respondent practices, and provide a brief description of Respondent's duties, responsibilities, and working schedule. These reports shall be submitted to the Compliance Officer every 3 months in a manner as directed by the compliance officer; and

c. Respondent shall make a mandatory appearance before the Board of Pharmacy during his last year of probation.

6. **Future Conduct**- Respondent shall not violate Chapter 456, 465, 499 or 893, Florida Statutes; the rules promulgated pursuant thereto;

or any other state or federal law, rule, or regulation relating to the practice or to the ability to practice pharmacy.

7. **Violation of Terms**- It is expressly understood that a violation of the provisions of this Settlement Agreement as approved and incorporated into the Final Order of the Board of Pharmacy shall constitute a violation of an order of the Board for which disciplinary action may be initiated against Respondent pursuant to Chapter 465, Florida Statutes.

8. **No Force or Effect until Final Order**- It is expressly understood that this Settlement Agreement is subject to approval by the Board and has no force or effect until the Board incorporates the terms of this Settlement Agreement into its Final Order.

9. **Purpose of Agreement**- This Settlement Agreement is executed by Respondent for the purpose of avoiding further administrative action with respect to this particular case. In this regard, Respondent authorizes the Board to review and examine all investigative file materials concerning Respondent prior to, or in conjunction with, consideration of the Settlement Agreement. Petitioner and Respondent agree to support this Settlement Agreement at the time it is presented to the Board and shall offer no evidence, testimony, or argument that disputes or

contravenes any stipulated fact or conclusion of law. Furthermore, should this Settlement Agreement not be accepted by the Board, it is agreed that the presentation and consideration of this Settlement Agreement and other documents and matters by the Board shall not unfairly or illegally prejudice the Board or any of its members from further participation, consideration, or resolution of these proceedings.

10. **Not Preclude Additional Proceedings**- Respondent and the Department fully understand that this Settlement Agreement as approved and incorporated into the Final Order will not preclude additional proceedings by the Board or Department against Respondent for acts or omissions not specifically set forth in the Administrative Complaint.

11. **Waiver of Attorney's Fees and Costs**- Respondent waives the right to seek any attorney's fees and costs from the Department in connection with this disciplinary proceeding.

12. **Waiver of Procedural Rights**- Respondent waives all rights to further administrative procedure and to appeal and further review of this Settlement Agreement and the Final Order.

13. **Current Addresses**- Respondent shall keep current his mailing address and his practice address with the Board of Pharmacy and

the Compliance Officer and shall notify the Board of Pharmacy and the Compliance Officer of any change of mailing address or practice address within 10 days of the change.

WHEREFORE, the parties request that the Board enter a Final Order approving and incorporating this Settlement Agreement in resolution of this matter.

SIGNED this 2 day of August, 2012

HARRY G. HORODECK, RPH
CASE NO. 2011-13626

STATE OF Florida

COUNTY OF Lee

Before me personally appeared Harry G. Horodeck, RPh, whose identity is known to me or by FL DL (type of identification), and who, under oath, acknowledges that his signature appears above.

Sworn to and subscribed before me this 2 day of August, 2012.

Notary Public
My Commission Expires: 5/1/2016

BETTY RENTERIA
MY COMMISSION # EE 194736
EXPIRES: May 1, 2016

APPROVED this 6th day of August, 2012.

JOHN H. ARMSTRONG, MD
State Surgeon General and
Secretary of Health

JOHN J. TRUITT
Assistant General Counsel
Fla. Bar No. 0084752
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bln C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: john_truitt@doh.state.fl.us

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

PETITIONER,

v. **CASE NO. 2011-13626**

HARRY G HORODECK, R.Ph.,

RESPONDENT.
_____/

ADMINISTRATIVE COMPLAINT

COMES NOW, Petitioner, Department of Health (Department), by and through its undersigned counsel, and files this Administrative Complaint before the Board of Pharmacy against Respondent, Harry G Horodeck, R.Ph., and in support thereof alleges:

1. Petitioner is the state department charged with regulating the practice of pharmacy pursuant to Section 20.43, Florida Statutes; Chapter 456, Florida Statutes; and Chapter 465, Florida Statutes.

2. At all times material to this Complaint, Respondent was a licensed pharmacist within the state of Florida, having been issued license number PS 12646.

EXHIBIT
A

3. Respondent's address of record is 2636 NW 8th Terrace, Cape Coral, Florida 33993.

4. On or about September 15, 2011, in the County Court of the Twentieth Judicial Circuit, in and for Lee County, Florida, in case number 11-MM-024964, an information was filed charging Respondent with petit theft for stealing property, on or about November 26, 2010, from the pharmacy where Respondent worked as a pharmacist.

5. On or about March 13, 2012, in County Court of the Twentieth Judicial Circuit, in and for Lee County, Florida, in case number 11-MM-024964, Respondent pled nolo contendere to the crime Larceny – Petit Theft, a second-degree misdemeanor violation of Chapter 812, Florida Statutes.

6. Larceny - Petit Theft from the pharmacy where Respondent worked as a pharmacist is a crime that relates to the practice of pharmacy, which is the licensee's profession.

7. Section 456.072(1)(c), Florida Statutes (2011), provides that being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which

relates to the practice of, or the ability to practice, a licensee's profession, constitutes grounds for discipline.

8. On or about March 3, 2012, Respondent pled nolo contendere to Larceny – Petit Theft to allegations Respondent stole from the pharmacy where Respondent worked as a pharmacist, which is a crime that relates to the practice of pharmacy, the licensee's profession.

9. Based on the foregoing, Respondent violated Section 456.072(1)(c), Florida Statutes (2011), by being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

WHEREFORE, Petitioner respectfully requests that the Board of Pharmacy enter an order imposing one or more of the following penalties: permanent revocation or suspension of Respondent's license, restriction of practice, imposition of an administrative fine, issuance of a reprimand, placement of Respondent on probation, corrective action, refund of fees billed or collected, remedial education and/or any other relief that the Board deems appropriate.

SIGNED this 26th day of June, 2012.

JOHN H. ARMSTRONG, MD
State Surgeon General and Secretary of Health

JOHN J. TRUITT
Assistant General Counsel
Fla. Bar No. 0084752
Florida Department of Health
Office of the General Counsel
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265
Telephone: (850) 245-4640
Facsimile: (850) 245-4683
Email: john_truitt@doh.state.fl.us

FILED
DEPARTMENT OF HEALTH
DEPUTY CLERK
CLERK Angel Sanders
DATE JUN 27 2012

PCP: 6/26/2012
PCP Members: Drs Fallon & Weiser

NOTICE OF RIGHTS

Respondent has the right to request a hearing to be conducted in accordance with Section 120.569 and 120.57, Florida Statutes, to be represented by counsel or other qualified representative, to present evidence and argument, to call and cross-examine witnesses and to have subpoena and subpoena duces tecum issued on his or her behalf if a hearing is requested.

NOTICE REGARDING ASSESSMENT OF COSTS

Respondent is placed on notice that Petitioner has incurred costs related to the investigation and prosecution of this matter. Pursuant to Section 456.072(4), Florida Statutes, the Board shall assess costs related to the investigation and prosecution of a disciplinary matter, which may include attorney hours and costs, on the Respondent in addition to any other discipline imposed.

April 1, 2013

Mr. Harry G Horodeck
2636 NW 8th Terrace
Cape Coral, FL 33993

Final Order filed: January 7, 2013
Case Number: 201113626
License Number: 12646

Dear Mr. Horodeck:

The Compliance Management Unit has received your payment of the fines and/or costs imposed in the Final Order for Case Number 201113626.

Amount Paid:	$5,556.67
Date Received:	March 21, 2013
Receipt Number:	912050606
Balance:	0

The mission of the Department of Health is to protect, promote, & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by calling (850) 245-4268.

Sincerely,

Sondra N. Allen

Sondra N. Allen
Operations Analyst II

/sna

SN

RECEIVED

03/22/2013 5,556.67
ID: 3585 Type: F
3016958
912050606

COMPLIANCE MANAGEMENT
FINE/COSTS INVOICE

Respondent:	**Harry G. Horodeck**		
Profession-License Number:	**2201 Pharmacist** **12646**	**Indv/Org #**	**5031327**
File Number:	**3585**	**Case Number:**	**201113626**

Fine:	**$ 2,000.00**	**Due Date: April 7, 2013**
Administrative Costs:	**$ 3,556.67**	**Due Date: April 7, 2013**
TOTAL:	**$ 5,556.67**	

Check enclosed # 1610210440

To receive credit for your payment attach cashier's check or money order here and return to:
Please make checks payable to the Department of Health

2201
12646

Department of Health
Compliance Management Unit, BIN C-76
P.O. Box 6320
Tallahassee, Florida 32314-6320

Partial payment shall be accepted, however full payment must be made by the due date specified in the Final Order. Each payment must be accompanied by a copy of this invoice. Please make additional copies if needed.

IMPORTANT: Payment in full of all fines and costs imposed by your Final Order are due upon the due date specified by the Final Order. Failure to pay all fines and costs on or before the due date specified will result in the following:

- A referral will be filed with Consumer Services for investigation regarding non-compliance with your Final Order and possible further disciplinary action.
- Failure to pay in full within thirty (30) days of the due date specified by the Final Order will result in the account being deemed "past due". Payment of "past due" accounts will avoid assignment to a collection agency for collection; however it will not result in closing of the referral for non-compliance with your Final Order."

April 8, 2013

Mr. Harry G. Horodeck
2636 NW 8th Terrace
Cape Coral, FL 33993

Final Order filed: January 7, 2013
Case Number: 201113626
License Number: 12646

Dear Mr. Horodeck:

The Compliance Management Unit has received your April 2013 respondent report. Your next respondent report is due July 7, 2013.

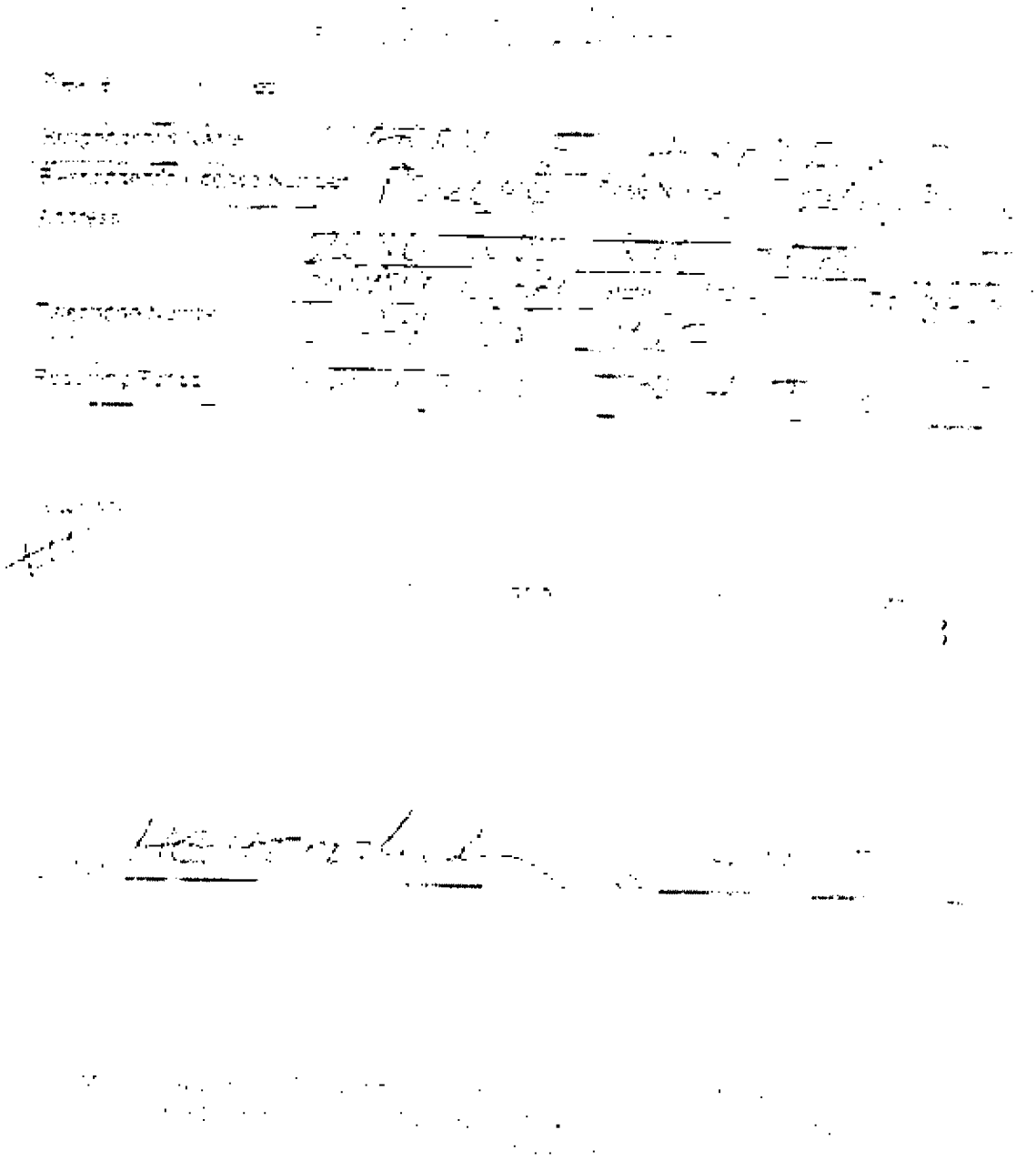
The mission of the Department of Health is to protect, promote, & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by telephone at (850) 245-4268.

Sincerely,

Sondra N. Allen

Sondra N. Allen
Operations Analyst II

/sna



June 24, 2013

Mr. Harry G. Horodeck, Rph
2636 NW 8th Terrace
Cape Coral, FL 33993

Final Order filed: January 7, 2013
Case Number: 201113626
License Number: 12646

Dear Mr. Horodeck:

The Compliance Management Unit has received your July 7, 2013 respondent report. Please contact your compliance officer once you are actively practicing pharmacy and your probation will resume at that time.

The mission of the Department of Health is to protect, promote, & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by telephone at (850) 245-4268.

Sincerely,

Sondra N. Allen

Sondra N. Allen
Operations Analyst II

/sna

BOARD OF PHARMACY
RESPONDENT'S QUARTERLY REPORT

Please print or write legibly.

Respondent's Name:	HARRY G. HORODECK
Respondent's License Number:	PS12646 Case Number: 2011113626
Address:	2636 NW 8th TER.
City	CAPE CORAL State FL Zip 33993
Telephone Number	239.989.9490
Reporting Period	From: 4.7.13 To: 7.7.13

Please initial

HH

According to the terms of my final order, I am required to notify the Department of Health of my employment status as a Pharmacist. I am not employed as a Pharmacist.

Signature: HHorodeck Date: 6.20.13

Mailing Address: Department of Health, Compliance Management Unit
4052 Bald Cypress Way, Bin C76 • Tallahassee, FL 32399
Fax: (850) 488-0796

September 26, 2013

Mr. Harry G. Horodeck, R.ph.
2636 NW 8th Terrace
Cape Coral, FL 33993

Final Order filed: January 7, 2013
Case Number: 201113626
License Number: 12646

Dear Mr. Horodeck:

The Compliance Management Unit has received your October 7, 2013 respondent report. Although you are not currently practicing pharmacy, you are required to submit quarterly respondent reports. Please contact your compliance officer when you return to the active practice of pharmacy and your probation will resume at that time.

The mission of the Department of Health is to protect, promote, & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by telephone at (850) 245-4268.

Sincerely,

Sondra N. Allen

Sondra N. Allen
Operations Analyst II

/sna

RECEIVED
BY:

BOARD OF PHARMACY
RESPONDENT'S QUARTERLY REPORT

Please print or write legibly.

Respondent's Name:	HARRY G. HORODECK
Respondent's License Number:	PS12646 Case Number: 2011113626
Address:	2636 NW 8th TER.
City	CAPE CORAL State FL Zip 33993
Telephone Number	239.989.9490
Reporting Period	From: 7.7.13 To: 10.7.13

Please initial

According to the terms of my final order, I am required to notify the Department of Health of my employment status as a Pharmacist. I am not employed as a Pharmacist.

Signature: HGHorodeck Date: 9.23.13

Mailing Address: Department of Health, Compliance Management Unit
4052 Bald Cypress Way, Bin C76 • Tallahassee, FL 32399
Fax: (850) 488-0796

January 3, 2014

Mr. Harry G. Horodeck, R.ph.
2636 NW 8th Terrace
Cape Coral, FL 33993

Final Order filed: January 7, 2013
Case Number: 201113626
License Number: 12646

Dear Mr. Horodeck:

The Compliance Management Unit has received your January 2014 respondent report. Although you are not currently practicing pharmacy, you are required to submit quarterly respondent reports. Please contact your compliance officer when you return to the active practice of pharmacy and your probation will resume at that time.

The mission of the Department of Health is to protect, promote, & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me by telephone at (850) 245-4268.

Sincerely,

Sondra N. Allen

Sondra N. Allen
Operations Analyst II

/sna

BOARD OF PHARMACY
RESPONDENT'S QUARTERLY REPORT

Please print or write legibly.

Respondent's Name:	HARRY G. HORODECK
Respondent's License Number:	PS12646
Case Number:	2011113626
Address:	2636 NW 8th TER.
City	CAPE CORAL
State	FL
Zip	33993
Telephone Number	239.989.9490
Reporting Period	From: To: 1.7.14

NEW ADDRESS - 3831 - N.W. 44 PL.
C.C. 33993

Please Initial HH

According to the terms of my final order, I am required to notify the Department of Health of my employment status as a Pharmacist. I am not employed as a Pharmacist.

Signature: HHorodeck Date: 12-21-13

Mailing Address: Department of Health, Compliance Management Unit
4052 Bald Cypress Way, Bin C76 • Tallahassee, FL 32399
Fax: (850) 488-0796

April 1, 2013

Mr. Harry G. Horodeck
2636 NW 8th Terrace
Cape Coral, FL 33993

Compliance Reference Number: 201113626

Dear Mr. Horodeck:

The Final Order in Case Number 201113626 required you to complete 12 hours of laws and rules continuing education by January 7, 2014. You have been issued credit for the 12 hour of laws and rules continuing education. Please retain a copy of this letter for your records.

Disciplinary continuing education hours may not be used for required license renewal.

The mission of the Department of Health is to protect, promote, & improve the health of all people in Florida through integrated state, county, & community efforts. If you have any questions, please contact me at (850) 245-4268.

Sincerely,

Sondra N. Allen

Sondra N. Allen
Operations Analyst II

/sna

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Horodeck

License#_____

has earned 1.5 continuing education credits for the successful completion of

Inspecting Pharmacies for Compliance to Florida Laws

BC-0165-0000-12-087-L03-P

issued Tuesday, December 04, 2012

Date of Program: December 2, 2012

Consultant Approval Number PSC372488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1269

Authorized by:

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Horodeck

License#_____

has earned 1.5 continuing education credits for the successful completion of

Registered Pharmacy Technicians And The Law: What Your Pharmacy Staff Needs to Know to Stay Compliant?

RC-0165-0000-12-089-L03-P

issued Tuesday, December 04, 2012

Date of Program: December 2, 2012

Consultant Approval Number PSC372488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1275

Authorized by:

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Horodeck

License#_____

has earned 1.5 continuing education credits for the successful completion of

Surviving Today's Aggressive Auditing Programs

RC-0165-0000-12-088-L03-P

issued Tuesday, December 04, 2012

Date of Program: December 2, 2012

Consultant approval Number PSC72488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1272

Authorized by:

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Herodeck

License#_____

has earned 1.5 continuing education credits for the successful completion of

Managing Public Policy Changes that Affect Patient Care

RC-0165-0000-12-086-L03-P

issued Tuesday, December 04, 2012

Date of Program: December 2, 2012

Consultant Approval Number PSC372488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1266

Authorized by:

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Horodeck

License#_____

has earned 1.5 continuing education credits for the successful completion of

Controlled Substance Compliance Under the Enforcement Looking Glass

RC-0165-0000-12-085-L03-P

effective Tuesday, December 04, 2012

Date of Program: December 1, 2012

Consultant Approval Number PSC372488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1263

Authorized by:

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Horodeck

License#_____

has earned 1.5 continuing education credits
for the successful completion of

Compounding Gold Standards and Compliance

RC-0165-0000-12-084-L03-P

issued Tuesday, December 04, 2012

Date of Program: December 1, 2012

Consultant Approval Number PSC372488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1260

Authorized by:

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Horodeck

License#_____

has earned 1.5 continuing education credits for the successful completion of

Legal Aspects of Dispensing Controlled Substances

RC-0165-0000-12-083-L03-P

issuedTuesday, December 04, 2012

Date of Program: December 1, 2012

Consultant Approval Number PSC372488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1258

Authorized by:

The Florida Pharmacy Association is accredited by the Accreditation Council for Pharmacy Education as a provider of pharmacy education. The Florida Pharmacy Association is also a Florida Department of Health approved CE provider.

This is to certify that

Harry G. Horodeck

License#_____

has earned 1.5 continuing education credits for the successful completion of

Update on Florida's Prescription Drug Monitoring Program

FC-0165-0000-12-082-L03-P

issued Tuesday, December 04, 2012

Date of Program: December 1, 2012

Consultant Approval Number PSC372488

This is an ACPE knowledge based activity

Issued by: Florida Pharmacy Association

Certificate ID: 14686734-1255

Authorized by:

March 3, 2014

Andrew Michael Maniscalco
4695 SW 18th Place, APT 2512 B
Gainesville, FL 32607

RE: Registered Pharmacy Technician Application

Dear Mr. Maniscalco,

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, April 2, 2014. The meeting is being held at the Marriott Westshore, 1001 N. Westshore Boulevard, Tampa, FL 33607. The meeting will begin at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.doh.state.fl.us/mqa/pharmacy/ph_meeting.html.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

Jay Cumbie,
Regulatory Specialist II

November 8, 2013

Andrew Michael Maniscalco
4695 SW 18th Place, Apt. 2512 B
Gainesville, Fl 32607

RE: Registered Pharmacy Technician Application

Dear Mr. Maniscalco:

This is to advise that the above reference matter will be reviewed by the Board at their next scheduled meeting which is Wednesday, December 4, 2013. The meeting is being held at the Hilton Hotel University of Florida, 1714 SW 34th Street, Gainesville, FL 32607, (352) 371-3600. The meeting begins at 9:00 a.m.

You are not required to appear; however, you are encouraged to do so. Issues are heard in the order they are listed on the agenda. We are unable to give you an exact time your request will be heard. Our office will follow up in writing after the meeting regarding the Board's decision.

You may print a copy of the agenda which will be available on the Board of Pharmacy website a week before the meeting at: http://www.floridaspharmacy.gov/meeting-information/upcoming-meetings/.

If you have any questions regarding this information, please contact me at 850-245-4444, ext. 3367.

Sincerely,

James Cumbie
Regulatory Specialist II
Florida Board of Pharmacy

Cumbie, James A

From: Andy Maniscalco <tekrock9.99@gmail.com>
Sent: Thursday, January 16, 2014 2:40 AM
To: Cumbie, James A
Subject: Request to appear at April Board Meeting in Tampa, FL

Follow Up Flag: Follow up
Flag Status: Completed

To James Cumbie or to whom it may concern:

I am a CPhT requesting to attend the Board Meeting in Tampa, FL on April 1st-2nd. I am trying to obtain my state license. I received a letter from the Florida Dept. of Health/Board of Pharmacy concerning the Board's decision for my application for a state license. The decision was that I am required to appear at the next available Board Meeting for my application to be considered. I would be deeply grateful if you could work my case into the agenda for the April Board Meeting. My file number is 52809. Please reply so I can confirm that this message was recieved. Thank you very much and have a great weekend!

Andrew M. Maniscalco, CPhT
File No. 52809

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

One or more pages have been removed from this document for security reasons

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456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

Mission:
To protect, promote, & improve the health of all people in Florida through integrated state, county & community efforts.

Florida HEALTH

Rick Scott
Governor

John H. Armstrong, MD, FACS
State Surgeon General & Secretary

Vision: To be the Healthiest State in the Nation

Initial Application for Licensure
Florida Board of Pharmacy
Florida Department of Health

Basic Data

Profession:	REGISTERED PHARMACY TECHNICIAN
Application Type:	REGISTERED PHARMACY TECHNICIAN INITIAL APPLICATION
Name:	MR. ANDREW MICHAEL MANISCALCO
Date of Birth:	06/23/1982
Place of Birth:	BIRMINGHAM, AL
Email Address:	TEKROCK9.99@GMAIL.COM

Mailing Address

4695 SW 18TH PL APT. 2512B
GAINESVILLE, FL 32607

Physical Location or Address of Employment

4695 SW 18TH PL APT. 2512B
GAINESVILLE, FL 32607

Phone Numbers

Home:	352-514-2939
Business:	352-514-2939

Equal Opportunity Data

Gender:	MALE
Race:	WHITE

Education History

Course Provider:	EXPRESS TRAINING SERVICES, LLC
Course Approved By:	FLORIDA BOARD OF PHARMACY APPROVED
Course Competion Date:	04/18/2013

Other Name History

No Other Name History data entered.

Secondary Work Location

Other State Licenses

License Number:	License Number:
License Type:	License Type:
Licensure Date:	Licensure Date:
Date of Expiration:	Date of Expiration:
Country:	Country:
State:	State:

Criminal History

Have you ever been convicted of, or entered a plea of guilty, nolo contendere, or no contest to, a crime in any jurisdiction other than a minor traffic offense? Your answer: **YES**

Discipline History

Has disciplinary action ever been taken against your pharmacy technician registration, or any other professional license you may have in this state or any other state?	Your answer: **NO**
Have you ever surrendered your pharmacist or any other professional license in another jurisdiction when disciplinary action was pending?	Your answer: **NO**
Are you presently under investigation or is any disciplinary action pending against you?	Your answer: **NO**

Questions related to Section 456.0635(2), Florida Statutes

Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under Chapter 409, F.S. (relating to social and economic assistance), Chapter 817, F.S. (relating to fraudulent practices), Chapter 893, F.S. (relating to drug abuse prevention and control) or a similar felony offense(s) in another state or jurisdiction?	Your answer: **NO**
For the felonies of the first or second degree, has it been more than 15 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
For the felonies of the third degree, has it been more than 10 years from the date of the plea, sentence and completion of any subsequent probation? (This question does not apply to felonies of the third degree under Section 893.13(6)(a), Florida Statutes).	Your answer: **N/A**
For the felonies of the third degree under Section 893.13(6)(a), Florida Statutes, has it been more than 5 years from the date of the plea, sentence and completion of any subsequent probation?	Your answer: **N/A**
Have you successfully completed a drug court program that resulted in the plea for the felony offense being withdrawn or the charges dismissed?	Your answer: **N/A**
Have you been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 (relating to controlled substances) or 42 U.S.C. ss. 1395-1396 (relating to public health, welfare, Medicare and Medicaid issues)?	Your answer: **NO**
Has it been more than 15 years before the date of application since the sentence and any subsequent period of probation for such conviction or plea ended?	Your answer: **N/A**
Have you ever been terminated for cause from the Florida Medicaid Program pursuant to Section 409.913, Florida Statutes?	Your answer: **NO**
If you have been terminated but reinstated, have you been in good standing with the Florida Medicaid Program for the most recent five years?	Your answer: **N/A**
Have you ever been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program?	Your answer: **NO**
Have you been in good standing with a state Medicaid program for the most recent five years?	Your answer: **N/A**
Did the termination occur at least 20 years before the date of this application?	Your answer: **N/A**
Are you currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities?	Your answer: **NO**
On or before July 1, 2009, were you enrolled in an educational or training program in the profession in which you are seeking licensure that was recognized by this profession's licensing board or the Department of Health?	Your answer: **N/A**

Additional Information

Availability for Disaster: Will you be available to provide health care services in special needs shelters or help staff disaster medical assistance teams during times of emergency or major disaster?	Your answer: **NO**

Military Veteran Fee Waiver

Date of Discharge:	Your answer: **N/A**

Application Statement

☒ Section 456.013(1)(a), F.S., requires that applicants supplement their applications as needed to reflect any material change in any circumstances or changes stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department.

The statements contained in this application are true, complete and correct and I agree that said statements shall form the basis of my application and I do authorize the Florida Board of Pharmacy to make any investigations they deem appropriate and to secure any additional information concerning me. I further authorize them to furnish any information they may have or have in the future concerning me to any person, corporation, institution, association, board or any municipal, county, state, or federal government agencies or units, and that I understand according to the Florida Board of Pharmacy statutes, a pharmacy technician registration may be revoked or suspended for presenting any false, fraudulent, or forged statement, certificate, diploma, or other thing, in connection with an application for a license or permit, as set forth in section 456.015(2)(a), F.S.

To Whom It May Concern:

Close to three years ago I was hospitalized voluntarily due to a horrible side effect produced by a medication that was introduced to my regimen at the time. The side effect was a mood change which gave me suicidal thoughts. While being treated, I was given another medication to help eliminate the depression produced by the combination of other medications I was prescribed prior. I was discharged in a couple of days. During that time period I had many stressors in my life, on top of some emotional problems. I had lost my job, and I was a college student trying to figure out what I wanted to major in. My relationship with my then significant other had fizzled out as well. I was also recovering from the trauma of an emotionally abusive upbringing. I had been diagnosed with A.D.D. and Mood Disorder NOS as I continued to seek help afterwards. Eventually I weaned off the medication entirely because no matter what I tried in regards to medication, it didn't help. I sought counseling which was most beneficial. Today I am fine, and I have learned to cope without the aid of medication. In regards to my eleven-year-old criminal charge, a lot has changed since. I was young and foolish and I made a mistake. Today I don't even drink alcohol. It destroys a lot of lives despite it being socially acceptable. I've witnessed it firsthand. I have recently taken an interest in pharmacy, maybe because my father is a physician. I seem to have a knack for it listening to and absorbing all of his medical jargon throughout the years. I am also a phlebotomist. I graduated top of the class for my pharmacy technician training. I was also the first to get PTCB certified. I desire the experience of working as a pharmacy technician while working towards a doctorate in pharmacy. Thank you for your time and consideration and have a wonderful day.

Sincerely,

Andrew M. Maniscalco, C.Ph.T., N.C.P.T.

CONFIDENTIAL AND EXEMPT MATERIALS

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Scroll down to see the available pages or advance to the next document if all pages have been removed.

SOME OR ALL PAGES IN THIS DOCUMENT ARE PATIENT RECORDS AND/OR DOCUMENTS THAT IDENTIFY THE PATIENT BY NAME AND ARE EXEMPT FROM PUBLIC RECORDS LAWS.

456.057 - Ownership and control of patient records; report or copies of records to be furnished.—

10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

CONFIDENTIAL AND EXEMPT MATERIALS

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STATE OF FLORIDA
vs.
MANISCALO ANDREW MICHAEL

THE COUNTY COURT
Y COUNTY, FLORIDA
CASE NO: 03-2002-CT-003090-AXXX-XX
DRIVING UNDER INFLUENCE

JUDGMENT AND SENTENCE

___ The defendant this day having been found guilty as a result of a (jury) (bench) trial and the Court having considered matters with respect to an appropriate sentence it is therefore,

✓ The defendant this day having entered a written plea of (guilty) (no contest) and having considered the circumstances surrounding the plea and finding that a factual basis exists to accept it; that the defendant has entered this plea freely and voluntarily, following an explanation by the Court of the matters contained therein; and that the defendant understands what is contained therein, and the Court finding that the defendant is not under the influence of any drug or spirits and appearing to be of sound mind, it is therefore:

ORDERED AND ADJUDGED ___ that adjudication of guilt is withheld
✓ the defendant is adjudicated guilty and the following sentence imposed:

___ The defendant is to pay the Clerk of this Court the following amounts on or before 4 or else obtain from the Judge a timely extension;

Fine (including costs & surcharge)	600.00
Restitution	
Other	40.00 PD Fee 50.00 BCADTF
TOTAL	690.00

The defendant is to pay the above over the probation period as set forth below (if an asterisk is placed in the "on or before" blank)

___ Failure to complete the sentence a ordered or else to obtain a timely extension will result in a jail sentence of ____ days, with credit for time served of _____.

___ Reduce to court costs of _____ is valid Florida Drivers License presented on or before due date.

✓ Produce a valid drivers license by _____.

✓ Incarceration in the county jail for 4 days (on each count consecutive/concurrent), with credit for 4 days time served. This case/cases to run (concurrent with/consecutive to): _____

___ Jail suspended until _____ on condition that defendant _____

___ Jail to be served at direction of Probation Officer.

✓ Probation supervised by SACD for a period of 6 months. as is more specifically set out in the Probation Order rendered contemporaneously herewith (consecutive/concurrent).

___ Unsupervised probation for a period of ____ months, during which defendant will engage in no conduct resulting in the filing of criminal charges against him/her, will carry out all other orders set forth in the judgement, and will _____

___ Defendant may substitute for any remaining jail sentence or fine as set forth above; ____ hours work in the County Work Program.

___ Restitution in an amount to be agreed upon between defendant and the victim or, in the absence of agreement, to be determined by the Court after notice and hearing.

✓ Defendant will peform 50 hours (community service work over the probation period/in the County Work Program).

✓ Complete the DUI School (1st offender/multiple offender) program during the probation period and complete alcohol treatment and counseling as required by law.

___ Complete ADI School (over the probation period/within the time provided to pay the fine set forth above).

___ Complete the (Money Management Course/Shoplifters Anonymous Course) over the probation period/within the time provided to pay the fine set forth above, and provide proof of completion to the Clerk).

___ Complete the Substance Abuse Awareness Course (over the probation period/within the time provided to pay the fine set forth above and provide proof of completion to Clerk).

✓ Defendant's driver license/privilege to drive in Florida is suspended/revoked for a period of 6 years/months.

___ Return confiscated _____ to defendant.

___ Complete DWLS/R Corrective Measures Program (over the probation period/within the time provided to pay the fine set forth above and provide proof of completion to the clerk).

___ Complete the P.A.V.E. Program (over the probation period/within the time provided to pay the fine set forth above and provide proof of completion to the Clerk).

___ Release Cash Bond

✓ Other: 1) Report to BBR w. ITT Sheet w/in 72 hrs of release
2) VAP
3) 10 day jail to be served at Bay Jail

___ Apply Cash Bond to fine

THE COURT now advises you that it is your right to appeal from this judgement and sentence within thirty (30) days from this date. Failure to appeal within the thirty (30) day period will be a waiver of your right to appeal. You also are entitled to assistance of counsel in taking an appeal, and upon your request and showing that your are entitled to an attorney at the expense of the State, the Court will appoint one for you for the purposes of appeal.

RECEIVED

SEP 16 2013

Florida Board of Pharmacy

DONE AND ORDERED in open court this 24th day of July, 2002 in Panama City, Bay County, Florida.

Copy: State Attorney
Defendant and /or Attorney

COUNTY JUDGE

THE SALVATION ARMY CORRECTIONS DEPARTMENT

IN THE COUNTY COURT OF
BAY COUNTY, FLORIDA

STATE OF FLORIDA
VS.
ANDREW MICHAEL MANISCALO CASE NUMBER: 02-CT-3090-A

TERMINATION OF PROBATION

THIS CAUSE coming on to be heard before the Honorable JOHN D. O'BRIEN, Judge, and it appearing that ANDREW MICHAEL MANISCALO hereinafter referred to as the defendant on the 24TH day of JULY, 20 02.

having entered a plea of: NO CONTEST

been found guilty by the: _____

in the above styled Court to the of the offense of DRIVING UNDER THE INFLUENCE and that said Court placed the defendant on probation for a term of SIX (6) MONTHS in accordance with Chapter 948, Florida Statutes.

It further appearing that the defendant has conformed to the conditions of said probation in a law-abiding manner and

WHEREFORE, the undersigned respectfully prays that this Honorable Court terminate the probation of the defendant and discharge him/her in accordance with the law.

Dated this 24 day of March, 20 04.

Ann Page
PROBATION SUPERVISOR

It is therefore ORDERED AND ADJUDGED that the probation of the defendant is terminated in accordance with Chapter 948, Florida Statutes.

It is further ORDERED that the Clerk of this Court file this order in his office, enter copy of the same in the appropriate docket book of the Court, and forthwith forward a copy of the same to the Probation Officer for use in compliance with the requirement of law.

DONE AND ORDERED in open Court this 24 day of March, 20 04

John D. O'Brien
PRESIDING JUDGE

EXPRESS
TRAINING SERVICES, LLC

"Getting your career on the right track"

This is to certify that

Andrew Maniscalco

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SEP 16 2013
Florida Board of Pharmacy

Has successfully completed the

Pharmacy Technician Training Program

CIE Training Code 3276

Sherri Kalishman RPBSP

Sherri Kalishman, Director of Education

April 19, 2013

Date

The 2012 Florida Statutes

Chapter 465 Pharmacy

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465.003 Definitions.
465.004 Board of Pharmacy.
465.005 Authority to make rules.
465.006 Disposition of fees; expenditures.
465.007 Licensure by examination.
465.0075 Licensure by endorsement; requirements; fee.
465.008 Renewal of license.
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465.0255 Expiration date of medicinal drugs; display; related use and storage instructions.
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465.187 Sale of medicinal drugs.
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465.189 Administration of vaccines and epinephrine autoinjection.
465.1901 Practice of orthotics and pedorthics.

465.001 Short Title.—This chapter shall be known as the "Florida Pharmacy Act." History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.002 Legislative findings; intent.—The Legislature finds that the practice of pharmacy is a learned profession. The sole legislative purpose for enacting this chapter is to ensure that every pharmacist practicing in this state and every pharmacy meet minimum requirements for safe practice. It is the legislative intent that pharmacists who fall below minimum competency or who otherwise present a danger to the public shall be prohibited from practicing in this state. History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.003 Definitions.—As used in this chapter, the term:

(1)"Administration" means the obtaining and giving of a single dose of medicinal drugs by a legally authorized person to a patient for her or his consumption.

(2)"Board" means the Board of Pharmacy.

(3)"Consultant pharmacist" means a pharmacist licensed by the department and certified as a consultant pharmacist pursuant to s. 465.0125.

(4)"Data communication device" means an electronic device that receives electronic information from one source and transmits or routes it to another, including, but not limited to, any such bridge, router, switch, or gateway.

(5)"Department" means the Department of Health.

(6)"Dispense" means the transfer of possession of one or more doses of a medicinal drug by a pharmacist to the ultimate consumer or her or his agent. As an element of dispensing, the pharmacist shall, prior to the actual physical transfer, interpret and assess the prescription order for potential adverse reactions, interactions, and dosage regimen she or he deems appropriate in the exercise of her or his professional judgment, and the pharmacist shall certify that the medicinal drug called for by the prescription is ready for transfer. The pharmacist shall also provide counseling on proper drug usage, either orally or in writing, if in the exercise of her or his professional judgment counseling is necessary. The actual sales transaction and delivery of such drug shall not be considered dispensing. The administration shall not be considered dispensing.

(7)"Institutional formulary system" means a method whereby the medical staff evaluates, appraises, and selects those medicinal drugs or proprietary preparations which in the medical staff's clinical judgment are most useful in patient care, and which are available for dispensing by a practicing pharmacist in a Class II institutional pharmacy.

(8)"Medicinal drugs" or "drugs" means those substances or preparations commonly known as "prescription" or "legend" drugs which are required by federal or state law to be dispensed only on a prescription, but shall not include patents or proprietary preparations as hereafter defined.

(9)"Patent or proprietary preparation" means a medicine in its unbroken, original package which is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof and which is not misbranded under the provisions of the Florida Drug and Cosmetic Act.

(10)"Pharmacist" means any person licensed pursuant to this chapter to practice the profession of pharmacy.

(11)(a)"Pharmacy" includes a community pharmacy, an institutional pharmacy, a nuclear pharmacy, a special pharmacy, and an Internet pharmacy.

1.The term "community pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis.

2.The term "institutional pharmacy" includes every location in a hospital, clinic, nursing home, dispensary, sanitarium, extended care facility, or other facility, hereinafter referred to as "health care institutions," where medicinal drugs are compounded, dispensed, stored, or sold.

3.The term "nuclear pharmacy" includes every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. The term "nuclear pharmacy" does not include hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.

4.The term "special pharmacy" includes every location where medicinal drugs are compounded, dispensed, stored, or sold if such locations are not otherwise defined in this subsection.

5.The term "Internet pharmacy" includes locations not otherwise licensed or issued a permit under this chapter, within or outside this state, which use the Internet to communicate with or obtain information from consumers in this state and use such communication or information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Any act described in this definition constitutes the practice of pharmacy as defined in subsection (13).

(b)The pharmacy department of any permittee shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purposes of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(12)"Pharmacy intern" means a person who is currently registered in, and attending, a duly accredited college or school of pharmacy, or who is a graduate of such a school or college of pharmacy, and who is duly and properly registered with the department as provided for under its rules.

(13)"Practice of the profession of pharmacy" includes compounding, dispensing, and consulting concerning contents, therapeutic values, and uses of any medicinal drug; consulting concerning therapeutic values and interactions of patent or proprietary preparations, whether pursuant to prescriptions or in the absence and entirely independent of such prescriptions or orders; and other pharmaceutical services. For purposes of this subsection, "other pharmaceutical services" means the monitoring of the patient's drug therapy and assisting the patient in the management of his or her drug therapy, and includes review of the patient's drug therapy and communication with the patient's prescribing health care provider as licensed under chapter 458, chapter 459, chapter 461, or chapter 466, or similar statutory provision in another jurisdiction, or such provider's agent or such other persons as specifically authorized by the patient, regarding the drug therapy. However, nothing in this subsection may be interpreted to permit an alteration of a

prescriber's directions, the diagnosis or treatment of any disease, the initiation of any drug therapy, the practice of medicine, or the practice of osteopathic medicine, unless otherwise permitted by law. "Practice of the profession of pharmacy" also includes any other act, service, operation, research, or transaction incidental to, or forming a part of, any of the foregoing acts, requiring, involving, or employing the science or art of any branch of the pharmaceutical profession, study, or training, and shall expressly permit a pharmacist to transmit information from persons authorized to prescribe medicinal drugs to their patients. The practice of the profession of pharmacy also includes the administration of vaccines to adults pursuant to s. 465.189.

(14)"Prescription" includes any order for drugs or medicinal supplies written or transmitted by any means of communication by a duly licensed practitioner authorized by the laws of the state to prescribe such drugs or medicinal supplies and intended to be dispensed by a pharmacist. The term also includes an orally transmitted order by the lawfully designated agent of such practitioner. The term also includes an order written or transmitted by a practitioner licensed to practice in a jurisdiction other than this state, but only if the pharmacist called upon to dispense such order determines, in the exercise of her or his professional judgment, that the order is valid and necessary for the treatment of a chronic or recurrent illness. The term "prescription" also includes a pharmacist's order for a product selected from the formulary created pursuant to s. 465.186. Prescriptions may be retained in written form or the pharmacist may cause them to be recorded in a data processing system, provided that such order can be produced in printed form upon lawful request.

(15)"Nuclear pharmacist" means a pharmacist licensed by the department and certified as a nuclear pharmacist pursuant to s. 465.0126.

(16)"Centralized prescription filling" means the filling of a prescription by one pharmacy upon request by another pharmacy to fill or refill the prescription. The term includes the performance by one pharmacy for another pharmacy of other pharmacy duties such as drug utilization review, therapeutic drug utilization review, claims adjudication, and the obtaining of refill authorizations.

(17)"Automated pharmacy system" means a mechanical system that delivers prescription drugs received from a Florida licensed pharmacy and maintains related transaction information.

History.—ss. 1, 7, ch. 79-226; s. 322, ch. 81-259; ss. 14, 15, ch. 81-302; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 82-179; s. 1, ch. 83-101; s. 36, ch. 83-216; s. 3, ch. 83-265; s. 29, ch. 83-329; s. 1, ch. 85-35; ss. 2, 26, 27, ch. 86-256; s. 1, ch. 88-172; s. 1, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 123, ch. 94-218; s. 239, ch. 97-103; s. 87, ch. 97-264; s. 118, ch. 99-397; s. 1, ch. 2002-182; s. 1, ch. 2004-25; s. 1, ch. 2004-387; s. 2, ch. 2007-152; s. 2, ch. 2012-60.

465.004 Board of Pharmacy.—

(1)The Board of Pharmacy is created within the department and shall consist of nine members to be appointed by the Governor and confirmed by the Senate.

(2)Seven members of the board must be licensed pharmacists who are residents of this state and who have been engaged in the practice of the profession of pharmacy in this state for at least 4 years and, to the extent practicable, represent the various pharmacy practice settings. Of the pharmacist members, one must be currently engaged in the practice of pharmacy in a community pharmacy, one must be currently engaged in the practice of pharmacy in a Class II institutional pharmacy or a Modified Class II institutional pharmacy, and five shall be pharmacists licensed in this state irrespective of practice setting. The remaining two members must be residents of the state who have never been licensed as pharmacists and who are in

no way connected with the practice of the profession of pharmacy. No person may be appointed as a consumer member who is in any way connected with a drug manufacturer or wholesaler. At least one member of the board must be 60 years of age or older.

(3)As the terms of the members expire, the Governor shall appoint successors for terms of 4 years, and such members shall serve until their successors are appointed.

(4)All provisions of chapter 456 relating to activities of the board shall apply.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 3, 26, 27, ch. 86-256; s. 16, ch. 87-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 124, ch. 94-218; s. 88, ch. 97-264; s. 67, ch. 98-166; s. 124, ch. 2000-160.

465.00 5Authority to make rules.—The Board of Pharmacy has authority to adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter conferring duties upon it.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 4, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 126, ch. 98-200.

465.006 Disposition of fees; expenditures.—All moneys received under this chapter shall be deposited and expended pursuant to the provisions of s. 456.025. All expenditures for duties of the board authorized by this chapter shall be paid upon presentation of vouchers approved by the executive director of the board.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 68, ch. 98-166; s. 125, ch. 2000-160.

465.007 Licensure by examination.—

(1)Any person desiring to be licensed as a pharmacist shall apply to the department to take the licensure examination. The department shall examine each applicant who the board certifies has:

(a)Completed the application form and remitted an examination fee set by the board not to exceed $100 plus the actual per applicant cost to the department for purchase of portions of the examination from the National Association of Boards of Pharmacy or a similar national organization. The fees authorized under this section shall be established in sufficient amounts to cover administrative costs.

(b)Submitted satisfactory proof that she or he is not less than 18 years of age and:

1.Is a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education; or

2.Is a graduate of a 4-year undergraduate pharmacy program of a school or college of pharmacy located outside the United States, has demonstrated proficiency in English by passing both the Test of English as a Foreign Language (TOEFL) and the Test of Spoken English (TSE), has passed the Foreign Pharmacy Graduate Equivalency Examination that is approved by rule of the board, and has completed a minimum of 500 hours in a supervised work activity program within this state under the supervision of a pharmacist licensed by the department, which program is approved by the board.

(c)Submitted satisfactory proof that she or he has completed an internship program approved by the board. No such board-approved program shall exceed 2,080 hours, all of which may be obtained prior to graduation.

(2)The department may permit an applicant who has satisfied all requirements of subsection (1), except those relating to age or the internship program, to take the written examination, but the passing of the examination shall confer no rights or

privileges upon the applicant in connection with the practice of pharmacy in this state.

(3)Except as provided in subsection (2), the department shall issue a license to practice pharmacy to any applicant who successfully completes the examination in accordance with this section.

History.—ss. 1, 7, ch. 79-226; ss. 13, 15, 23, 25, 30, 34, 62, ch. 80-406; ss. 2, 3, ch. 81-318; s. 30, ch. 83-329; ss. 5, 26, 27, ch. 86-256; s. 13, ch. 88-205; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 240, ch. 97-103.

465.0075 Licensure by endorsement; requirements; fee.—

(1)The department shall issue a license by endorsement to any applicant who applies to the department and remits a nonrefundable fee of not more than $100, as set by the board, and whom the board certifies:

(a)Has met the qualifications for licensure in s. 465.007(1)(b) and (c);

(b)Has obtained a passing score, as established by rule of the board, on the licensure examination of the National Association of Boards of Pharmacy or a similar nationally recognized examination, if the board certifies that the applicant has taken the required examination;

(c)1.Has submitted evidence of the active licensed practice of pharmacy, including practice in community or public health by persons employed by a governmental entity, in another jurisdiction for at least 2 of the immediately preceding 5 years or evidence of successful completion of board-approved postgraduate training or a board-approved clinical competency examination within the year immediately preceding application for licensure; or

2.Has completed an internship meeting the requirements of s. 465.007(1)(c) within the 2 years immediately preceding application; and

(d)Has obtained a passing score on the pharmacy jurisprudence portions of the licensure examination, as required by board rule.

(2)An applicant licensed in another state for a period in excess of 2 years from the date of application for licensure in this state shall submit a total of at least 30 hours of board-approved continuing education for the 2 calendar years immediately preceding application.

(3)The department may not issue a license by endorsement to any applicant who is under investigation in any jurisdiction for an act or offense that would constitute a violation of this chapter until the investigation is complete, at which time the provisions of s. 465.016 apply.

(4)The department may not issue a license by endorsement to any applicant whose license to practice pharmacy has been suspended or revoked in another state or who is currently the subject of any disciplinary proceeding in another state.

History.—s. 1, ch. 2001-166; s. 1, ch. 2008-216.

465.008 Renewal of license.—

(1)The department shall renew a license upon receipt of the renewal application, verification of compliance with s. 465.009, and receipt of a fee set by the board not to exceed $250.

(2)The department shall adopt rules establishing a procedure for the biennial renewal of licenses.

(3)Any person licensed under this chapter for 50 years or more is exempt from the payment of the renewal or delinquent fee, and the department shall issue a lifetime license to such a person.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 6, 26, 27, ch. 86-256; s. 7, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 178, ch. 94-119; s. 32, ch. 2001-277.

465.009 Continuing professional pharmaceutical education.—

(1)No license renewal shall be issued by the department until the licensee submits proof satisfactory to the board that during the 2 years prior to her or his application for renewal the licensee has participated in not less than 30 hours of continuing professional pharmaceutical education in courses approved by the board.

(2)The board shall approve only those courses that build upon the basic courses offered in the curricula of accredited colleges or schools of pharmacy, and the board shall require that the provider meets the educational standards for the program design, administration, and evaluation established by the board.

(3)Upon initial licensure, the department may reduce the number of required hours consistent with the requirements of biennial renewal.

(4)The department may make exception from the requirements of this section in an emergency or hardship case.

(5)The board may adopt rules within the requirements of this section that are necessary for its implementation, including a rule creating a committee composed of equal representation from the board, the colleges of pharmacy in the state, and practicing pharmacists within the state, whose purpose shall be to approve the content of each course offered for continuing education credit prior to the time such course is offered.

(6)Notwithstanding subsections (1)-(5):

(a)Each pharmacist certified to administer a vaccine or epinephrine autoinjection under s. 465.189 must complete a 3-hour continuing education course, which shall be offered by a statewide professional association of physicians in this state accredited to provide educational activities designated for the American Medical Association Physician's Recognition Award (AMA PRA) Category I credit, on the safe and effective administration of vaccines and epinephrine autoinjection as part of biennial relicensure or recertification. This course may be offered in a distance-learning format and must be included in the 30 hours of continuing professional pharmaceutical education specified in subsection (1).

(b)Each pharmacist must submit confirmation of having completed the course specified in paragraph (a) on a form provided by the board when submitting fees for license renewal.

(c)Failure to comply with paragraphs (a) and (b) results in the revocation of the authorization for a pharmacist to administer a vaccine or epinephrine autoinjection under s. 465.189. Such authorization may be restored upon completion of such requirements.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 7, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 241, ch. 97-103; s. 1, ch. 2002-184; s. 3, ch. 2012-60.

465.012 Reactivation of license; continuing education.—

(1)The board shall prescribe by rule continuing education requirements as a condition of reactivating a license. The continuing education requirements for reactivating a license shall be at least 15 classroom hours for each year the license was inactive in addition to completion of the number of hours required for renewal on the date the license became inactive.

(2)The board shall adopt rules relating to application procedures for inactive status, to the biennial renewal of inactive licenses, and to the reactivation of

licenses. The board shall prescribe by rule an application fee for inactive status, a renewal fee for inactive status, a delinquency fee, and a fee for the reactivation of a license. None of these fees may exceed the biennial renewal fee established by the board for an active license. The department may not reactivate a license unless the inactive or delinquent licensee has paid any applicable biennial renewal or delinquency fee, or both, and a reactivation fee.
History.—ss. 1, 7, ch. 79-226; s. 323, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 2, 30, ch. 82-179; s. 3, ch. 83-265; ss. 8, 26, 27, ch. 86-256; s. 8, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 179, ch. 94-119.

465.0125 Consultant pharmacist license; application, renewal, fees; responsibilities; rules.—

(1)The department shall issue or renew a consultant pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for consultant pharmacist initial licensure or renewal as promulgated by the board by rule and a fee set by the board not to exceed $250. The consultant pharmacist shall be responsible for maintaining all drug records required by law and for establishing drug handling procedures for the safe handling and storage of drugs. The consultant pharmacist may also be responsible for ordering and evaluating any laboratory or clinical testing when, in the judgment of the consultant pharmacist, such activity is necessary for the proper performance of the consultant pharmacist's responsibilities. Such laboratory or clinical testing may be ordered only with regard to patients residing in a nursing home facility, and then only when authorized by the medical director of the nursing home facility. The consultant pharmacist must have completed such additional training and demonstrate such additional qualifications in the practice of institutional pharmacy as shall be required by the board in addition to licensure as a registered pharmacist.

(2)Notwithstanding the provisions of subsection (1), a consultant pharmacist or a doctor of pharmacy licensed in this state may also be responsible for ordering and evaluating any laboratory or clinical testing for persons under the care of a licensed home health agency when, in the judgment of the consultant pharmacist or doctor of pharmacy, such activity is necessary for the proper performance of his or her responsibilities and only when authorized by a practitioner licensed under chapter 458, chapter 459, chapter 461, or chapter 466. In order for the consultant pharmacist or doctor of pharmacy to qualify and accept this authority, he or she must receive 3 hours of continuing education relating to laboratory and clinical testing as established by the board.

(3)The board shall promulgate rules necessary to implement and administer this section.

History.—s. 31, ch. 83-329; s. 1, ch. 85-65; ss. 9, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 1, ch. 93-231; s. 89, ch. 97-264.

465.0126 Nuclear pharmacist license; application, renewal, fees.—The department shall issue or renew a nuclear pharmacist license upon receipt of an initial or renewal application which conforms to the requirements for nuclear pharmacist initial licensure or biennial renewal as established by the board by rule and receipt of a fee established by the board by rule not to exceed $250, which fee shall be in addition to the initial licensure or biennial renewal fee for pharmacists. The nuclear pharmacist shall be responsible for the compounding and the dispensing of nuclear pharmaceuticals, for maintaining all drug records required by law, for establishing drug handling procedures for the safe handling and storage of radiopharmaceuticals and medicinal drugs, for providing the security of the prescription department, and

for complying with such other rules as relate to the practice of the profession of pharmacy. The nuclear pharmacist must have completed such additional training and must demonstrate such additional qualifications in the practice of nuclear pharmacy as is required by the board by rule in addition to licensure as a registered pharmacist. The board shall adopt rules necessary to implement and administer this section. The requirements of this section do not apply to hospitals licensed under chapter 395 or the nuclear medicine facilities of such hospitals.
History.—s. 2, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.013 Registration of pharmacy interns.—The department shall register as pharmacy interns persons certified by the board as being enrolled in an intern program at an accredited school or college of pharmacy or who are graduates of accredited schools or colleges of pharmacy and are not yet licensed in the state. The board may refuse to certify to the department or may revoke the registration of any intern for good cause, including grounds enumerated in this chapter for revocation of pharmacists' licenses.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.014 Pharmacy technician.—

(1)A person other than a licensed pharmacist or pharmacy intern may not engage in the practice of the profession of pharmacy, except that a licensed pharmacist may delegate to pharmacy technicians who are registered pursuant to this section those duties, tasks, and functions that do not fall within the purview of s. 465.003(13). All such delegated acts shall be performed under the direct supervision of a licensed pharmacist who shall be responsible for all such acts performed by persons under his or her supervision. A pharmacy registered technician, under the supervision of a pharmacist, may initiate or receive communications with a practitioner or his or her agent, on behalf of a patient, regarding refill authorization requests. A licensed pharmacist may not supervise more than one registered pharmacy technician unless otherwise permitted by the guidelines adopted by the board. The board shall establish guidelines to be followed by licensees or permittees in determining the circumstances under which a licensed pharmacist may supervise more than one but not more than three pharmacy technicians.

(2)Any person who wishes to work as a pharmacy technician in this state must register by filing an application with the board on a form adopted by rule of the board. The board shall register each applicant who has remitted a registration fee set by the board, not to exceed $50 biennially; has completed the application form and remitted a nonrefundable application fee set by the board, not to exceed $50; is at least 17 years of age; and has completed a pharmacy technician training program approved by the Board of Pharmacy. Notwithstanding any requirements in this subsection, any registered pharmacy technician registered pursuant to this section before January 1, 2011, who has worked as a pharmacy technician for a minimum of 1,500 hours under the supervision of a licensed pharmacist or received certification as a pharmacy technician by certification program accredited by the National Commission for Certifying Agencies is exempt from the requirement to complete an initial training program for purposes of registration as required by this subsection.

(3)A person whose license to practice pharmacy has been denied, suspended, or restricted for disciplinary purposes is not eligible to register as a pharmacy technician.

(4)Notwithstanding the requirements of this section or any other provision of law, a pharmacy technician student who is enrolled in a pharmacy technician training

program that is approved by the board may be placed in a pharmacy for the purpose of obtaining practical training. A pharmacy technician student shall wear identification that indicates his or her student status when performing the functions of a pharmacy technician, and registration under this section is not required.

(5)Notwithstanding the requirements of this section or any other provision of law, a person who is licensed by the state as a pharmacy intern may be employed as a registered pharmacy technician without paying a registration fee or filing an application with the board to register as a pharmacy technician.

(6)As a condition of registration renewal, a registered pharmacy technician shall complete 20 hours biennially of continuing education courses approved by the board or the Accreditation Council for Pharmacy Education, of which 4 hours must be via live presentation and 2 hours must be related to the prevention of medication errors and pharmacy law.

(7)The board shall adopt rules that require each registration issued by the board under this section to be displayed in such a manner as to make it available to the public and to facilitate inspection by the department. The board may adopt other rules as necessary to administer this section.

(8)If the board finds that an applicant for registration as a pharmacy technician or that a registered pharmacy technician has committed an act that constitutes grounds for discipline as set forth in s. 456.072(1) or has committed an act that constitutes grounds for denial of a license or disciplinary action as set forth in this chapter, including an act that constitutes a substantial violation of s. 456.072(1) or a violation of this chapter which occurred before the applicant or registrant was registered as a pharmacy technician, the board may enter an order imposing any of the penalties specified in s. 456.072(2) against the applicant or registrant.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 10, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 242, ch. 97-103; s. 192, ch. 97-264; s. 120, ch. 99-397; ss. 2, 3, 4, ch. 2008-216.

465.015 Violations and penalties.—

(1)It is unlawful for any person to own, operate, maintain, open, establish, conduct, or have charge of, either alone or with another person or persons, a pharmacy:

(a)Which is not registered under the provisions of this chapter.

(b)In which a person not licensed as a pharmacist in this state or not registered as an intern in this state or in which an intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist fills, compounds, or dispenses any prescription or dispenses medicinal drugs.

(2)It is unlawful for any person:

(a)To make a false or fraudulent statement, either for herself or himself or for another person, in any application, affidavit, or statement presented to the board or in any proceeding before the board.

(b)To fill, compound, or dispense prescriptions or to dispense medicinal drugs if such person does not hold an active license as a pharmacist in this state, is not registered as an intern in this state, or is an intern not acting under the direct and immediate personal supervision of a licensed pharmacist.

(c)To sell or dispense drugs as defined in s. 465.003(8) without first being furnished with a prescription.

(d)To sell samples or complimentary packages of drug products.

(3)It is unlawful for any pharmacist to knowingly fail to report to the sheriff or other chief law enforcement agency of the county where the pharmacy is located within 24 hours after learning of any instance in which a person obtained or

attempted to obtain a controlled substance, as defined in s. 893.02, or at the close of business on the next business day, whichever is later, that the pharmacist knew or believed was obtained or attempted to be obtained through fraudulent methods or representations from the pharmacy at which the pharmacist practiced pharmacy. Any pharmacist who knowingly fails to make such a report within 24 hours after learning of the fraud or attempted fraud or at the close of business on the next business day, whichever is later, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. A sufficient report of the fraudulent obtaining of controlled substances under this subsection must contain, at a minimum, a copy of the prescription used or presented and a narrative, including all information available to the pharmacist concerning the transaction, such as the name and telephone number of the prescribing physician; the name, description, and any personal identification information pertaining to the person who presented the prescription; and all other material information, such as photographic or video surveillance of the transaction.

(4)(a)It is unlawful for any person other than a pharmacist licensed under this chapter to use the title "pharmacist" or "druggist" or otherwise lead the public to believe that she or he is engaged in the practice of pharmacy.

(b)It is unlawful for any person other than an owner of a pharmacy registered under this chapter to display any sign or to take any other action that would lead the public to believe that such person is engaged in the business of compounding, dispensing, or retailing any medicinal drugs. This paragraph shall not preclude a person not licensed as a pharmacist from owning a pharmacy.

(c)It is unlawful for a person, firm, or corporation that is not licensed or registered under this chapter to:

1.Use in a trade name, sign, letter, or advertisement any term, including "drug," "pharmacy," "prescription drugs," "Rx," or "apothecary," which implies that the person, firm, or corporation is licensed or registered to practice pharmacy in this state.

2.Hold himself or herself out to others as a person, firm, or corporation licensed or registered to practice pharmacy in this state.

(d)It is unlawful for a person who is not registered as a pharmacy technician under this chapter or who is not otherwise exempt from the requirement to register as a pharmacy technician, to perform the functions of a registered pharmacy technician, or hold himself or herself out to others as a person who is registered to perform the functions of a registered pharmacy technician in this state.

(5)Any person who violates any provision of subsection (1) or subsection (4) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. Any person who violates any provision of subsection (2) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In any warrant, information, or indictment, it shall not be necessary to negative any exceptions, and the burden of any exception shall be upon the defendant.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 11, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 91, ch. 91-224; s. 4, ch. 91-429; s. 243, ch. 97-103; s. 121, ch. 99-397; s. 55, ch. 2000-318; s. 2, ch. 2004-25; s. 5, ch. 2008-216; s. 10, ch. 2011-141.

465.0155 Standards of practice.—Consistent with the provisions of this act, the board shall adopt by rule standards of practice relating to the practice of pharmacy which shall be binding on every state agency and shall be applied by such agencies

when enforcing or implementing any authority granted by any applicable statute, rule, or regulation, whether federal or state.
History.—ss. 12, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0156 Registration of nonresident pharmacies.—

(1)Any pharmacy which is located outside this state and which ships, mails, or delivers, in any manner, a dispensed medicinal drug into this state shall be considered a nonresident pharmacy, shall be registered with the board, shall provide pharmacy services at a high level of protection and competence, and shall disclose to the board the following specific information:

(a)That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed;

(b)The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to residents of this state. This disclosure shall be made within 30 days after any change of location, corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to residents of this state;

(c)That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to the residents of this state;

(d)That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed; and

(e)That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.

(2)Applications for nonresident pharmacy registration under this section shall be made on a form furnished by the board. The board may require such information as the board deems reasonably necessary to carry out the purposes of this section. The board may grant an exemption from the registration requirements of this section to any nonresident pharmacy which confines its dispensing activity to isolated transactions. The board may define by rule the term isolated transactions.

(3)The registration fee and the biennial renewal fee shall be the fee specified in s. 465.022.

(4)The board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy for failure to comply with s. 465.025 or with any requirement of this section in accordance with the provisions of this chapter.

(5)In addition to the prohibitions of subsection (4) the board may deny, revoke, or suspend registration of, or fine or reprimand, a nonresident pharmacy in accordance with the provisions of this chapter for conduct which causes serious bodily injury or serious psychological injury to a resident of this state if the board has referred the matter to the regulatory or licensing agency in the state in which the pharmacy is located and the regulatory or licensing agency fails to investigate within 180 days of the referral.

(6)It is unlawful for any nonresident pharmacy which is not registered pursuant to this section to advertise its services in this state, or for any person who is a resident of this state to advertise the pharmacy services of a nonresident pharmacy which has not registered with the board, with the knowledge that the advertisement will or is likely to induce members of the public in this state to use the pharmacy to fill prescriptions.

(7)This section does not apply to Internet pharmacies required to be permitted under s. 465.0197.

(8)Notwithstanding s. 465.003(10), for purposes of this section, the registered pharmacy and the pharmacist designated by the registered pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

History.—ss. 13, 27, ch. 86-256; s. 3, ch. 89-218; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 31, ch. 95-144; s. 90, ch. 97-264; s. 2, ch. 2004-387.

465.016 Disciplinary actions.—

(1)The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):

(a)Obtaining a license by misrepresentation or fraud or through an error of the department or the board.

(b)Procuring or attempting to procure a license for any other person by making or causing to be made any false representation.

(c)Permitting any person not licensed as a pharmacist in this state or not registered as an intern in this state, or permitting a registered intern who is not acting under the direct and immediate personal supervision of a licensed pharmacist, to fill, compound, or dispense any prescriptions in a pharmacy owned and operated by such pharmacist or in a pharmacy where such pharmacist is employed or on duty.

(d)Being unfit or incompetent to practice pharmacy by reason of:

1.Habitual intoxication.

2.The misuse or abuse of any medicinal drug appearing in any schedule set forth in chapter 893.

3.Any abnormal physical or mental condition which threatens the safety of persons to whom she or he might sell or dispense prescriptions, drugs, or medical supplies or for whom she or he might manufacture, prepare, or package, or supervise the manufacturing, preparation, or packaging of, prescriptions, drugs, or medical supplies.

(e)Violating chapter 499; 21 U.S.C. ss. 301-392, known as the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or chapter 893.

(f)Having been convicted or found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a crime which directly relates to the ability to practice pharmacy or to the practice of pharmacy. A plea of nolo contendere constitutes a conviction for purposes of this provision.

(g)Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in s. 465.019(6) or s. 465.025.

(h)Having been disciplined by a regulatory agency in another state for any offense that would constitute a violation of this chapter.

(i)Compounding, dispensing, or distributing a legend drug, including any controlled substance, other than in the course of the professional practice of pharmacy. For purposes of this paragraph, it shall be legally presumed that the compounding, dispensing, or distributing of legend drugs in excessive or inappropriate quantities is

not in the best interests of the patient and is not in the course of the professional practice of pharmacy.

(j)Making or filing a report or record which the licensee knows to be false, intentionally or negligently failing to file a report or record required by federal or state law, willfully impeding or obstructing such filing, or inducing another person to do so. Such reports or records include only those which the licensee is required to make or file in her or his capacity as a licensed pharmacist.

(k)Failing to make prescription fee or price information readily available by failing to provide such information upon request and upon the presentation of a prescription for pricing or dispensing. Nothing in this section shall be construed to prohibit the quotation of price information on a prescription drug to a potential consumer by telephone.

(l)Placing in the stock of any pharmacy any part of any prescription compounded or dispensed which is returned by a patient; however, in a hospital, nursing home, correctional facility, or extended care facility in which unit-dose medication is dispensed to inpatients, each dose being individually sealed and the individual unit dose or unit-dose system labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any, the unused unit dose of medication may be returned to the pharmacy for redispensing. Each pharmacist shall maintain appropriate records for any unused or returned medicinal drugs.

(m)Being unable to practice pharmacy with reasonable skill and safety by reason of illness, use of drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. A pharmacist affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that she or he can resume the competent practice of pharmacy with reasonable skill and safety to her or his customers.

(n)Violating a rule of the board or department or violating an order of the board or department previously entered in a disciplinary hearing.

(o)Failing to report to the department any licensee under chapter 458 or under chapter 459 who the pharmacist knows has violated the grounds for disciplinary action set out in the law under which that person is licensed and who provides health care services in a facility licensed under chapter 395, or a health maintenance organization certificated under part I of chapter 641, in which the pharmacist also provides services.

(p)Failing to notify the Board of Pharmacy in writing within 20 days of the commencement or cessation of the practice of the profession of pharmacy in Florida when such commencement or cessation of the practice of the profession of pharmacy in Florida was a result of a pending or completed disciplinary action or investigation in another jurisdiction.

(q)Using or releasing a patient's records except as authorized by this chapter and chapter 456.

(r)Violating any provision of this chapter or chapter 456, or any rules adopted pursuant thereto.

(s)Dispensing any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship.

(t)Committing an error or omission during the performance of a specific function of prescription drug processing, which includes, for purposes of this paragraph:

1.Receiving, interpreting, or clarifying a prescription.

2.Entering prescription data into the pharmacy's record.

3.Verifying or validating a prescription.

4.Performing pharmaceutical calculations.

5.Performing prospective drug review as defined by the board.
6.Obtaining refill and substitution authorizations.
7.Interpreting or acting on clinical data.
8.Performing therapeutic interventions.
9.Providing drug information concerning a patient's prescription.
10.Providing patient counseling.

(2)The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

(3)The board shall not reinstate the license of a pharmacist, or cause a license to be issued to a person it has deemed unqualified, until such time as it is satisfied that she or he has complied with all the terms and conditions set forth in the final order and that such person is capable of safely engaging in the practice of pharmacy.

(4)The board shall by rule establish guidelines for the disposition of disciplinary cases involving specific types of violations. Such guidelines may include minimum and maximum fines, periods of supervision or probation, or conditions of probation or reissuance of a license.

History.—ss. 1, 7, ch. 79-226; ss. 13, 15, 24, 25, 30, 34, 62, ch. 80-406; s. 324, ch. 81-259; ss. 2, 3, ch. 81-318; s. 3, ch. 83-101; s. 37, ch. 83-216; ss. 32, 119, ch. 83-329; s. 1, ch. 84-364; ss. 26, 27, ch. 86-256; s. 41, ch. 88-1; s. 20, ch. 88-277; s. 2, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 45, ch. 92-149; s. 32, ch. 95-144; s. 244, ch. 97-103; s. 91, ch. 97-264; s. 119, ch. 99-397; s. 126, ch. 2000-160; s. 33, ch. 2001-277; s. 3, ch. 2004-387; s. 10, ch. 2005-240; s. 5, ch. 2008-184; s. 11, ch. 2011-141.

465.0161 Distribution of medicinal drugs without a permit.—An Internet pharmacy that distributes a medicinal drug to any person in this state without being permitted as a pharmacy under this chapter commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 4, ch. 2004-387.

465.017 Authority to inspect; disposal.—

(1)Duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours any pharmacy, hospital, clinic, wholesale establishment, manufacturer, physician's office, or any other place in the state in which drugs and medical supplies are manufactured, packed, packaged, made, stored, sold, offered for sale, exposed for sale, or kept for sale for the purpose of:

(a)Determining if any of the provisions of this chapter or any rule promulgated under its authority is being violated;

(b)Securing samples or specimens of any drug or medical supply after paying or offering to pay for such sample or specimen; or

(c)Securing such other evidence as may be needed for prosecution under this chapter.

(2)(a)Except as permitted by this chapter, and chapters 406, 409, 456, 499, and 893, records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs shall not be furnished to any person other than to the patient for whom the drugs were dispensed, or her or his legal representative, or to the department pursuant to existing law, or, in the event that the patient is incapacitated or unable to request said records, her or his spouse except upon the written authorization of such patient. Such records may be furnished in any civil or

criminal proceeding, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or her or his legal representative by the party seeking such records.

(b)The board shall adopt rules to establish practice guidelines for pharmacies to dispose of records maintained in a pharmacy relating to the filling of prescriptions and the dispensing of medicinal drugs. Such rules shall be consistent with the duty to preserve the confidentiality of such records in accordance with applicable state and federal law.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 1, 2, ch. 85-151; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 125, ch. 94-218; s. 245, ch. 97-103; s. 127, ch. 2000-160; s. 1, ch. 2003-166.

465.018 Community pharmacies; permits.—

(1)Any person desiring a permit to operate a community pharmacy shall apply to the department.

(2)If the board office certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit. No permit shall be issued unless a licensed pharmacist is designated as the prescription department manager.

(3)The board may suspend or revoke the permit of, or may refuse to issue a permit to:

(a)Any person who has been disciplined or who has abandoned a permit or allowed a permit to become void after written notice that disciplinary proceedings had been or would be brought against the permit;

(b)Any person who is an officer, director, or person interested directly or indirectly in a person or business entity that has had a permit disciplined or abandoned or become void after written notice that disciplinary proceedings had been or would be brought against the permit; or

(c)Any person who is or has been an officer of a business entity, or who was interested directly or indirectly in a business entity, the permit of which has been disciplined or abandoned or become null and void after written notice that disciplinary proceedings had been or would be brought against the permit.

(4)In addition to any other remedies provided by law, the board may deny the application or suspend or revoke the license, registration, or certificate of any entity regulated or licensed by it if the applicant, licensee, registrant, or licenseholder, or, in the case of a corporation, partnership, or other business entity, if any officer, director, agent, or managing employee of that business entity or any affiliated person, partner, or shareholder having an ownership interest equal to 5 percent or greater in that business entity, has failed to pay all outstanding fines, liens, or overpayments assessed by final order of the department, unless a repayment plan is approved by the department, or has failed to comply with any repayment plan.

(5)In reviewing any application requesting a change of ownership or a change of licensee or registrant, the transferor shall, before board approval of the change, repay or make arrangements to repay any amounts owed to the department. If the transferor fails to repay or make arrangements to repay the amounts owed to the department, the license or registration may not be issued to the transferee until repayment or until arrangements for repayment are made.

(6)Passing an onsite inspection is a prerequisite to the issuance of an initial permit or a permit for a change of location. The department must make the inspection within 90 days before issuance of the permit.

(7)Community pharmacies that dispense controlled substances must maintain a record of all controlled substance dispensing consistent with the requirements of s.

893.07 and must make the record available to the department and law enforcement agencies upon request.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 3, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 12, ch. 2011-141.

465.0181 Community pharmacy permit required to dispense Schedule II or Schedule III controlled substances.—In order to dispense controlled substances listed in Schedule II or Schedule III, as provided in s. 893.03, on or after July 1, 2012, a community pharmacy permittee must be permitted pursuant to this chapter, as amended by this act, and any rules adopted thereunder.
History.—s. 13, ch. 2011-141.

465.019 Institutional pharmacies; permits.—

(1)Any institution desiring to operate an institutional pharmacy shall apply to the department. If the board certifies that the application complies with the laws of the state and the rules of the board governing pharmacies, the department shall issue the permit.

(2)The following classes of institutional pharmacies are established:

(a)"Class I institutional pharmacies" are those institutional pharmacies in which all medicinal drugs are administered from individual prescription containers to the individual patient and in which medicinal drugs are not dispensed on the premises, except that nursing homes licensed under part II of chapter 400 may purchase medical oxygen for administration to residents. No medicinal drugs may be dispensed in a Class I institutional pharmacy.

(b)"Class II institutional pharmacies" are those institutional pharmacies which employ the services of a registered pharmacist or pharmacists who, in practicing institutional pharmacy, shall provide dispensing and consulting services on the premises to patients of that institution, for use on the premises of that institution. However, an institutional pharmacy located in an area or county included in an emergency order or proclamation of a state of emergency declared by the Governor may provide dispensing and consulting services to individuals who are not patients of the institution. However, a single dose of a medicinal drug may be obtained and administered to a patient on a valid physician's drug order under the supervision of a physician or charge nurse, consistent with good institutional practice procedures. The obtaining and administering of such single dose of a medicinal drug shall be pursuant to drug-handling procedures established by a consultant pharmacist. Medicinal drugs may be dispensed in a Class II institutional pharmacy, but only in accordance with the provisions of this section.

(c)"Modified Class II institutional pharmacies" are those institutional pharmacies in short-term, primary care treatment centers that meet all the requirements for a Class II permit, except space and equipment requirements.

(3)Medicinal drugs shall be stocked, stored, compounded, dispensed, or administered in any health care institution only when that institution has secured an institutional pharmacy permit from the department.

(4)Medicinal drugs shall be dispensed in an institutional pharmacy to outpatients only when that institution has secured a community pharmacy permit from the department. However, an individual licensed to prescribe medicinal drugs in this state may dispense up to a 24-hour supply of a medicinal drug to any patient of an emergency department of a hospital that operates a Class II institutional pharmacy, provided that the physician treating the patient in such hospital's emergency department determines that the medicinal drug is warranted and that community pharmacy services are not readily accessible, geographically or otherwise, to the

patient. Such dispensing from the emergency department must be in accordance with the procedures of the hospital. For any such patient for whom a medicinal drug is warranted for a period to exceed 24 hours, an individual licensed to prescribe such drug must dispense a 24-hour supply of such drug to the patient and must provide the patient with a prescription for such drug for use after the initial 24-hour period. The board may adopt rules necessary to carry out the provisions of this subsection.

(5)All institutional pharmacies shall be under the professional supervision of a consultant pharmacist, and the compounding and dispensing of medicinal drugs shall be done only by a licensed pharmacist. Every institutional pharmacy that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(6)In a Class II institutional pharmacy, an institutional formulary system may be adopted with approval of the medical staff for the purpose of identifying those medicinal drugs and proprietary preparations that may be dispensed by the pharmacists employed in such institution. A facility with a Class II institutional permit which is operating under the formulary system shall establish policies and procedures for the development of the system in accordance with the joint standards of the American Hospital Association and American Society of Hospital Pharmacists for the utilization of a hospital formulary system, which formulary shall be approved by the medical staff.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 2, ch. 83-101; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 29, ch. 93-211; s. 244, ch. 98-166; s. 36, ch. 99-397; s. 79, ch. 2001-277; s. 6, ch. 2008-216.

465.0193 Nuclear pharmacy permits.—Any person desiring a permit to operate a nuclear pharmacy shall apply to the department. If the board certifies that the application complies with applicable law, the department shall issue the permit. No permit shall be issued unless a duly licensed and qualified nuclear pharmacist is designated as being responsible for activities described in s. 465.0126. The permittee shall notify the department within 10 days of any change of the licensed pharmacist responsible for the compounding and dispensing of nuclear pharmaceuticals.

History.—ss. 33, 118, ch. 83-329; ss. 15, 26, 27, ch. 86-256; s. 4, ch. 88-172; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0196 Special pharmacy permits.—Any person desiring a permit to operate a special pharmacy shall apply to the department for a special pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. A permit may not be issued unless a licensed pharmacist is designated to undertake the professional supervision of the compounding and dispensing of all drugs dispensed by the pharmacy. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs occurs. The permittee shall notify the department within 10 days after any change of the licensed pharmacist responsible for such duties. Each permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

History.—ss. 34, 118, ch. 83-329; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 92, ch. 97-264; s. 122, ch. 99-397; s. 80, ch. 2001-277; s. 5, ch. 2004-387; s. 7, ch. 2008-216.

465.0197 Internet pharmacy permits.—

(1)Any person desiring a permit to operate an Internet pharmacy shall apply to the department for an Internet pharmacy permit. If the board certifies that the application complies with the applicable laws and rules of the board governing the practice of the profession of pharmacy, the department shall issue the permit. A permit may not be issued unless a licensed pharmacist is designated as the prescription department manager for dispensing medicinal drugs to persons in this state. The licensed pharmacist shall be responsible for maintaining all drug records and for providing for the security of the area in the facility in which the compounding, storing, and dispensing of medicinal drugs to persons in this state occurs. The permittee shall notify the department within 30 days after any change of the licensed pharmacist responsible for such duties. A permittee that employs or otherwise uses registered pharmacy technicians shall have a written policy and procedures manual specifying those duties, tasks, and functions that a registered pharmacy technician is allowed to perform.

(2)An Internet pharmacy must obtain a permit under this section to sell medicinal drugs to persons in this state.

(3)An Internet pharmacy shall provide pharmacy services at a high level of protection and competence and shall disclose to the board the following specific information:

(a)That it maintains at all times a valid, unexpired license, permit, or registration to operate the pharmacy in compliance with the laws of the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed.

(b)The location, names, and titles of all principal corporate officers and the pharmacist who serves as the prescription department manager for dispensing medicinal drugs to persons in this state. This disclosure shall be made within 30 days after any change of location, principal corporate officer, or pharmacist serving as the prescription department manager for dispensing medicinal drugs to persons in this state.

(c)That it complies with all lawful directions and requests for information from the regulatory or licensing agency of all states in which it is licensed as well as with all requests for information made by the board pursuant to this section. It shall respond directly to all communications from the board concerning emergency circumstances arising from errors in the dispensing of medicinal drugs to persons in this state.

(d)That it maintains its records of medicinal drugs dispensed to patients in this state so that the records are readily retrievable from the other business records of the pharmacy and from the records of other medicinal drugs dispensed.

(e)That during its regular hours of operation but not less than 6 days per week, for a minimum of 40 hours per week, a toll-free telephone service shall be provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed medicinal drugs.

(4)Notwithstanding s. 465.003(10), for purposes of this section, the Internet pharmacy and the pharmacist designated by the Internet pharmacy as the prescription department manager or the equivalent must be licensed in the state of location in order to dispense into this state.

History.—s. 6, ch. 2004-387; s. 8, ch. 2008-216.

465.022 Pharmacies; general requirements; fees.—

(1)The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter. Such rules shall include, but shall not be limited to, rules relating to:

(a)General drug safety measures.

(b)Minimum standards for the physical facilities of pharmacies.

(c)Safe storage of floor-stock drugs.

(d)Functions of a pharmacist in an institutional pharmacy, consistent with the size and scope of the pharmacy.

(e)Procedures for the safe storage and handling of radioactive drugs.

(f)Procedures for the distribution and disposition of medicinal drugs distributed pursuant to s. 499.028.

(g)Procedures for transfer of prescription files and medicinal drugs upon the change of ownership or closing of a pharmacy.

(h)Minimum equipment which a pharmacy shall at all times possess to fill prescriptions properly.

(i)Procedures for the dispensing of controlled substances to minimize dispensing based on fraudulent representations or invalid practitioner-patient relationships.

(2)A pharmacy permit may be issued only to a natural person who is at least 18 years of age, to a partnership comprised of at least one natural person and all of whose partners are at least 18 years of age, to a governmental agency, or to a business entity that is properly registered with the Secretary of State, if required by law, and has been issued a federal employer tax identification number. Permits issued to business entities may be issued only to entities whose affiliated persons, members, partners, officers, directors, and agents, including persons required to be fingerprinted under subsection (3), are not less than 18 years of age.

(3)Any person or business entity, before engaging in the operation of a pharmacy, shall file with the board a sworn application on forms provided by the department. For purposes of this section, any person required to provide fingerprints under this subsection is an affiliated person within the meaning of s. 465.023(1).

(a)An application for a pharmacy permit must include a set of fingerprints from each person having an ownership interest of 5 percent or greater and from any person who, directly or indirectly, manages, oversees, or controls the operation of the applicant, including officers and members of the board of directors of an applicant that is a corporation. The applicant must provide payment in the application for the cost of state and national criminal history records checks.

1.For corporations having more than $100 million of business taxable assets in this state, in lieu of these fingerprint requirements, the department shall require the prescription department manager or consultant pharmacist of record who will be directly involved in the management and operation of the pharmacy to submit a set of fingerprints.

2.A representative of a corporation described in subparagraph 1. satisfies the requirement to submit a set of his or her fingerprints if the fingerprints are on file with the department or the Agency for Health Care Administration, meet the fingerprint specifications for submission by the Department of Law Enforcement, and are available to the department.

(b)The department shall annually submit the fingerprints provided by the applicant to the Department of Law Enforcement for a state criminal history records check. The Department of Law Enforcement shall annually forward the fingerprints to the Federal Bureau of Investigation for a national criminal history records check. The department shall report the results of annual criminal history records checks to wholesale distributors permitted under chapter 499 for the purposes of s. 499.0121(15).

(c)In addition to those documents required by the department or board, each applicant having any financial or ownership interest greater than 5 percent in the subject of the application must submit a signed affidavit disclosing any financial or ownership interest greater than 5 percent in any pharmacy permitted in the past 5 years, which pharmacy has closed voluntarily or involuntarily, has filed a voluntary relinquishment of its permit, has had its permit suspended or revoked, or has had an injunction issued against it by a regulatory agency. The affidavit must disclose the reason such entity was closed, whether voluntary or involuntary.

(4)An application for a pharmacy permit must include the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The board must review the policies and procedures and may deny a permit if the policies and procedures are insufficient to reasonably prevent such dispensing. The department may phase in the submission and review of policies and procedures over one 18-month period beginning July 1, 2011.

(5)The department or board shall deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant:

(a)Has obtained a permit by misrepresentation or fraud.

(b)Has attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation.

(c)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy.

(d)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(e)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, since July 1, 2009.

(f)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970 or 42 U.S.C. ss. 1395-1396 since July 1, 2009.

(g)Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5-year period.

(h)Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5-year period and the termination occurred at least 20 years before the date of the application.

(i)Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(j)Has dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.

For felonies in which the defendant entered a plea of guilty or nolo contendere in an agreement with the court to enter a pretrial intervention or drug diversion program, the department shall deny the application if upon final resolution of the case the licensee has failed to successfully complete the program.

(6)The department or board may deny an application for a pharmacy permit if the applicant or an affiliated person, partner, officer, director, or prescription department manager or consultant pharmacist of record of the applicant has violated or failed to comply with any provision of this chapter; chapter 499, the Florida Drug and Cosmetic Act; chapter 893; 21 U.S.C. ss. 301-392, the Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq., the Comprehensive Drug Abuse Prevention and Control Act; or any rules or regulations promulgated thereunder unless the violation or noncompliance is technical.

(7)After the application has been filed with the board and the permit fee provided in this section has been received, the board shall cause the application to be fully investigated, both as to the qualifications of the applicant and the prescription department manager or consultant pharmacist designated to be in charge and as to the premises and location described in the application.

(8)The Board of Pharmacy shall have the authority to determine whether a bona fide transfer of ownership is present and that the sale of a pharmacy is not being accomplished for the purpose of avoiding an administrative prosecution.

(9)Upon the completion of the investigation of an application, the board shall approve or deny the application. If approved, the permit shall be issued by the department.

(10)A permittee must notify the department, on a form approved by the board, within 10 days after any change in prescription department manager or consultant pharmacist of record.

(11)A permittee must notify the department of the identity of the prescription department manager within 10 days after employment. The prescription department manager must comply with the following requirements:

(a)The prescription department manager of a permittee must obtain and maintain all drug records required by any state or federal law to be obtained by a pharmacy, including, but not limited to, records required by or under this chapter, chapter 499, or chapter 893. The prescription department manager must ensure the permittee's compliance with all rules adopted under those chapters as they relate to the practice of the profession of pharmacy and the sale of prescription drugs.

(b)The prescription department manager must ensure the security of the prescription department. The prescription department manager must notify the board of any theft or significant loss of any controlled substances within 1 business day after discovery of the theft or loss.

(c)A registered pharmacist may not serve as the prescription department manager in more than one location unless approved by the board.

(12)The board shall adopt rules that require the keeping of such records of prescription drugs as are necessary for the protection of public health, safety, and welfare.

(a)All required records documenting prescription drug distributions shall be readily available or immediately retrievable during an inspection by the department.

(b)The records must be maintained for 4 years after the creation or receipt of the record, whichever is later.

(13)Permits issued by the department are not transferable.

(14)The board shall set the fees for the following:

(a)Initial permit fee not to exceed $250.

(b)Biennial permit renewal not to exceed $250.

(c)Delinquent fee not to exceed $100.
(d)Change of location fee not to exceed $100.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 36, ch. 82-225; ss. 16, 26, 27, ch. 86-256; s. 6, ch. 88-172; s. 14, ch. 88-205; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 127, ch. 98-200; s. 27, ch. 2009-223; s. 14, ch. 2011-141.

465.023 Pharmacy permittee; disciplinary action.—
(1)The department or the board may revoke or suspend the permit of any pharmacy permittee, and may fine, place on probation, or otherwise discipline any pharmacy permittee if the permittee, or any affiliated person, partner, officer, director, or agent of the permittee, including a person fingerprinted under s. 465.022(3), has:
(a)Obtained a permit by misrepresentation or fraud or through an error of the department or the board;
(b)Attempted to procure, or has procured, a permit for any other person by making, or causing to be made, any false representation;
(c)Violated any of the requirements of this chapter or any of the rules of the Board of Pharmacy; of chapter 499, known as the "Florida Drug and Cosmetic Act"; of 21 U.S.C. ss. 301-392, known as the "Federal Food, Drug, and Cosmetic Act"; of 21 U.S.C. ss. 821 et seq., known as the Comprehensive Drug Abuse Prevention and Control Act; or of chapter 893;
(d)Been convicted or found guilty, regardless of adjudication, of a felony or any other crime involving moral turpitude in any of the courts of this state, of any other state, or of the United States;
(e)Been convicted or disciplined by a regulatory agency of the Federal Government or a regulatory agency of another state for any offense that would constitute a violation of this chapter;
(f)Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, the profession of pharmacy;
(g)Been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud; or
(h)Dispensed any medicinal drug based upon a communication that purports to be a prescription as defined by s. 465.003(14) or s. 893.02 when the pharmacist knows or has reason to believe that the purported prescription is not based upon a valid practitioner-patient relationship that includes a documented patient evaluation, including history and a physical examination adequate to establish the diagnosis for which any drug is prescribed and any other requirement established by board rule under chapter 458, chapter 459, chapter 461, chapter 463, chapter 464, or chapter 466.
(2)If a pharmacy permit is revoked or suspended, the owner, manager, or proprietor shall cease to operate the establishment as a pharmacy as of the effective date of such suspension or revocation. In the event of such revocation or suspension, the owner, manager, or proprietor shall remove from the premises all signs and symbols identifying the premises as a pharmacy. The period of such suspension shall be prescribed by the Board of Pharmacy, but in no case shall it exceed 1 year. In the event that the permit is revoked, the person owning or operating the establishment shall not be entitled to make application for a permit to operate a pharmacy for a period of 1 year from the date of such revocation. Upon the effective date of such revocation, the permittee shall advise the Board of Pharmacy of the disposition of the medicinal drugs located on the premises. Such

disposition shall be subject to continuing supervision and approval by the Board of Pharmacy.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 38, ch. 83-216; ss. 35, 119, ch. 83-329; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 33, ch. 95-144; s. 7, ch. 2004-387; s. 6, ch. 2008-184; s. 28, ch. 2009-223.

465.0235 Automated pharmacy systems used by long-term care facilities, hospices, or state correctional institutions.—

(1)A pharmacy may provide pharmacy services to a long-term care facility or hospice licensed under chapter 400 or chapter 429 or a state correctional institution operated under chapter 944 through the use of an automated pharmacy system that need not be located at the same location as the pharmacy.

(2)Medicinal drugs stored in bulk or unit of use in an automated pharmacy system servicing a long-term care facility, hospice, or correctional institution are part of the inventory of the pharmacy providing pharmacy services to that facility, hospice, or institution, and drugs delivered by the automated pharmacy system are considered to have been dispensed by that pharmacy.

(3)The operation of an automated pharmacy system must be under the supervision of a Florida-licensed pharmacist. To qualify as a supervisor for an automated pharmacy system, the pharmacist need not be physically present at the site of the automated pharmacy system and may supervise the system electronically. The Florida-licensed pharmacist shall be required to develop and implement policies and procedures designed to verify that the medicinal drugs delivered by the automated dispensing system are accurate and valid and that the machine is properly restocked.

(4)The Legislature does not intend this section to limit the current practice of pharmacy in this state. This section is intended to allow automated pharmacy systems to enhance the ability of a pharmacist to provide pharmacy services in locations that do not employ a full-time pharmacist. This section does not limit or replace the use of a consultant pharmacist.

(5)The board shall adopt rules governing the use of an automated pharmacy system by January 1, 2005, which must specify:

(a)Recordkeeping requirements;

(b)Security requirements; and

(c)Labeling requirements that permit the use of unit-dose medications if the facility, hospice, or institution maintains medication-administration records that include directions for use of the medication and the automated pharmacy system identifies:

1.The dispensing pharmacy;

2.The prescription number;

3.The name of the patient; and

4.The name of the prescribing practitioner.

History.—s. 3, ch. 2004-25; s. 92, ch. 2006-197.

465.024Promoting sale of certain drugs prohibited.—

(1)It is declared that the unrestricted use of certain controlled substances, causing abnormal reactions that may interfere with the user's physical reflexes and judgments, may create hazardous circumstances which may cause accidents to the user and to others, thereby affecting the public health, safety, and welfare. It is further declared to be in the public interest to limit the means of promoting the sale and use of these drugs. All provisions of this section shall be liberally construed to carry out these objectives and purposes.

(2)No pharmacist, owner, or employee of a retail drug establishment shall use any communication media to promote or advertise the use or sale of any controlled substance appearing in any schedule in chapter 893.

(3)This section shall not prohibit the advertising of any medicinal drugs, other than those controlled substances specified in chapter 893, or any patent or proprietary preparation, provided the advertising is not false, misleading, or deceptive.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0244 Information disclosure.—Every pharmacy shall make available on its Internet website a link to the performance outcome and financial data that is published by the Agency for Health Care Administration pursuant to s. 408.05(3)(k) and shall place in the area where customers receive filled prescriptions notice that such information is available electronically and the address of its Internet website.

History.—s. 39, ch. 2004-297; s. 14, ch. 2006-261.

465.025 Substitution of drugs.—

(1)As used in this section:

(a)"Brand name" means the registered trademark name given to a drug product by its manufacturer, labeler, or distributor.

(b)"Generically equivalent drug product" means a drug product with the same active ingredient, finished dosage form, and strength.

(c)"Prescriber" means any practitioner licensed to prescribe medicinal drugs.

(2)A pharmacist who receives a prescription for a brand name drug shall, unless requested otherwise by the purchaser, substitute a less expensive, generically equivalent drug product that is:

(a)Distributed by a business entity doing business, and subject to suit and service of legal process, in the United States; and

(b)Listed in the formulary of generic and brand name drug products as provided in subsection (5) for the brand name drug prescribed,

unless the prescriber writes the words "MEDICALLY NECESSARY," in her or his own handwriting, on the face of a written prescription; unless, in the case of an oral prescription, the prescriber expressly indicates to the pharmacist that the brand name drug prescribed is medically necessary; or unless, in the case of a prescription that is electronically generated and transmitted, the prescriber makes an overt act when transmitting the prescription to indicate that the brand name drug prescribed is medically necessary. When done in conjunction with the electronic transmission of the prescription, the prescriber's overt act indicates to the pharmacist that the brand name drug prescribed is medically necessary.

(3)(a)Any pharmacist who substitutes any drug as provided in subsection (2) shall notify the person presenting the prescription of such substitution, together with the existence and amount of the retail price difference between the brand name drug and the drug substituted for it, and shall inform the person presenting the prescription that such person may refuse the substitution as provided in subsection (2).

(b)Any pharmacist substituting a less expensive drug product shall pass on to the consumer the full amount of the savings realized by such substitution.

(4)Each pharmacist shall maintain a record of any substitution of a generically equivalent drug product for a prescribed brand name drug as provided in this section.

(5)Each community pharmacy shall establish a formulary of generic and brand name drug products which, if selected as the drug product of choice, would not pose a threat to the health and safety of patients receiving prescription medication. In compiling the list of generic and brand name drug products for inclusion in the formulary, the pharmacist shall rely on drug product research, testing, information, and formularies compiled by other pharmacies, by states, by the United States Department of Health, Education, and Welfare, by the United States Department of Health and Human Services, or by any other source which the pharmacist deems reliable. Each community pharmacy shall make such formulary available to the public, the Board of Pharmacy, or any physician requesting same. This formulary shall be revised following each addition, deletion, or modification of said formulary.

(6)The Board of Pharmacy and the Board of Medicine shall establish by rule a formulary of generic drug type and brand name drug products which are determined by the boards to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, would pose a threat to the health and safety of patients receiving prescription medication.

(a)The formulary may be added to or deleted from as the Board of Pharmacy and the Board of Medicine deem appropriate. Any person who requests any inclusion, addition, or deletion of a generic drug type or brand name drug product to the formulary shall have the burden of proof to show cause why such inclusion, addition, or deletion should be made.

(b)Upon adoption of the formulary required by this subsection, and upon each addition, deletion, or modification to the formulary, the Board of Pharmacy shall mail a copy to each manager of the prescription department of each community pharmacy licensed by the state, each nonresident pharmacy registered in the state, and each board regulating practitioners licensed by the laws of the state to prescribe drugs shall incorporate such formulary into its rules. No pharmacist shall substitute a generically equivalent drug product for a prescribed brand name drug product if the brand name drug product or the generic drug type drug product is included in the said formulary.

(7)Every community pharmacy shall display in a prominent place that is in clear and unobstructed public view, at or near the place where prescriptions are dispensed, a sign in block letters not less than 1 inch in height which shall read: "CONSULT YOUR PHARMACIST CONCERNING THE AVAILABILITY OF A LESS EXPENSIVE GENERICALLY EQUIVALENT DRUG AND THE REQUIREMENTS OF FLORIDA LAW."

(8)The standard of care to be applied to the acts of any pharmacist performing professional services in compliance with this section when a substitution is made by said pharmacist shall be that which would apply to the performance of professional services in the dispensing of a prescription order prescribing a drug by generic name. In no event when a pharmacist substitutes a drug shall the prescriber be liable in any action for loss, damage, injury, or death to any person occasioned by or arising from the use or nonuse of the substituted drug, unless the original drug was incorrectly prescribed.

History.—ss. 1, 7, ch. 79-226; s. 325, ch. 81-259; ss. 2, 3, ch. 81-318; ss. 26, 27, ch. 86-256; s. 4, ch. 89-218; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 20, ch. 91-220; s. 4, ch. 91-429; s. 246, ch. 97-103; s. 4, ch. 2006-271.

465.0251 Generic drugs; removal from formulary under specified circumstances.—

(1)The Board of Pharmacy and the Board of Medicine shall remove any generic named drug product from the formulary established by s. 465.025(6), if every commercially marketed equivalent of that drug product is "A" rated as

therapeutically equivalent to a reference listed drug or is a reference listed drug as referred to in "Approved Drug Products with Therapeutic Equivalence Evaluations" (Orange Book) published by the United States Food and Drug Administration.

(2)Nothing in this act shall alter or amend s. 465.025 as to existing law providing for the authority of physicians to prohibit generic drug substitution by writing "medically necessary" on the prescription.

History.—ss. 1, 2, ch. 2001-146.

465.0255 Expiration date of medicinal drugs; display; related use and storage instructions.—

(1)The manufacturer, repackager, or other distributor of any medicinal drug shall display the expiration date of each drug in a readable fashion on the container and on its packaging. The term "readable" means conspicuous and bold.

(2)Each pharmacist for a community pharmacy dispensing medicinal drugs and each practitioner dispensing medicinal drugs on an outpatient basis shall display on the outside of the container of each medicinal drug dispensed, or in other written form delivered to the purchaser:

(a)The expiration date when provided by the manufacturer, repackager, or other distributor of the drug; or

(b)An earlier beyond-use date for expiration, which may be up to 1 year after the date of dispensing.

The dispensing pharmacist or practitioner must provide information concerning the expiration date to the purchaser upon request and must provide appropriate instructions regarding the proper use and storage of the drug.

(3)This section does not impose liability on the dispensing pharmacist or practitioner for damages related to, or caused by, a medicinal drug that loses its effectiveness prior to the expiration date displayed by the dispensing pharmacist or practitioner.

(4)The provisions of this section are intended to notify the patient receiving a medicinal drug of the information required by this section, and the dispensing pharmacist or practitioner shall not be liable for the patient's failure to heed such notice or to follow the instructions for storage.

History.—ss. 1, 2, ch. 93-44; s. 8, ch. 2004-387.

465.026 Filling of certain prescriptions.—Nothing contained in this chapter shall be construed to prohibit a pharmacist licensed in this state from filling or refilling a valid prescription which is on file in a pharmacy located in this state or in another state and has been transferred from one pharmacy to another by any means, including any electronic means, under the following conditions:

(1)Prior to dispensing any transferred prescription, the dispensing pharmacist must, either verbally or by any electronic means, do all of the following:

(a)Advise the patient that the prescription on file at the other pharmacy must be canceled before it may be filled or refilled.

(b)Determine that the prescription is valid and on file at the other pharmacy and that the prescription may be filled or refilled, as requested, in accordance with the prescriber's intent expressed on the prescription.

(c)Notify the pharmacist or pharmacy where the prescription is on file that the prescription must be canceled.

(d)Record in writing, or by any electronic means, the prescription order, the name of the pharmacy at which the prescription was on file, the prescription number, the

name of the drug and the original amount dispensed, the date of original dispensing, and the number of remaining authorized refills.

(e)Obtain the consent of the prescriber to the refilling of the prescription when the prescription, in the dispensing pharmacist's professional judgment, so requires. Any interference with the professional judgment of the dispensing pharmacist by any pharmacist or pharmacy permittee, or its agents or employees, shall be grounds for discipline.

(2)Upon receipt of a prescription transfer request, if the pharmacist is satisfied in her or his professional judgment that the request is valid, or if the request has been validated by any electronic means, the pharmacist or pharmacy must do all of the following:

(a)Transfer the information required by paragraph (1)(d) accurately and completely.

(b)Record on the prescription, or by any electronic means, the requesting pharmacy and pharmacist and the date of request.

(c)Cancel the prescription on file by electronic means or by recording the word "void" on the prescription record. No further prescription information shall be given or medication dispensed pursuant to the original prescription.

(3)If a transferred prescription is not dispensed within a reasonable time, the pharmacist shall, by any means, so notify the transferring pharmacy. Such notice shall serve to revalidate the canceled prescription. The pharmacist who has served such notice shall then cancel the prescription in the same manner as set forth in paragraph (2)(c).

(4)In the case of a prescription to be transferred from or to a pharmacy located in another state, it shall be the responsibility of the pharmacist or pharmacy located in the State of Florida to verify, whether by electronic means or otherwise, that the person or entity involved in the transfer is a licensed pharmacist or pharmacy in the other state.

(5)Electronic transfers of prescriptions are permitted regardless of whether the transferor or transferee pharmacy is open for business.

(6)The transfer of a prescription for medicinal drugs listed in Schedules III, IV, and V appearing in chapter 893 for the purpose of refill dispensing is permissible, subject to the requirements of this section and federal law. Compliance with federal law shall be deemed compliance with the requirements of this section.

History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; s. 1, ch. 85-71; ss. 17, 26, 27, ch. 86-256; s. 1, ch. 90-2; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 247, ch. 97-103; s. 93, ch. 97-264; s. 4, ch. 2004-25; s. 9, ch. 2004-387; s. 1, ch. 2006-243.

465.0265 Centralized prescription filling.—

(1)A pharmacy licensed under this chapter may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.

(2)Each pharmacy performing or contracting for the performance of centralized prescription filling pursuant to this section must maintain a policy and procedures manual, which shall be made available to the board or its agent upon request. The policy and procedures manual shall include the following information:

(a)A description of how each pharmacy will comply with federal and state laws, rules, and regulations.

(b)The procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient.

(c)The procedure for tracking the prescription during each stage of the filling and dispensing process.

(d)The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription.

(e)The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.

(f)The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(3)The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as set forth in s. 465.026 or as a wholesale distribution as set forth in s. 499.003(54).

(4)The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.

History.—s. 2, ch. 2002-182; s. 40, ch. 2008-207; s. 38, ch. 2010-161.

465.0266 Common database.—Nothing contained in this chapter shall be construed to prohibit the dispensing by a pharmacist licensed in this state or another state of a prescription contained in a common database, and such dispensing shall not constitute a transfer as defined in s. 465.026(1)-(6), provided that the following conditions are met:

(1)All pharmacies involved in the transactions pursuant to which the prescription is dispensed are under common ownership and utilize a common database.

(2)All pharmacies involved in the transactions pursuant to which the prescription is dispensed and all pharmacists engaging in dispensing functions are properly licensed, permitted, or registered in this state or another state.

(3)The common database maintains a record of all pharmacists involved in the process of dispensing a prescription.

(4)The owner of the common database maintains a policy and procedures manual that governs its participating pharmacies, pharmacists, and pharmacy employees and that is available to the board or its agent upon request. The policy and procedures manual shall include the following information:

(a)A best practices model detailing how each pharmacy and each pharmacist accessing the common database will comply with applicable federal and state laws, rules, and regulations.

(b)The procedure for maintaining appropriate records for regulatory oversight for tracking a prescription during each stage of the filling and dispensing process, identifying the pharmacists involved in filling and dispensing the prescription and counseling the patient, and responding to any requests for information made by the board under s. 465.0156.

(c)The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.

(d)A quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care through the use of the common database.

Any pharmacist dispensing a prescription has at all times the right and obligation to exercise his or her independent professional judgment. Notwithstanding other provisions in this section, no pharmacist licensed in this state participating in the dispensing of a prescription pursuant to

this section shall be responsible for the acts and omissions of another person participating in the dispensing process provided such person is not under the direct supervision and control of the pharmacist licensed in this state.

History.—s. 2, ch. 2006-243.

465.027 Exceptions.—This chapter shall not be construed to prohibit the sale of home remedies or preparations commonly known as patents or proprietary preparations, when such are sold only in original or unbroken packages, nor shall this chapter be construed to prevent businesses from engaging in the sale of sundries or patents or proprietary preparations.
History.—ss. 1, 7, ch. 79-226; ss. 2, 3, ch. 81-318; ss. 18, 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.0275 Emergency prescription refill.—In the event a pharmacist receives a request for a prescription refill and the pharmacist is unable to readily obtain refill authorization from the prescriber, the pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication, with the exception of those areas or counties included in an emergency order or proclamation of a state of emergency declared by the Governor, in which the executive order may authorize the pharmacist to dispense up to a 30-day supply, providing that:

(1)The prescription is not for a medicinal drug listed in Schedule II appearing in chapter 893.

(2)The medication is essential to the maintenance of life or to the continuation of therapy in a chronic condition.

(3)In the pharmacist's professional judgment, the interruption of therapy might reasonably produce undesirable health consequences or may cause physical or mental discomfort.

(4)The dispensing pharmacist creates a written order containing all of the prescription information required by this chapter and chapters 499 and 893 and signs that order.

(5)The dispensing pharmacist notifies the prescriber of the emergency dispensing within a reasonable time after such dispensing.
History.—ss. 19, 27, ch. 86-256; s. 3, ch. 89-77; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 30, ch. 93-211.

465.0276 Dispensing practitioner.—

(1)(a)A person may not dispense medicinal drugs unless licensed as a pharmacist or otherwise authorized under this chapter to do so, except that a practitioner authorized by law to prescribe drugs may dispense such drugs to her or his patients in the regular course of her or his practice in compliance with this section.

(b)A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:

1.The dispensing of complimentary packages of medicinal drugs which are labeled as a drug sample or complimentary drug as defined in s. 499.028 to the practitioner's own patients in the regular course of her or his practice without the payment of a fee or remuneration of any kind, whether direct or indirect, as provided in subsection (5).

2.The dispensing of controlled substances in the health care system of the Department of Corrections.

3.The dispensing of a controlled substance listed in Schedule II or Schedule III in connection with the performance of a surgical procedure. The amount dispensed pursuant to the subparagraph may not exceed a 14-day supply. This exception does not allow for the dispensing of a controlled substance listed in Schedule II or Schedule III more than 14 days after the performance of the surgical procedure. For purposes of this subparagraph, the term "surgical procedure" means any procedure in any setting which involves, or reasonably should involve:

a.Perioperative medication and sedation that allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory function and the ability to respond purposefully to verbal or tactile stimulation and makes intra- and postoperative monitoring necessary; or

b.The use of general anesthesia or major conduction anesthesia and preoperative sedation.

4.The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

5.The dispensing of methadone in a facility licensed under s. 397.427 where medication-assisted treatment for opiate addiction is provided.

6.The dispensing of a controlled substance listed in Schedule II or Schedule III to a patient of a facility licensed under part IV of chapter 400.

(2)A practitioner who dispenses medicinal drugs for human consumption for fee or remuneration of any kind, whether direct or indirect, must:

(a)Register with her or his professional licensing board as a dispensing practitioner and pay a fee not to exceed $100 at the time of such registration and upon each renewal of her or his license. Each appropriate board shall establish such fee by rule.

(b)Comply with and be subject to all laws and rules applicable to pharmacists and pharmacies, including, but not limited to, this chapter and chapters 499 and 893 and all federal laws and federal regulations.

(c)Before dispensing any drug, give the patient a written prescription and orally or in writing advise the patient that the prescription may be filled in the practitioner's office or at any pharmacy.

(3)The department shall inspect any facility where a practitioner dispenses medicinal drugs pursuant to subsection (2) in the same manner and with the same frequency as it inspects pharmacies for the purpose of determining whether the practitioner is in compliance with all statutes and rules applicable to her or his dispensing practice.

(4)The registration of any practitioner who has been found by her or his respective board to have dispensed medicinal drugs in violation of this chapter shall be subject to suspension or revocation.

(5)A practitioner who confines her or his activities to the dispensing of complimentary packages of medicinal drugs to the practitioner's own patients in the regular course of her or his practice, without the payment of fee or remuneration of any kind, whether direct or indirect, and who herself or himself dispenses such drugs is not required to register pursuant to this section. The practitioner must dispense such drugs in the manufacturer's labeled package with the practitioner's name, patient's name, and date dispensed, or, if such drugs are not dispensed in the manufacturer's labeled package, they must be dispensed in a container which bears the following information:

(a)Practitioner's name;

(b)Patient's name;

(c)Date dispensed;
(d)Name and strength of drug; and
(e)Directions for use.
History.—ss. 20, 27, ch. 86-256; s. 1, ch. 88-159; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 95, ch. 92-149; s. 248, ch. 97-103; s. 11, ch. 2010-211; s. 15, ch. 2011-141.

465.035 Dispensing of medicinal drugs pursuant to facsimile of prescription.—
(1)Notwithstanding any other provision of this chapter, it is lawful for a pharmacy to dispense medicinal drugs, including controlled substances authorized under subsection (2), based on reception of an electronic facsimile of the original prescription if all of the following conditions are met:
(a)In the course of the transaction the pharmacy complies with laws and administrative rules relating to pharmacies and pharmacists.
(b)Except in the case of the transmission of a prescription by a person authorized by law to prescribe medicinal drugs:
1.The facsimile system making the transmission provides the pharmacy receiving the transmission with audio communication via telephonic, electronic, or similar means with the person presenting the prescription.
2.At the time of the delivery of the medicinal drugs, the pharmacy has in its possession the original prescription for the medicinal drug involved.
3.The recipient of the prescription shall sign a log and shall indicate the name and address of both the recipient and the patient for whom the medicinal drug was prescribed.
(2)Controlled substances listed in Schedule II as defined in s. 893.03(2) may be dispensed as provided in this section to the extent allowed by 21 C.F.R. s. 1306.11.
History.—s. 5, ch. 90-341; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 8, ch. 91-201; s. 4, ch. 91-429; s. 94, ch. 97-264; s. 5, ch. 99-186.

465.185 Rebates prohibited; penalties.—
(1)It is unlawful for any person to pay or receive any commission, bonus, kickback, or rebate or engage in any split-fee arrangement in any form whatsoever with any physician, surgeon, organization, agency, or person, either directly or indirectly, for patients referred to a pharmacy registered under this chapter.
(2)The department shall adopt rules which assess administrative penalties for acts prohibited by subsection (1). In the case of an entity licensed by the department, such penalties may include any disciplinary action available to the department under the appropriate licensing laws. In the case of an entity not licensed by the department, such penalties may include:
(a)A fine not to exceed $1,000.
(b)If applicable, a recommendation by the department to the appropriate regulatory agency that disciplinary action be taken.
History.—s. 2, ch. 79-106; s. 326, ch. 81-259; s. 2, ch. 81-318; ss. 26, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429; s. 125, ch. 92-149.

465.186 Pharmacist's order for medicinal drugs; dispensing procedure; development of formulary.—
(1)There is hereby created a committee composed of two members of the Board of Medicine licensed under chapter 458 chosen by said board, one member of the Board of Osteopathic Medicine licensed under chapter 459 chosen by said board, three members of the Board of Pharmacy licensed under this chapter and chosen by said board, and one additional person with a background in health care or pharmacology

chosen by the committee. The committee shall establish a formulary of medicinal drug products and dispensing procedures which shall be used by a pharmacist when ordering and dispensing such drug products to the public. Dispensing procedures may include matters related to reception of patient, description of his or her condition, patient interview, patient physician referral, product selection, and dispensing and use limitations. In developing the formulary of medicinal drug products, the committee may include products falling within the following categories:

(a)Any medicinal drug of single or multiple active ingredients in any strengths when such active ingredients have been approved individually or in combination for over-the-counter sale by the United States Food and Drug Administration.

(b)Any medicinal drug recommended by the United States Food and Drug Administration Advisory Panel for transfer to over-the-counter status pending approval by the United States Food and Drug Administration.

(c)Any medicinal drug containing any antihistamine or decongestant as a single active ingredient or in combination.

(d)Any medicinal drug containing fluoride in any strength.

(e)Any medicinal drug containing lindane in any strength.

(f)Any over-the-counter proprietary drug under federal law that has been approved for reimbursement by the Florida Medicaid Program.

(g)Any topical anti-infectives excluding eye and ear topical anti-infectives.

However, any drug which is sold as an over-the-counter proprietary drug under federal law shall not be included in the formulary or otherwise affected by this section.

(2)The Board of Pharmacy, the Board of Medicine, and the Board of Osteopathic Medicine shall adopt by rule a formulary of medicinal drugs and dispensing procedures as established by the committee. A pharmacist may order and dispense a product from the formulary pursuant to the established dispensing procedure, as adopted by the boards, for each drug in conjunction with its inclusion in the formulary. Any drug product ordered by a pharmacist shall be selected and dispensed only by the pharmacist so ordering, and said order shall not be refilled, nor shall another medicinal drug be ordered for the same condition unless such act is consistent with dispensing procedures established by the committee. Appropriate referral to another health care provider is indicated under such circumstances. On each occasion of such dispensing, the pharmacist shall create and maintain a prescription record in the form required by law.

(3)Affixed to the container containing a medicinal drug dispensed pursuant to this section shall be a label bearing the following information:

(a)The name of the pharmacist ordering the medication.

(b)The name and address of the pharmacy from which the medication was dispensed.

(c)The date of dispensing.

(d)The order number or other identification adequate to readily identify the order.

(e)The name of the patient for whom the medicinal drug was ordered.

(f)The directions for use of the medicinal drug ordered.

(g)A clear, concise statement that the order may not be refilled.

(4)Any pharmacist performing the services authorized by this section shall be eligible for reimbursement by third party prescription programs when so provided by contract or when otherwise provided by such program.

(5)Any person ordering or dispensing medicinal drugs in violation of this section shall be guilty of a misdemeanor of the first degree, and such violation shall be punishable as provided in s. 775.082 or s. 775.083.

History.—ss. 2, 3, ch. 85-35; ss. 26, 27, ch. 86-256; s. 56, ch. 87-225; s. 59, ch. 91-137; s. 21, ch. 91-140; s. 6, ch. 91-156; s. 21, ch. 91-220; s. 92, ch. 91-224; s. 4, ch. 91-429; s. 96, ch. 92-149; s. 249, ch. 97-103; s. 95, ch. 97-264.

465.187 Sale of medicinal drugs.—The sale of medicinal drugs dispensed upon the order of a practitioner pursuant to this chapter shall be entitled to the exemption from sales tax provided for in s. 212.08.
History.—ss. 21, 27, ch. 86-256; s. 59, ch. 91-137; s. 6, ch. 91-156; s. 4, ch. 91-429.

465.188 Medicaid audits of pharmacies.—

(1)Notwithstanding any other law, when an audit of the Medicaid-related records of a pharmacy licensed under chapter 465 is conducted, such audit must be conducted as provided in this section.

(a)The agency conducting the audit must give the pharmacist at least 1 week's prior notice of the initial audit for each audit cycle.

(b)An audit must be conducted by a pharmacist licensed in this state.

(c)Any clerical or recordkeeping error, such as a typographical error, scrivener's error, or computer error regarding a document or record required under the Medicaid program does not constitute a willful violation and is not subject to criminal penalties without proof of intent to commit fraud.

(d)A pharmacist may use the physician's record or other order for drugs or medicinal supplies written or transmitted by any means of communication for purposes of validating the pharmacy record with respect to orders or refills of a legend or narcotic drug.

(e)A finding of an overpayment or underpayment must be based on the actual overpayment or underpayment and may not be a projection based on the number of patients served having a similar diagnosis or on the number of similar orders or refills for similar drugs.

(f)Each pharmacy shall be audited under the same standards and parameters.

(g)A pharmacist must be allowed at least 10 days in which to produce documentation to address any discrepancy found during an audit.

(h)The period covered by an audit may not exceed 1 calendar year.

(i)An audit may not be scheduled during the first 5 days of any month due to the high volume of prescriptions filled during that time.

(j)The audit report must be delivered to the pharmacist within 90 days after conclusion of the audit. A final audit report shall be delivered to the pharmacist within 6 months after receipt of the preliminary audit report or final appeal, as provided for in subsection (2), whichever is later.

(k)The audit criteria set forth in this section applies only to audits of claims submitted for payment subsequent to July 11, 2003. Notwithstanding any other provision in this section, the agency conducting the audit shall not use the accounting practice of extrapolation in calculating penalties for Medicaid audits.

(2)The Agency for Health Care Administration shall establish a process under which a pharmacist may obtain a preliminary review of an audit report and may appeal an unfavorable audit report without the necessity of obtaining legal counsel. The preliminary review and appeal may be conducted by an ad hoc peer review panel, appointed by the agency, which consists of pharmacists who maintain an active practice. If, following the preliminary review, the agency or review panel finds that an unfavorable audit report is unsubstantiated, the agency shall dismiss the audit report without the necessity of any further proceedings.

(3)This section does not apply to investigative audits conducted by the Medicaid Fraud Control Unit of the Department of Legal Affairs.

(4)This section does not apply to any investigative audit conducted by the Agency for Health Care Administration when the agency has reliable evidence that the claim that is the subject of the audit involves fraud, willful misrepresentation, or abuse under the Medicaid program.

History.—s. 1, ch. 2003-277; s. 11, ch. 2004-344.

465.189 Administration of vaccines and epinephrine autoinjection.—

(1)In accordance with guidelines of the Centers for Disease Control and Prevention for each recommended immunization or vaccine, a pharmacist may administer the following vaccines to an adult within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459:

(a)Influenza vaccine.

(b)Pneumococcal vaccine.

(2)In accordance with guidelines of the Centers for Disease Control and Prevention, a pharmacist may administer the shingles vaccine within the framework of an established protocol and pursuant to a written or electronic prescription issued to the patient by a physician licensed under chapter 458 or chapter 459.

(3)In order to address any unforeseen allergic reaction, a pharmacist may administer epinephrine using an autoinjector delivery system within the framework of an established protocol under a supervising physician licensed under chapter 458 or chapter 459.

(4)A pharmacist may not enter into a protocol unless he or she maintains at least $200,000 of professional liability insurance and has completed training in administering vaccines authorized under this section.

(5)A pharmacist administering vaccines under this section shall maintain and make available patient records using the same standards for confidentiality and maintenance of such records as those that are imposed on health care practitioners under s. 456.057. These records shall be maintained for a minimum of 5 years.

(6)The decision by a supervising physician licensed under chapter 458 or chapter 459 to enter into a protocol under this section is a professional decision on the part of the practitioner, and a person may not interfere with a physician's decision as to entering into such a protocol. A pharmacist may not enter into a protocol that is to be performed while acting as an employee without the written approval of the owner of the pharmacy. Pharmacists shall forward vaccination records to the department for inclusion in the state registry of immunization information.

(7)Any pharmacist seeking to administer vaccines to adults under this section must be certified to administer such vaccines pursuant to a certification program approved by the Board of Pharmacy in consultation with the Board of Medicine and the Board of Osteopathic Medicine. The certification program shall, at a minimum, require that the pharmacist attend at least 20 hours of continuing education classes approved by the board. The program shall have a curriculum of instruction concerning the safe and effective administration of such vaccines, including, but not limited to, potential allergic reactions to such vaccines.

(8)The written protocol between the pharmacist and supervising physician under this section must include particular terms and conditions imposed by the supervising physician upon the pharmacist relating to the administration of vaccines by the pharmacist pursuant to this section. The written protocol shall include, at a minimum, specific categories and conditions among patients for whom the supervising physician authorizes the pharmacist to administer such vaccines. The terms, scope, and conditions set forth in the written protocol between the pharmacist

and the supervising physician must be appropriate to the pharmacist's training and certification for administering such vaccines. Pharmacists who have been delegated the authority to administer vaccines under this section by the supervising physician under the protocol shall provide evidence of current certification by the Board of Pharmacy to the supervising physician. A supervising physician shall review the administration of such vaccines by the pharmacist pursuant to the written protocol between them, and this review shall take place as outlined in the written protocol. The process and schedule for the review shall be outlined in the written protocol between the pharmacist and the supervising physician.

(9)The pharmacist shall submit to the Board of Pharmacy a copy of his or her protocol or written agreement to administer vaccines under this section.

History.—s. 3, ch. 2007-152; s. 1, ch. 2012-60.

465.1901 Practice of orthotics and pedorthics.—The provisions of chapter 468 relating to orthotics or pedorthics do not apply to any licensed pharmacist or to any person acting under the supervision of a licensed pharmacist. The practice of orthotics or pedorthics by a pharmacist or any of the pharmacist's employees acting under the supervision of a pharmacist shall be construed to be within the meaning of the term "practice of the profession of pharmacy" as set forth in s. 465.003(13), and shall be subject to regulation in the same manner as any other pharmacy practice. The Board of Pharmacy shall develop rules regarding the practice of orthotics and pedorthics by a pharmacist. Any pharmacist or person under the supervision of a pharmacist engaged in the practice of orthotics or pedorthics is not precluded from continuing that practice pending adoption of these rules.

History.—s. 3, ch. 2009-202.

CHAPTER 893

DRUG ABUSE PREVENTION AND CONTROL

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893.01Short title.—This chapter shall be cited and known as the “Florida Comprehensive Drug Abuse Prevention and Control Act.”

History.—s. 1, ch. 73-331.

893.02Definitions.—The following words and phrases as used in this chapter shall have the following meanings, unless the context otherwise requires:

(1)“Administer” means the direct application of a controlled substance, whether by injection, inhalation, ingestion, or any other means, to the body of a person or animal.

(2)“Analog” or “chemical analog” means a structural derivative of a parent compound that is a controlled substance.

(3)“Cannabis” means all parts of any plant of the genus *Cannabis*, whether growing or not; the seeds thereof; the resin extracted from any part of the plant; and every compound, manufacture, salt, derivative, mixture, or preparation of the plant or its seeds or resin.

(4)“Controlled substance” means any substance named or described in Schedules I-V of s. 893.03. Laws controlling the manufacture, distribution, preparation, dispensing, or administration of such substances are drug abuse laws.

(5)“Cultivating” means the preparation of any soil or hydroponic medium for the planting of a controlled substance or the tending and care or harvesting of a controlled substance.

(6)“Deliver” or “delivery” means the actual, constructive, or attempted transfer from one person to another of a controlled substance, whether or not there is an agency relationship.

(7)“Dispense” means the transfer of possession of one or more doses of a medicinal drug by a pharmacist or other licensed practitioner to the ultimate consumer thereof or to one who represents that it is his or her intention not to consume or use the same but to transfer the same to the ultimate consumer or user for consumption by the ultimate consumer or user.

(8)“Distribute” means to deliver, other than by administering or dispensing, a controlled substance.

(9)“Distributor” means a person who distributes.

(10)“Department” means the Department of Health.

(11)“Homologue” means a chemical compound in a series in which each compound differs by one or more alkyl functional groups on an alkyl side chain.

(12)“Hospital” means an institution for the care and treatment of the sick and injured, licensed pursuant to the provisions of chapter 395 or owned or operated by the state or Federal Government.

(13)“Laboratory” means a laboratory approved by the Drug Enforcement Administration as proper to be entrusted with the custody of controlled substances for scientific, medical, or instructional purposes or to aid law enforcement officers and prosecuting attorneys in the enforcement of this chapter.

(14)“Listed chemical” means any precursor chemical or essential chemical named or described in s. 893.033.

(15)(a)“Manufacture” means the production, preparation, propagation, compounding, cultivating, growing, conversion, or processing of a controlled substance, either directly or indirectly, by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, and includes any packaging of the substance or labeling or relabeling of its container, except that this term does not include the preparation, compounding, packaging, or labeling of a controlled substance by:

1.A practitioner or pharmacist as an incident to his or her administering or delivering of a controlled substance in the course of his or her professional practice.

2.A practitioner, or by his or her authorized agent under the practitioner’s supervision, for the purpose of, or as an incident to, research, teaching, or chemical analysis, and not for sale.

(b)“Manufacturer” means and includes every person who prepares, derives, produces, compounds, or repackages any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to manufacturers of patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists employed thereby, are specifically excluded from this definition.

(16)“Mixture” means any physical combination of two or more substances.

(17)“Patient” means an individual to whom a controlled substance is lawfully dispensed or administered pursuant to the provisions of this chapter.

(18)“Pharmacist” means a person who is licensed pursuant to chapter 465 to practice the profession of pharmacy in this state.

(19)“Possession” includes temporary possession for the purpose of verification or testing, irrespective of dominion or control.

(20)“Potential for abuse” means that a substance has properties of a central nervous system

stimulant or depressant or an hallucinogen that create a substantial likelihood of its being:

(a)Used in amounts that create a hazard to the user's health or the safety of the community;

(b)Diverted from legal channels and distributed through illegal channels; or

(c)Taken on the user's own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.

(21)"Practitioner" means a physician licensed pursuant to chapter 458, a dentist licensed pursuant to chapter 466, a veterinarian licensed pursuant to chapter 474, an osteopathic physician licensed pursuant to chapter 459, a naturopath licensed pursuant to chapter 462, or a podiatric physician licensed pursuant to chapter 461, provided such practitioner holds a valid federal controlled substance registry number.

(22)"Prescription" means and includes an order for drugs or medicinal supplies written, signed, or transmitted by word of mouth, telephone, telegram, or other means of communication by a duly licensed practitioner licensed by the laws of the state to prescribe such drugs or medicinal supplies, issued in good faith and in the course of professional practice, intended to be filled, compounded, or dispensed by another person licensed by the laws of the state to do so, and meeting the requirements of s. 893.04. The term also includes an order for drugs or medicinal supplies so transmitted or written by a physician, dentist, veterinarian, or other practitioner licensed to practice in a state other than Florida, but only if the pharmacist called upon to fill such an order determines, in the exercise of his or her professional judgment, that the order was issued pursuant to a valid patient-physician relationship, that it is authentic, and that the drugs or medicinal supplies so ordered are considered necessary for the continuation of treatment of a chronic or recurrent illness. However, if the physician writing the prescription is not known to the pharmacist, the pharmacist shall obtain proof to a reasonable certainty of the validity of said prescription. A prescription order for a controlled substance shall not be issued on the same prescription blank with another prescription order for a controlled substance which is named or described in a different schedule, nor shall any prescription order for a controlled substance be issued on the same prescription blank as a prescription order for a medicinal drug, as defined in s. 465.003(8), which does not fall within the definition of a controlled substance as defined in this act.

(23)"Wholesaler" means any person who acts as a jobber, wholesale merchant, or broker, or an agent thereof, who sells or distributes for resale any drug as defined by the Florida Drug and Cosmetic Act. However, this definition does not apply to persons who sell only patent or proprietary preparations as defined in the Florida Pharmacy Act. Pharmacies, and pharmacists

employed thereby, are specifically excluded from this definition.

History.—s. 2, ch. 73-331; s. 1, ch. 75-18; s. 470, ch. 77-147; s. 1, ch. 77-174; s. 184, ch. 79-164; s. 1, ch. 79-325; s. 37, ch. 82-225; s. 169, ch. 83-216; s. 1, ch. 85-242; s. 1, ch. 91-279; s. 1, ch. 92-19; s. 1434, ch. 97-102; s. 104, ch. 97-264; s. 234, ch. 98-166; s. 300, ch. 99-8; s. 10, ch. 99-186; s. 1, ch. 2000-320; s. 3, ch. 2001-55; s. 10, ch. 2002-78; s. 13, ch. 2005-128; s. 1, ch. 2008-184; s. 18, ch. 2010-117; s. 1, ch. 2011-73.

893.03Standards and schedules.—The substances enumerated in this section are controlled by this chapter. The controlled substances listed or to be listed in Schedules I, II, III, IV, and V are included by whatever official, common, usual, chemical, or trade name designated. The provisions of this section shall not be construed to include within any of the schedules contained in this section any excluded drugs listed within the purview of 21 C.F.R. s. 1308.22, styled "Excluded Substances"; 21 C.F.R. s. 1308.24, styled "Exempt Chemical Preparations"; 21 C.F.R. s. 1308.32, styled "Exempted Prescription Products"; or 21 C.F.R. s. 1308.34, styled "Exempt Anabolic Steroid Products."

(1)SCHEDULE I.—A substance in Schedule I has a high potential for abuse and has no currently accepted medical use in treatment in the United States and in its use under medical supervision does not meet accepted safety standards. The following substances are controlled in Schedule I:

(a)Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

1.Acetyl-alpha-methylfentanyl.

2.Acetylmethadol.

3.Allylprodine.

4.Alphacetylmethadol (except levo-alphacetylmethadol, also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).

5.Alphamethadol.

6.Alpha-methylfentanyl (N-[1-(alpha-methyl-betaphenyl) ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4-(N-propanilido) piperidine).

7.Alpha-methylthiofentanyl.

8.Alphameprodine.

9.Benzethidine.

10.Benzylfentanyl.

11.Betacetylmethadol.

12.Beta-hydroxyfentanyl.

13.Beta-hydroxy-3-methylfentanyl.

14.Betameprodine.

15.Betamethadol.

16.Betaprodine.

17.Clonitazene.

18.Dextromoramide.

19.Diampromide.

20.Diethylthiambutene.

21.Difenoxin.

22.Dimenoxadol.

23.Dimepheptanol.

24.Dimethylthiambutene.

25.Dioxaphetyl butyrate.

26.Dipipanone.

27.Ethylmethylthiambutene.

28.Etonitazene.

29.Etoxeridine.

30.Flunitrazepam.

31.Furethidine.

32.Hydroxypethidine.

33.Ketobemidone.

34.Levomoramide.

35.Levophenacylmorphan.

36.1-Methyl-4-Phenyl-4-Propionoxypiperidine (MPPP).

37.3-Methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide).

38.3-Methylthiofentanyl.

39.3, 4-Methylenedioxymethamphetamine (MDMA).

40.Morpheridine.

41.Noracymethadol.

42.Norlevorphanol.

43.Normethadone.

44.Norpipanone.

45.Para-Fluorofentanyl.

46.Phenadoxone.

47.Phenampromide.

48.Phenomorphan.

49.Phenoperidine.

50.1-(2-Phenylethyl)-4-Phenyl-4-Acetyloxypiperidine (PEPAP).

51.Piritramide.

52.Proheptazine.

53.Properidine.

54.Propiram.

55.Racemoramide.

56.Thenylfentanyl.

57.Thiofentanyl.

58.Tilidine.

59.Trimeperidine.

(b)Unless specifically excepted or unless listed in another schedule, any of the following substances, their salts, isomers, and salts of isomers, whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

1.Acetorphine.

2.Acetyldihydrocodeine.

3.Benzylmorphine.

4.Codeine methylbromide.

5.Codeine-N-Oxide.

6.Cyprenorphine.

7.Desomorphine.

8.Dihydromorphine.

9.Drotebanol.

10.Etorphine (except hydrochloride salt).

11.Heroin.

12.Hydromorphinol.

13.Methyldesorphine.

14.Methyldihydromorphine.

15.Monoacetylmorphine.

16.Morphine methylbromide.

17.Morphine methylsulfonate.

18.Morphine-N-Oxide.

19.Myrophine.

20.Nicocodine.

21.Nicomorphine.

22.Normorphine.

23.Pholcodine.

24.Thebacon.

(c)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation that contains any quantity of the following hallucinogenic substances or that contains any of their salts, isomers, and salts of isomers, if the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation:

1.Alpha-ethyltryptamine.

2.2-Amino-4-methyl-5-phenyl-2-oxazoline (4-methylaminorex).

3.2-Amino-5-phenyl-2-oxazoline (Aminorex).

4.4-Bromo-2,5-dimethoxyamphetamine.

5.4-Bromo-2,5-dimethoxyphenethylamine.

6.Bufotenine.

7.Cannabis.

8.Cathinone.

9.Diethyltryptamine.

10.2,5-Dimethoxyamphetamine.

11.2,5-Dimethoxy-4-ethylamphetamine (DOET).

12.Dimethyltryptamine.

13.N-Ethyl-1-phenylcyclohexylamine (PCE) (Ethylamine analog of phencyclidine).

14.N-Ethyl-3-piperidyl benzilate.

15.N-ethylamphetamine.

16.Fenethylline.

17.N-Hydroxy-3,4-methylenedioxyamphetamine.

18.Ibogaine.

19.Lysergic acid diethylamide (LSD).

20.Mescaline.

21.Methcathinone.

22.5-Methoxy-3,4-methylenedioxyamphetamine.

23.4-methoxyamphetamine.

24.4-methoxymethamphetamine.

25.4-Methyl-2,5-dimethoxyamphetamine.

26.3,4-Methylenedioxy-N-ethylamphetamine.

27.3,4-Methylenedioxyamphetamine.

28.N-Methyl-3-piperidyl benzilate.

29.N,N-dimethylamphetamine.

30.Parahexyl.

31.Peyote.

32.N-(1-Phenylcyclohexyl)-pyrrolidine (PCPY) (Pyrrolidine analog of phencyclidine).

33.Psilocybin.

34.Psilocyn.

35.*Salvia divinorum*, except for any drug product approved by the United States Food and Drug Administration which contains *Salvia divinorum* or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

36.Salvinorin A, except for any drug product approved by the United States Food and Drug Administration which contains Salvinorin A or its isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, if the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

37.Tetrahydrocannabinols.

38.1-[1-(2-Thienyl)-cyclohexyl]-piperidine (TCP) (Thiophene analog of phencyclidine).

39.3,4,5-Trimethoxyamphetamine.

40.3,4-Methylenedioxymethcathinone.

41.3,4-Methylenedioxypyrovalerone (MDPV).

42.Methylmethcathinone.

43.Methoxymethcathinone.

44.Fluoromethcathinone.

45.Methylethcathinone.

46.2-[(1R,3S)-3-hydroxycyclohexyl]-5-(2-methyloctan-2-yl)phenol, also known as CP 47,497 and its dimethyloctyl (C8) homologue.

47.(6aR,10aR)-9-(hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo [c]chromen-1-ol, also known as HU-210.

48.1-Pentyl-3-(1-naphthoyl)indole, also known as JWH-018.

49.1-Butyl-3-(1-naphthoyl)indole, also known as JWH-073.

50.1-[2-(4-morpholinyl)ethyl]-3-(1-naphthoyl) indole, also known as JWH-200.

51.BZP (Benzylpiperazine).

52.Fluorophenylpiperazine.

53.Methylphenylpiperazine.

54.Chlorophenylpiperazine.

55.Methoxyphenylpiperazine.

56.DBZP (1,4-dibenzylpiperazine).

57.TFMPP (3-Trifluoromethylphenylpiperazine).

58.MBDB (Methylbenzodioxolylbutanamine).

59.5-Hydroxy-alpha-methyltryptamine.

60.5-Hydroxy-N-methyltryptamine.

61.5-Methoxy-N-methyl-N-isopropyltryptamine.

62.5-Methoxy-alpha-methyltryptamine.

63.Methyltryptamine.

64.5-Methoxy-N,N-dimethyltryptamine.

65.5-Methyl-N,N-dimethyltryptamine.

66.Tyramine (4-Hydroxyphenethylamine).

67.5-Methoxy-N,N-Diisopropyltryptamine.

68.DiPT (N,N-Diisopropyltryptamine).

69.DPT (N,N-Dipropyltryptamine).

70.4-Hydroxy-N,N-diisopropyltryptamine.

71.N,N-Diallyl-5-Methoxytryptamine.

72.DOI (4-Iodo-2,5-dimethoxyamphetamine).

73.DOC (4-Chloro-2,5-dimethoxyamphetamine).

74.2C-E (4-Ethyl-2,5-dimethoxyphenethylamine).

75.2C-T-4 (2,5-Dimethoxy-4-isopropylthiophenethylamine).

76.2C-C (4-Chloro-2,5-dimethoxyphenethylamine).

77.2C-T (2,5-Dimethoxy-4-methylthiophenethylamine).

78.2C-T-2 (2,5-Dimethoxy-4-ethylthiophenethylamine).

79.2C-T-7 (2,5-Dimethoxy-4-(n)-propylthiophenethylamine).

80.2C-I (4-Iodo-2,5-dimethoxyphenethylamine).

81.Butylone (beta-keto-N-methylbenzodioxolylpropylamine).

82.Ethcathinone.

83.Ethylone (3,4-methylenedioxy-N-ethylcathinone).

84.Naphyrone (naphthylpyrovalerone).

85.N-N-Dimethyl-3,4-methylenedioxycathinone.

86.N-N-Diethyl-3,4-methylenedioxycathinone.

87.3,4-methylenedioxy-propiophenone.

88.2-Bromo-3,4-Methylenedioxypropiophenone.

89.3,4-methylenedioxy-propiophenone-2-oxime.

90.N-Acetyl-3,4-methylenedioxycathinone.

91.N-Acetyl-N-Methyl-3,4-Methylenedioxycathinone.

92.N-Acetyl-N-Ethyl-3,4-Methylenedioxycathinone.

93.Bromomethcathinone.

94.Buphedrone (alpha-methylamino-butyrophenone).

95.Eutylone (beta-Keto-Ethylbenzodioxolylbutanamine).

96.Dimethylcathinone.

97.Dimethylmethcathinone.

98.Pentylone (beta-Keto-Methylbenzodioxolylpentanamine).

99.(MDPPP) 3,4-Methylenedioxy-alpha-pyrrolidinopropiophenone.

100.(MDPBP) 3,4-Methylenedioxy-alpha-pyrrolidinobutiophenone.

101.Methoxy-alpha-pyrrolidinopropiophenone (MOPPP).

102.Methyl-alpha-pyrrolidinohexiophenone (MPHP).

103.Benocyclidine (BCP) or benzothiophenylcyclohexylpiperidine (BTCP).

104.Fluoromethylaminobutyrophenone (F-MABP).

105.Methoxypyrrolidinobutyrophenone (MeO-PBP).

106.Ethyl-pyrrolidinobutyrophenone (Et-PBP).

107.3-Methyl-4-Methoxymethcathinone (3-Me-4-MeO-MCAT).

108.Methylethylaminobutyrophenone (Me-EABP).

109.Methylamino-butyrophenone (MABP).

110.Pyrrolidinopropiophenone (PPP).

111.Pyrrolidinobutiophenone (PBP).

112.Pyrrolidinovalerophenone (PVP).

113.Methyl-alpha-pyrrolidinopropiophenone (MPPP).

114.JWH-007 (1-pentyl-2-methyl-3-(1-naphthoyl)indole).

115.JWH-015 (2-Methyl-1-propyl-1H-indol-3-yl)-1-naphthalenylmethanone).

116.JWH-019 (Naphthalen-1-yl-(1-hexylindol-3-yl)methanone).

117.JWH-020 (1-heptyl-3-(1-naphthoyl)indole).

118.JWH-072 (Naphthalen-1-yl-(1-propyl-1H-indol-3-yl)methanone).

119.JWH-081 (4-methoxynaphthalen-1-yl-(1-pentylindol-3-yl)methanone).

120.JWH-122 (1-Pentyl-3-(4-methyl-1-naphthoyl)indole).

121.JWH-133 ((6aR,10aR)-3-(1,1-Dimethylbutyl)-6a,7,10,10a-tetrahydro-6,6,9-trimethyl-6H-dibenzo[b,d]pyran)).

122.JWH-175 (3-(naphthalen-1-ylmethyl)-1-pentyl-1H-indole).

123.JWH-201 (1-pentyl-3-(4-methoxyphenylacetyl)indole).

124.JWH-203 (2-(2-chlorophenyl)-1-(1-pentylindol-3-yl)ethanone).

125.JWH-210 (4-ethylnaphthalen-1-yl-(1-pentylindol-3-yl)methanone).

126.JWH-250 (2-(2-methoxyphenyl)-1-(1-pentylindol-3-yl)ethanone).

127.JWH-251 (2-(2-methylphenyl)-1-(1-pentyl-1H-indol-3-yl)ethanone).

128.JWH-302 (1-pentyl-3-(3-methoxyphenylacetyl)indole).

129.JWH-398 (1-pentyl-3-(4-chloro-1-naphthoyl)indole).

130.HU-211 ((6aS,10aS)-9-(Hydroxymethyl)-6,6-dimethyl-3-(2-methyloctan-2-yl)-6a,7,10,10a-tetrahydrobenzo[c]chromen-1-ol).

131.HU-308 ([(1R,2R,5R)-2-[2,6-dimethoxy-4-(2-methyloctan-2-yl)phenyl]-7,7-dimethyl-4-bicyclo[3.1.1]hept-3-enyl] methanol).

132.HU-331 (3-hydroxy-2-[(1R,6R)-3-methyl-6-(1- methylethenyl)-2-cyclohexen-1-yl]-5-pentyl-2,5-cyclohexadiene-1,4-dione).

133.CB-13 (Naphthalen-1-yl-(4-pentyloxynaphthalen-1-yl)methanone).

134.CB-25 (N-cyclopropyl-11-(3-hydroxy-5-pentylphenoxy)-undecanamide).

135.CB-52 (N-cyclopropyl-11-(2-hexyl-5-hydroxyphenoxy)-undecanamide).

136.CP 55,940 (2-[(1R,2R,5R)-5-hydroxy-2-(3-hydroxypropyl)cyclohexyl]-5-(2-methyloctan-2-yl)phenol).

137.AM-694 (1-[(5-fluoropentyl)-1H-indol-3-yl]-(2-iodophenyl)methanone).

138.AM-2201 (1-[(5-fluoropentyl)-1H-indol-3-yl]-(naphthalen-1-yl)methanone).

139.RCS-4 ((4-methoxyphenyl) (1-pentyl-1H-indol-3-yl)methanone).

140.RCS-8 (1-(1-(2-cyclohexylethyl)-1H-indol-3-yl)-2-(2-methoxyphenylethanone).

141.WIN55,212-2 ((R)-(+)-[2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).

142.WIN55,212-3 ([(3S)-2,3-Dihydro-5-methyl-3-(4-morpholinylmethyl)pyrrolo[1,2,3-de]-1,4-benzoxazin-6-yl]-1-naphthalenylmethanone).

(d)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including any of its salts, isomers, optical isomers, salts of their isomers, and salts of these optical isomers whenever the existence of such isomers and salts is possible within the specific chemical designation:

1.1,4-Butanediol.

2.Gamma-butyrolactone (GBL).

3.Gamma-hydroxybutyric acid (GHB).

4.Methaqualone.

5.Mecloqualone.

(2)SCHEDULE II.—A substance in Schedule II has a high potential for abuse and has a currently accepted but severely restricted medical use in treatment in the United States, and abuse of the substance may lead to severe psychological or physical dependence. The following substances are controlled in Schedule II:

(a)Unless specifically excepted or unless listed in another schedule, any of the following substances, whether produced directly or indirectly by extraction from substances of vegetable origin or independently by means of chemical synthesis:

1.Opium and any salt, compound, derivative, or preparation of opium, except nalmefene or isoquinoline alkaloids of opium, including, but not limited to the following:

a.Raw opium.

b.Opium extracts.

c.Opium fluid extracts.

d.Powdered opium.

e.Granulated opium.

f.Tincture of opium.

g.Codeine.

h.Ethylmorphine.

i.Etorphine hydrochloride.

j.Hydrocodone.

k.Hydromorphone.

l.Levo-alphacetylmethadol (also known as levo-alpha-acetylmethadol, levomethadyl acetate, or LAAM).

m.Metopon (methyldihydromorphinone).

n.Morphine.

o.Oxycodone.

p.Oxymorphone.

q.Thebaine.

2.Any salt, compound, derivative, or preparation of a substance which is chemically equivalent to or identical with any of the substances referred to in subparagraph 1., except that these substances shall not include the isoquinoline alkaloids of opium.

3.Any part of the plant of the species *Papaver somniferum, L.*

4.Cocaine or ecgonine, including any of their stereoisomers, and any salt, compound, derivative, or preparation of cocaine or ecgonine.

(b)Unless specifically excepted or unless listed in another schedule, any of the following substances, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation:

1.Alfentanil.

2.Alphaprodine.

3.Anileridine.

4.Bezitramide.

5.Bulk propoxyphene (nondosage forms).

6.Carfentanil.

7.Dihydrocodeine.

8.Diphenoxylate.

9.Fentanyl.

10.Isomethadone.

11.Levomethorphan.

12.Levorphanol.

13.Metazocine.

14.Methadone.

15.Methadone-Intermediate,4-cyano-2-dimethylamino-4,4-diphenylbutane.

16.Moramide-Intermediate,2-methyl-3-morpholoino-1,1-diphenylpropane-carboxylic acid.

17.Nabilone.

18.Pethidine (meperidine).

19.Pethidine-Intermediate-A,4-cyano-1-methyl-4-phenylpiperidine.

20.Pethidine-Intermediate-B,ethyl-4-phenylpiperidine-4-carboxylate.

21.Pethidine-Intermediate-C,1-methyl-4- phenylpiperidine-4-carboxylic acid.

22.Phenazocine.

23.Phencyclidine.

24.1-Phenylcyclohexylamine.

25.Piminodine.

26.1-Piperidinocyclohexanecarbonitrile.

27.Racemethorphan.

28.Racemorphan.

29.Sufentanil.

(c)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including their salts, isomers, optical isomers, salts of their isomers, and salts of their optical isomers:

1.Amobarbital.

2.Amphetamine.

3.Glutethimide.

4.Methamphetamine.

5.Methylphenidate.

6.Pentobarbital.

7.Phenmetrazine.

8.Phenylacetone.

9.Secobarbital.

(3)SCHEDULE III.—A substance in Schedule III has a potential for abuse less than the substances contained in Schedules I and II and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to moderate or low physical dependence or high psychological dependence or, in the case of anabolic steroids, may lead to physical damage. The following substances are controlled in Schedule III:

(a)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a depressant or stimulant effect on the nervous system:

1.Any substance which contains any quantity of a derivative of barbituric acid, including thiobarbituric acid, or any salt of a derivative of barbituric acid or thiobarbituric acid, including, but not limited to, butabarbital and butalbital.

2.Benzphetamine.

3.Chlorhexadol.

4.Chlorphentermine.

5.Clortermine.

6.Lysergic acid.

7.Lysergic acid amide.

8.Methyprylon.

9.Phendimetrazine.

10.Sulfondiethylmethane.

11.Sulfonethylmethane.

12.Sulfonmethane.

13.Tiletamine and zolazepam or any salt thereof.

(b)Nalorphine.

(c)Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing limited quantities of any of the following controlled substances or any salts thereof:

1.Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with an equal or greater quantity of an isoquinoline alkaloid of opium.

2.Not more than 1.8 grams of codeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

3.Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15

milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium.

4.Not more than 300 milligrams of hydrocodone per 100 milliliters or not more than 15 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients that are not controlled substances.

5.Not more than 1.8 grams of dihydrocodeine per 100 milliliters or not more than 90 milligrams per dosage unit, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

6.Not more than 300 milligrams of ethylmorphine per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.

7.Not more than 50 milligrams of morphine per 100 milliliters or per 100 grams, with recognized therapeutic amounts of one or more active ingredients which are not controlled substances.

For purposes of charging a person with a violation of s. 893.135 involving any controlled substance described in subparagraph 3. or subparagraph 4., the controlled substance is a Schedule III controlled substance pursuant to this paragraph but the weight of the controlled substance per milliliters or per dosage unit is not relevant to the charging of a violation of s. 893.135. The weight of the controlled substance shall be determined pursuant to s. 893.135(6).

(d)Anabolic steroids.

1.The term “anabolic steroid” means any drug or hormonal substance, chemically and pharmacologically related to testosterone, other than estrogens, progestins, and corticosteroids, that promotes muscle growth and includes:

a.Androsterone.

b.Androsterone acetate.

c.Boldenone.

d.Boldenone acetate.

e.Boldenone benzoate.

f.Boldenone undecylenate.

g.Chlorotestosterone (4-chlortestosterone).

h.Clostebol.

i.Dehydrochlormethyltestosterone.

j.Dihydrotestosterone (4-dihydrotestosterone).

k.Drostanolone.

l.Ethylestrenol.

m.Fluoxymesterone.

n.Formebulone (formebolone).

o.Mesterolone.

p.Methandienone.

q.Methandranone.

r.Methandriol.

s.Methandrostenolone.

t.Methenolone.

u.Methyltestosterone.

v.Mibolerone.

w.Nandrolone.

x.Norethandrolone.

y.Nortestosterone.

z.Nortestosterone decanoate.

aa.Nortestosterone phenylpropionate.

bb.Nortestosterone propionate.

cc.Oxandrolone.

dd.Oxymesterone.

ee.Oxymetholone.

ff.Stanolone.

gg.Stanozolol.

hh.Testolactone.

ii.Testosterone.

jj.Testosterone acetate.

kk.Testosterone benzoate.

ll.Testosterone cypionate.

mm.Testosterone decanoate.

nn.Testosterone enanthate.

oo.Testosterone isocaproate.

pp.Testosterone oleate.

qq.Testosterone phenylpropionate.

rr.Testosterone propionate.

ss.Testosterone undecanoate.

tt.Trenbolone.

uu.Trenbolone acetate.

vv.Any salt, ester, or isomer of a drug or substance described or listed in this subparagraph if that salt, ester, or isomer promotes muscle growth.

2.The term does not include an anabolic steroid that is expressly intended for administration

through implants to cattle or other nonhuman species and that has been approved by the United States Secretary of Health and Human Services for such administration. However, any person who prescribes, dispenses, or distributes such a steroid for human use is considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this paragraph.

(e)Ketamine, including any isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of such isomers, esters, ethers, and salts is possible within the specific chemical designation.

(f)Dronabinol (synthetic THC) in sesame oil and encapsulated in a soft gelatin capsule in a drug product approved by the United States Food and Drug Administration.

(g)Any drug product containing gamma-hydroxybutyric acid, including its salts, isomers, and salts of isomers, for which an application is approved under s. 505 of the Federal Food, Drug, and Cosmetic Act.

(4)SCHEDULE IV.—A substance in Schedule IV has a low potential for abuse relative to the substances in Schedule III and has a currently accepted medical use in treatment in the United States, and abuse of the substance may lead to limited physical or psychological dependence relative to the substances in Schedule III. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances, including its salts, isomers, and salts of isomers whenever the existence of such salts, isomers, and salts of isomers is possible within the specific chemical designation, are controlled in Schedule IV:

(a)Alprazolam.

(b)Barbital.

(c)Bromazepam.

(d)Camazepam.

(e)Cathine.

(f)Chloral betaine.

(g)Chloral hydrate.

(h)Chlordiazepoxide.

(i)Clobazam.

(j)Clonazepam.

(k)Clorazepate.

(l)Clotiazepam.

(m)Cloxazolam.

(n)Delorazepam.

(o)Propoxyphene (dosage forms).

(p)Diazepam.

(q)Diethylpropion.

(r)Estazolam.

(s)Ethchlorvynol.

(t)Ethinamate.

(u)Ethyl loflazepate.

(v)Fencamfamin.

(w)Fenfluramine.

(x)Fenproporex.

(y)Fludiazepam.

(z)Flurazepam.

(aa)Halazepam.

(bb)Haloxazolam.

(cc)Ketazolam.

(dd)Loprazolam.

(ee)Lorazepam.

(ff)Lormetazepam.

(gg)Mazindol.

(hh)Mebutamate.

(ii)Medazepam.

(jj)Mefenorex.

(kk)Meprobamate.

(ll)Methohexital.

(mm)Methylphenobarbital.

(nn)Midazolam.

(oo)Nimetazepam.

(pp)Nitrazepam.

(qq)Nordiazepam.

(rr)Oxazepam.

(ss)Oxazolam.

(tt)Paraldehyde.

(uu)Pemoline.

(vv)Pentazocine.

(ww)Phenobarbital.

(xx)Phentermine.

(yy)Pinazepam.

(zz)Pipradrol.

(aaa)Prazepam.

(bbb)Propylhexedrine, excluding any patent or proprietary preparation containing propylhexedrine, unless otherwise provided by federal law.

(ccc)Quazepam.

(ddd)Tetrazepam.

(eee)SPA[(-)-1 dimethylamino-1, 2 diphenylethane].

(fff)Temazepam.

(ggg)Triazolam.

(hhh)Not more than 1 milligram of difenoxin and not less than 25 micrograms of atropine sulfate per dosage unit.

(iii)Butorphanol tartrate.

(jjj)Carisoprodol.

(5)SCHEDULE V.—A substance, compound, mixture, or preparation of a substance in Schedule V has a low potential for abuse relative to the substances in Schedule IV and has a currently accepted medical use in treatment in the United States, and abuse of such compound, mixture, or preparation may lead to limited physical or psychological dependence relative to the substances in Schedule IV.

(a)Substances controlled in Schedule V include any compound, mixture, or preparation containing any of the following limited quantities of controlled substances, which shall include one or more active medicinal ingredients which are not controlled substances in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by the controlled substance alone:

1.Not more than 200 milligrams of codeine per 100 milliliters or per 100 grams.

2.Not more than 100 milligrams of dihydrocodeine per 100 milliliters or per 100 grams.

3.Not more than 100 milligrams of ethylmorphine per 100 milliliters or per 100 grams.

4.Not more than 2.5 milligrams of diphenoxylate and not less than 25 micrograms of atropine sulfate per dosage unit.

5.Not more than 100 milligrams of opium per 100 milliliters or per 100 grams.

(b)Narcotic drugs. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation containing any of the following narcotic drugs and their salts: Buprenorphine.

(c)Stimulants. Unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substances having a stimulant effect on the central nervous system, including its salts, isomers, and salts of isomers: Pyrovalerone.

History.—s. 3, ch. 73-331; s. 247, ch. 77-104; s. 1, ch. 77-174; ss. 1, 2, ch. 78-195; s. 2, ch. 79-325; s. 1, ch. 80-353; s. 1, ch. 82-16; s. 1, ch. 84-89; s. 2, ch. 85-242; s. 1, ch. 86-147; s. 2, ch. 87-243; s. 1, ch. 87-299; s. 1, ch. 88-59; s. 3, ch. 89-281; s. 54, ch. 92-69; s. 1, ch. 93-92; s. 4, ch. 95-415; s. 1, ch. 96-360; ss. 1, 5, ch. 97-1; s. 96, ch. 97-264; s. 1, ch. 99-186; s. 2, ch. 2000-320; s. 1, ch. 2001-55; s. 5, ch. 2001-57; s. 1, ch. 2002-78; s. 2, ch. 2003-10; s. 1, ch. 2008-88; s. 2, ch. 2011-73; s. 1, ch. 2011-90; s. 1, ch. 2012-23.

[1]**Note.**—Section 1, ch. 97-1, added paragraph (4)(w) listing fenfluramine. Section 5, ch. 97-1, repealed paragraph (4)(w) effective upon the removal of fenfluramine from the schedules of controlled substances in 21 C.F.R. s. 1308. The Drug Enforcement Administration of the United States Department of Justice filed a proposed final rule removing fenfluramine from the schedules, *see* 62 F.R. 24620, May 6, 1997.

893.0301Death resulting from apparent drug overdose; reporting requirements.—If a person dies of an apparent drug overdose:

(1)A law enforcement agency shall prepare a report identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03 which is found on or near the deceased or among the deceased's possessions. The report must identify the person who prescribed the controlled substance, if known or ascertainable. Thereafter, the law enforcement agency shall submit a copy of the report to the medical examiner.

(2)A medical examiner who is preparing a report pursuant to s. 406.11 shall include in the report information identifying each prescribed controlled substance listed in Schedule II, Schedule III, or Schedule IV of s. 893.03 that was found in, on, or near the deceased or among the deceased's possessions.

History.—s. 6, ch. 2007-156.

893.031Industrial exceptions to controlled substance scheduling.—

(1)For the purpose of this section, the following meanings of terms shall apply:

(a)"Manufacture" means any process or operation necessary for manufacturing a product.

(b)"Distribution" means any process or operation necessary for distributing a product, including, but not limited to, wholesaling, delivery or transport, and storage.

(c)"Manufacturer of 1,4-Butanediol" means a person who is involved in the manufacture of 1,4-Butanediol for use in the manufacture of an industrial product and who provides that manufactured 1,4-Butanediol to a distributor of 1,4-Butanediol or a manufacturer of an industrial product.

(d)"Distributor of 1,4-Butanediol" means a person who is involved in the distribution of 1,4-Butanediol.

(e)"Manufacturer of gamma-butyrolactone (GBL)" means a person who:

1.Is involved in the manufacture of gamma-butyrolactone (GBL) for use in the manufacture of an industrial product and who provides that manufactured gamma-butyrolactone (GBL) to a

distributor of gamma-butyrolactone (GBL) or a manufacturer of an industrial product; and

2.Is in compliance with any requirements to register with the United States Drug Enforcement Administration as a List I Chemical registrant.

(f)"Distributor of gamma-butyrolactone (GBL)" means a person who:

1.Is involved in the distribution of gamma-butyrolactone (GBL); and

2.Is in compliance with any requirements to register with the United States Drug Enforcement Administration as a List I Chemical registrant.

(g)"Manufacturer of an industrial product" means a person who is involved in the manufacture of an industrial product in which that person acquires:

1.1,4-Butanediol from a manufacturer of 1,4-Butanediol or a distributor of 1,4-Butanediol and who possesses that substance for use in the manufacture of an industrial product; or

2.Gamma-butyrolactone (GBL) from a manufacturer of gamma-butyrolactone (GBL) or a distributor of gamma-butyrolactone (GBL) and who possesses that substance for use in the manufacture of an industrial product.

(h)"Distributor of an industrial product" means a person who is involved in the distribution of an industrial product.

(i)"Industrial product" means a nondrug, noncontrolled finished product that is not for human consumption.

(j)"Finished product" means a product:

1.That does not contain either 1,4-Butanediol or gamma-butyrolactone (GBL); or

2.From which neither 1,4-Butanediol nor gamma-butyrolactone (GBL) can be readily extracted or readily synthesized and which is not sold for human consumption.

(2)1,4-Butanediol is excepted from scheduling pursuant to s. 893.03(1)(d)1. when that substance is in the possession of:

(a)A manufacturer of 1,4-Butanediol or a distributor of 1,4-Butanediol;

(b)A manufacturer of an industrial product or a distributor of an industrial product; or

(c)A person possessing a finished product.

(3)Gamma-butyrolactone (GBL) is excepted from scheduling pursuant to s. 893.03(1)(d)2. when that substance is in the possession of:

(a)A manufacturer of gamma-butyrolactone (GBL) or a distributor of gamma-butyrolactone (GBL);

(b)A manufacturer of an industrial product or a distributor of an industrial product; or

(c)A person possessing a finished product.

(4)This section does not apply to:

(a)A manufacturer of 1,4-Butanediol or a distributor of 1,4-Butanediol who sells, delivers, or otherwise distributes that substance to a person who is not a distributor of 1,4-Butanediol or a

manufacturer of an industrial product;

(b)A manufacturer of gamma-butyrolactone (GBL) or a distributor of gamma-butyrolactone (GBL) who sells, delivers, or otherwise distributes that substance to a person who is not a distributor of gamma-butyrolactone (GBL) or a manufacturer of an industrial product;

(c)A person who possesses 1,4-Butanediol but who is not a manufacturer of 1,4-Butanediol, a distributor of 1,4-Butanediol, a manufacturer of an industrial product, a distributor of an industrial product, or a person possessing a finished product as described in paragraph (2)(c) or paragraph (3)(c);

(d)A person who possesses gamma-butyrolactone (GBL) but who is not a manufacturer of gamma-butyrolactone (GBL), a distributor of gamma-butyrolactone (GBL), a manufacturer of an industrial product, a distributor of an industrial product, or a person possessing a finished product as described in paragraph (2)(c) or paragraph (3)(c);

(e)A person who extracts or synthesizes either 1,4-Butanediol or gamma-butyrolactone (GBL) from a finished product as described in subparagraph(1)(j)2. or a person who extracts or synthesizes 1,4-Butanediol or gamma-butyrolactone (GBL) from any product or material, unless such extraction or synthesis is authorized by law; or

(f)A person whose possession of either 1,4-Butanediol or gamma-butyrolactone (GBL) is not in compliance with the requirements of this section or whose possession of either of those substances is not specifically authorized by law.

History.—s. 1, ch. 2003-10.

893.033Listed chemicals.—The chemicals listed in this section are included by whatever official, common, usual, chemical, or trade name designated.

(1)PRECURSOR CHEMICALS.—The term "listed precursor chemical" means a chemical that may be used in manufacturing a controlled substance in violation of this chapter and is critical to the creation of the controlled substance, and such term includes any salt, optical isomer, or salt of an optical isomer, whenever the existence of such salt, optical isomer, or salt of optical isomer is possible within the specific chemical designation. The following are "listed precursor chemicals":

(a)Anthranilic acid.

(b)Benzaldehyde.

(c)Benzyl cyanide.

(d)Chloroephedrine.

(e)Chloropseudoephedrine.

(f)Ephedrine.

(g)Ergonovine.

(h)Ergotamine.

(i)Hydriodic acid.

(j)Ethylamine.

(k)Isosafrole.

(l)Methylamine.

(m)3, 4-Methylenedioxyphenyl-2-propanone.

(n)N-acetylanthranilic acid.

(o)N-ethylephedrine.

(p)N-ethylpseudoephedrine.

(q)N-methylephedrine.

(r)N-methylpseudoephedrine.

(s)Nitroethane.

(t)Norpseudoephedrine.

(u)Phenylacetic acid.

(v)Phenylpropanolamine.

(w)Piperidine.

(x)Piperonal.

(y)Propionic anhydride.

(z)Pseudoephedrine.

(aa)Safrole.

(2)ESSENTIAL CHEMICALS.—The term "listed essential chemical" means a chemical that may be used as a solvent, reagent, or catalyst in manufacturing a controlled substance in violation of this chapter. The following are "listed essential chemicals":

(a)Acetic anhydride.

(b)Acetone.

(c)Anhydrous ammonia.

(d)Benzyl chloride.

(e)2-Butanone.

(f)Ethyl ether.

(g)Hydrochloric gas.

(h)Hydriodic acid.

(i)Iodine.

(j)Potassium permanganate.

(k)Toluene.

History.—s. 2, ch. 91-279; s. 6, ch. 2001-57; s. 2, ch. 2003-15; s. 1, ch. 2005-128.

893.035Control of new substances; findings of fact; delegation of authority to Attorney General to control substances by rule.—

(1)(a)New substances are being created which are not controlled under the provisions of this

chapter but which have a potential for abuse similar to or greater than that for substances controlled under this chapter. These new substances are sometimes called “designer drugs” because they can be designed to produce a desired pharmacological effect and to evade the controlling statutory provisions. Designer drugs are being manufactured, distributed, possessed, and used as substitutes for controlled substances.

(b)The hazards attributable to the traffic in and use of these designer drugs are increased because their unregulated manufacture produces variations in purity and concentration.

(c)Many such new substances are untested, and it cannot be immediately determined whether they have useful medical or chemical purposes.

(d)The uncontrolled importation, manufacture, distribution, possession, or use of these designer drugs has a substantial and detrimental impact on the health and safety of the people of Florida.

(e)These designer drugs can be created more rapidly than they can be identified and controlled by action of the Legislature. There is a need for a speedy and expert administrative determination of their proper classification under this chapter. It is therefore necessary to delegate to an administrative agency restricted authority to identify and classify new substances that have a potential for abuse, so that they can be controlled in the same manner as other substances currently controlled under this chapter.

(2)The Attorney General shall apply the provisions of this section to any substance not currently controlled under the provisions of s. 893.03. The Attorney General may by rule:

(a)Add a substance to a schedule established by s. 893.03, or transfer a substance between schedules, if he or she finds that it has a potential for abuse and he or she makes with respect to it the other findings appropriate for classification in the particular schedule under s. 893.03 in which it is to be placed.

(b)Remove a substance previously added to a schedule if he or she finds the substance does not meet the requirements for inclusion in that schedule.

Rules adopted under this section shall be made pursuant to the rulemaking procedures prescribed by chapter 120.

(3)(a)The term “potential for abuse” in this section means that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being:

1.Used in amounts that create a hazard to the user’s health or the safety of the community;

2.Diverted from legal channels and distributed through illegal channels; or

3.Taken on the user’s own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to

assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.

(b)The terms “immediate precursor” and “narcotic drug” shall be given the same meanings as provided by s. 102 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 802, as amended and in effect on April 1, 1985.

(4)In making any findings under this section, the Attorney General shall consider the following factors with respect to each substance proposed to be controlled or removed from control:

(a)Its actual or relative potential for abuse.

(b)Scientific evidence of its pharmacological effect, if known.

(c)The state of current scientific knowledge regarding the drug or other substance.

(d)Its history and current pattern of abuse.

(e)The scope, duration, and significance of abuse.

(f)What, if any, risk there is to the public health.

(g)Its psychic or physiological dependence liability.

(h)Whether the substance is an immediate precursor of a substance already controlled under this chapter.

The findings and conclusions of the United States Attorney General or his or her delegee, as set forth in the Federal Register, with respect to any substance pursuant to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985, shall be admissible as evidence in any rulemaking proceeding under this section, including an emergency rulemaking proceeding under subsection (7).

(5)Before initiating proceedings under subsection (2), the Attorney General shall request from the Department of Health and the Department of Law Enforcement a medical and scientific evaluation of the substance under consideration and a recommendation as to the appropriate classification, if any, of such substance as a controlled substance. In responding to this request, the Department of Health and the Department of Law Enforcement shall consider the factors listed in subsection (4). The Department of Health and the Department of Law Enforcement shall respond to this request promptly and in writing; however, their response is not subject to chapter 120. If both the Department of Health and the Department of Law Enforcement recommend that a substance not be controlled, the Attorney General shall not control that substance. If the Attorney General determines, based on the evaluations and recommendations of the Department of Health and the Department of Law Enforcement and all other available evidence, that there is substantial evidence of potential for abuse, he or she shall initiate proceedings under paragraph (2)(a) with respect to that substance.

(6)(a)The Attorney General shall by rule exempt any nonnarcotic substance controlled by rule under this section from the application of this section if such substance may, under the Federal

Food, Drug, and Cosmetic Act, be lawfully sold over the counter without a prescription.

(b)The Attorney General may by rule exempt any compound, mixture, or preparation containing a substance controlled by rule under this section from the application of this section if he or she finds that such compound, mixture, or preparation meets the requirements of either of the following subcategories:

1.A mixture or preparation containing a nonnarcotic substance controlled by rule, which mixture or preparation is approved for prescription use and which contains one or more other active ingredients which are not listed in any schedule and which are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse.

2.A compound, mixture, or preparation which contains any substance controlled by rule, which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse.

(7)(a)If the Attorney General finds that the scheduling of a substance in Schedule I of s. 893.03 on a temporary basis is necessary to avoid an imminent hazard to the public safety, he or she may by rule and without regard to the requirements of subsection (5) relating to the Department of Health and the Department of Law Enforcement schedule such substance in Schedule I if the substance is not listed in any other schedule of s. 893.03. The Attorney General shall be required to consider, with respect to his or her finding of imminent hazard to the public safety, only those factors set forth in paragraphs (3)(a) and (4)(d), (e), and (f), including actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(b)The Attorney General may use emergency rulemaking provisions under s. 120.54(4) in scheduling substances under this subsection. Notwithstanding the provisions of s. 120.54(4)(c), any rule adopted under this subsection shall not expire except as provided in subsection (9).

(8)(a)Upon the effective date of a rule adopted pursuant to this section adding or transferring a substance to a schedule under s. 893.03, such substance shall be deemed included in that schedule, and all provisions of this chapter applicable to substances in that schedule shall be deemed applicable to such substance.

(b)A rule adopted pursuant to this section shall continue in effect until it is repealed; until it is declared invalid in proceedings under s. 120.56 or in proceedings before a court of competent jurisdiction; or until it expires under the provisions of subsection (9).

(9)The Attorney General shall report to the Legislature by March 1 of each year concerning the rules adopted under this section during the previous year. Each rule so reported shall expire on the following June 30 unless the Legislature adopts the provisions thereof as an amendment to this chapter.

(10)The repeal, expiration, or determination of invalidity of any rule shall not operate to

create any claim or cause of action against any law enforcement officer or other enforcing authority for actions taken in good faith in reliance on the validity of the rule.

(11)In construing this section, due consideration and great weight should be given to interpretations of the United States Attorney General and the federal courts relating to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985. All substantive rules adopted under this part shall not be inconsistent with the rules of the United States Attorney General and the decisions of the federal courts interpreting the provisions of s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985.

(12)The adoption of a rule transferring a substance from one schedule to another or removing a substance from a schedule pursuant to this section shall not affect prosecution or punishment for any crime previously committed with respect to that substance.

History.—s. 3, ch. 85-242; s. 72, ch. 87-226; s. 255, ch. 94-218; s. 318, ch. 96-410; s. 1826, ch. 97-102; s. 16, ch. 99-186.

893.0355Control of scheduled substances; delegation of authority to Attorney General to reschedule substance, or delete substance, by rule.—

(1)The Legislature has determined that, from time to time, additional testings, approvals, or scientific evidence may indicate that controlled substances listed in Schedules I, II, III, IV, and V hereof have a greater potential for beneficial medical use in treatment in the United States than was evident when such substances were initially scheduled. It is the intent of the Legislature to quickly provide a method for an immediate change to the scheduling and control of such substances to allow for the beneficial medical use thereof so that more flexibility will be available than is possible through rescheduling legislatively.

(2)The Attorney General is hereby delegated the authority to adopt rules rescheduling specified substances to a less controlled schedule, or deleting specified substances from a schedule, upon a finding that reduced control of such substances is in the public interest. In determining whether reduced control of a substance is in the public interest, the Attorney General shall consider the following:

(a)Whether the substance has been rescheduled or deleted from any schedule by rule adopted by the United States Attorney General pursuant to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811.

(b)The substance's actual or relative potential for abuse.

(c)Scientific evidence of the substance's pharmacological effect, if known.

(d)The state of current scientific knowledge regarding the substance.

(e)The substance's history and current pattern of abuse.

(f)The scope, duration, and significance of abuse.

(g)What, if any, risk there is to the public health.

(h)The substance's psychic or physiological dependence liability.

(3)In making the public interest determination, the Attorney General shall give great weight to the scheduling rules adopted by the United States Attorney General subsequent to such substances being listed in Schedules I, II, III, IV, and V hereof, to achieve the original legislative purpose of the Florida Comprehensive Drug Abuse Prevention and Control Act of maintaining uniformity between the laws of Florida and the laws of the United States with respect to controlled substances.

(4)Rulemaking under this section shall be in accordance with the procedural requirements of chapter 120, including the emergency rule provisions found in s. 120.54. The Attorney General may initiate proceedings for adoption, amendment, or repeal of any rule on his or her own motion or upon the petition of any interested party.

(5)Upon the effective date of a rule adopted pursuant to this section, the rule's rescheduling or deletion of a substance shall be effective for all purposes under this chapter.

(6)Rules adopted pursuant to this section shall be reviewed each year by the Legislature. Each rule shall remain in effect until the effective date of legislation that provides for a different scheduling of a substance than that set forth in such rule.

(7)The adoption of a rule rescheduling a substance or deleting a substance from control pursuant to this section shall not affect prosecution or punishment for any crime previously committed with respect to that substance.

(8)The provisions of this section apply only to substances controlled expressly by statute and not to substances controlled by rules adopted under the authority granted in the provisions of s. 893.035.

History.—s. 4, ch. 85-242; s. 1435, ch. 97-102.

893.0356Control of new substances; findings of fact; "controlled substance analog" defined.—

(1)(a)New substances are being created which are not controlled under the provisions of this chapter but which have a potential for abuse similar to or greater than that for substances controlled under this chapter. These new substances are called "controlled substance analogs," and can be designed to produce a desired pharmacological effect and to evade the controlling statutory provisions. Controlled substance analogs are being manufactured, distributed, possessed, and used as substitutes for controlled substances.

(b)The hazards attributable to the traffic in and use of controlled substance analogs are increased because their unregulated manufacture produces variations in purity and concentration.

(c)Many such new substances are untested, and it cannot be immediately determined whether they have useful medical or chemical purposes.

(d)The uncontrolled importation, manufacture, distribution, possession, or use of controlled

substance analogs has a substantial and detrimental impact on the health and safety of the people of Florida.

(e)Controlled substance analogs can be created more rapidly than they can be identified and controlled by action of the Legislature. There is a need for a speedy determination of their proper classification under this chapter. It is therefore necessary to identify and classify new substances that have a potential for abuse, so that they can be controlled in the same manner as other substances currently controlled under this chapter.

(2)(a)As used in this section, "controlled substance analog" means a substance which, due to its chemical structure and potential for abuse, meets the following criteria:

1.Is substantially similar to that of a controlled substance listed in Schedule I or Schedule II of s. 893.03; and

2.Has a stimulant, depressant, or hallucinogenic effect on the central nervous system or is represented or intended to have a stimulant, depressant, or hallucinogenic effect on the central nervous system substantially similar to or greater than that of a controlled substance listed in Schedule I or Schedule II of s. 893.03.

(b)"Controlled substance analog" does not include:

1.A controlled substance;

2.Any substance for which there is an approved new drug application;

3.Any compound, mixture, or preparation which contains any controlled substance which is not for administration to a human being or animal, and which is packaged in such form or concentration, or with adulterants or denaturants, so that as packaged it does not present any significant potential for abuse; or

4.Any substance to which an investigational exemption applies under s. 505 of the Food, Drug, and Cosmetic Act, 21 U.S.C. 355, but only to the extent that conduct with respect to the substance is pursuant to such exemption.

(3)The term "potential for abuse" in this section means that a substance has properties as a central nervous system stimulant or depressant or a hallucinogen that create a substantial likelihood of its being:

(a)Used in amounts that create a hazard to the user's health or the safety of the community;

(b)Diverted from legal channels and distributed through illegal channels; or

(c)Taken on the user's own initiative rather than on the basis of professional medical advice.

Proof of potential for abuse can be based upon a showing that these activities are already taking place, or upon a showing that the nature and properties of the substance make it reasonable to assume that there is a substantial likelihood that such activities will take place, in other than isolated or occasional instances.

(4)The following factors shall be relevant to a finding that a substance is a controlled

substance analog within the purview of this section:

(a)Its actual or relative potential for abuse.

(b)Scientific evidence of its pharmacological effect, if known.

(c)The state of current scientific knowledge regarding the substance.

(d)Its history and current pattern of abuse.

(e)The scope, duration, and significance of abuse.

(f)What, if any, risk there is to the public health.

(g)Its psychic or physiological dependence liability.

(h)Its diversion from legitimate channels, and clandestine importation, manufacture, or distribution.

(i)Whether the substance is an immediate precursor of a substance already controlled under this chapter.

(5)A controlled substance analog shall, for purposes of drug abuse prevention and control, be treated as a controlled substance in Schedule I of s. 893.03.

(6)In construing this section, due consideration and great weight should be given to interpretations of the United States Attorney General and the federal courts relating to s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985. New substances controlled under this section shall not be treated in a manner inconsistent with the rules of the United States Attorney General and the decisions of the federal courts interpreting the provisions of s. 201 of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. s. 811, as amended and in effect on April 1, 1985.

(7)The treatment of a new substance as a controlled substance pursuant to this section shall not affect prosecution or punishment for any crime previously committed with respect to that substance.

History.—s. 3, ch. 87-243; s. 11, ch. 99-186; s. 20, ch. 2000-320.

893.04Pharmacist and practitioner.—

(1)A pharmacist, in good faith and in the course of professional practice only, may dispense controlled substances upon a written or oral prescription of a practitioner, under the following conditions:

(a)Oral prescriptions must be promptly reduced to writing by the pharmacist or recorded electronically if permitted by federal law.

(b)The written prescription must be dated and signed by the prescribing practitioner on the day when issued.

(c)There shall appear on the face of the prescription or written record thereof for the controlled substance the following information:

1.The full name and address of the person for whom, or the owner of the animal for which,

the controlled substance is dispensed.

2.The full name and address of the prescribing practitioner and the practitioner's federal controlled substance registry number shall be printed thereon.

3.If the prescription is for an animal, the species of animal for which the controlled substance is prescribed.

4.The name of the controlled substance prescribed and the strength, quantity, and directions for use thereof.

5.The number of the prescription, as recorded in the prescription files of the pharmacy in which it is filled.

6.The initials of the pharmacist filling the prescription and the date filled.

(d)The prescription shall be retained on file by the proprietor of the pharmacy in which it is filled for a period of 2 years.

(e)Affixed to the original container in which a controlled substance is delivered upon a prescription or authorized refill thereof, as hereinafter provided, there shall be a label bearing the following information:

1.The name and address of the pharmacy from which such controlled substance was dispensed.

2.The date on which the prescription for such controlled substance was filled.

3.The number of such prescription, as recorded in the prescription files of the pharmacy in which it is filled.

4.The name of the prescribing practitioner.

5.The name of the patient for whom, or of the owner and species of the animal for which, the controlled substance is prescribed.

6.The directions for the use of the controlled substance prescribed in the prescription.

7.A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

(f)A prescription for a controlled substance listed in Schedule II may be dispensed only upon a written prescription of a practitioner, except that in an emergency situation, as defined by regulation of the Department of Health, such controlled substance may be dispensed upon oral prescription but is limited to a 72-hour supply. A prescription for a controlled substance listed in Schedule II may not be refilled.

(g)A prescription for a controlled substance listed in Schedule III, Schedule IV, or Schedule V may not be filled or refilled more than five times within a period of 6 months after the date on which the prescription was written unless the prescription is renewed by a practitioner.

(2)(a)A pharmacist may not dispense a controlled substance listed in Schedule II, Schedule III, or Schedule IV to any patient or patient's agent without first determining, in the exercise of her or

his professional judgment, that the order is valid. The pharmacist may dispense the controlled substance, in the exercise of her or his professional judgment, when the pharmacist or pharmacist's agent has obtained satisfactory patient information from the patient or the patient's agent.

(b)Any pharmacist who dispenses by mail a controlled substance listed in Schedule II, Schedule III, or Schedule IV is exempt from the requirement to obtain suitable identification for the prescription dispensed by mail if the pharmacist has obtained the patient's identification through the patient's prescription benefit plan.

(c)Any controlled substance listed in Schedule III or Schedule IV may be dispensed by a pharmacist upon an oral prescription if, before filling the prescription, the pharmacist reduces it to writing or records the prescription electronically if permitted by federal law. Such prescriptions must contain the date of the oral authorization.

(d)Each written prescription prescribed by a practitioner in this state for a controlled substance listed in Schedule II, Schedule III, or Schedule IV must include both a written and a numerical notation of the quantity of the controlled substance prescribed on the face of the prescription and a notation of the date, with the abbreviated month written out on the face of the prescription. A pharmacist may, upon verification by the prescriber, document any information required by this paragraph. If the prescriber is not available to verify a prescription, the pharmacist may dispense the controlled substance but may insist that the person to whom the controlled substance is dispensed provide valid photographic identification. If a prescription includes a numerical notation of the quantity of the controlled substance or date, but does not include the quantity or date written out in textual format, the pharmacist may dispense the controlled substance without verification by the prescriber of the quantity or date if the pharmacy previously dispensed another prescription for the person to whom the prescription was written.

(e)A pharmacist may not dispense more than a 30-day supply of a controlled substance listed in Schedule III upon an oral prescription issued in this state.

(f)A pharmacist may not knowingly fill a prescription that has been forged for a controlled substance listed in Schedule II, Schedule III, or Schedule IV.

(3)Notwithstanding subsection (1), a pharmacist may dispense a one-time emergency refill of up to a 72-hour supply of the prescribed medication for any medicinal drug other than a medicinal drug listed in Schedule II, in compliance with the provisions of s. 465.0275.

(4)The legal owner of any stock of controlled substances in a pharmacy, upon discontinuance of dealing in controlled substances, may sell said stock to a manufacturer, wholesaler, or pharmacy. Such controlled substances may be sold only upon an order form, when such an order form is required for sale by the drug abuse laws of the United States or this state, or regulations pursuant thereto.

History.—s. 4, ch. 73-331; s. 2, ch. 75-18; s. 12, ch. 79-12; s. 2, ch. 90-2; s. 1436, ch. 97-102; s. 301, ch. 99-8; s. 2, ch. 2007-156; s. 5, ch. 2009-202.

893.05Practitioners and persons administering controlled substances in their absence.—

(1)A practitioner, in good faith and in the course of his or her professional practice only, may prescribe, administer, dispense, mix, or otherwise prepare a controlled substance, or the practitioner may cause the same to be administered by a licensed nurse or an intern practitioner under his or her direction and supervision only. A veterinarian may so prescribe, administer, dispense, mix, or prepare a controlled substance for use on animals only, and may cause it to be administered by an assistant or orderly under the veterinarian's direction and supervision only.

(2)When any controlled substance is dispensed by a practitioner, there shall be affixed to the original container in which the controlled substance is delivered a label on which appears:

(a)The date of delivery.

(b)The directions for use of such controlled substance.

(c)The name and address of such practitioner.

(d)The name of the patient and, if such controlled substance is prescribed for an animal, a statement describing the species of the animal.

(e)A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

(3)Any person who obtains from a practitioner or the practitioner's agent, or pursuant to prescription, any controlled substance for administration to a patient during the absence of such practitioner shall return to such practitioner any unused portion of such controlled substance when it is no longer required by the patient.

History.—s. 5, ch. 73-331; s. 1437, ch. 97-102.

893.055Prescription drug monitoring program.—

(1)As used in this section, the term:

(a)"Patient advisory report" or "advisory report" means information provided by the department in writing, or as determined by the department, to a prescriber, dispenser, pharmacy, or patient concerning the dispensing of controlled substances. All advisory reports are for informational purposes only and impose no obligations of any nature or any legal duty on a prescriber, dispenser, pharmacy, or patient. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The advisory reports issued by the department are not subject to discovery or introduction into evidence in any civil or administrative action against a prescriber, dispenser, pharmacy, or patient arising out of matters that are the subject of the report; and a person who participates in preparing, reviewing, issuing, or any other activity related to an advisory report may not be permitted or required to testify in any such civil action as to any findings, recommendations, evaluations, opinions, or other actions taken in connection with

preparing, reviewing, or issuing such a report.

(b)“Controlled substance” means a controlled substance listed in Schedule II, Schedule III, or Schedule IV in s. 893.03.

(c)“Dispenser” means a pharmacy, dispensing pharmacist, or dispensing health care practitioner.

(d)“Health care practitioner” or “practitioner” means any practitioner who is subject to licensure or regulation by the department under chapter 458, chapter 459, chapter 461, chapter 462, chapter 464, chapter 465, or chapter 466.

(e)“Health care regulatory board” means any board for a practitioner or health care practitioner who is licensed or regulated by the department.

(f)“Pharmacy” means any pharmacy that is subject to licensure or regulation by the department under chapter 465 and that dispenses or delivers a controlled substance to an individual or address in this state.

(g)“Prescriber” means a prescribing physician, prescribing practitioner, or other prescribing health care practitioner.

(h)“Active investigation” means an investigation that is being conducted with a reasonable, good faith belief that it could lead to the filing of administrative, civil, or criminal proceedings, or that is ongoing and continuing and for which there is a reasonable, good faith anticipation of securing an arrest or prosecution in the foreseeable future.

(i)“Law enforcement agency” means the Department of Law Enforcement, a Florida sheriff’s department, a Florida police department, or a law enforcement agency of the Federal Government which enforces the laws of this state or the United States relating to controlled substances, and which its agents and officers are empowered by law to conduct criminal investigations and make arrests.

(j)“Program manager” means an employee of or a person contracted by the Department of Health who is designated to ensure the integrity of the prescription drug monitoring program in accordance with the requirements established in paragraphs (2)(a) and (b).

(2)(a)The department shall design and establish a comprehensive electronic database system that has controlled substance prescriptions provided to it and that provides prescription information to a patient’s health care practitioner and pharmacist who inform the department that they wish the patient advisory report provided to them. Otherwise, the patient advisory report will not be sent to the practitioner, pharmacy, or pharmacist. The system shall be designed to provide information regarding dispensed prescriptions of controlled substances and shall not infringe upon the legitimate prescribing or dispensing of a controlled substance by a prescriber or dispenser acting in good faith and in the course of professional practice. The system shall be consistent with standards of the American Society for Automation in Pharmacy (ASAP). The electronic system shall

also comply with the Health Insurance Portability and Accountability Act (HIPAA) as it pertains to protected health information (PHI), electronic protected health information (EPHI), and all other relevant state and federal privacy and security laws and regulations. The department shall establish policies and procedures as appropriate regarding the reporting, accessing the database, evaluation, management, development, implementation, operation, storage, and security of information within the system. The reporting of prescribed controlled substances shall include a dispensing transaction with a dispenser pursuant to chapter 465 or through a dispensing transaction to an individual or address in this state with a pharmacy that is not located in this state but that is otherwise subject to the jurisdiction of this state as to that dispensing transaction. The reporting of patient advisory reports refers only to reports to patients, pharmacies, and practitioners. Separate reports that contain patient prescription history information and that are not patient advisory reports are provided to persons and entities as authorized in paragraphs (7)(b) and (c) and s. 893.0551.

(b)The department, when the direct support organization receives at least $20,000 in nonstate moneys or the state receives at least $20,000 in federal grants for the prescription drug monitoring program, shall adopt rules as necessary concerning the reporting, accessing the database, evaluation, management, development, implementation, operation, security, and storage of information within the system, including rules for when patient advisory reports are provided to pharmacies and prescribers. The patient advisory report shall be provided in accordance with s. 893.13(7)(a)8. The department shall work with the professional health care licensure boards, such as the Board of Medicine, the Board of Osteopathic Medicine, and the Board of Pharmacy; other appropriate organizations, such as the Florida Pharmacy Association, the Florida Medical Association, the Florida Retail Federation, and the Florida Osteopathic Medical Association, including those relating to pain management; and the Attorney General, the Department of Law Enforcement, and the Agency for Health Care Administration to develop rules appropriate for the prescription drug monitoring program.

(c)All dispensers and prescribers subject to these reporting requirements shall be notified by the department of the implementation date for such reporting requirements.

(d)The program manager shall work with professional health care licensure boards and the stakeholders listed in paragraph (b) to develop rules appropriate for identifying indicators of controlled substance abuse.

(3)The pharmacy dispensing the controlled substance and each prescriber who directly dispenses a controlled substance shall submit to the electronic system, by a procedure and in a format established by the department and consistent with an ASAP-approved format, the following information for inclusion in the database:

(a)The name of the prescribing practitioner, the practitioner’s federal Drug Enforcement

Administration registration number, the practitioner's National Provider Identification (NPI) or other appropriate identifier, and the date of the prescription.

(b)The date the prescription was filled and the method of payment, such as cash by an individual, insurance coverage through a third party, or Medicaid payment. This paragraph does not authorize the department to include individual credit card numbers or other account numbers in the database.

(c)The full name, address, and date of birth of the person for whom the prescription was written.

(d)The name, national drug code, quantity, and strength of the controlled substance dispensed.

(e)The full name, federal Drug Enforcement Administration registration number, and address of the pharmacy or other location from which the controlled substance was dispensed. If the controlled substance was dispensed by a practitioner other than a pharmacist, the practitioner's full name, federal Drug Enforcement Administration registration number, and address.

(f)The name of the pharmacy or practitioner, other than a pharmacist, dispensing the controlled substance and the practitioner's National Provider Identification (NPI).

(g)Other appropriate identifying information as determined by department rule.

(4)Each time a controlled substance is dispensed to an individual, the controlled substance shall be reported to the department through the system as soon thereafter as possible, but not more than 7 days after the date the controlled substance is dispensed unless an extension is approved by the department for cause as determined by rule. A dispenser must meet the reporting requirements of this section by providing the required information concerning each controlled substance that it dispensed in a department-approved, secure methodology and format. Such approved formats may include, but are not limited to, submission via the Internet, on a disc, or by use of regular mail.

(5)When the following acts of dispensing or administering occur, the following are exempt from reporting under this section for that specific act of dispensing or administration:

(a)A health care practitioner when administering a controlled substance directly to a patient if the amount of the controlled substance is adequate to treat the patient during that particular treatment session.

(b)A pharmacist or health care practitioner when administering a controlled substance to a patient or resident receiving care as a patient at a hospital, nursing home, ambulatory surgical center, hospice, or intermediate care facility for the developmentally disabled which is licensed in this state.

(c)A practitioner when administering or dispensing a controlled substance in the health care system of the Department of Corrections.

(d)A practitioner when administering a controlled substance in the emergency room of a licensed hospital.

(e)A health care practitioner when administering or dispensing a controlled substance to a person under the age of 16.

(f)A pharmacist or a dispensing practitioner when dispensing a one-time, 72-hour emergency resupply of a controlled substance to a patient.

(6)The department may establish when to suspend and when to resume reporting information during a state-declared or nationally declared disaster.

(7)(a)A practitioner or pharmacist who dispenses a controlled substance must submit the information required by this section in an electronic or other method in an ASAP format approved by rule of the department unless otherwise provided in this section. The cost to the dispenser in submitting the information required by this section may not be material or extraordinary. Costs not considered to be material or extraordinary include, but are not limited to, regular postage, electronic media, regular electronic mail, and facsimile charges.

(b)A pharmacy, prescriber, or dispenser shall have access to information in the prescription drug monitoring program's database which relates to a patient of that pharmacy, prescriber, or dispenser in a manner established by the department as needed for the purpose of reviewing the patient's controlled substance prescription history. Other access to the program's database shall be limited to the program's manager and to the designated program and support staff, who may act only at the direction of the program manager or, in the absence of the program manager, as authorized. Access by the program manager or such designated staff is for prescription drug program management only or for management of the program's database and its system in support of the requirements of this section and in furtherance of the prescription drug monitoring program. Confidential and exempt information in the database shall be released only as provided in paragraph (c) and s. 893.0551. The program manager, designated program and support staff who act at the direction of or in the absence of the program manager, and any individual who has similar access regarding the management of the database from the prescription drug monitoring program shall submit fingerprints to the department for background screening. The department shall follow the procedure established by the Department of Law Enforcement to request a statewide criminal history record check and to request that the Department of Law Enforcement forward the fingerprints to the Federal Bureau of Investigation for a national criminal history record check.

(c)The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that is confidential and exempt under s. 893.0551. Prior to release, the request shall

be verified as authentic and authorized with the requesting organization by the program manager, the program manager's program and support staff, or as determined in rules by the department as being authentic and as having been authorized by the requesting entity:

1.The department or its relevant health care regulatory boards responsible for the licensure, regulation, or discipline of practitioners, pharmacists, or other persons who are authorized to prescribe, administer, or dispense controlled substances and who are involved in a specific controlled substance investigation involving a designated person for one or more prescribed controlled substances.

2.The Attorney General for Medicaid fraud cases involving prescribed controlled substances.

3.A law enforcement agency during active investigations regarding potential criminal activity, fraud, or theft regarding prescribed controlled substances.

4.A patient or the legal guardian or designated health care surrogate of an incapacitated patient as described in s. 893.0551 who, for the purpose of verifying the accuracy of the database information, submits a written and notarized request that includes the patient's full name, address, and date of birth, and includes the same information if the legal guardian or health care surrogate submits the request. The request shall be validated by the department to verify the identity of the patient and the legal guardian or health care surrogate, if the patient's legal guardian or health care surrogate is the requestor. Such verification is also required for any request to change a patient's prescription history or other information related to his or her information in the electronic database.

Information in the database for the electronic prescription drug monitoring system is not discoverable or admissible in any civil or administrative action, except in an investigation and disciplinary proceeding by the department or the appropriate regulatory board.

(d)The following entities shall not be allowed direct access to information in the prescription drug monitoring program database but may request from the program manager and, when authorized by the program manager, the program manager's program and support staff, information that contains no identifying information of any patient, physician, health care practitioner, prescriber, or dispenser and that is not confidential and exempt:

1.Department staff for the purpose of calculating performance measures pursuant to subsection (8).

2.The Program Implementation and Oversight Task Force for its reporting to the Governor, the President of the Senate, and the Speaker of the House of Representatives regarding the prescription drug monitoring program. This subparagraph expires July 1, 2012.

(e)All transmissions of data required by this section must comply with relevant state and federal privacy and security laws and regulations. However, any authorized agency or person under s. 893.0551 receiving such information as allowed by s. 893.0551 may maintain the information

received for up to 24 months before purging it from his or her records or maintain it for longer than 24 months if the information is pertinent to ongoing health care or an active law enforcement investigation or prosecution.

(f)The program manager, upon determining a pattern consistent with the rules established under paragraph (2)(d) and having cause to believe a violation of s. 893.13(7)(a)8., (8)(a), or (8)(b) has occurred, may provide relevant information to the applicable law enforcement agency.

(8)To assist in fulfilling program responsibilities, performance measures shall be reported annually to the Governor, the President of the Senate, and the Speaker of the House of Representatives by the department each December 1, beginning in 2011. Data that does not contain patient, physician, health care practitioner, prescriber, or dispenser identifying information may be requested during the year by department employees so that the department may undertake public health care and safety initiatives that take advantage of observed trends. Performance measures may include, but are not limited to, efforts to achieve the following outcomes:

(a)Reduction of the rate of inappropriate use of prescription drugs through department education and safety efforts.

(b)Reduction of the quantity of pharmaceutical controlled substances obtained by individuals attempting to engage in fraud and deceit.

(c)Increased coordination among partners participating in the prescription drug monitoring program.

(d)Involvement of stakeholders in achieving improved patient health care and safety and reduction of prescription drug abuse and prescription drug diversion.

(9)Any person who willfully and knowingly fails to report the dispensing of a controlled substance as required by this section commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10)All costs incurred by the department in administering the prescription drug monitoring program shall be funded through federal grants or private funding applied for or received by the state. The department may not commit funds for the monitoring program without ensuring funding is available. The prescription drug monitoring program and the implementation thereof are contingent upon receipt of the nonstate funding. The department and state government shall cooperate with the direct-support organization established pursuant to subsection (11) in seeking federal grant funds, other nonstate grant funds, gifts, donations, or other private moneys for the department so long as the costs of doing so are not considered material. Nonmaterial costs for this purpose include, but are not limited to, the costs of mailing and personnel assigned to research or apply for a grant. Notwithstanding the exemptions to competitive-solicitation requirements under s. 287.057(3)(f), the department shall comply with the competitive-solicitation requirements under

s. 287.057 for the procurement of any goods or services required by this section. Funds provided, directly or indirectly, by prescription drug manufacturers may not be used to implement the program.

(11)The department may establish a direct-support organization that has a board consisting of at least five members to provide assistance, funding, and promotional support for the activities authorized for the prescription drug monitoring program.

(a)As used in this subsection, the term "direct-support organization" means an organization that is:

1.A Florida corporation not for profit incorporated under chapter 617, exempted from filing fees, and approved by the Department of State.

2.Organized and operated to conduct programs and activities; raise funds; request and receive grants, gifts, and bequests of money; acquire, receive, hold, and invest, in its own name, securities, funds, objects of value, or other property, either real or personal; and make expenditures or provide funding to or for the direct or indirect benefit of the department in the furtherance of the prescription drug monitoring program.

(b)The direct-support organization is not considered a lobbying firm within the meaning of s. 11.045.

(c)The State Surgeon General shall appoint a board of directors for the direct-support organization. Members of the board shall serve at the pleasure of the State Surgeon General. The State Surgeon General shall provide guidance to members of the board to ensure that moneys received by the direct-support organization are not received from inappropriate sources. Inappropriate sources include, but are not limited to, donors, grantors, persons, or organizations that may monetarily or substantively benefit from the purchase of goods or services by the department in furtherance of the prescription drug monitoring program.

(d)The direct-support organization shall operate under written contract with the department. The contract must, at a minimum, provide for:

1.Approval of the articles of incorporation and bylaws of the direct-support organization by the department.

2.Submission of an annual budget for the approval of the department.

3.Certification by the department that the direct-support organization is complying with the terms of the contract in a manner consistent with and in furtherance of the goals and purposes of the prescription drug monitoring program and in the best interests of the state. Such certification must be made annually and reported in the official minutes of a meeting of the direct-support organization.

4.The reversion, without penalty, to the state of all moneys and property held in trust by the direct-support organization for the benefit of the prescription drug monitoring program if the

direct-support organization ceases to exist or if the contract is terminated.

5.The fiscal year of the direct-support organization, which must begin July 1 of each year and end June 30 of the following year.

6.The disclosure of the material provisions of the contract to donors of gifts, contributions, or bequests, including such disclosure on all promotional and fundraising publications, and an explanation to such donors of the distinction between the department and the direct-support organization.

7.The direct-support organization's collecting, expending, and providing of funds to the department for the development, implementation, and operation of the prescription drug monitoring program as described in this section and s. 2, chapter 2009-198, Laws of Florida, as long as the task force is authorized. The direct-support organization may collect and expend funds to be used for the functions of the direct-support organization's board of directors, as necessary and approved by the department. In addition, the direct-support organization may collect and provide funding to the department in furtherance of the prescription drug monitoring program by:

a.Establishing and administering the prescription drug monitoring program's electronic database, including hardware and software.

b.Conducting studies on the efficiency and effectiveness of the program to include feasibility studies as described in subsection (13).

c.Providing funds for future enhancements of the program within the intent of this section.

d.Providing user training of the prescription drug monitoring program, including distribution of materials to promote public awareness and education and conducting workshops or other meetings, for health care practitioners, pharmacists, and others as appropriate.

e.Providing funds for travel expenses.

f.Providing funds for administrative costs, including personnel, audits, facilities, and equipment.

g.Fulfilling all other requirements necessary to implement and operate the program as outlined in this section.

(e)The activities of the direct-support organization must be consistent with the goals and mission of the department, as determined by the department, and in the best interests of the state. The direct-support organization must obtain a written approval from the department for any activities in support of the prescription drug monitoring program before undertaking those activities.

(f)The department may permit, without charge, appropriate use of administrative services, property, and facilities of the department by the direct-support organization, subject to this section. The use must be directly in keeping with the approved purposes of the direct-support organization and may not be made at times or places that would unreasonably interfere with

opportunities for the public to use such facilities for established purposes. Any moneys received from rentals of facilities and properties managed by the department may be held in a separate depository account in the name of the direct-support organization and subject to the provisions of the letter of agreement with the department. The letter of agreement must provide that any funds held in the separate depository account in the name of the direct-support organization must revert to the department if the direct-support organization is no longer approved by the department to operate in the best interests of the state.

(g)The department may adopt rules under s. 120.54 to govern the use of administrative services, property, or facilities of the department or office by the direct-support organization.

(h)The department may not permit the use of any administrative services, property, or facilities of the state by a direct-support organization if that organization does not provide equal membership and employment opportunities to all persons regardless of race, color, religion, gender, age, or national origin.

(i)The direct-support organization shall provide for an independent annual financial audit in accordance with s. 215.981. Copies of the audit shall be provided to the department and the Office of Policy and Budget in the Executive Office of the Governor.

(j)The direct-support organization may not exercise any power under s. 617.0302(12) or (16).

(12)A prescriber or dispenser may have access to the information under this section which relates to a patient of that prescriber or dispenser as needed for the purpose of reviewing the patient's controlled drug prescription history. A prescriber or dispenser acting in good faith is immune from any civil, criminal, or administrative liability that might otherwise be incurred or imposed for receiving or using information from the prescription drug monitoring program. This subsection does not create a private cause of action, and a person may not recover damages against a prescriber or dispenser authorized to access information under this subsection for accessing or failing to access such information.

(13)To the extent that funding is provided for such purpose through federal or private grants or gifts and other types of available moneys, the department shall study the feasibility of enhancing the prescription drug monitoring program for the purposes of public health initiatives and statistical reporting that respects the privacy of the patient, the prescriber, and the dispenser. Such a study shall be conducted in order to further improve the quality of health care services and safety by improving the prescribing and dispensing practices for prescription drugs, taking advantage of advances in technology, reducing duplicative prescriptions and the overprescribing of prescription drugs, and reducing drug abuse. The requirements of the National All Schedules Prescription Electronic Reporting (NASPER) Act are authorized in order to apply for federal NASPER funding. In addition, the direct-support organization shall provide funding for the department to conduct training for health care practitioners and other appropriate persons in using the monitoring

program to support the program enhancements.

(14)A pharmacist, pharmacy, or dispensing health care practitioner or his or her agent, before releasing a controlled substance to any person not known to such dispenser, shall require the person purchasing, receiving, or otherwise acquiring the controlled substance to present valid photographic identification or other verification of his or her identity to the dispenser. If the person does not have proper identification, the dispenser may verify the validity of the prescription and the identity of the patient with the prescriber or his or her authorized agent. Verification of health plan eligibility through a real-time inquiry or adjudication system will be considered to be proper identification. This subsection does not apply in an institutional setting or to a long-term care facility, including, but not limited to, an assisted living facility or a hospital to which patients are admitted. As used in this subsection, the term "proper identification" means an identification that is issued by a state or the Federal Government containing the person's photograph, printed name, and signature or a document considered acceptable under 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

(15)The Agency for Health Care Administration shall continue the promotion of electronic prescribing by health care practitioners, health care facilities, and pharmacies under s. 408.0611.

(16)The department shall adopt rules pursuant to ss. 120.536(1) and 120.54 to administer the provisions of this section, which shall include as necessary the reporting, accessing, evaluation, management, development, implementation, operation, and storage of information within the monitoring program's system.

History.—s. 1, ch. 2009-198; s. 41, ch. 2010-151; s. 12, ch. 2010-211; s. 50, ch. 2011-4; s. 23, ch. 2011-141; s. 86, ch. 2012-5.

893.0551Public records exemption for the prescription drug monitoring program.—

(1)For purposes of this section, the term:

(a)"Active investigation" has the same meaning as provided in s. 893.055.

(b)"Dispenser" has the same meaning as provided in s. 893.055.

(c)"Health care practitioner" or "practitioner" has the same meaning as provided in s. 893.055.

(d)"Health care regulatory board" has the same meaning as provided in s. 893.055.

(e)"Law enforcement agency" has the same meaning as provided in s. 893.055.

(f)"Pharmacist" means any person licensed under chapter 465 to practice the profession of pharmacy.

(g)"Pharmacy" has the same meaning as provided in s. 893.055.

(h)"Prescriber" has the same meaning as provided in s. 893.055.

(2)The following information of a patient or patient's agent, a health care practitioner, a dispenser, an employee of the practitioner who is acting on behalf of and at the direction of the

practitioner, a pharmacist, or a pharmacy that is contained in records held by the department under s. 893.055 is confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution:

(a)Name.

(b)Address.

(c)Telephone number.

(d)Insurance plan number.

(e)Government-issued identification number.

(f)Provider number.

(g)Drug Enforcement Administration number.

(h)Any other unique identifying information or number.

(3)The department shall disclose such confidential and exempt information to the following entities after using a verification process to ensure the legitimacy of that person's or entity's request for the information:

(a)The Attorney General and his or her designee when working on Medicaid fraud cases involving prescription drugs or when the Attorney General has initiated a review of specific identifiers of Medicaid fraud regarding prescription drugs. The Attorney General or his or her designee may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. The Attorney General's Medicaid fraud investigators may not have direct access to the department's database.

(b)The department's relevant health care regulatory boards responsible for the licensure, regulation, or discipline of a practitioner, pharmacist, or other person who is authorized to prescribe, administer, or dispense controlled substances and who is involved in a specific controlled substances investigation for prescription drugs involving a designated person. The health care regulatory boards may request information from the department but may not have direct access to its database. The health care regulatory boards may provide such information to a law enforcement agency pursuant to ss. 456.066 and 456.073.

(c)A law enforcement agency that has initiated an active investigation involving a specific violation of law regarding prescription drug abuse or diversion of prescribed controlled substances. The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of prescription drug abuse or prescription drug diversion law as it relates to controlled substances. A law enforcement agency may request information from the department but may not have direct access to its database.

(d)A health care practitioner who certifies that the information is necessary to provide medical treatment to a current patient in accordance with ss. 893.05 and 893.055.

(e)A pharmacist who certifies that the requested information will be used to dispense controlled substances to a current patient in accordance with ss. 893.04 and 893.055.

(f)A patient or the legal guardian or designated health care surrogate for an incapacitated patient, if applicable, making a request as provided in s. 893.055(7)(c)4.

(g)The patient's pharmacy, prescriber, or dispenser who certifies that the information is necessary to provide medical treatment to his or her current patient in accordance with s. 893.055.

(4)The department shall disclose such confidential and exempt information to the applicable law enforcement agency in accordance with s. 893.055(7)(f). The law enforcement agency may disclose the confidential and exempt information received from the department to a criminal justice agency as defined in s. 119.011 as part of an active investigation that is specific to a violation of s. 893.13(7)(a)8., s. 893.13(8)(a), or s. 893.13(8)(b).

(5)Any agency or person who obtains such confidential and exempt information pursuant to this section must maintain the confidential and exempt status of that information.

(6)Any person who willfully and knowingly violates this section commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(7)This section is subject to the Open Government Sunset Review Act in accordance with s. 119.15 and shall stand repealed on October 2, 2014, unless reviewed and saved from repeal through reenactment by the Legislature.

History.—s. 1, ch. 2009-197; s. 13, ch. 2010-211; s. 51, ch. 2011-4.

893.06Distribution of controlled substances; order forms; labeling and packaging requirements.—

(1)Controlled substances in Schedules I and II shall be distributed by a duly licensed manufacturer, distributor, or wholesaler to a duly licensed manufacturer, wholesaler, distributor, practitioner, pharmacy, as defined in chapter 465, hospital, or laboratory only pursuant to an order form. It shall be deemed a compliance with this subsection if the parties to the transaction have complied with federal law respecting the use of order forms.

(2)Possession or control of controlled substances obtained as authorized by this section shall be lawful if in the regular course of business, occupation, profession, employment, or duty.

(3)A person in charge of a hospital or laboratory or in the employ of this state or of any other state, or of any political subdivision thereof, and a master or other proper officer of a ship or aircraft, who obtains controlled substances under the provisions of this section or otherwise, shall not administer, dispense, or otherwise use such controlled substances within this state, except within the scope of her or his employment or official duty, and then only for scientific or medicinal purposes and subject to the provisions of this chapter.

(4)It shall be unlawful to distribute a controlled substance in a commercial container unless such container bears a label showing the name and address of the manufacturer, the quantity, kind, and form of controlled substance contained therein, and the identifying symbol for such substance, as required by federal law. No person except a pharmacist, for the purpose of dispensing a prescription, or a practitioner, for the purpose of dispensing a controlled substance to a patient, shall alter, deface, or remove any labels so affixed.

History.—s. 6, ch. 73-331; s. 1438, ch. 97-102.

893.065Counterfeit-resistant prescription blanks for controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V.—The Department of Health shall develop and adopt by rule the form and content for a counterfeit-resistant prescription blank which must be used by practitioners for the purpose of prescribing a controlled substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V pursuant to s. 456.42. The Department of Health may require the prescription blanks to be printed on distinctive, watermarked paper and to bear the preprinted name, address, and category of professional licensure of the practitioner and that practitioner's federal registry number for controlled substances. The prescription blanks may not be transferred.

History.—s. 4, ch. 2007-156; s. 24, ch. 2011-141.

893.07Records.—

(1)Every person who engages in the manufacture, compounding, mixing, cultivating, growing, or by any other process producing or preparing, or in the dispensing, importation, or, as a wholesaler, distribution, of controlled substances shall:

(a)On January 1, 1974, or as soon thereafter as any person first engages in such activity, and every second year thereafter, make a complete and accurate record of all stocks of controlled substances on hand. The inventory may be prepared on the regular physical inventory date which is nearest to, and does not vary by more than 6 months from, the biennial date that would otherwise apply. As additional substances are designated for control under this chapter, they shall be inventoried as provided for in this subsection.

(b)On and after January 1, 1974, maintain, on a current basis, a complete and accurate record of each substance manufactured, received, sold, delivered, or otherwise disposed of by him or her, except that this subsection shall not require the maintenance of a perpetual inventory.

Compliance with the provisions of federal law pertaining to the keeping of records of controlled substances shall be deemed a compliance with the requirements of this subsection.

(2)The record of controlled substances received shall in every case show:

(a)The date of receipt.

(b)The name and address of the person from whom received.

(c)The kind and quantity of controlled substances received.

(3)The record of all controlled substances sold, administered, dispensed, or otherwise disposed of shall show:

(a)The date of selling, administering, or dispensing.

(b)The correct name and address of the person to whom or for whose use, or the owner and species of animal for which, sold, administered, or dispensed.

(c)The kind and quantity of controlled substances sold, administered, or dispensed.

(4)Every inventory or record required by this chapter, including prescription records, shall be maintained:

(a)Separately from all other records of the registrant, or

(b)Alternatively, in the case of Schedule III, IV, or V controlled substances, in such form that information required by this chapter is readily retrievable from the ordinary business records of the registrant.

In either case, the records described in this subsection shall be kept and made available for a period of at least 2 years for inspection and copying by law enforcement officers whose duty it is to enforce the laws of this state relating to controlled substances. Law enforcement officers are not required to obtain a subpoena, court order, or search warrant in order to obtain access to or copies of such records.

(5)Each person described in subsection (1) shall:

(a)Maintain a record which shall contain a detailed list of controlled substances lost, destroyed, or stolen, if any; the kind and quantity of such controlled substances; and the date of the discovering of such loss, destruction, or theft.

(b)In the event of the discovery of the theft or significant loss of controlled substances, report such theft or significant loss to the sheriff of that county within 24 hours after discovery. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(3), (4), or (5) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083. A person who fails to report a theft or significant loss of a substance listed in s. 893.03(2) within 24 hours after discovery as required in this paragraph commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

History.—s. 7, ch. 73-331; s. 1439, ch. 97-102; s. 25, ch. 2011-141.

893.08Exceptions.—

(1)The following may be distributed at retail without a prescription, but only by a registered pharmacist:

(a)Any compound, mixture, or preparation described in Schedule V.

(b)Any compound, mixture, or preparation containing any depressant or stimulant substance described in s. 893.03(2)(a) or (c) except any amphetamine drug or sympathomimetic amine drug

or compound designated as a Schedule II controlled substance pursuant to this chapter; in s. 893.03(3)(a); or in Schedule IV, if:

1.The compound, mixture, or preparation contains one or more active medicinal ingredients not having depressant or stimulant effect on the central nervous system, and

2.Such ingredients are included therein in such combinations, quantity, proportion, or concentration as to vitiate the potential for abuse of the controlled substances which do have a depressant or stimulant effect on the central nervous system.

(2)No compound, mixture, or preparation may be dispensed under subsection (1) unless such substance may, under the Federal Food, Drug, and Cosmetic Act, be lawfully sold at retail without a prescription.

(3)The exemptions authorized by this section shall be subject to the following conditions:

(a)The compounds, mixtures, and preparations referred to in subsection (1) may be dispensed to persons under age 18 only on prescription. A bound volume must be maintained as a record of sale at retail of excepted compounds, mixtures, and preparations, and the pharmacist must require suitable identification from every unknown purchaser.

(b)Such compounds, mixtures, and preparations shall be sold by the pharmacist in good faith as a medicine and not for the purpose of evading the provisions of this chapter. The pharmacist may, in his or her discretion, withhold sale to any person whom the pharmacist reasonably believes is attempting to purchase excepted compounds, mixtures, or preparations for the purpose of abuse.

(c)The total quantity of controlled substance listed in Schedule V which may be sold to any one purchaser within a given 48-hour period shall not exceed 120 milligrams of codeine, 60 milligrams dihydrocodeine, 30 milligrams of ethyl morphine, or 240 milligrams of opium.

(d)Nothing in this section shall be construed to limit the kind and quantity of any controlled substance that may be prescribed, administered, or dispensed to any person, or for the use of any person or animal, when it is prescribed, administered, or dispensed in compliance with the general provisions of this chapter.

(4)The dextrorotatory isomer of 3-methoxy-n-methylmorphinan and its salts (dextromethorphan) shall not be deemed to be included in any schedule by reason of enactment of this chapter.

History.—s. 8, ch. 73-331; s. 1, ch. 77-174; s. 6, ch. 80-354; s. 4, ch. 89-281; s. 2, ch. 93-92; s. 1440, ch. 97-102; s. 105, ch. 97-264; s. 12, ch. 99-186.

893.09Enforcement.—

(1)The Department of Law Enforcement, all state agencies which regulate professions or institutions affected by the provisions of this chapter, and all peace officers of the state shall enforce all provisions of this chapter except those specifically delegated, and shall cooperate with

all agencies charged with the enforcement of the laws of the United States, this state, and all other states relating to controlled substances.

(2)Any agency authorized to enforce this chapter shall have the right to institute an action in its own name to enjoin the violation of any of the provisions of this chapter. Said action for an injunction shall be in addition to any other action, proceeding, or remedy authorized by law.

(3)All law enforcement officers whose duty it is to enforce this chapter shall have authority to administer oaths in connection with their official duties, and any person making a material false statement under oath before such law enforcement officers shall be deemed guilty of perjury and subject to the same punishment as prescribed for perjury.

(4)It shall be unlawful and punishable as provided in chapter 843 for any person to interfere with any such law enforcement officer in the performance of the officer's official duties. It shall also be unlawful for any person falsely to represent himself or herself to be authorized to enforce the drug abuse laws of this state, the United States, or any other state.

(5)No civil or criminal liability shall be imposed by virtue of this chapter upon any person whose duty it is to enforce the provisions of this chapter, by reason of his or her being lawfully engaged in the enforcement of any law or municipal ordinance relating to controlled substances.

History.—s. 9, ch. 73-331; s. 1, ch. 77-174; s. 30, ch. 79-8; s. 1441, ch. 97-102.

893.10Burden of proof; photograph or video recording of evidence.—

(1)It is not necessary for the state to negative any exemption or exception set forth in this chapter in any indictment, information, or other pleading or in any trial, hearing, or other proceeding under this chapter, and the burden of going forward with the evidence with respect to any exemption or exception is upon the person claiming its benefit.

(2)In the prosecution of an offense involving the manufacture of a controlled substance, a photograph or video recording of the manufacturing equipment used in committing the offense, including, but not limited to, grow lights, growing trays, and chemical fertilizers, may be introduced as competent evidence of the existence and use of the equipment and is admissible in the prosecution of the offense to the same extent as if the property were introduced as evidence.

(3)After a law enforcement agency documents the manufacturing equipment by photography or video recording, the manufacturing equipment may be destroyed on site and left in disrepair. The law enforcement agency destroying the equipment is immune from civil liability for the destruction of the equipment. The destruction of the equipment must be recorded by the supervising law enforcement officer in the manner described in s. 893.12(1)(a), and records must be maintained for 24 months.

History.—s. 10, ch. 73-331; s. 1442, ch. 97-102; s. 3, ch. 2008-184; s. 19, ch. 2010-117.

893.101Legislative findings and intent.—

(1)The Legislature finds that the cases of *Scott v. State*, Slip Opinion No. SC94701 (Fla. 2002)

and *Chicone v. State*, 684 So.2d 736 (Fla. 1996), holding that the state must prove that the defendant knew of the illicit nature of a controlled substance found in his or her actual or constructive possession, were contrary to legislative intent.

(2)The Legislature finds that knowledge of the illicit nature of a controlled substance is not an element of any offense under this chapter. Lack of knowledge of the illicit nature of a controlled substance is an affirmative defense to the offenses of this chapter.

(3)In those instances in which a defendant asserts the affirmative defense described in this section, the possession of a controlled substance, whether actual or constructive, shall give rise to a permissive presumption that the possessor knew of the illicit nature of the substance. It is the intent of the Legislature that, in those cases where such an affirmative defense is raised, the jury shall be instructed on the permissive presumption provided in this subsection.

History.—s. 1, ch. 2002-258.

893.105Testing and destruction of seized substances.—

(1)Any controlled substance or listed chemical seized as evidence may be sample tested and weighed by the seizing agency after the seizure. Any such sample and the analysis thereof shall be admissible into evidence in any civil or criminal action for the purpose of proving the nature, composition, and weight of the substance seized. In addition, the seizing agency may photograph or videotape, for use at trial, the controlled substance or listed chemical seized.

(2)Controlled substances or listed chemicals that are not retained for sample testing as provided in subsection (1) may be destroyed pursuant to a court order issued in accordance with s. 893.12.

History.—s. 1, ch. 82-88; s. 3, ch. 91-279.

893.11Suspension, revocation, and reinstatement of business and professional licenses.—For the purposes of s. 120.60(6), any conviction in any court reported to the Comprehensive Case Information System of the Florida Association of Court Clerks and Comptrollers, Inc., for the sale of, or trafficking in, a controlled substance or for conspiracy to sell, or traffic in, a controlled substance constitutes an immediate serious danger to the public health, safety, or welfare, and is grounds for disciplinary action by the licensing state agency. A state agency shall initiate an immediate emergency suspension of an individual professional license issued by the agency, in compliance with the procedures for summary suspensions in s. 120.60(6), upon the agency's findings of the licensee's conviction in any court reported to the Comprehensive Case Information System of the Florida Association of Court Clerks and Comptrollers, Inc., for the sale of, or trafficking in, a controlled substance, or for conspiracy to sell, or traffic in, a controlled substance. Before renewing any professional license, a state agency that issues a professional license must use the Comprehensive Case Information System of the Florida Association of Court Clerks and Comptrollers, Inc., to obtain information relating to any conviction for the sale of, or trafficking in,

a controlled substance or for conspiracy to sell, or traffic in, a controlled substance. The clerk of court shall provide electronic access to each state agency at no cost and also provide certified copies of the judgment upon request to the agency. Upon a showing by any such convicted defendant whose professional license has been suspended or revoked pursuant to this section that his or her civil rights have been restored or upon a showing that the convicted defendant meets the following criteria, the agency head may reinstate or reactivate such license when:

(1)The person has complied with the conditions of paragraphs (a) and (b) which shall be monitored by the Department of Corrections while the person is under any supervisory sanction. If the person fails to comply with provisions of these paragraphs by either failing to maintain treatment or by testing positive for drug use, the department shall notify the licensing agency, which shall revoke the license. The person under supervision may:

(a)Seek evaluation and enrollment in, and once enrolled maintain enrollment in until completion, a drug treatment and rehabilitation program which is approved or regulated by the Department of Children and Family Services. The treatment and rehabilitation program shall be specified by:

1.The court, in the case of court-ordered supervisory sanctions;

2.The Parole Commission, in the case of parole, control release, or conditional release; or

3.The Department of Corrections, in the case of imprisonment or any other supervision required by law.

(b)Submit to periodic urine drug testing pursuant to procedures prescribed by the Department of Corrections. If the person is indigent, the costs shall be paid by the Department of Corrections; or

(2)The person has successfully completed an appropriate program under the Correctional Education Program.

(3)As used in this section, the term “professional license” includes any license, permit, or certificate that authorizes a person to practice his or her profession. However, the term does not include any of the taxes, fees, or permits regulated, controlled, or administered by the Department of Revenue in accordance with s. 213.05.

History.—s. 11, ch. 73-331; s. 1, ch. 77-117; s. 19, ch. 78-95; s. 3, ch. 90-266; s. 126, ch. 91-112; s. 14, ch. 95-325; s. 1443, ch. 97-102; s. 302, ch. 99-8; s. 18, ch. 2012-100.

893.12Contraband; seizure, forfeiture, sale.—

(1)All substances controlled by this chapter and all listed chemicals, which substances or chemicals are handled, delivered, possessed, or distributed contrary to any provisions of this chapter, and all such controlled substances or listed chemicals the lawful possession of which is not established or the title to which cannot be ascertained, are declared to be contraband, are subject to seizure and confiscation by any person whose duty it is to enforce the provisions of the chapter,

and shall be disposed of as follows:

(a)Except as in this section otherwise provided, the court having jurisdiction shall order such controlled substances or listed chemicals forfeited and destroyed. A record of the place where said controlled substances or listed chemicals were seized, of the kinds and quantities of controlled substances or listed chemicals destroyed, and of the time, place, and manner of destruction shall be kept, and a return under oath reporting said destruction shall be made to the court by the officer who destroys them.

(b)Upon written application by the Department of Health, the court by whom the forfeiture of such controlled substances or listed chemicals has been decreed may order the delivery of any of them to said department for distribution or destruction as hereinafter provided.

(c)Upon application by any hospital or laboratory within the state not operated for private gain, the department may, in its discretion, deliver any controlled substances or listed chemicals that have come into its custody by authority of this section to the applicant for medical use. The department may from time to time deliver excess stocks of such controlled substances or listed chemicals to the United States Drug Enforcement Administration or destroy same.

(d)The department shall keep a full and complete record of all controlled substances or listed chemicals received and of all controlled substances or listed chemicals disposed of, showing:

1.The exact kinds, quantities, and forms of such controlled substances or listed chemicals;

2.The persons from whom received and to whom delivered;

3.By whose authority received, delivered, and destroyed; and

4.The dates of the receipt, disposal, or destruction,

which record shall be open to inspection by all persons charged with the enforcement of federal and state drug abuse laws.

(2)(a)Any vessel, vehicle, aircraft, or drug paraphernalia as defined in s. 893.145 which has been or is being used in violation of any provision of this chapter or in, upon, or by means of which any violation of this chapter has taken or is taking place may be seized and forfeited as provided by the Florida Contraband Forfeiture Act.

(b)All real property, including any right, title, leasehold interest, and other interest in the whole of any lot or tract of land and any appurtenances or improvements, which real property is used, or intended to be used, in any manner or part, to commit or to facilitate the commission of, or which real property is acquired with proceeds obtained as a result of, a violation of any provision of this chapter related to a controlled substance described in s. 893.03(1) or (2) may be seized and forfeited as provided by the Florida Contraband Forfeiture Act except that no property shall be forfeited under this paragraph to the extent of an interest of an owner or lienholder by reason of any act or omission established by that owner or lienholder to have been committed or omitted without the knowledge or consent of that owner or lienholder.

(c)All moneys, negotiable instruments, securities, and other things of value furnished or intended to be furnished by any person in exchange for a controlled substance described in s. 893.03(1) or (2) or a listed chemical in violation of any provision of this chapter, all proceeds traceable to such an exchange, and all moneys, negotiable instruments, and securities used or intended to be used to facilitate any violation of any provision of this chapter or which are acquired with proceeds obtained in violation of any provision of this chapter may be seized and forfeited as provided by the Florida Contraband Forfeiture Act, except that no property shall be forfeited under this paragraph to the extent of an interest of an owner or lienholder by reason of any act or omission established by that owner or lienholder to have been committed or omitted without the knowledge or consent of that owner or lienholder.

(d)All books, records, and research, including formulas, microfilm, tapes, and data which are used, or intended for use, or which are acquired with proceeds obtained, in violation of any provision of this chapter related to a controlled substance described in s. 893.03(1) or (2) or a listed chemical may be seized and forfeited as provided by the Florida Contraband Forfeiture Act.

(e)If any of the property described in this subsection:

1.Cannot be located;

2.Has been transferred to, sold to, or deposited with, a third party;

3.Has been placed beyond the jurisdiction of the court;

4.Has been substantially diminished in value by any act or omission of the defendant; or

5.Has been commingled with any property which cannot be divided without difficulty,

the court shall order the forfeiture of any other property of the defendant up to the value of any property subject to forfeiture under this subsection.

(3)Any law enforcement agency is empowered to authorize or designate officers, agents, or other persons to carry out the seizure provisions of this section. It shall be the duty of any officer, agent, or other person so authorized or designated, or authorized by law, whenever she or he shall discover any vessel, vehicle, aircraft, real property or interest in real property, money, negotiable instrument, security, book, record, or research which has been or is being used or intended to be used, or which is acquired with proceeds obtained, in violation of any of the provisions of this chapter, or in, upon, or by means of which any violation of this chapter has taken or is taking place, to seize such vessel, vehicle, aircraft, real property or interest in real property, money, negotiable instrument, security, book, record, or research and place it in the custody of such person as may be authorized or designated for that purpose by the respective law enforcement agency pursuant to these provisions.

(4)The rights of any bona fide holder of a duly recorded mortgage or duly recorded vendor's privilege on the property seized under this chapter shall not be affected by the seizure.

History.—s. 12, ch. 73-331; ss. 10, 11, ch. 74-385; s. 471, ch. 77-147; s. 185, ch. 79-164; s. 4, ch. 80-30; s. 9, ch.

80-68; s. 5, ch. 89-148; s. 4, ch. 91-279; s. 1444, ch. 97-102; s. 1, ch. 98-395; s. 303, ch. 99-8; s. 13, ch. 99-186; s. 21, ch. 2000-320; s. 17, ch. 2004-11.

893.13Prohibited acts; penalties.—

(1)(a)Except as authorized by this chapter and chapter 499, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance. Any person who violates this provision with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(b)Except as provided in this chapter, it is unlawful to sell or deliver in excess of 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. Any person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a child care facility as defined in s. 402.302 or a public or private elementary, middle, or secondary school between the hours of 6 a.m. and 12 midnight, or at any time in, on, or within 1,000 feet of real property comprising a state, county, or municipal park, a community center, or a publicly owned recreational facility. For the purposes of this paragraph, the term “community center” means a facility operated by a nonprofit community-based organization for the provision of recreational, social, or educational services to the public. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. The defendant must be sentenced to a minimum term of imprisonment of 3 calendar years unless the offense was committed within 1,000 feet of the real property comprising a child care facility as defined in s. 402.302.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must

be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

This paragraph does not apply to a child care facility unless the owner or operator of the facility posts a sign that is not less than 2 square feet in size with a word legend identifying the facility as a licensed child care facility and that is posted on the property of the child care facility in a conspicuous place where the sign is reasonably visible to the public.

(d)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a public or private college, university, or other postsecondary educational institution. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(e)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance not authorized by law in, on, or within 1,000 feet of a physical place for worship at which a church or religious organization regularly conducts religious services or within 1,000 feet of a convenience business as defined in s. 812.171. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(f)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising a public housing facility at any time. For purposes

of this section, the term “real property comprising a public housing facility” means real property, as defined in s. 421.03(12), of a public corporation created as a housing authority pursuant to part I of chapter 421. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.Any other controlled substance, except as lawfully sold, manufactured, or delivered, must be sentenced to pay a $500 fine and to serve 100 hours of public service in addition to any other penalty prescribed by law.

(g)Except as authorized by this chapter, it is unlawful for any person to manufacture methamphetamine or phencyclidine, or possess any listed chemical as defined in s. 893.033 in violation of s. 893.149 and with intent to manufacture methamphetamine or phencyclidine. If any person violates this paragraph and:

1.The commission or attempted commission of the crime occurs in a structure or conveyance where any child under 16 years of age is present, the person commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition, the defendant must be sentenced to a minimum term of imprisonment of 5 calendar years.

2.The commission of the crime causes any child under 16 years of age to suffer great bodily harm, the person commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition, the defendant must be sentenced to a minimum term of imprisonment of 10 calendar years.

(h)Except as authorized by this chapter, it is unlawful for any person to sell, manufacture, or deliver, or possess with intent to sell, manufacture, or deliver, a controlled substance in, on, or within 1,000 feet of the real property comprising an assisted living facility, as that term is used in chapter 429. Any person who violates this paragraph with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4. commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)(a)Except as authorized by this chapter and chapter 499, it is unlawful for any person to purchase, or possess with intent to purchase, a controlled substance. Any person who violates this

provision with respect to:

1.A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

3.A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(b)Except as provided in this chapter, it is unlawful to purchase in excess of 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. Any person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)Any person who delivers, without consideration, not more than 20 grams of cannabis, as defined in this chapter, commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For the purposes of this paragraph, "cannabis" does not include the resin extracted from the plants of the genus *Cannabis* or any compound manufacture, salt, derivative, mixture, or preparation of such resin.

(4)Except as authorized by this chapter, it is unlawful for any person 18 years of age or older to deliver any controlled substance to a person under the age of 18 years, or to use or hire a person under the age of 18 years as an agent or employee in the sale or delivery of such a substance, or to use such person to assist in avoiding detection or apprehension for a violation of this chapter. Any person who violates this provision with respect to:

(a)A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b), or (2)(c)4., commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

Imposition of sentence may not be suspended or deferred, nor shall the person so convicted be placed on probation.

(5)It is unlawful for any person to bring into this state any controlled substance unless the possession of such controlled substance is authorized by this chapter or unless such person is licensed to do so by the appropriate federal agency. Any person who violates this provision with respect to:

(a)A controlled substance named or described in s. 893.03(1)(a), (1)(b), (1)(d), (2)(a), (2)(b),

or (2)(c)4., commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A controlled substance named or described in s. 893.03(1)(c), (2)(c)1., (2)(c)2., (2)(c)3., (2)(c)5., (2)(c)6., (2)(c)7., (2)(c)8., (2)(c)9., (3), or (4) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c)A controlled substance named or described in s. 893.03(5) commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(6)(a)It is unlawful for any person to be in actual or constructive possession of a controlled substance unless such controlled substance was lawfully obtained from a practitioner or pursuant to a valid prescription or order of a practitioner while acting in the course of his or her professional practice or to be in actual or constructive possession of a controlled substance except as otherwise authorized by this chapter. Any person who violates this provision commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)If the offense is the possession of not more than 20 grams of cannabis, as defined in this chapter, or 3 grams or less of a controlled substance described in s. 893.03(1)(c)46.-50. and 114.-142., the person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. For the purposes of this subsection, "cannabis" does not include the resin extracted from the plants of the genus *Cannabis*, or any compound manufacture, salt, derivative, mixture, or preparation of such resin, and a controlled substance described in s. 893.03(1)(c)46.-50. and 114.-142. does not include the substance in a powdered form.

(c)Except as provided in this chapter, it is unlawful to possess in excess of 10 grams of any substance named or described in s. 893.03(1)(a) or (1)(b), or any combination thereof, or any mixture containing any such substance. Any person who violates this paragraph commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d)Notwithstanding any provision to the contrary of the laws of this state relating to arrest, a law enforcement officer may arrest without warrant any person who the officer has probable cause to believe is violating the provisions of this chapter relating to possession of cannabis.

(7)(a)A person may not:

1.Distribute or dispense a controlled substance in violation of this chapter.

2.Refuse or fail to make, keep, or furnish any record, notification, order form, statement, invoice, or information required under this chapter.

3.Refuse entry into any premises for any inspection or refuse to allow any inspection authorized by this chapter.

4.Distribute a controlled substance named or described in s. 893.03(1) or (2) except pursuant to an order form as required by s. 893.06.

5.Keep or maintain any store, shop, warehouse, dwelling, building, vehicle, boat, aircraft, or

other structure or place which is resorted to by persons using controlled substances in violation of this chapter for the purpose of using these substances, or which is used for keeping or selling them in violation of this chapter.

6.Use to his or her own personal advantage, or reveal, any information obtained in enforcement of this chapter except in a prosecution or administrative hearing for a violation of this chapter.

7.Possess a prescription form which has not been completed and signed by the practitioner whose name appears printed thereon, unless the person is that practitioner, is an agent or employee of that practitioner, is a pharmacist, or is a supplier of prescription forms who is authorized by that practitioner to possess those forms.

8.Withhold information from a practitioner from whom the person seeks to obtain a controlled substance or a prescription for a controlled substance that the person making the request has received a controlled substance or a prescription for a controlled substance of like therapeutic use from another practitioner within the previous 30 days.

9.Acquire or obtain, or attempt to acquire or obtain, possession of a controlled substance by misrepresentation, fraud, forgery, deception, or subterfuge.

10.Affix any false or forged label to a package or receptacle containing a controlled substance.

11.Furnish false or fraudulent material information in, or omit any material information from, any report or other document required to be kept or filed under this chapter or any record required to be kept by this chapter.

12.Store anhydrous ammonia in a container that is not approved by the United States Department of Transportation to hold anhydrous ammonia or is not constructed in accordance with sound engineering, agricultural, or commercial practices.

13.With the intent to obtain a controlled substance or combination of controlled substances that are not medically necessary for the person or an amount of a controlled substance or substances that is not medically necessary for the person, obtain or attempt to obtain from a practitioner a controlled substance or a prescription for a controlled substance by misrepresentation, fraud, forgery, deception, subterfuge, or concealment of a material fact. For purposes of this subparagraph, a material fact includes whether the person has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph 8.

(b)A health care practitioner, with the intent to provide a controlled substance or combination of controlled substances that are not medically necessary to his or her patient or an amount of controlled substances that is not medically necessary for his or her patient, may not provide a controlled substance or a prescription for a controlled substance by misrepresentation, fraud,

forgery, deception, subterfuge, or concealment of a material fact. For purposes of this paragraph, a material fact includes whether the patient has an existing prescription for a controlled substance issued for the same period of time by another practitioner or as described in subparagraph (a)8.

(c)Any person who violates the provisions of subparagraphs (a)1.-7. commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083; except that, upon a second or subsequent violation, the person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d)Any person who violates the provisions of subparagraphs (a)8.-12. commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(e)A person or health care practitioner who violates the provisions of subparagraph (a)13. or paragraph (b) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, if any controlled substance that is the subject of the offense is listed in Schedule II, Schedule III, or Schedule IV.

(8)(a)Notwithstanding subsection (9), a prescribing practitioner may not:

1.Knowingly assist a patient, other person, or the owner of an animal in obtaining a controlled substance through deceptive, untrue, or fraudulent representations in or related to the practice of the prescribing practitioner's professional practice;

2.Employ a trick or scheme in the practice of the prescribing practitioner's professional practice to assist a patient, other person, or the owner of an animal in obtaining a controlled substance;

3.Knowingly write a prescription for a controlled substance for a fictitious person; or

4.Write a prescription for a controlled substance for a patient, other person, or an animal if the sole purpose of writing such prescription is to provide a monetary benefit to, or obtain a monetary benefit for, the prescribing practitioner.

(b)If the prescribing practitioner wrote a prescription or multiple prescriptions for a controlled substance for the patient, other person, or animal for which there was no medical necessity, or which was in excess of what was medically necessary to treat the patient, other person, or animal, that fact does not give rise to any presumption that the prescribing practitioner violated subparagraph (a)1., but may be considered with other competent evidence in determining whether the prescribing practitioner knowingly assisted a patient, other person, or the owner of an animal to obtain a controlled substance in violation of subparagraph (a)1.

(c)A person who violates paragraph (a) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(d)Notwithstanding paragraph (c), if a prescribing practitioner has violated paragraph (a) and received $1,000 or more in payment for writing one or more prescriptions or, in the case of a prescription written for a controlled substance described in s. 893.135, has written one or more

prescriptions for a quantity of a controlled substance which, individually or in the aggregate, meets the threshold for the offense of trafficking in a controlled substance under s. 893.15, the violation is reclassified as a felony of the second degree and ranked in level 4 of the Criminal Punishment Code.

(9)The provisions of subsections (1)-(8) are not applicable to the delivery to, or actual or constructive possession for medical or scientific use or purpose only of controlled substances by, persons included in any of the following classes, or the agents or employees of such persons, for use in the usual course of their business or profession or in the performance of their official duties:

(a)Pharmacists.

(b)Practitioners.

(c)Persons who procure controlled substances in good faith and in the course of professional practice only, by or under the supervision of pharmacists or practitioners employed by them, or for the purpose of lawful research, teaching, or testing, and not for resale.

(d)Hospitals that procure controlled substances for lawful administration by practitioners, but only for use by or in the particular hospital.

(e)Officers or employees of state, federal, or local governments acting in their official capacity only, or informers acting under their jurisdiction.

(f)Common carriers.

(g)Manufacturers, wholesalers, and distributors.

(h)Law enforcement officers for bona fide law enforcement purposes in the course of an active criminal investigation.

(10)If a person violates any provision of this chapter and the violation results in a serious injury to a state or local law enforcement officer as defined in s. 943.10, firefighter as defined in s. 633.30, emergency medical technician as defined in s. 401.23, paramedic as defined in s. 401.23, employee of a public utility or an electric utility as defined in s. 366.02, animal control officer as defined in s. 828.27, volunteer firefighter engaged by state or local government, law enforcement officer employed by the Federal Government, or any other local, state, or Federal Government employee injured during the course and scope of his or her employment, the person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the injury sustained results in death or great bodily harm, the person commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 13, ch. 73-331; s. 1, ch. 76-200; s. 1, ch. 77-174; s. 2, ch. 79-1; s. 3, ch. 79-325; s. 5, ch. 80-30; s. 2, ch. 80-70; s. 490, ch. 81-259; s. 2, ch. 82-16; s. 52, ch. 83-215; s. 1, ch. 84-77; s. 5, ch. 85-242; s. 4, ch. 87-243; s. 2, ch. 88-381; s. 4, ch. 89-281; s. 1, ch. 89-524; ss. 1, 6, ch. 90-111; s. 1, ch. 93-59; s. 2, ch. 93-92; s. 1, ch. 93-194; ss. 22, 23, ch. 93-406; s. 2, ch. 96-360; s. 2, ch. 97-1; s. 1, ch. 97-43; s. 1827, ch. 97-102; s. 22, ch. 97-194; s. 106, ch. 97-264; s. 1, ch. 97-269; s. 47, ch. 97-271; s. 1, ch. 98-22; s. 1, ch. 99-154; s. 14, ch. 99-186; s. 3, ch. 2000-320;

s. 11, ch. 2002-78; s. 2, ch. 2002-81; s. 3, ch. 2003-10; s. 1, ch. 2003-95; s. 2, ch. 2005-128; s. 108, ch. 2006-197; s. 2, ch. 2006-306; s. 2, ch. 2008-88; s. 6, ch. 2010-113; ss. 3, 4, ch. 2011-73; s. 2, ch. 2011-90; s. 26, ch. 2011-141; s. 2, ch. 2012-23.

893.135Trafficking; mandatory sentences; suspension or reduction of sentences; conspiracy to engage in trafficking.—

(1)Except as authorized in this chapter or in chapter 499 and notwithstanding the provisions of s. 893.13:

(a)Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, in excess of 25 pounds of cannabis, or 300 or more cannabis plants, commits a felony of the first degree, which felony shall be known as "trafficking in cannabis," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity of cannabis involved:

1.Is in excess of 25 pounds, but less than 2,000 pounds, or is 300 or more cannabis plants, but not more than 2,000 cannabis plants, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $25,000.

2.Is 2,000 pounds or more, but less than 10,000 pounds, or is 2,000 or more cannabis plants, but not more than 10,000 cannabis plants, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $50,000.

3.Is 10,000 pounds or more, or is 10,000 or more cannabis plants, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $200,000.

For the purpose of this paragraph, a plant, including, but not limited to, a seedling or cutting, is a "cannabis plant" if it has some readily observable evidence of root formation, such as root hairs. To determine if a piece or part of a cannabis plant severed from the cannabis plant is itself a cannabis plant, the severed piece or part must have some readily observable evidence of root formation, such as root hairs. Callous tissue is not readily observable evidence of root formation. The viability and sex of a plant and the fact that the plant may or may not be a dead harvested plant are not relevant in determining if the plant is a "cannabis plant" or in the charging of an offense under this paragraph. Upon conviction, the court shall impose the longest term of imprisonment provided for in this paragraph.

(b)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 28 grams or more of cocaine, as described in s. 893.03(2)(a)4., or of any mixture containing cocaine, but less than 150 kilograms of cocaine or any such mixture, commits a felony of the first degree, which felony shall be known as "trafficking in cocaine," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 28 grams or more, but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 200 grams or more, but less than 400 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 400 grams or more, but less than 150 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 150 kilograms or more of cocaine, as described in s. 893.03(2)(a)4., commits the first degree felony of trafficking in cocaine. A person who has been convicted of the first degree felony of trafficking in cocaine under this subparagraph shall be punished by life imprisonment and is ineligible for any form of discretionary early release except pardon or executive clemency or conditional medical release under s. 947.149. However, if the court determines that, in addition to committing any act specified in this paragraph:

a.The person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or

b.The person's conduct in committing that act led to a natural, though not inevitable, lethal result,

such person commits the capital felony of trafficking in cocaine, punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

3.Any person who knowingly brings into this state 300 kilograms or more of cocaine, as described in s. 893.03(2)(a)4., and who knows that the probable result of such importation would be the death of any person, commits capital importation of cocaine, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(c)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 4 grams or more of any morphine, opium, oxycodone, hydrocodone, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 4 grams or more of any mixture containing any such substance, but less than 30 kilograms of such substance or mixture, commits a felony of the first degree, which felony shall be known as "trafficking in illegal drugs," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 4 grams or more, but less than 14 grams, such person shall be sentenced to a mandatory

minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 28 grams or more, but less than 30 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 calendar years and pay a fine of $500,000.

2.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 30 kilograms or more of any morphine, opium, oxycodone, hydrocodone, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 30 kilograms or more of any mixture containing any such substance, commits the first degree felony of trafficking in illegal drugs. A person who has been convicted of the first degree felony of trafficking in illegal drugs under this subparagraph shall be punished by life imprisonment and is ineligible for any form of discretionary early release except pardon or executive clemency or conditional medical release under s. 947.149. However, if the court determines that, in addition to committing any act specified in this paragraph:

a.The person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or

b.The person's conduct in committing that act led to a natural, though not inevitable, lethal result,

such person commits the capital felony of trafficking in illegal drugs, punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

3.Any person who knowingly brings into this state 60 kilograms or more of any morphine, opium, oxycodone, hydrocodone, hydromorphone, or any salt, derivative, isomer, or salt of an isomer thereof, including heroin, as described in s. 893.03(1)(b), (2)(a), (3)(c)3., or (3)(c)4., or 60 kilograms or more of any mixture containing any such substance, and who knows that the probable result of such importation would be the death of any person, commits capital importation of illegal drugs, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(d)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 28 grams or more of phencyclidine or of any mixture containing phencyclidine, as described in s. 893.03(2)(b), commits a felony of the first degree, which felony shall be known as "trafficking in phencyclidine,"

punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 28 grams or more, but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 200 grams or more, but less than 400 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 400 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly brings into this state 800 grams or more of phencyclidine or of any mixture containing phencyclidine, as described in s. 893.03(2)(b), and who knows that the probable result of such importation would be the death of any person commits capital importation of phencyclidine, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(e)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 200 grams or more of methaqualone or of any mixture containing methaqualone, as described in s. 893.03(1)(d), commits a felony of the first degree, which felony shall be known as “trafficking in methaqualone,” punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 200 grams or more, but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more, but less than 25 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 25 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly brings into this state 50 kilograms or more of methaqualone or of any mixture containing methaqualone, as described in s. 893.03(1)(d), and who knows that the probable result of such importation would be the death of any person commits capital importation of methaqualone, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(f)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 14 grams or more of

amphetamine, as described in s. 893.03(2)(c)2., or methamphetamine, as described in s. 893.03(2)(c)4., or of any mixture containing amphetamine or methamphetamine, or phenylacetone, phenylacetic acid, pseudoephedrine, or ephedrine in conjunction with other chemicals and equipment utilized in the manufacture of amphetamine or methamphetamine, commits a felony of the first degree, which felony shall be known as "trafficking in amphetamine," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 14 grams or more, but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 28 grams or more, but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 200 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly manufactures or brings into this state 400 grams or more of amphetamine, as described in s. 893.03(2)(c)2., or methamphetamine, as described in s. 893.03(2)(c)4., or of any mixture containing amphetamine or methamphetamine, or phenylacetone, phenylacetic acid, pseudoephedrine, or ephedrine in conjunction with other chemicals and equipment used in the manufacture of amphetamine or methamphetamine, and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of amphetamine, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(g)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 4 grams or more of flunitrazepam or any mixture containing flunitrazepam as described in s. 893.03(1)(a) commits a felony of the first degree, which felony shall be known as "trafficking in flunitrazepam," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 4 grams or more but less than 14 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 14 grams or more but less than 28 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 28 grams or more but less than 30 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 25 calendar years and pay a fine of $500,000.

2.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state or who is knowingly in actual or constructive possession of 30 kilograms or more of flunitrazepam or any mixture containing flunitrazepam as described in s. 893.03(1)(a) commits the first degree felony of trafficking in flunitrazepam. A person who has been convicted of the first degree felony of trafficking in flunitrazepam under this subparagraph shall be punished by life imprisonment and is ineligible for any form of discretionary early release except pardon or executive clemency or conditional medical release under s. 947.149. However, if the court determines that, in addition to committing any act specified in this paragraph:

a.The person intentionally killed an individual or counseled, commanded, induced, procured, or caused the intentional killing of an individual and such killing was the result; or

b.The person's conduct in committing that act led to a natural, though not inevitable, lethal result,

such person commits the capital felony of trafficking in flunitrazepam, punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(h)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 kilogram or more of gamma-hydroxybutyric acid (GHB), as described in s. 893.03(1)(d), or any mixture containing gamma-hydroxybutyric acid (GHB), commits a felony of the first degree, which felony shall be known as "trafficking in gamma-hydroxybutyric acid (GHB)," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 kilogram or more but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more but less than 10 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 10 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly manufactures or brings into this state 150 kilograms or more of gamma-hydroxybutyric acid (GHB), as described in s. 893.03(1)(d), or any mixture containing gamma-hydroxybutyric acid (GHB), and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of gamma-hydroxybutyric acid (GHB), a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(i)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 kilogram or more of gamma-butyrolactone (GBL), as described in s. 893.03(1)(d), or any mixture containing gamma-butyrolactone (GBL), commits a felony of the first degree, which felony shall be known as "trafficking in gamma-butyrolactone (GBL)," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 kilogram or more but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more but less than 10 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 10 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

2.Any person who knowingly manufactures or brings into the state 150 kilograms or more of gamma-butyrolactone (GBL), as described in s. 893.03(1)(d), or any mixture containing gamma-butyrolactone (GBL), and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of gamma-butyrolactone (GBL), a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(j)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 kilogram or more of 1,4-Butanediol as described in s. 893.03(1)(d), or of any mixture containing 1,4-Butanediol, commits a felony of the first degree, which felony shall be known as "trafficking in 1,4-Butanediol," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 kilogram or more, but less than 5 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 kilograms or more, but less than 10 kilograms, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 10 kilograms or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $500,000.

2.Any person who knowingly manufactures or brings into this state 150 kilograms or more of 1,4-Butanediol as described in s. 893.03(1)(d), or any mixture containing 1,4-Butanediol, and who

knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of 1,4-Butanediol, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(k)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 10 grams or more of any of the following substances described in s. 893.03(1)(a) or (c):

a.3,4-Methylenedioxymethamphetamine (MDMA);

b.4-Bromo-2,5-dimethoxyamphetamine;

c.4-Bromo-2,5-dimethoxyphenethylamine;

d.2,5-Dimethoxyamphetamine;

e.2,5-Dimethoxy-4-ethylamphetamine (DOET);

f.N-ethylamphetamine;

g.N-Hydroxy-3,4-methylenedioxyamphetamine;

h.5-Methoxy-3,4-methylenedioxyamphetamine;

i.4-methoxyamphetamine;

j.4-methoxymethamphetamine;

k.4-Methyl-2,5-dimethoxyamphetamine;

l.3,4-Methylenedioxy-N-ethylamphetamine;

m.3,4-Methylenedioxyamphetamine;

n.N,N-dimethylamphetamine; or

o.3,4,5-Trimethoxyamphetamine,

individually or in any combination of or any mixture containing any substance listed in sub-subparagraphs a.-o., commits a felony of the first degree, which felony shall be known as "trafficking in Phenethylamines," punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

2.If the quantity involved:

a.Is 10 grams or more but less than 200 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 200 grams or more, but less than 400 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 400 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $250,000.

3.Any person who knowingly manufactures or brings into this state 30 kilograms or more of any of the following substances described in s. 893.03(1)(a) or (c):

a.3,4-Methylenedioxymethamphetamine (MDMA);

b.4-Bromo-2,5-dimethoxyamphetamine;

c.4-Bromo-2,5-dimethoxyphenethylamine;

d.2,5-Dimethoxyamphetamine;

e.2,5-Dimethoxy-4-ethylamphetamine (DOET);

f.N-ethylamphetamine;

g.N-Hydroxy-3,4-methylenedioxyamphetamine;

h.5-Methoxy-3,4-methylenedioxyamphetamine;

i.4-methoxyamphetamine;

j.4-methoxymethamphetamine;

k.4-Methyl-2,5-dimethoxyamphetamine;

l.3,4-Methylenedioxy-N-ethylamphetamine;

m.3,4-Methylenedioxyamphetamine;

n.N,N-dimethylamphetamine; or

o.3,4,5-Trimethoxyamphetamine,

individually or in any combination of or any mixture containing any substance listed in sub-subparagraphs a.-o., and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of Phenethylamines, a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(l)1.Any person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of, 1 gram or more of lysergic acid diethylamide (LSD) as described in s. 893.03(1)(c), or of any mixture containing lysergic acid diethylamide (LSD), commits a felony of the first degree, which felony shall be known as "trafficking in lysergic acid diethylamide (LSD)," punishable as provided in s. 775.082, s. 775.083, or s. 775.084. If the quantity involved:

a.Is 1 gram or more, but less than 5 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 3 years, and the defendant shall be ordered to pay a fine of $50,000.

b.Is 5 grams or more, but less than 7 grams, such person shall be sentenced to a mandatory minimum term of imprisonment of 7 years, and the defendant shall be ordered to pay a fine of $100,000.

c.Is 7 grams or more, such person shall be sentenced to a mandatory minimum term of imprisonment of 15 calendar years and pay a fine of $500,000.

2.Any person who knowingly manufactures or brings into this state 7 grams or more of lysergic

acid diethylamide (LSD) as described in s. 893.03(1)(c), or any mixture containing lysergic acid diethylamide (LSD), and who knows that the probable result of such manufacture or importation would be the death of any person commits capital manufacture or importation of lysergic acid diethylamide (LSD), a capital felony punishable as provided in ss. 775.082 and 921.142. Any person sentenced for a capital felony under this paragraph shall also be sentenced to pay the maximum fine provided under subparagraph 1.

(2)A person acts knowingly under subsection (1) if that person intends to sell, purchase, manufacture, deliver, or bring into this state, or to actually or constructively possess, any of the controlled substances listed in subsection (1), regardless of which controlled substance listed in subsection (1) is in fact sold, purchased, manufactured, delivered, or brought into this state, or actually or constructively possessed.

(3)Notwithstanding the provisions of s. 948.01, with respect to any person who is found to have violated this section, adjudication of guilt or imposition of sentence shall not be suspended, deferred, or withheld, nor shall such person be eligible for parole prior to serving the mandatory minimum term of imprisonment prescribed by this section. A person sentenced to a mandatory minimum term of imprisonment under this section is not eligible for any form of discretionary early release, except pardon or executive clemency or conditional medical release under s. 947.149, prior to serving the mandatory minimum term of imprisonment.

(4)The state attorney may move the sentencing court to reduce or suspend the sentence of any person who is convicted of a violation of this section and who provides substantial assistance in the identification, arrest, or conviction of any of that person's accomplices, accessories, coconspirators, or principals or of any other person engaged in trafficking in controlled substances. The arresting agency shall be given an opportunity to be heard in aggravation or mitigation in reference to any such motion. Upon good cause shown, the motion may be filed and heard in camera. The judge hearing the motion may reduce or suspend the sentence if the judge finds that the defendant rendered such substantial assistance.

(5)Any person who agrees, conspires, combines, or confederates with another person to commit any act prohibited by subsection (1) commits a felony of the first degree and is punishable as if he or she had actually committed such prohibited act. Nothing in this subsection shall be construed to prohibit separate convictions and sentences for a violation of this subsection and any violation of subsection (1).

(6)A mixture, as defined in s. 893.02, containing any controlled substance described in this section includes, but is not limited to, a solution or a dosage unit, including but not limited to, a pill or tablet, containing a controlled substance. For the purpose of clarifying legislative intent regarding the weighing of a mixture containing a controlled substance described in this section, the weight of the controlled substance is the total weight of the mixture, including the controlled

substance and any other substance in the mixture. If there is more than one mixture containing the same controlled substance, the weight of the controlled substance is calculated by aggregating the total weight of each mixture.

(7)For the purpose of further clarifying legislative intent, the Legislature finds that the opinion in *Hayes v. State*, 750 So. 2d 1 (Fla. 1999) does not correctly construe legislative intent. The Legislature finds that the opinions in *State v. Hayes*, 720 So. 2d 1095 (Fla. 4th DCA 1998) and *State v. Baxley*, 684 So. 2d 831 (Fla. 5th DCA 1996) correctly construe legislative intent.

History.—s. 1, ch. 79-1; s. 1, ch. 80-70; s. 2, ch. 80-353; s. 491, ch. 81-259; s. 1, ch. 82-2; s. 3, ch. 82-16; s. 53, ch. 83-215; s. 5, ch. 87-243; ss. 1, 4, ch. 89-281; s. 1, ch. 90-112; s. 3, ch. 93-92; s. 24, ch. 93-406; s. 15, ch. 95-184; s. 5, ch. 95-415; s. 54, ch. 96-388; s. 3, ch. 97-1; s. 1828, ch. 97-102; s. 23, ch. 97-194; s. 9, ch. 99-188; s. 4, ch. 2000-320; s. 2, ch. 2001-55; s. 7, ch. 2001-57; ss. 1, 2, 3, ch. 2002-212; s. 4, ch. 2003-10; s. 3, ch. 2005-128; s. 7, ch. 2008-184; s. 5, ch. 2011-73; s. 3, ch. 2011-90.

893.1351Ownership, lease, rental, or possession for trafficking in or manufacturing a controlled substance.—

(1)A person may not own, lease, or rent any place, structure, or part thereof, trailer, or other conveyance with the knowledge that the place, structure, trailer, or conveyance will be used for the purpose of trafficking in a controlled substance, as provided in s. 893.135; for the sale of a controlled substance, as provided in s. 893.13; or for the manufacture of a controlled substance intended for sale or distribution to another. A person who violates this subsection commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)A person may not knowingly be in actual or constructive possession of any place, structure, or part thereof, trailer, or other conveyance with the knowledge that the place, structure, or part thereof, trailer, or conveyance will be used for the purpose of trafficking in a controlled substance, as provided in s. 893.135; for the sale of a controlled substance, as provided in s. 893.13; or for the manufacture of a controlled substance intended for sale or distribution to another. A person who violates this subsection commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)A person who is in actual or constructive possession of a place, structure, trailer, or conveyance with the knowledge that the place, structure, trailer, or conveyance is being used to manufacture a controlled substance intended for sale or distribution to another and who knew or should have known that a minor is present or resides in the place, structure, trailer, or conveyance commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4)For the purposes of this section, proof of the possession of 25 or more cannabis plants constitutes prima facie evidence that the cannabis is intended for sale or distribution.

History.—s. 1, ch. 91-118; s. 10, ch. 99-188; s. 22, ch. 2000-320; s. 1, ch. 2002-212; s. 14, ch. 2005-128; s. 2, ch.

2008-184.

893.138Local administrative action to abate drug-related, prostitution-related, or stolen-property-related public nuisances and criminal gang activity.—

(1)It is the intent of this section to promote, protect, and improve the health, safety, and welfare of the citizens of the counties and municipalities of this state by authorizing the creation of administrative boards with authority to impose administrative fines and other noncriminal penalties in order to provide an equitable, expeditious, effective, and inexpensive method of enforcing ordinances in counties and municipalities under circumstances when a pending or repeated violation continues to exist.

(2)Any place or premises that has been used:

(a)On more than two occasions within a 6-month period, as the site of a violation of s. 796.07;

(b)On more than two occasions within a 6-month period, as the site of the unlawful sale, delivery, manufacture, or cultivation of any controlled substance;

(c)On one occasion as the site of the unlawful possession of a controlled substance, where such possession constitutes a felony and that has been previously used on more than one occasion as the site of the unlawful sale, delivery, manufacture, or cultivation of any controlled substance;

(d)By a criminal gang for the purpose of conducting criminal gang activity as defined by s. 874.03; or

(e)On more than two occasions within a 6-month period, as the site of a violation of s. 812.019 relating to dealing in stolen property

may be declared to be a public nuisance, and such nuisance may be abated pursuant to the procedures provided in this section.

(3)Any pain-management clinic, as described in s. 458.3265 or s. 459.0137, which has been used on more than two occasions within a 6-month period as the site of a violation of:

(a)Section 784.011, s. 784.021, s. 784.03, or s. 784.045, relating to assault and battery;

(b)Section 810.02, relating to burglary;

(c)Section 812.014, relating to dealing in theft;

(d)Section 812.131, relating to robbery by sudden snatching; or

(e)Section 893.13, relating to the unlawful distribution of controlled substances,

may be declared to be a public nuisance, and such nuisance may be abated pursuant to the procedures provided in this section.

(4)Any county or municipality may, by ordinance, create an administrative board to hear complaints regarding the nuisances described in subsection (2). Any employee, officer, or resident of the county or municipality may bring a complaint before the board after giving not less than 3 days' written notice of such complaint to the owner of the place or premises at his or her last known address. After a hearing in which the board may consider any evidence, including evidence

of the general reputation of the place or premises, and at which the owner of the premises shall have an opportunity to present evidence in his or her defense, the board may declare the place or premises to be a public nuisance as described in subsection (2).

(5)If the board declares a place or premises to be a public nuisance, it may enter an order requiring the owner of such place or premises to adopt such procedure as may be appropriate under the circumstances to abate any such nuisance or it may enter an order immediately prohibiting:

(a)The maintaining of the nuisance;

(b)The operating or maintaining of the place or premises, including the closure of the place or premises or any part thereof; or

(c)The conduct, operation, or maintenance of any business or activity on the premises which is conducive to such nuisance.

(6)An order entered under subsection (5) shall expire after 1 year or at such earlier time as is stated in the order.

(7)An order entered under subsection (5) may be enforced pursuant to the procedures contained in s. 120.69. This subsection does not subject a municipality that creates a board under this section, or the board so created, to any other provision of chapter 120.

(8)The board may bring a complaint under s. 60.05 seeking temporary and permanent injunctive relief against any nuisance described in subsection (2).

(9)This section does not restrict the right of any person to proceed under s. 60.05 against any public nuisance.

(10)As used in this section, the term “controlled substance” includes any substance sold in lieu of a controlled substance in violation of s. 817.563 or any imitation controlled substance defined in s. 817.564.

(11)The provisions of this section may be supplemented by a county or municipal ordinance. The ordinance may include, but is not limited to, provisions that establish additional penalties for public nuisances, including fines not to exceed $250 per day; provide for the payment of reasonable costs, including reasonable attorney fees associated with investigations of and hearings on public nuisances; provide for continuing jurisdiction for a period of 1 year over any place or premises that has been or is declared to be a public nuisance; establish penalties, including fines not to exceed $500 per day for recurring public nuisances; provide for the recording of orders on public nuisances so that notice must be given to subsequent purchasers, successors in interest, or assigns of the real property that is the subject of the order; provide that recorded orders on public nuisances may become liens against the real property that is the subject of the order; and provide for the foreclosure of property subject to a lien and the recovery of all costs, including reasonable attorney fees, associated with the recording of orders and foreclosure. No lien created pursuant to

the provisions of this section may be foreclosed on real property which is a homestead under s. 4, Art. X of the State Constitution. Where a local government seeks to bring an administrative action, based on a stolen property nuisance, against a property owner operating an establishment where multiple tenants, on one site, conduct their own retail business, the property owner shall not be subject to a lien against his or her property or the prohibition of operation provision if the property owner evicts the business declared to be a nuisance within 90 days after notification by registered mail to the property owner of a second stolen property conviction of the tenant. The total fines imposed pursuant to the authority of this section shall not exceed $15,000. Nothing contained within this section prohibits a county or municipality from proceeding against a public nuisance by any other means.

History.—s. 7, ch. 87-243; s. 2, ch. 90-207; s. 1, ch. 91-143; s. 6, ch. 93-227; s. 1, ch. 94-242; s. 42, ch. 96-388; s. 1829, ch. 97-102; s. 1, ch. 97-200; s. 2, ch. 98-395; s. 1, ch. 2000-111; s. 5, ch. 2001-66; s. 24, ch. 2008-238; s. 27, ch. 2011-141; s. 87, ch. 2012-5.

893.145"Drug paraphernalia" defined.—The term "drug paraphernalia" means all equipment, products, and materials of any kind which are used, intended for use, or designed for use in planting, propagating, cultivating, growing, harvesting, manufacturing, compounding, converting, producing, processing, preparing, testing, analyzing, packaging, repackaging, storing, containing, concealing, transporting, injecting, ingesting, inhaling, or otherwise introducing into the human body a controlled substance in violation of this chapter or s. 877.111. Drug paraphernalia is deemed to be contraband which shall be subject to civil forfeiture. The term includes, but is not limited to:

(1)Kits used, intended for use, or designed for use in the planting, propagating, cultivating, growing, or harvesting of any species of plant which is a controlled substance or from which a controlled substance can be derived.

(2)Kits used, intended for use, or designed for use in manufacturing, compounding, converting, producing, processing, or preparing controlled substances.

(3)Isomerization devices used, intended for use, or designed for use in increasing the potency of any species of plant which is a controlled substance.

(4)Testing equipment used, intended for use, or designed for use in identifying, or in analyzing the strength, effectiveness, or purity of, controlled substances.

(5)Scales and balances used, intended for use, or designed for use in weighing or measuring controlled substances.

(6)Diluents and adulterants, such as quinine hydrochloride, mannitol, mannite, dextrose, and lactose, used, intended for use, or designed for use in cutting controlled substances.

(7)Separation gins and sifters used, intended for use, or designed for use in removing twigs and seeds from, or in otherwise cleaning or refining, cannabis.

(8)Blenders, bowls, containers, spoons, and mixing devices used, intended for use, or designed for use in compounding controlled substances.

(9)Capsules, balloons, envelopes, and other containers used, intended for use, or designed for use in packaging small quantities of controlled substances.

(10)Containers and other objects used, intended for use, or designed for use in storing, concealing, or transporting controlled substances.

(11)Hypodermic syringes, needles, and other objects used, intended for use, or designed for use in parenterally injecting controlled substances into the human body.

(12)Objects used, intended for use, or designed for use in ingesting, inhaling, or otherwise introducing cannabis, cocaine, hashish, hashish oil, or nitrous oxide into the human body, such as:

(a)Metal, wooden, acrylic, glass, stone, plastic, or ceramic pipes, with or without screens, permanent screens, hashish heads, or punctured metal bowls.

(b)Water pipes.

(c)Carburetion tubes and devices.

(d)Smoking and carburetion masks.

(e)Roach clips: meaning objects used to hold burning material, such as a cannabis cigarette, that has become too small or too short to be held in the hand.

(f)Miniature cocaine spoons, and cocaine vials.

(g)Chamber pipes.

(h)Carburetor pipes.

(i)Electric pipes.

(j)Air-driven pipes.

(k)Chillums.

(l)Bongs.

(m)Ice pipes or chillers.

(n)A cartridge or canister, which means a small metal device used to contain nitrous oxide.

(o)A charger, sometimes referred to as a “cracker,” which means a small metal or plastic device that contains an interior pin that may be used to expel nitrous oxide from a cartridge or container.

(p)A charging bottle, which means a device that may be used to expel nitrous oxide from a cartridge or canister.

(q)A whip-it, which means a device that may be used to expel nitrous oxide.

(r)A tank.

(s)A balloon.

(t)A hose or tube.

(u)A 2-liter-type soda bottle.

(v)Duct tape.

History.—s. 1, ch. 80-30; s. 6, ch. 2000-320; s. 15, ch. 2000-360.

893.146Determination of paraphernalia.—In determining whether an object is drug paraphernalia, a court or other authority or jury shall consider, in addition to all other logically relevant factors, the following:

(1)Statements by an owner or by anyone in control of the object concerning its use.

(2)The proximity of the object, in time and space, to a direct violation of this act.

(3)The proximity of the object to controlled substances.

(4)The existence of any residue of controlled substances on the object.

(5)Direct or circumstantial evidence of the intent of an owner, or of anyone in control of the object, to deliver it to persons who he or she knows, or should reasonably know, intend to use the object to facilitate a violation of this act. The innocence of an owner, or of anyone in control of the object, as to a direct violation of this act shall not prevent a finding that the object is intended for use, or designed for use, as drug paraphernalia.

(6)Instructions, oral or written, provided with the object concerning its use.

(7)Descriptive materials accompanying the object which explain or depict its use.

(8)Any advertising concerning its use.

(9)The manner in which the object is displayed for sale.

(10)Whether the owner, or anyone in control of the object, is a legitimate supplier of like or related items to the community, such as a licensed distributor of or dealer in tobacco products.

(11)Direct or circumstantial evidence of the ratio of sales of the object or objects to the total sales of the business enterprise.

(12)The existence and scope of legitimate uses for the object in the community.

(13)Expert testimony concerning its use.

History.—s. 2, ch. 80-30; s. 1445, ch. 97-102.

893.147Use, possession, manufacture, delivery, transportation, or advertisement of drug paraphernalia.—

(1)USE OR POSSESSION OF DRUG PARAPHERNALIA.—It is unlawful for any person to use, or to possess with intent to use, drug paraphernalia:

(a)To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of this chapter; or

(b)To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this chapter.

Any person who violates this subsection is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(2)MANUFACTURE OR DELIVERY OF DRUG PARAPHERNALIA.—It is unlawful for any person to deliver, possess with intent to deliver, or manufacture with intent to deliver drug paraphernalia, knowing, or under circumstances where one reasonably should know, that it will be used:

(a)To plant, propagate, cultivate, grow, harvest, manufacture, compound, convert, produce, process, prepare, test, analyze, pack, repack, store, contain, or conceal a controlled substance in violation of this act; or

(b)To inject, ingest, inhale, or otherwise introduce into the human body a controlled substance in violation of this act.

Any person who violates this subsection is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)DELIVERY OF DRUG PARAPHERNALIA TO A MINOR.—

(a)Any person 18 years of age or over who violates subsection (2) by delivering drug paraphernalia to a person under 18 years of age is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)It is unlawful for any person to sell or otherwise deliver hypodermic syringes, needles, or other objects which may be used, are intended for use, or are designed for use in parenterally injecting substances into the human body to any person under 18 years of age, except that hypodermic syringes, needles, or other such objects may be lawfully dispensed to a person under 18 years of age by a licensed practitioner, parent, or legal guardian or by a pharmacist pursuant to a valid prescription for same. Any person who violates the provisions of this paragraph is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4)TRANSPORTATION OF DRUG PARAPHERNALIA.—It is unlawful to use, possess with the intent to use, or manufacture with the intent to use drug paraphernalia, knowing or under circumstances in which one reasonably should know that it will be used to transport:

(a)A controlled substance in violation of this chapter; or

(b)Contraband as defined in s. 932.701(2)(a)1.

Any person who violates this subsection commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5)ADVERTISEMENT OF DRUG PARAPHERNALIA.—It is unlawful for any person to place in any newspaper, magazine, handbill, or other publication any advertisement, knowing, or under circumstances where one reasonably should know, that the purpose of the advertisement, in whole or in part, is to promote the sale of objects designed or intended for use as drug paraphernalia. Any person who violates this subsection is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

History.—s. 3, ch. 80-30; s. 1, ch. 81-149; s. 54, ch. 83-215; s. 1, ch. 85-8; s. 223, ch. 91-224; s. 16, ch. 2000-360.

893.149Unlawful possession of listed chemical.—

(1)It is unlawful for any person to knowingly or intentionally:

(a)Possess a listed chemical with the intent to unlawfully manufacture a controlled substance;

(b)Possess or distribute a listed chemical knowing, or having reasonable cause to believe, that the listed chemical will be used to unlawfully manufacture a controlled substance.

(2)Any person who violates this section commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)This section does not apply to a public employee or private contractor authorized to clean up or dispose of hazardous waste or toxic substances resulting from the prohibited activities listed in s. 893.13(1)(g).

(4)Any damages arising out of the unlawful possession of, storage of, or tampering with a listed chemical, as defined in s. 893.033, shall be the sole responsibility of the person or persons unlawfully possessing, storing, or tampering with the listed chemical. In no case shall liability for damages arising out of the unlawful possession of, storage of, or tampering with a listed chemical extend to the lawful owner, installer, maintainer, designer, manufacturer, possessor, or seller of the listed chemical, unless such damages arise out of the acts or omissions of the owner, installer, maintainer, designer, manufacturer, possessor, or seller which constitute negligent misconduct or failure to abide by the laws regarding the possession or storage of a listed chemical.

History.—s. 5, ch. 91-279; s. 3, ch. 2003-15; s. 4, ch. 2005-128.

893.1495Retail sale of ephedrine and related compounds.—

(1)For purposes of this section, the term "ephedrine or related compounds" means ephedrine, pseudoephedrine, phenylpropanolamine, or any of their salts, optical isomers, or salts of optical isomers.

(2)A person may not knowingly obtain or deliver to an individual in any retail over-the-counter sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds in excess of the following amounts:

(a)In any single day, any number of packages that contain a total of 3.6 grams of ephedrine or related compounds;

(b)In any single retail, over-the-counter sale, three packages, regardless of weight, containing ephedrine or related compounds; or

(c)In any 30-day period, in any number of retail, over-the-counter sales, a total of 9 grams or more of ephedrine or related compounds.

(3)A person may not knowingly display and offer for retail sale any nonprescription compound, mixture, or preparation containing ephedrine or related compounds other than behind a checkout counter where the public is not permitted or other such location that is not otherwise accessible to the general public.

(4)A person who is the owner or primary operator of a retail outlet where any nonprescription

compound, mixture, or preparation containing ephedrine or related compounds is available for sale may not knowingly allow an employee to engage in the retail sale of such compound, mixture, or preparation unless the employee has completed an employee training program that shall include, at a minimum, basic instruction on state and federal regulations relating to the sale and distribution of such compounds, mixtures, or preparations.

(5)(a)Any person purchasing, receiving, or otherwise acquiring any nonprescription compound, mixture, or preparation containing any detectable quantity of ephedrine or related compounds must:

1.Be at least 18 years of age.

2.Produce a government-issued photo identification showing his or her name, date of birth, address, and photo identification number or an alternative form of identification acceptable under federal regulation 8 C.F.R. s. 274a.2(b)(1)(v)(A) and (B).

3.Sign his or her name on a record of the purchase, either on paper or on an electronic signature capture device.

(b)The Department of Law Enforcement shall approve an electronic recordkeeping system for the purpose of recording and monitoring the real-time purchase of products containing ephedrine or related compounds and for the purpose of monitoring this information in order to prevent or investigate illegal purchases of these products. The approved electronic recordkeeping system shall be provided to a pharmacy or retailer without any additional cost or expense. A pharmacy or retailer may request an exemption from electronic reporting from the Department of Law Enforcement if the pharmacy or retailer lacks the technology to access the electronic recordkeeping system and such pharmacy or retailer maintains a sales volume of less than 72 grams of ephedrine or related compounds in a 30-day period. The electronic recordkeeping system shall record the following:

1.The date and time of the transaction.

2.The name, date of birth, address, and photo identification number of the purchaser, as well as the type of identification and the government of issuance.

3.The number of packages purchased, the total grams per package, and the name of the compound, mixture, or preparation containing ephedrine or related compounds.

4.The signature of the purchaser, or a unique number relating the transaction to a paper signature maintained at the retail premises.

(c)The electronic recordkeeping system shall provide for:

1.Real-time tracking of nonprescription over-the-counter sales under this section.

2.The blocking of nonprescription over-the-counter sales in excess of those allowed by the laws of this state or federal law.

(6)A nonprescription compound, mixture, or preparation containing any quantity of ephedrine

or related compounds may not be sold over the counter unless reported to an electronic recordkeeping system approved by the Department of Law Enforcement. This subsection does not apply if the pharmacy or retailer has received an exemption from the Department of Law Enforcement under paragraph (5)(b).

(7)Prior to completing a transaction, a pharmacy or retailer distributing products containing ephedrine or related compounds to consumers in this state shall submit all required data into an electronic recordkeeping system approved by the Department of Law Enforcement at the point of sale or through an interface with the electronic recordkeeping system, unless granted an exemption by the Department of Law Enforcement pursuant to paragraph (5)(b).

(8)The data submitted to the electronic recordkeeping system must be retained within the system for no less than 2 years following the date of entry.

(9)The requirements of this section relating to the marketing, sale, or distribution of products containing ephedrine or related compounds supersede any local ordinance or regulation passed by a county, municipality, or other local governmental authority.

(10)This section does not apply to:

(a)Licensed manufacturers manufacturing and lawfully distributing products in the channels of commerce.

(b)Wholesalers lawfully distributing products in the channels of commerce.

(c)Health care facilities licensed under chapter 395.

(d)Licensed long-term care facilities.

(e)Government-operated health departments.

(f)Physicians' offices.

(g)Publicly operated prisons, jails, or juvenile correctional facilities or private adult or juvenile correctional facilities under contract with the state.

(h)Public or private educational institutions maintaining health care programs.

(i)Government-operated or industry-operated medical facilities serving employees of the government or industry operating them.

(11)Any individual who violates subsection (2), subsection (3), or subsection (4) commits:

(a)For a first offense, a misdemeanor of the second degree, punishable as provided in s. 775.083.

(b)For a second offense, a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(c)For a third or subsequent offense, a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(12)Information contained within the electronic recordkeeping system shall be disclosed in a manner authorized by state or federal law. Any retailer or entity that collects information on

behalf of a retailer as required by the Combat Methamphetamine Epidemic Act of 2005 and this section may not access or use that information, except for law enforcement purposes pursuant to state or federal law or to facilitate a product recall for public health and safety.

(13)A person who sells any product containing ephedrine or related compounds who in good faith releases information under this section to federal, state, or local law enforcement officers, or any person acting on behalf of such an officer, is immune from civil liability for the release unless the release constitutes gross negligence or intentional, wanton, or willful misconduct.

(14)The Department of Law Enforcement shall contract or enter into a memorandum of understanding, as applicable, with a private third-party administrator to implement the electronic recordkeeping system required by this section.

(15)The Department of Law Enforcement shall adopt rules necessary to implement this section.

History.—s. 5, ch. 2005-128; s. 1, ch. 2010-191.

893.15Rehabilitation.—Any person who violates s. 893.13(6)(a) or (b) relating to possession may, in the discretion of the trial judge, be required to participate in a substance abuse services program approved or regulated by the Department of Children and Family Services pursuant to the provisions of chapter 397, provided the director of such program approves the placement of the defendant in such program. Such required participation shall be imposed in addition to any penalty or probation otherwise prescribed by law. However, the total time of such penalty, probation, and program participation shall not exceed the maximum length of sentence possible for the offense.

History.—s. 15, ch. 73-331; s. 46, ch. 91-110; s. 40, ch. 93-39; s. 3, ch. 94-107; s. 39, ch. 97-194; s. 304, ch. 99-8.

893.165County alcohol and other drug abuse treatment or education trust funds.—

(1)Counties in which there is established or in existence a comprehensive alcohol and other drug abuse treatment or education program which meets the standards for qualification of such programs by the Department of Children and Family Services are authorized to establish a County Alcohol and Other Drug Abuse Trust Fund for the purpose of receiving the assessments collected pursuant to s. 938.23 and disbursing assistance grants on an annual basis to such alcohol and other drug abuse treatment or education program.

(2)Assessments collected by the clerks of court pursuant to s. 938.23 shall be remitted to the board of county commissioners of the county in which the indictment was found or the prosecution commenced for payment into the County Alcohol and Other Drug Abuse Trust Fund. The county commissioners shall require a full report from all clerks of county courts and clerks of circuit courts once each month of the amount of assessments imposed by their courts.

(3)(a)No county shall receive assessments collected pursuant to s. 938.23 in an amount exceeding that county's jurisdictional share as described in subsection (2).

(b)Assessments collected by clerks of circuit courts having more than one county in the

circuit, for any county in the circuit which does not have a County Alcohol and Other Drug Abuse Trust Fund, shall be remitted to the Department of Children and Family Services, in accordance with administrative rules adopted, for deposit into the department's Grants and Donations Trust Fund for distribution pursuant to the guidelines and priorities developed by the department.

(4)No assessments shall be remitted to a county until the board of county commissioners has submitted documentation to the court substantiating the establishment of its County Alcohol and Other Drug Abuse Trust Fund.

(5)If the board of county commissioners chooses to establish a County Alcohol and Other Drug Abuse Trust Fund, the board shall be responsible for the establishment of such fund and its implementation, administration, supervision, and evaluation.

(6)In order to receive assistance grants from the County Alcohol and Other Drug Abuse Trust Fund, county alcohol and other drug abuse prevention, treatment, or education programs shall be designated by the board of county commissioners as the chosen program recipients. Designations shall be made annually, based on success of the programs.

(7)An alcohol and other drug abuse treatment or education program recipient shall, in seeking assistance grants from the County Alcohol and Other Drug Abuse Trust Fund, provide the board of county commissioners with detailed financial information and requests for expenditures.

History.—s. 4, ch. 88-381; s. 3, ch. 93-194; s. 37, ch. 97-271; s. 305, ch. 99-8; s. 5, ch. 2009-47.

893.20Continuing criminal enterprise.—

(1)Any person who commits three or more felonies under this chapter in concert with five or more other persons with respect to whom such person occupies a position of organizer, a supervisory position, or any other position of management and who obtains substantial assets or resources from these acts is guilty of engaging in a continuing criminal enterprise.

(2)A person who commits the offense of engaging in a continuing criminal enterprise is guilty of a life felony, punishable pursuant to the Criminal Punishment Code and by a fine of $500,000.

(3)Notwithstanding the provisions of s. 948.01, with respect to any person who is found to have violated this section, adjudication of guilt or imposition of sentence may not be suspended, deferred, or withheld.

(4)This section does not prohibit separate convictions and sentences for violation of this section and for felony violations of this chapter.

(5)This section must be interpreted in concert with its federal analog, 21 U.S.C. s. 848.

History.—s. 1, ch. 89-145; s. 25, ch. 93-406; s. 24, ch. 97-194.

893.21Drug-related overdoses; medical assistance; immunity from prosecution.—

(1)A person acting in good faith who seeks medical assistance for an individual experiencing a drug-related overdose may not be charged, prosecuted, or penalized pursuant to this chapter for possession of a controlled substance if the evidence for possession of a controlled substance was

obtained as a result of the person's seeking medical assistance.

(2)A person who experiences a drug-related overdose and is in need of medical assistance may not be charged, prosecuted, or penalized pursuant to this chapter for possession of a controlled substance if the evidence for possession of a controlled substance was obtained as a result of the overdose and the need for medical assistance.

(3)Protection in this section from prosecution for possession offenses under this chapter may not be grounds for suppression of evidence in other criminal prosecutions.

History.—s. 2, ch. 2012-36

Title XXXII

REGULATION OF PROFESSIONS AND OCCUPATIONS

CHAPTER 456

HEALTH PROFESSIONS AND OCCUPATIONS: GENERAL PROVISIONS

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45 6.001Definitions.—As used in this chapter, the term:

(1)"Board" means any board or commission, or other statutorily created entity to the extent such entity is authorized to exercise regulatory or rulemaking functions, within the department, except that, for ss. 456.003-456.018, 456.022, 456.023, 456.025-456.034, and 456.039-456.082, "board" means only a board, or other statutorily created entity to the extent such entity is authorized to exercise regulatory or rulemaking functions, within the Division of Medical Quality Assurance.

(2)"Consumer member" means a person appointed to serve on a specific board or who has served on a specific board, who is not, and never has been, a member or practitioner of the profession, or of any closely related profession, regulated by such board.

(3)“Department” means the Department of Health.

(4)“Health care practitioner” means any person licensed under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 462; chapter 463; chapter 464; chapter 465; chapter 466; chapter 467; part I, part II, part III, part V, part X, part XIII, or part XIV of chapter 468; chapter 478; chapter 480; part III or part IV of chapter 483; chapter 484; chapter 486; chapter 490; or chapter 491.

(5)“License” means any permit, registration, certificate, or license, including a provisional license, issued by the department.

(6)“Licensee” means any person or entity issued a permit, registration, certificate, or license, including a provisional license, by the department.

(7)“Profession” means any activity, occupation, profession, or vocation regulated by the department in the Division of Medical Quality Assurance.

History.—s. 33, ch. 97-261; s. 72, ch. 99-397; s. 36, ch. 2000-160; s. 2, ch. 2002-199.

Note.—Former s. 455.501.

456.002Applicability.—This chapter applies only to the regulation by the department of professions.

History.—s. 34, ch. 97-261; s. 37, ch. 2000-160.

Note.—Former s. 455.504.

456.003Legislative intent; requirements.—

(1)It is the intent of the Legislature that persons desiring to engage in any lawful profession regulated by the department shall be entitled to do so as a matter of right if otherwise qualified.

(2)The Legislature further believes that such professions shall be regulated only for the preservation of the health, safety, and welfare of the public under the police powers of the state. Such professions shall be regulated when:

(a)Their unregulated practice can harm or endanger the health, safety, and welfare of the public, and when the potential for such harm is recognizable and clearly outweighs any anticompetitive impact which may result from regulation.

(b)The public is not effectively protected by other means, including, but not limited to, other state statutes, local ordinances, or federal legislation.

(c)Less restrictive means of regulation are not available.

(3)It is further legislative intent that the use of the term “profession” with respect to those activities licensed and regulated by the department shall not be deemed to mean that such activities are not occupations for other purposes in state or federal law.

(4)(a)Neither the department nor any board may create unreasonably restrictive and extraordinary standards that deter qualified persons from entering the various professions. Neither the department nor any board may take any action that tends to create or maintain an economic condition that unreasonably restricts competition, except as specifically provided by law.

(b)Neither the department nor any board may create a regulation that has an unreasonable effect on job creation or job retention in the state or that places unreasonable restrictions on the ability of individuals who seek to practice or who are practicing a profession or occupation to find employment.

(c)The Legislature shall evaluate proposals to increase the regulation of regulated professions or occupations to determine the effect of increased regulation on job creation or retention and employment opportunities.

(5)Policies adopted by the department shall ensure that all expenditures are made in the most cost-effective manner to maximize competition, minimize licensure costs, and maximize public access to meetings conducted for the purpose of professional regulation. The long-range planning function of the department shall be implemented to facilitate effective operations and to eliminate inefficiencies.

(6)Unless expressly and specifically granted in statute, the duties conferred on the boards do not include the enlargement, modification, or contravention of the lawful scope of practice of the profession regulated by the boards. This subsection shall not prohibit the boards, or the department when there is no board, from taking disciplinary action or issuing a declaratory statement.

History.—s. 38, ch. 97-261; s. 135, ch. 99-251; s. 38, ch. 2000-160; s. 57, ch. 2001-277.

Note.—Former s. 455.517.

456.004Department; powers and duties.—The department, for the professions under its jurisdiction, shall:

(1)Adopt rules establishing a procedure for the biennial renewal of licenses; however, the department may issue up to a 4-year license to selected licensees notwithstanding any other provisions of law to the contrary. The rules shall specify the expiration dates of licenses and the process for tracking compliance with continuing education requirements, financial responsibility requirements, and any other conditions of renewal set forth in statute or rule. Fees for such renewal shall not exceed the fee caps for individual professions on an annualized basis as authorized by law.

(2)Appoint the executive director of each board, subject to the approval of the board.

(3)Submit an annual budget to the Legislature at a time and in the manner provided by law.

(4)Develop a training program for persons newly appointed to membership on any board. The program shall familiarize such persons with the substantive and procedural laws and rules and fiscal information relating to the regulation of the appropriate profession and with the structure of the department.

(5)Adopt rules pursuant to ss. 120.536(1) and 120.54 to implement the provisions of this chapter.

(6)Establish by rules procedures by which the department shall use the expert or technical advice of the appropriate board for the purposes of investigation, inspection, evaluation of applications, other duties of the department, or any other areas the department may deem appropriate.

(7)Require all proceedings of any board or panel thereof and all formal or informal proceedings conducted by the department, an administrative law judge, or a hearing officer with respect to

licensing or discipline to be electronically recorded in a manner sufficient to assure the accurate transcription of all matters so recorded.

(8)Select only those investigators, or consultants who undertake investigations, who meet criteria established with the advice of the respective boards.

(9)Work cooperatively with the Department of Revenue to establish an automated method for periodically disclosing information relating to current licensees to the Department of Revenue, the state's Title IV-D agency. The purpose of this subsection is to promote the public policy of this state relating to child support as established in s. 409.2551. The department shall, when directed by the court or the Department of Revenue pursuant to s. 409.2598, suspend or deny the license of any licensee found not to be in compliance with a support order, a subpoena, an order to show cause, or a written agreement with the Department of Revenue. The department shall issue or reinstate the license without additional charge to the licensee when notified by the court or the Department of Revenue that the licensee has complied with the terms of the support order. The department is not liable for any license denial or suspension resulting from the discharge of its duties under this subsection.

(10)Set an examination fee that includes all costs to develop, purchase, validate, administer, and defend the examination and is an amount certain to cover all administrative costs plus the actual per-applicant cost of the examination.

(11)Work cooperatively with the Agency for Health Care Administration and the judicial system to recover Medicaid overpayments by the Medicaid program. The department shall investigate and prosecute health care practitioners who have not remitted amounts owed to the state for an overpayment from the Medicaid program pursuant to a final order, judgment, or stipulation or settlement.

History.—s. 39, ch. 97-261; s. 118, ch. 98-200; s. 74, ch. 99-397; s. 39, ch. 2000-160; s. 52, ch. 2001-158; s. 5, ch. 2001-277; s. 6, ch. 2008-92; s. 21, ch. 2009-223.

Note.—Former s. 455.521.

456.005Long-range policy planning.—To facilitate efficient and cost-effective regulation, the department and the board, if appropriate, shall develop and implement a long-range policy planning and monitoring process that includes recommendations specific to each profession. The process shall include estimates of revenues, expenditures, cash balances, and performance statistics for each profession. The period covered may not be less than 5 years. The department, with input from the boards and licensees, shall develop and adopt the long-range plan. The department shall monitor compliance with the plan and, with input from the boards and licensees, shall annually update the plans. The department shall provide concise management reports to the boards quarterly. As part of the review process, the department shall evaluate:

(1)Whether the department, including the boards and the various functions performed by the

department, is operating efficiently and effectively and if there is a need for a board or council to assist in cost-effective regulation.

(2)How and why the various professions are regulated.

(3)Whether there is a need to continue regulation, and to what degree.

(4)Whether or not consumer protection is adequate, and how it can be improved.

(5)Whether there is consistency between the various practice acts.

(6)Whether unlicensed activity is adequately enforced.

The plans shall include conclusions and recommendations on these and other issues as appropriate.

History.—s. 40, ch. 97-261; s. 40, ch. 2000-160; s. 61, ch. 2008-6; s. 148, ch. 2010-102.

Note.—Former s. 455.524.

456.006Contacting boards through department.—Each board under the jurisdiction of the department may be contacted through the headquarters of the department in the City of Tallahassee.

History.—s. 41, ch. 97-261; s. 40, ch. 2000-160.

Note.—Former s. 455.527.

456.007Board members.—Notwithstanding any provision of law to the contrary, any person who otherwise meets the requirements of law for board membership and who is connected in any way with any medical college, dental college, or community college may be appointed to any board so long as that connection does not result in a relationship wherein such college represents the person's principal source of income. However, this section shall not apply to the physicians required by s. 458.307(2) to be on the faculty of a medical school in this state or on the full-time staff of a teaching hospital in this state.

History.—s. 2, ch. 84-161; s. 1, ch. 84-271; s. 3, ch. 88-392; s. 42, ch. 97-261; s. 17, ch. 97-264; s. 40, ch. 2000-160.

Note.—Former s. 455.206; s. 455.531.

456.008Accountability and liability of board members.—

(1)Each board member shall be accountable to the Governor for the proper performance of duties as a member of the board. The Governor shall investigate any legally sufficient complaint or unfavorable written report received by the Governor or by the department or a board concerning the actions of the board or its individual members. The Governor may suspend from office any board member for malfeasance, misfeasance, neglect of duty, drunkenness, incompetence, permanent inability to perform his or her official duties, or commission of a felony.

(2)Each board member and each former board member serving on a probable cause panel shall be exempt from civil liability for any act or omission when acting in the member's official capacity, and the department shall defend any such member in any action against any board or member of a board arising from any such act or omission. In addition, the department may defend the member's company or business in any action against the company or business if the department determines that the

actions from which the suit arises are actions taken by the member in the member's official capacity and were not beyond the member's statutory authority. In providing such defense, the department may employ or utilize the legal services of the Department of Legal Affairs or outside counsel retained pursuant to s. 287.059. Fees and costs of providing legal services provided under this subsection shall be paid from a trust fund used by the department to implement this chapter, subject to the provisions of s. 456.025.

History.—s. 45, ch. 97-261; s. 21, ch. 99-7; s. 153, ch. 99-251; s. 41, ch. 2000-160.

Note.—Former s. 455.541.

456.009Legal and investigative services.—

(1)The department shall provide board counsel for boards within the department by contracting with the Department of Legal Affairs, by retaining private counsel pursuant to s. 287.059, or by providing department staff counsel. The primary responsibility of board counsel shall be to represent the interests of the citizens of the state. A board shall provide for the periodic review and evaluation of the services provided by its board counsel. Fees and costs of such counsel shall be paid from a trust fund used by the department to implement this chapter, subject to the provisions of s. 456.025. All contracts for independent counsel shall provide for periodic review and evaluation by the board and the department of services provided.

(2)The department may employ or use the legal services of outside counsel and the investigative services of outside personnel. However, no attorney employed or utilized by the department shall prosecute a matter and provide legal services to the board with respect to the same matter.

(3)Any person retained by the department under contract to review materials, make site visits, or provide expert testimony regarding any complaint or application filed with the department relating to a profession under the jurisdiction of the department shall be considered an agent of the department in determining the state insurance coverage and sovereign immunity protection applicability of ss. 284.31 and 768.28.

History.—s. 60, ch. 97-261; s. 154, ch. 99-251; s. 42, ch. 2000-160.

Note.—Former s. 455.594.

456.011Boards; organization; meetings; compensation and travel expenses.—

(1)Each board within the department shall comply with the provisions of this chapter.

(2)The board shall annually elect from among its number a chairperson and vice chairperson.

(3)The board shall meet at least once annually and may meet as often as is necessary. Meetings shall be conducted through teleconferencing or other technological means, unless disciplinary hearings involving standard of care, sexual misconduct, fraud, impairment, or felony convictions; licensure denial hearings; or controversial rule hearings are being conducted; or unless otherwise approved in advance of the meeting by the director of the Division of Medical Quality Assurance. The chairperson or a quorum of the board shall have the authority to call meetings, except as provided above relating to

in-person meetings. A quorum shall be necessary for the conduct of official business by the board or any committee thereof. Unless otherwise provided by law, 51 percent or more of the appointed members of the board or any committee, when applicable, shall constitute a quorum. The membership of committees of the board, except as otherwise authorized pursuant to this chapter or the applicable practice act, shall be composed of currently appointed members of the board. The vote of a majority of the members of the quorum shall be necessary for any official action by the board or committee. Three consecutive unexcused absences or absences constituting 50 percent or more of the board's meetings within any 12-month period shall cause the board membership of the member in question to become void, and the position shall be considered vacant. The board, or the department when there is no board, shall, by rule, define unexcused absences.

(4)Unless otherwise provided by law, a board member or former board member serving on a probable cause panel shall be compensated $50 for each day in attendance at an official meeting of the board and for each day of participation in any other business involving the board. Each board shall adopt rules defining the phrase "other business involving the board," but the phrase may not routinely be defined to include telephone conference calls that last less than 4 hours. A board member also shall be entitled to reimbursement for expenses pursuant to s. 112.061. Travel out of state shall require the prior approval of the State Surgeon General.

(5)When two or more boards have differences between them, the boards may elect to, or the State Surgeon General may request that the boards, establish a special committee to settle those differences. The special committee shall consist of three members designated by each board, who may be members of the designating board or other experts designated by the board, and of one additional person designated and agreed to by the members of the special committee. In the event the special committee cannot agree on the additional designee, upon request of the special committee, the State Surgeon General may select the designee. The committee shall recommend rules necessary to resolve the differences. If a rule adopted pursuant to this provision is challenged, the participating boards shall share the costs associated with defending the rule or rules. The department shall provide legal representation for any special committee established pursuant to this section.

History.—s. 43, ch. 97-261; s. 43, ch. 2000-160; s. 10, ch. 2001-277; s. 62, ch. 2008-6.

Note.—Former s. 455.534.

456.012Board rules; final agency action; challenges.—

(1)The State Surgeon General shall have standing to challenge any rule or proposed rule of a board under its jurisdiction pursuant to s. 120.56. In addition to challenges for any invalid exercise of delegated legislative authority, the administrative law judge, upon such a challenge by the State Surgeon General, may declare all or part of a rule or proposed rule invalid if it:

(a)Does not protect the public from any significant and discernible harm or damages;

(b)Unreasonably restricts competition or the availability of professional services in the state or in a

significant part of the state; or

(c)Unnecessarily increases the cost of professional services without a corresponding or equivalent public benefit.

However, there shall not be created a presumption of the existence of any of the conditions cited in this subsection in the event that the rule or proposed rule is challenged.

(2)In addition, either the State Surgeon General or the board shall be a substantially interested party for purposes of s. 120.54(7). The board may, as an adversely affected party, initiate and maintain an action pursuant to s. 120.68 challenging the final agency action.

(3)No board created within the department shall have standing to challenge a rule or proposed rule of another board. However, if there is a dispute between boards concerning a rule or proposed rule, the boards may avail themselves of the provisions of s. 456.011(5).

History.—s. 46, ch. 97-261; s. 44, ch. 2000-160; s. 63, ch. 2008-6.

Note.—Former s. 455.544.

456.013Department; general licensing provisions.—

(1)(a)Any person desiring to be licensed in a profession within the jurisdiction of the department shall apply to the department in writing to take the licensure examination. The application shall be made on a form prepared and furnished by the department. The application form must be available on the World Wide Web and the department may accept electronically submitted applications beginning July 1, 2001. The application shall require the social security number of the applicant, except as provided in paragraph (b). The form shall be supplemented as needed to reflect any material change in any circumstance or condition stated in the application which takes place between the initial filing of the application and the final grant or denial of the license and which might affect the decision of the department. If an application is submitted electronically, the department may require supplemental materials, including an original signature of the applicant and verification of credentials, to be submitted in a nonelectronic format. An incomplete application shall expire 1 year after initial filing. In order to further the economic development goals of the state, and notwithstanding any law to the contrary, the department may enter into an agreement with the county tax collector for the purpose of appointing the county tax collector as the department's agent to accept applications for licenses and applications for renewals of licenses. The agreement must specify the time within which the tax collector must forward any applications and accompanying application fees to the department.

(b)If an applicant has not been issued a social security number by the Federal Government at the time of application because the applicant is not a citizen or resident of this country, the department may process the application using a unique personal identification number. If such an applicant is otherwise eligible for licensure, the board, or the department when there is no board, may issue a temporary license to the applicant, which shall expire 30 days after issuance unless a social security number is obtained and submitted in writing to the department. Upon receipt of the applicant's social

security number, the department shall issue a new license, which shall expire at the end of the current biennium.

(2)Before the issuance of any license, the department shall charge an initial license fee as determined by the applicable board or, if there is no board, by rule of the department. Upon receipt of the appropriate license fee, the department shall issue a license to any person certified by the appropriate board, or its designee, as having met the licensure requirements imposed by law or rule. The license shall consist of a wallet-size identification card and a wall card measuring 6 1/2 inches by 5 inches. The licensee shall surrender to the department the wallet-size identification card and the wall card if the licensee's license is issued in error or is revoked.

(3)(a)The board, or the department when there is no board, may refuse to issue an initial license to any applicant who is under investigation or prosecution in any jurisdiction for an action that would constitute a violation of this chapter or the professional practice acts administered by the department and the boards, until such time as the investigation or prosecution is complete, and the time period in which the licensure application must be granted or denied shall be tolled until 15 days after the receipt of the final results of the investigation or prosecution.

(b)If an applicant has been convicted of a felony related to the practice or ability to practice any health care profession, the board, or the department when there is no board, may require the applicant to prove that his or her civil rights have been restored.

(c)In considering applications for licensure, the board, or the department when there is no board, may require a personal appearance of the applicant. If the applicant is required to appear, the time period in which a licensure application must be granted or denied shall be tolled until such time as the applicant appears. However, if the applicant fails to appear before the board at either of the next two regularly scheduled board meetings, or fails to appear before the department within 30 days if there is no board, the application for licensure shall be denied.

(4)When any administrative law judge conducts a hearing pursuant to the provisions of chapter 120 with respect to the issuance of a license by the department, the administrative law judge shall submit his or her recommended order to the appropriate board, which shall thereupon issue a final order. The applicant for licensure may appeal the final order of the board in accordance with the provisions of chapter 120.

(5)A privilege against civil liability is hereby granted to any witness for any information furnished by the witness in any proceeding pursuant to this section, unless the witness acted in bad faith or with malice in providing such information.

(6)As a condition of renewal of a license, the Board of Medicine, the Board of Osteopathic Medicine, the Board of Chiropractic Medicine, and the Board of Podiatric Medicine shall each require licensees which they respectively regulate to periodically demonstrate their professional competency by completing at least 40 hours of continuing education every 2 years. The boards may require by rule that up to 1 hour of the required 40 or more hours be in the area of risk management or cost

containment. This provision shall not be construed to limit the number of hours that a licensee may obtain in risk management or cost containment to be credited toward satisfying the 40 or more required hours. This provision shall not be construed to require the boards to impose any requirement on licensees except for the completion of at least 40 hours of continuing education every 2 years. Each of such boards shall determine whether any specific continuing education requirements not otherwise mandated by law shall be mandated and shall approve criteria for, and the content of, any continuing education mandated by such board. Notwithstanding any other provision of law, the board, or the department when there is no board, may approve by rule alternative methods of obtaining continuing education credits in risk management. The alternative methods may include attending a board meeting at which another licensee is disciplined, serving as a volunteer expert witness for the department in a disciplinary case, or serving as a member of a probable cause panel following the expiration of a board member's term. Other boards within the Division of Medical Quality Assurance, or the department if there is no board, may adopt rules granting continuing education hours in risk management for attending a board meeting at which another licensee is disciplined, for serving as a volunteer expert witness for the department in a disciplinary case, or for serving as a member of a probable cause panel following the expiration of a board member's term.

(7)The boards, or the department when there is no board, shall require the completion of a 2-hour course relating to prevention of medical errors as part of the licensure and renewal process. The 2-hour course shall count towards the total number of continuing education hours required for the profession. The course shall be approved by the board or department, as appropriate, and shall include a study of root-cause analysis, error reduction and prevention, and patient safety. In addition, the course approved by the Board of Medicine and the Board of Osteopathic Medicine shall include information relating to the five most misdiagnosed conditions during the previous biennium, as determined by the board. If the course is being offered by a facility licensed pursuant to chapter 395 for its employees, the board may approve up to 1 hour of the 2-hour course to be specifically related to error reduction and prevention methods used in that facility.

(8)The respective boards within the jurisdiction of the department, or the department when there is no board, may adopt rules to provide for the use of approved videocassette courses, not to exceed 5 hours per subject, to fulfill the continuing education requirements of the professions they regulate. Such rules shall provide for prior approval of the board, or the department when there is no board, of the criteria for and content of such courses and shall provide for a videocassette course validation form to be signed by the vendor and the licensee and submitted to the department, along with the license renewal application, for continuing education credit.

(9)Any board that currently requires continuing education for renewal of a license, or the department if there is no board, shall adopt rules to establish the criteria for continuing education courses. The rules may provide that up to a maximum of 25 percent of the required continuing education hours can be fulfilled by the performance of pro bono services to the indigent or to

underserved populations or in areas of critical need within the state where the licensee practices. The board, or the department if there is no board, must require that any pro bono services be approved in advance in order to receive credit for continuing education under this subsection. The standard for determining indigency shall be that recognized by the Federal Poverty Income Guidelines produced by the United States Department of Health and Human Services. The rules may provide for approval by the board, or the department if there is no board, that a part of the continuing education hours can be fulfilled by performing research in critical need areas or for training leading to advanced professional certification. The board, or the department if there is no board, may make rules to define underserved and critical need areas. The department shall adopt rules for administering continuing education requirements adopted by the boards or the department if there is no board.

(10)Notwithstanding any law to the contrary, an elected official who is licensed under a practice act administered by the Division of Medical Quality Assurance may hold employment for compensation with any public agency concurrent with such public service. Such dual service must be disclosed according to any disclosure required by applicable law.

(11)In any instance in which a licensee or applicant to the department is required to be in compliance with a particular provision by, on, or before a certain date, and if that date occurs on a Saturday, Sunday, or a legal holiday, then the licensee or applicant is deemed to be in compliance with the specific date requirement if the required action occurs on the first succeeding day which is not a Saturday, Sunday, or legal holiday.

(12)Pursuant to the federal Personal Responsibility and Work Opportunity Reconciliation Act of 1996, each party is required to provide his or her social security number in accordance with this section. Disclosure of social security numbers obtained through this requirement shall be limited to the purpose of administration of the Title IV-D program for child support enforcement.

History.—s. 44, ch. 92-33; s. 1, ch. 93-27; s. 23, ch. 93-129; s. 27, ch. 95-144; s. 2, ch. 96-309; s. 209, ch. 96-410; s. 1079, ch. 97-103; s. 64, ch. 97-170; s. 51, ch. 97-261; s. 54, ch. 97-278; ss. 7, 237, 262, ch. 98-166; s. 145, ch. 99-251; s. 76, ch. 99-397; s. 45, ch. 2000-160; s. 20, ch. 2000-318; ss. 11, 68, ch. 2001-277; s. 11, ch. 2003-416; s. 1, ch. 2005-62.

Note.—Former s. 455.2141; s. 455.564.

456.0135General background screening provisions.—

(1)An application for initial licensure received on or after January 1, 2013, under chapter 458, chapter 459, chapter 460, chapter 461, chapter 464, or s. 465.022 shall include fingerprints pursuant to procedures established by the department through a vendor approved by the Department of Law Enforcement and fees imposed for the initial screening and retention of fingerprints. Fingerprints must be submitted electronically to the Department of Law Enforcement for state processing, and the Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for national processing. Each board, or the department if there is no board, shall screen the results to determine if an applicant meets licensure requirements. For any subsequent renewal of the applicant's

license that requires a national criminal history check, the department shall request the Department of Law Enforcement to forward the retained fingerprints of the applicant to the Federal Bureau of Investigation.

(2)All fingerprints submitted to the Department of Law Enforcement as required under subsection (1) shall be retained by the Department of Law Enforcement as provided under s. 943.05(2)(g) and (h) and (3). The department shall notify the Department of Law Enforcement regarding any person whose fingerprints have been retained but who is no longer licensed.

(3)The costs of fingerprint processing, including the cost for retaining fingerprints, shall be borne by the applicant subject to the background screening.

History.—s. 13, ch. 2012-73.

456.014Public inspection of information required from applicants; exceptions; examination hearing.—

(1)All information required by the department of any applicant shall be a public record and shall be open to public inspection pursuant to s. 119.07, except financial information, medical information, school transcripts, examination questions, answers, papers, grades, and grading keys, which are confidential and exempt from s. 119.07(1) and shall not be discussed with or made accessible to anyone except the program director of an approved program or accredited program as provided in s. 464.019(7), members of the board, the department, and staff thereof, who have a bona fide need to know such information. Any information supplied to the department by any other agency which is exempt from the provisions of chapter 119 or is confidential shall remain exempt or confidential pursuant to applicable law while in the custody of the department or the agency.

(2)The department shall establish by rule the procedure by which an applicant, and the applicant's attorney, may review examination questions and answers. Examination questions and answers are not subject to discovery but may be introduced into evidence and considered only in camera in any administrative proceeding under chapter 120. If an administrative hearing is held, the department shall provide challenged examination questions and answers to the administrative law judge. The examination questions and answers provided at the hearing are confidential and exempt from s. 119.07(1), unless invalidated by the administrative law judge.

(3)Unless an applicant notifies the department at least 5 days prior to an examination hearing of the applicant's inability to attend, or unless an applicant can demonstrate an extreme emergency for failing to attend, the department may require an applicant who fails to attend to pay reasonable attorney's fees, costs, and court costs of the department for the examination hearing.

History.—s. 76, ch. 97-261; s. 46, ch. 2000-160; s. 1, ch. 2010-37.

Note.—Former s. 455.647.

456.015Limited licenses.—

(1)It is the intent of the Legislature that, absent a threat to the health, safety, and welfare of the

public, the use of retired professionals in good standing to serve the indigent, underserved, or critical need populations of this state should be encouraged. To that end, the board, or the department when there is no board, may adopt rules to permit practice by retired professionals as limited licensees under this section.

(2)Any person desiring to obtain a limited license, when permitted by rule, shall submit to the board, or the department when there is no board, an application and fee, not to exceed $300, and an affidavit stating that the applicant has been licensed to practice in any jurisdiction in the United States for at least 10 years in the profession for which the applicant seeks a limited license. The affidavit shall also state that the applicant has retired or intends to retire from the practice of that profession and intends to practice only pursuant to the restrictions of the limited license granted pursuant to this section. If the applicant for a limited license submits a notarized statement from the employer stating that the applicant will not receive monetary compensation for any service involving the practice of her or his profession, the application and all licensure fees shall be waived.

(3)The board, or the department when there is no board, may deny limited licensure to an applicant who has committed, or is under investigation or prosecution for, any act which would constitute the basis for discipline pursuant to the provisions of this chapter or the applicable practice act.

(4)The recipient of a limited license may practice only in the employ of public agencies or institutions or nonprofit agencies or institutions which meet the requirements of s. 501(c)(3) of the Internal Revenue Code, and which provide professional liability coverage for acts or omissions of the limited licensee. A limited licensee may provide services only to the indigent, underserved, or critical need populations within the state. The standard for determining indigency shall be that recognized by the Federal Poverty Income Guidelines produced by the United States Department of Health and Human Services. The board, or the department when there is no board, may adopt rules to define underserved and critical need areas and to ensure implementation of this section.

(5)A board, or the department when there is no board, may provide by rule for supervision of limited licensees to protect the health, safety, and welfare of the public.

(6)Each applicant granted a limited license is subject to all the provisions of this chapter and the respective practice act under which the limited license is issued which are not in conflict with this section.

(7)This section does not apply to chapter 458 or chapter 459.

History.—s. 50, ch. 97-261; s. 22, ch. 99-7; s. 47, ch. 2000-160.

Note.—Former s. 455.561.

456.016Use of professional testing services.—Notwithstanding any other provision of law to the contrary, the department may use a professional testing service to prepare, administer, grade, and evaluate any computerized examination, when that service is available and approved by the board, or

the department if there is no board.

History.—s. 53, ch. 97-261; s. 48, ch. 2000-160.

Note.—Former s. 455.571.

456.01 7Examinations.—

(1)(a)The department shall provide, contract, or approve services for the development, preparation, administration, scoring, score reporting, and evaluation of all examinations, in consultation with the appropriate board. The department shall certify that examinations developed and approved by the department adequately and reliably measure an applicant's ability to practice the profession regulated by the department. After an examination developed or approved by the department has been administered, the board, or the department when there is no board, may reject any question which does not reliably measure the general areas of competency specified in the rules of the board. The department may contract for the preparation, administration, scoring, score reporting, and evaluation of examinations, when such services are available and approved by the board.

(b)For each examination developed by the department or contracted vendor, to the extent not otherwise specified by statute, the board, or the department when there is no board, shall by rule specify the general areas of competency to be covered by each examination, the relative weight to be assigned in grading each area tested, and the score necessary to achieve a passing grade. The department shall assess fees to cover the actual cost for any purchase, development, validation, administration, and defense of required examinations. This subsection does not apply to national examinations approved and administered pursuant to paragraph (c). If a practical examination is deemed to be necessary, the rules shall specify the criteria by which examiners are to be selected, the grading criteria to be used by the examiner, the relative weight to be assigned in grading each criterion, and the score necessary to achieve a passing grade. When a mandatory standardization exercise for a practical examination is required by law, the board, or the department when there is no board, may conduct such exercise. Therefore, board members, or employees of the department when there is no board, may serve as examiners at a practical examination with the consent of the board or department, as appropriate.

(c)The board, or the department when there is no board, shall approve by rule the use of one or more national examinations that the department has certified as meeting requirements of national examinations and generally accepted testing standards pursuant to department rules.

1.Providers of examinations seeking certification shall pay the actual costs incurred by the department in making a determination regarding the certification. The name and number of a candidate may be provided to a national contractor for the limited purpose of preparing the grade tape and information to be returned to the board or department; or, to the extent otherwise specified by rule, the candidate may apply directly to the vendor of the national examination and supply test score information to the department. The department may delegate to the board the duty to provide and

administer the examination. Any national examination approved by a board, or the department when there is no board, prior to October 1, 1997, is deemed certified under this paragraph.

2.Neither the board nor the department may administer a state-developed written examination if a national examination has been certified by the department. The examination may be administered electronically if adequate security measures are used, as determined by rule of the department.

3.The board, or the department when there is no board, may administer a state-developed practical or clinical examination, as required by the applicable practice act, if all costs of development, purchase, validation, administration, review, and defense are paid by the examination candidate prior to the administration of the examination. If a national practical or clinical examination is available and certified by the department pursuant to this section, the board, or the department when there is no board, may administer the national examination.

4.It is the intent of the Legislature to reduce the costs associated with state examinations and to encourage the use of national examinations whenever possible.

(d)Each board, or the department when there is no board, shall adopt rules regarding the security and monitoring of examinations. The department shall implement those rules adopted by the respective boards. In order to maintain the security of examinations, the department may employ the procedures set forth in s. 456.065 to seek fines and injunctive relief against an examinee who violates the provisions of s. 456.018 or the rules adopted pursuant to this paragraph. The department, or any agent thereof, may, for the purposes of investigation, confiscate any written, photographic, or recording material or device in the possession of the examinee at the examination site which the department deems necessary to enforce such provisions or rules. The scores of candidates who have taken state-developed examinations shall be provided to the candidates electronically using a candidate identification number, and the department shall post the aggregate scores on the department's website without identifying the names of the candidates.

(e)If the professional board with jurisdiction over an examination concurs, the department may, for a fee, share with any other state's licensing authority or a national testing entity an examination or examination item bank developed by or for the department unless prohibited by a contract entered into by the department for development or purchase of the examination. The department, with the concurrence of the appropriate board, shall establish guidelines that ensure security of a shared exam and shall require that any other state's licensing authority comply with those guidelines. Those guidelines shall be approved by the appropriate professional board. All fees paid by the user shall be applied to the department's examination and development program for professions regulated by this chapter.

(f)The department may adopt rules necessary to administer this subsection.

(2)For each examination developed by the department or a contracted vendor, the board, or the department when there is no board, shall adopt rules providing for reexamination of any applicants who failed an examination developed by the department or a contracted vendor. If both a written and

a practical examination are given, an applicant shall be required to retake only the portion of the examination on which the applicant failed to achieve a passing grade, if the applicant successfully passes that portion within a reasonable time, as determined by rule of the board, or the department when there is no board, of passing the other portion. Except for national examinations approved and administered pursuant to this section, the department shall provide procedures for applicants who fail an examination developed by the department or a contracted vendor to review their examination questions, answers, papers, grades, and grading key for the questions the candidate answered incorrectly or, if not feasible, the parts of the examination failed. Applicants shall bear the actual cost for the department to provide examination review pursuant to this subsection. An applicant may waive in writing the confidentiality of the applicant's examination grades. Notwithstanding any other provisions, only candidates who fail an examination with a score that is less than 10 percent below the minimum score required to pass the examination shall be entitled to challenge the validity of the examination at hearing.

(3)For each examination developed or administered by the department or a contracted vendor, an accurate record of each applicant's examination questions, answers, papers, grades, and grading key shall be kept for a period of not less than 2 years immediately following the examination, and such record shall thereafter be maintained or destroyed as provided in chapters 119 and 257. This subsection does not apply to national examinations approved and administered pursuant to this section.

(4)Meetings of any member of the department or of any board within the department held for the exclusive purpose of creating or reviewing licensure examination questions or proposed examination questions are exempt from the provisions of s. 286.011 and s. 24(b), Art. I of the State Constitution. Any public records, such as tape recordings, minutes, or notes, generated during or as a result of such meetings are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution. However, these exemptions shall not affect the right of any person to review an examination as provided in subsection (2).

(5)For examinations developed by the department or a contracted vendor, each board, or the department when there is no board, may provide licensure examinations in an applicant's native language. Notwithstanding any other provision of law, applicants for examination or reexamination pursuant to this subsection shall bear the full cost for the department's development, preparation, validation, administration, grading, and evaluation of any examination in a language other than English prior to the examination being administered. Requests for translated examinations must be on file in the board office at least 6 months prior to the scheduled examination. When determining whether it is in the public interest to allow the examination to be translated into a language other than English, the board shall consider the percentage of the population who speak the applicant's native language. Applicants must apply for translation to the applicable board at least 6 months prior to the scheduled examination.

(6)In addition to meeting any other requirements for licensure by examination or by endorsement, and notwithstanding the provisions in paragraph (1)(c), an applicant may be required by a board, or the department when there is no board, to certify competency in state laws and rules relating to the applicable practice act. Beginning October 1, 2001, all laws and rules examinations shall be administered electronically unless the laws and rules examination is administered concurrently with another written examination for that profession or unless the electronic administration would be substantially more expensive.

(7)The department may post examination scores electronically on the Internet in lieu of mailing the scores to each applicant. The electronic posting of the examination scores meets the requirements of chapter 120 if the department also posts along with the examination scores a notification of the rights set forth in chapter 120. The date of receipt for purposes of chapter 120 is the date the examination scores are posted electronically. The department shall also notify the applicant when scores are posted electronically of the availability of postexamination review, if applicable.

History.—s. 46, ch. 92-33; s. 23, ch. 93-129; s. 1, ch. 95-367; s. 304, ch. 96-406; s. 1081, ch. 97-103; s. 54, ch. 97-261; s. 238, ch. 98-166; s. 79, ch. 99-397; s. 49, ch. 2000-160; s. 46, ch. 2000-318; s. 12, ch. 2001-277; s. 2, ch. 2005-62.

Note.—Former s. 455.2173; s. 455.574.

456.018Penalty for theft or reproduction of an examination.—In addition to, or in lieu of, any other discipline imposed pursuant to s. 456.072, the theft of an examination in whole or in part or the act of reproducing or copying any examination administered by the department, whether such examination is reproduced or copied in part or in whole and by any means, constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 55, ch. 97-261; s. 50, ch. 2000-160; s. 27, ch. 2000-318.

Note.—Former s. 455.577.

456.019Restriction on requirement of citizenship.—A person is not disqualified from practicing an occupation or profession regulated by the state solely because she or he is not a United States citizen.

History.—s. 36, ch. 97-261; s. 20, ch. 99-7; s. 51, ch. 2000-160.

Note.—Former s. 455.511.

456.021Qualification of immigrants for examination to practice a licensed profession or occupation.—

(1)It is the declared purpose of this section to encourage the use of foreign-speaking Florida residents duly qualified to become actively qualified in their professions so that all people of this state may receive better services.

(2)Any person who has successfully completed, or is currently enrolled in, an approved course of study created pursuant to chapters 74-105 and 75-177, Laws of Florida, shall be deemed qualified for

examination and reexaminations for a professional or occupational license which shall be administered in the English language unless 15 or more such applicants request that the reexamination be administered in their native language. In the event that such reexamination is administered in a foreign language, the full cost to the board of preparing and administering it shall be borne by the applicants.

(3)Each board within the department shall adopt and implement programs designed to qualify for examination all persons who were resident nationals of the Republic of Cuba and who, on July 1, 1977, were residents of this state.

History.—s. 37, ch. 97-261; s. 51, ch. 2000-160.

Note.—Former s. 455.514.

456.022Foreign-trained professionals; special examination and license provisions.—

(1)When not otherwise provided by law, within its jurisdiction, the department shall by rule provide procedures under which exiled professionals may be examined within each practice act. A person shall be eligible for such examination if the person:

(a)Immigrated to the United States after leaving the person's home country because of political reasons, provided such country is located in the Western Hemisphere and lacks diplomatic relations with the United States;

(b)Applies to the department and submits a fee;

(c)Was a Florida resident immediately preceding the person's application;

(d)Demonstrates to the department, through submission of documentation verified by the applicant's respective professional association in exile, that the applicant was graduated with an appropriate professional or occupational degree from a college or university; however, the department may not require receipt of any documentation from the Republic of Cuba as a condition of eligibility under this section;

(e)Lawfully practiced the profession for at least 3 years;

(f)Prior to 1980, successfully completed an approved course of study pursuant to chapters 74-105 and 75-177, Laws of Florida; and

(g)Presents a certificate demonstrating the successful completion of a continuing education program which offers a course of study that will prepare the applicant for the examination offered under subsection (2). The department shall develop rules for the approval of such programs for its boards.

(2)Upon request of a person who meets the requirements of subsection (1) and submits an examination fee, the department, for its boards, shall provide a written practical examination which tests the person's current ability to practice the profession competently in accordance with the actual practice of the profession. Evidence of meeting the requirements of subsection (1) shall be treated by the department as evidence of the applicant's preparation in the academic and preprofessional fundamentals necessary for successful professional practice, and the applicant shall not be examined

by the department on such fundamentals.

(3)The fees charged for the examinations offered under subsection (2) shall be established by the department, for its boards, by rule and shall be sufficient to develop or to contract for the development of the examination and its administration, grading, and grade reviews.

(4)The department shall examine any applicant who meets the requirements of subsections (1) and (2). Upon passing the examination and the issuance of the license, a licensee is subject to the administrative requirements of this chapter and the respective practice act under which the license is issued. Each applicant so licensed is subject to all provisions of this chapter and the respective practice act under which the license was issued.

(5)Upon a request by an applicant otherwise qualified under this section, the examinations offered under subsection (2) may be given in the applicant's native language, provided that any translation costs are borne by the applicant.

(6)The department, for its boards, shall not issue an initial license to, or renew a license of, any applicant or licensee who is under investigation or prosecution in any jurisdiction for an action which would constitute a violation of this chapter or the professional practice acts administered by the department and the boards until such time as the investigation or prosecution is complete, at which time the provisions of the professional practice acts shall apply.

History.—s. 56, ch. 97-261; s. 52, ch. 2000-160.

Note.—Former s. 455.581.

456.023Exemption for certain out-of-state or foreign professionals; limited practice permitted.—

(1)A professional of any other state or of any territory or other jurisdiction of the United States or of any other nation or foreign jurisdiction is exempt from the requirements of licensure under this chapter and the applicable professional practice act under the agency with regulatory jurisdiction over the profession if that profession is regulated in this state under the agency with regulatory jurisdiction over the profession and if that person:

(a)Holds, if so required in the jurisdiction in which that person practices, an active license to practice that profession.

(b)Engages in the active practice of that profession outside the state.

(c)Is employed or designated in that professional capacity by a sports entity visiting the state for a specific sporting event.

(2)A professional's practice under this section is limited to the members, coaches, and staff of the team for which that professional is employed or designated and to any animals used if the sporting event for which that professional is employed or designated involves animals. A professional practicing under authority of this section shall not have practice privileges in any licensed health care facility or veterinary facility without the approval of that facility.

History.—s. 57, ch. 97-261; s. 53, ch. 2000-160.

Note.—Former s. 455.584.

456.024Members of Armed Forces in good standing with administrative boards or the department; spouses.—

(1)Any member of the Armed Forces of the United States now or hereafter on active duty who, at the time of becoming such a member, was in good standing with any administrative board of the state, or the department when there is no board, and was entitled to practice or engage in his or her profession or vocation in the state shall be kept in good standing by such administrative board, or the department when there is no board, without registering, paying dues or fees, or performing any other act on his or her part to be performed, as long as he or she is a member of the Armed Forces of the United States on active duty and for a period of 6 months after discharge from active duty as a member of the Armed Forces of the United States, provided he or she is not engaged in his or her licensed profession or vocation in the private sector for profit.

(2)The boards listed in s. 20.43, or the department when there is no board, shall adopt rules exempting the spouses of members of the Armed Forces of the United States from licensure renewal provisions, but only in cases of absence from the state because of their spouses' duties with the Armed Forces.

(3)(a)The board, or the department if there is no board, may issue a temporary professional license to the spouse of an active duty member of the Armed Forces of the United States who submits to the department:

1.A completed application upon a form prepared and furnished by the department in accordance with the board's rules;

2.The required application fee;

3.Proof that the applicant is married to a member of the Armed Forces of the United States who is on active duty;

4.Proof that the applicant holds a valid license for the profession issued by another state, the District of Columbia, or a possession or territory of the United States, and is not the subject of any disciplinary proceeding in any jurisdiction in which the applicant holds a license to practice a profession regulated by this chapter;

5.Proof that the applicant's spouse is assigned to a duty station in this state pursuant to the member's official active duty military orders; and

6.Proof that the applicant would otherwise be entitled to full licensure under the appropriate practice act, and is eligible to take the respective licensure examination as required in Florida.

(b)The applicant must also submit to the Department of Law Enforcement a complete set of fingerprints. The Department of Law Enforcement shall conduct a statewide criminal history check and forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check.

(c)Each board, or the department if there is no board, shall review the results of the state and federal criminal history checks according to the level 2 screening standards in s. 435.04 when granting an exemption and when granting or denying the temporary license.

(d)The applicant shall pay the cost of fingerprint processing. If the fingerprints are submitted through an authorized agency or vendor, the agency or vendor shall collect the required processing fees and remit the fees to the Department of Law Enforcement.

(e)The department shall set an application fee, which may not exceed the cost of issuing the license.

(f)A temporary license expires 12 months after the date of issuance and is not renewable.

(g)An applicant for a temporary license under this subsection is subject to the requirements under s. 456.013(3)(a) and (c).

(h)An applicant shall be deemed ineligible for a temporary license pursuant to this section if the applicant:

1.Has been convicted of or pled nolo contendere to, regardless of adjudication, any felony or misdemeanor related to the practice of a health care profession;

2.Has had a health care provider license revoked or suspended from another of the United States, the District of Columbia, or a United States territory;

3.Has been reported to the National Practitioner Data Bank, unless the applicant has successfully appealed to have his or her name removed from the data bank; or

4.Has previously failed the Florida examination required to receive a license to practice the profession for which the applicant is seeking a license.

(i)The board, or department if there is no board, may revoke a temporary license upon finding that the individual violated the profession's governing practice act.

(j)An applicant who is issued a temporary professional license to practice as a dentist pursuant to this section must practice under the indirect supervision, as defined in s. 466.003, of a dentist licensed pursuant to chapter 466.

History.—s. 35, ch. 97-261; s. 19, ch. 99-7; s. 73, ch. 99-397; s. 54, ch. 2000-160; s. 1, ch. 2011-95.

Note.—Former s. 455.507.

456.025Fees; receipts; disposition.—

(1)It is the intent of the Legislature that all costs of regulating health care professions and practitioners shall be borne solely by licensees and licensure applicants. It is also the intent of the Legislature that fees should be reasonable and not serve as a barrier to licensure. Moreover, it is the intent of the Legislature that the department operate as efficiently as possible and regularly report to the Legislature additional methods to streamline operational costs. Therefore, the boards in consultation with the department, or the department if there is no board, shall, by rule, set renewal fees which:

(a)Shall be based on revenue projections prepared using generally accepted accounting procedures;

(b)Shall be adequate to cover all expenses relating to that board identified in the department's long-range policy plan, as required by s. 456.005;

(c)Shall be reasonable, fair, and not serve as a barrier to licensure;

(d)Shall be based on potential earnings from working under the scope of the license;

(e)Shall be similar to fees imposed on similar licensure types;

(f)Shall not be more than 10 percent greater than the actual cost to regulate that profession for the previous biennium; and

(g)Shall be subject to challenge pursuant to chapter 120.

(2)The chairpersons of the boards and councils listed in s. 20.43(3)(g) shall meet annually at division headquarters to review the long-range policy plan required by s. 456.005 and current and proposed fee schedules. The chairpersons shall make recommendations for any necessary statutory changes relating to fees and fee caps. Such recommendations shall be compiled by the Department of Health and be included in the annual report to the Legislature required by s. 456.026 as well as be included in the long-range policy plan required by s. 456.005.

(3)Each board within the jurisdiction of the department, or the department when there is no board, shall determine by rule the amount of license fees for the profession it regulates, based upon long-range estimates prepared by the department of the revenue required to implement laws relating to the regulation of professions by the department and the board. Each board, or the department if there is no board, shall ensure that license fees are adequate to cover all anticipated costs and to maintain a reasonable cash balance, as determined by rule of the agency, with advice of the applicable board. If sufficient action is not taken by a board within 1 year after notification by the department that license fees are projected to be inadequate, the department shall set license fees on behalf of the applicable board to cover anticipated costs and to maintain the required cash balance. The department shall include recommended fee cap increases in its annual report to the Legislature. Further, it is the legislative intent that no regulated profession operate with a negative cash balance. The department may provide by rule for advancing sufficient funds to any profession operating with a negative cash balance. The advancement may be for a period not to exceed 2 consecutive years, and the regulated profession must pay interest. Interest shall be calculated at the current rate earned on investments of a trust fund used by the department to implement this chapter. Interest earned shall be allocated to the various funds in accordance with the allocation of investment earnings during the period of the advance.

(4)Each board, or the department if there is no board, may charge a fee not to exceed $25, as determined by rule, for the issuance of a wall certificate pursuant to s. 456.013(2) requested by a licensee who was licensed prior to July 1, 1998, or for the issuance of a duplicate wall certificate requested by any licensee.

(5)Each board, or the department if there is no board, may, by rule, assess and collect a one-time fee from each active status licensee and each inactive status licensee in an amount necessary to eliminate a cash deficit or, if there is not a cash deficit, in an amount sufficient to maintain the financial integrity of the professions as required in this section. Not more than one such assessment may be made in any 4-year period without specific legislative authorization.

(6)If the cash balance of the trust fund at the end of any fiscal year exceeds the total appropriation provided for the regulation of the health care professions in the prior fiscal year, the boards, in consultation with the department, may lower the license renewal fees.

(7)Each board, or the department if there is no board, shall establish, by rule, a fee not to exceed $250 for anyone seeking approval to provide continuing education courses or programs and shall establish by rule a biennial renewal fee not to exceed $250 for the renewal of providership of such courses. The fees collected from continuing education providers shall be used for the purposes of reviewing course provider applications, monitoring the integrity of the courses provided, covering legal expenses incurred as a result of not granting or renewing a providership, and developing and maintaining an electronic continuing education tracking system. The department shall implement an electronic continuing education tracking system for each new biennial renewal cycle for which electronic renewals are implemented after the effective date of this act and shall integrate such system into the licensure and renewal system. All approved continuing education providers shall provide information on course attendance to the department necessary to implement the electronic tracking system. The department shall, by rule, specify the form and procedures by which the information is to be submitted.

(8)All moneys collected by the department from fees or fines or from costs awarded to the agency by a court shall be paid into a trust fund used by the department to implement this chapter. The Legislature shall appropriate funds from this trust fund sufficient to carry out this chapter and the provisions of law with respect to professions regulated by the Division of Medical Quality Assurance within the department and the boards. The department may contract with public and private entities to receive and deposit revenue pursuant to this section. The department shall maintain separate accounts in the trust fund used by the department to implement this chapter for every profession within the department. To the maximum extent possible, the department shall directly charge all expenses to the account of each regulated profession. For the purpose of this subsection, direct charge expenses include, but are not limited to, costs for investigations, examinations, and legal services. For expenses that cannot be charged directly, the department shall provide for the proportionate allocation among the accounts of expenses incurred by the department in the performance of its duties with respect to each regulated profession. The regulation by the department of professions, as defined in this chapter, shall be financed solely from revenue collected by it from fees and other charges and deposited in the Medical Quality Assurance Trust Fund, and all such revenue is hereby appropriated to the department. However, it is legislative intent that each profession shall operate within its

anticipated fees. The department may not expend funds from the account of a profession to pay for the expenses incurred on behalf of another profession, except that the Board of Nursing must pay for any costs incurred in the regulation of certified nursing assistants. The department shall maintain adequate records to support its allocation of agency expenses. The department shall provide any board with reasonable access to these records upon request. On or before October 1 of each year, the department shall provide each board an annual report of revenue and direct and allocated expenses related to the operation of that profession. The board shall use these reports and the department's adopted long-range plan to determine the amount of license fees. A condensed version of this information, with the department's recommendations, shall be included in the annual report to the Legislature prepared under s. 456.026.

(9)The department shall provide a management report of revenues and expenditures, performance measures, and recommendations to each board at least once a quarter.

(10)If a duplicate license is required or requested by the licensee, the board or, if there is no board, the department may charge a fee as determined by rule not to exceed $25 before issuance of the duplicate license.

(11)The department or the appropriate board shall charge a fee not to exceed $25 for the certification of a public record. The fee shall be determined by rule of the department. The department or the appropriate board shall assess a fee for duplicating a public record as provided in s. 119.07(4).

History.—s. 49, ch. 92-33; s. 23, ch. 93-129; s. 58, ch. 97-261; s. 80, ch. 99-397; s. 55, ch. 2000-160; ss. 32, 164, ch. 2000-318; s. 73, ch. 2001-62; s. 6, ch. 2001-277; s. 12, ch. 2003-416; s. 45, ch. 2004-335; s. 149, ch. 2010-102.

Note.—Former s. 455.220; s. 455.587.

456.026Annual report concerning finances, administrative complaints, disciplinary actions, and recommendations.—The department is directed to prepare and submit a report to the President of the Senate and the Speaker of the House of Representatives by November 1 of each year. In addition to finances and any other information the Legislature may require, the report shall include statistics and relevant information, profession by profession, detailing:

(1)The revenues, expenditures, and cash balances for the prior year, and a review of the adequacy of existing fees.

(2)The number of complaints received and investigated.

(3)The number of findings of probable cause made.

(4)The number of findings of no probable cause made.

(5)The number of administrative complaints filed.

(6)The disposition of all administrative complaints.

(7)A description of disciplinary actions taken.

(8)A description of any effort by the department to reduce or otherwise close any investigation or

disciplinary proceeding not before the Division of Administrative Hearings under chapter 120 or otherwise not completed within 1 year after the initial filing of a complaint under this chapter.

(9)The status of the development and implementation of rules providing for disciplinary guidelines pursuant to s. 456.079.

(10)Such recommendations for administrative and statutory changes necessary to facilitate efficient and cost-effective operation of the department and the various boards.

History.—s. 75, ch. 97-261; s. 56, ch. 2000-160; s. 4, ch. 2002-254.

Note.—Former s. 455.644.

456.027Education; accreditation.—Notwithstanding any other provision of law, educational programs and institutions which are required by statute to be accredited, but which were accredited by an agency that has since ceased to perform an accrediting function, shall be recognized until such programs and institutions are accredited by a qualified successor to the original accrediting agency, an accrediting agency recognized by the United States Department of Education, or an accrediting agency recognized by the board, or the department when there is no board.

History.—s. 48, ch. 97-261; s. 57, ch. 2000-160.

Note.—Former s. 455.551.

456.028Consultation with postsecondary education boards prior to adoption of changes to training requirements.—Any state agency or board that has jurisdiction over the regulation of a profession or occupation shall consult with the Commission for Independent Education, the Board of Governors of the State University System, and the State Board of Education prior to adopting any changes to training requirements relating to entry into the profession or occupation. This consultation must allow the educational board to provide advice regarding the impact of the proposed changes in terms of the length of time necessary to complete the training program and the fiscal impact of the changes. The educational board must be consulted only when an institution offering the training program falls under its jurisdiction.

History.—s. 49, ch. 97-261; s. 35, ch. 98-421; s. 57, ch. 2000-160; s. 72, ch. 2004-5; s. 14, ch. 2004-41; s. 54, ch. 2007-217.

Note.—Former s. 455.554.

456.029Education; substituting demonstration of competency for clock-hour requirements.—Any board, or the department when there is no board, that requires student completion of a specific number of clock hours of classroom instruction for initial licensure purposes shall establish the minimal competencies that such students must demonstrate in order to be licensed. The demonstration of such competencies may be substituted for specific classroom clock-hour requirements established in statute or rule which are related to instructional programs for licensure purposes. Student demonstration of the established minimum competencies shall be certified by the educational institution. The provisions

of this section shall not apply to boards for which federal licensure standards are more restrictive or stringent than the standards prescribed in statute.

History.—s. 47, ch. 97-261; s. 57, ch. 2000-160.

Note.—Former s. 455.547.

456.031Requirement for instruction on domestic violence.—

(1)(a)The appropriate board shall require each person licensed or certified under chapter 458, chapter 459, part I of chapter 464, chapter 466, chapter 467, chapter 490, or chapter 491 to complete a 2-hour continuing education course, approved by the board, on domestic violence, as defined in s. 741.28, as part of every third biennial relicensure or recertification. The course shall consist of information on the number of patients in that professional's practice who are likely to be victims of domestic violence and the number who are likely to be perpetrators of domestic violence, screening procedures for determining whether a patient has any history of being either a victim or a perpetrator of domestic violence, and instruction on how to provide such patients with information on, or how to refer such patients to, resources in the local community, such as domestic violence centers and other advocacy groups, that provide legal aid, shelter, victim counseling, batterer counseling, or child protection services.

(b)Each such licensee or certificateholder shall submit confirmation of having completed such course, on a form provided by the board, when submitting fees for every third biennial renewal.

(c)The board may approve additional equivalent courses that may be used to satisfy the requirements of paragraph (a). Each licensing board that requires a licensee to complete an educational course pursuant to this subsection may include the hour required for completion of the course in the total hours of continuing education required by law for such profession unless the continuing education requirements for such profession consist of fewer than 30 hours biennially.

(d)Any person holding two or more licenses subject to the provisions of this subsection shall be permitted to show proof of having taken one board-approved course on domestic violence, for purposes of relicensure or recertification for additional licenses.

(e)Failure to comply with the requirements of this subsection shall constitute grounds for disciplinary action under each respective practice act and under s. 456.072(1)(k). In addition to discipline by the board, the licensee shall be required to complete such course.

(2)Each board may adopt rules to carry out the provisions of this section.

History.—s. 4, ch. 95-187; s. 61, ch. 97-261; s. 58, ch. 2000-160; s. 6, ch. 2000-295; s. 112, ch. 2000-318; s. 1, ch. 2001-176; s. 1, ch. 2001-250; s. 105, ch. 2001-277; s. 1, ch. 2006-251.

Note.—Former s. 455.222; s. 455.597.

456.032Hepatitis B or HIV carriers.—

(1)The department and each appropriate board within the Division of Medical Quality Assurance shall have the authority to establish procedures to handle, counsel, and provide other services to

health care professionals within their respective boards who are infected with hepatitis B or the human immunodeficiency virus.

(2)Any person licensed by the department and any other person employed by a health care facility who contracts a blood-borne infection shall have a rebuttable presumption that the illness was contracted in the course and scope of his or her employment, provided that the person, as soon as practicable, reports to the person's supervisor or the facility's risk manager any significant exposure, as that term is defined in s. 381.004(1)(c), to blood or body fluids. The employer may test the blood or body fluid to determine if it is infected with the same disease contracted by the employee. The employer may rebut the presumption by the preponderance of the evidence. Except as expressly provided in this subsection, there shall be no presumption that a blood-borne infection is a job-related injury or illness.

History.—s. 75, ch. 91-297; s. 76, ch. 94-218; s. 62, ch. 97-261; s. 81, ch. 99-397; s. 59, ch. 2000-160; s. 121, ch. 2012-184.

Note.—Former s. 455.2224; s. 455.601.

456.033Requirement for instruction for certain licensees on HIV and AIDS.—The following requirements apply to each person licensed or certified under chapter 457; chapter 458; chapter 459; chapter 460; chapter 461; chapter 463; part I of chapter 464; chapter 465; chapter 466; part II, part III, part V, or part X of chapter 468; or chapter 486:

(1)Each person shall be required by the appropriate board to complete no later than upon first renewal a continuing educational course, approved by the board, on human immunodeficiency virus and acquired immune deficiency syndrome as part of biennial relicensure or recertification. The course shall consist of education on the modes of transmission, infection control procedures, clinical management, and prevention of human immunodeficiency virus and acquired immune deficiency syndrome. Such course shall include information on current Florida law on acquired immune deficiency syndrome and its impact on testing, confidentiality of test results, treatment of patients, and any protocols and procedures applicable to human immunodeficiency virus counseling and testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to ss. 381.004 and 384.25.

(2)Each person shall submit confirmation of having completed the course required under subsection (1), on a form as provided by the board, when submitting fees for first renewal.

(3)The board shall have the authority to approve additional equivalent courses that may be used to satisfy the requirements in subsection (1). Each licensing board that requires a licensee to complete an educational course pursuant to this section may count the hours required for completion of the course included in the total continuing educational requirements as required by law.

(4)Any person holding two or more licenses subject to the provisions of this section shall be permitted to show proof of having taken one board-approved course on human immunodeficiency virus

and acquired immune deficiency syndrome, for purposes of relicensure or recertification for additional licenses.

(5)Failure to comply with the above requirements shall constitute grounds for disciplinary action under each respective licensing chapter and s. 456.072(1)(e). In addition to discipline by the board, the licensee shall be required to complete the course.

History.—s. 63, ch. 97-261; s. 4, ch. 98-171; s. 9, ch. 99-331; s. 82, ch. 99-397; s. 60, ch. 2000-160; s. 113, ch. 2000-318; s. 2, ch. 2001-176; s. 2, ch. 2001-250; s. 106, ch. 2001-277; s. 2, ch. 2006-251.

Note.—Former s. 455.604.

456.035Address of record.—

(1)Each licensee of the department is solely responsible for notifying the department in writing of the licensee's current mailing address and place of practice, as defined by rule of the board or the department if there is no board. Electronic notification shall be allowed by the department; however, it shall be the responsibility of the licensee to ensure that the electronic notification was received by the department. A licensee's failure to notify the department of a change of address constitutes a violation of this section, and the licensee may be disciplined by the board or the department if there is no board.

(2)Notwithstanding any other law, service by regular mail to a licensee's last known address of record with the department constitutes adequate and sufficient notice to the licensee for any official communication to the licensee by the board or the department except when other service is required under s. 456.076.

History.—s. 97, ch. 97-261; s. 39, ch. 98-166; s. 62, ch. 2000-160; s. 13, ch. 2001-277.

Note.—Former s. 455.717.

456.036Licenses; active and inactive status; delinquency.—

(1)A licensee may practice a profession only if the licensee has an active status license. A licensee who practices a profession with an inactive status license, a retired status license, or a delinquent license is in violation of this section and s. 456.072, and the board, or the department if there is no board, may impose discipline on the licensee.

(2)Each board, or the department if there is no board, shall permit a licensee to choose, at the time of licensure renewal, an active, inactive, or retired status.

(3)Each board, or the department if there is no board, shall by rule impose a fee for renewal of an active or inactive status license. The renewal fee for an inactive status license may not exceed the fee for an active status license.

(4)Notwithstanding any other provision of law to the contrary, a licensee may change licensure status at any time.

(a)Active status licensees choosing inactive status at the time of license renewal must pay the inactive status renewal fee, and, if applicable, the delinquency fee and the fee to change licensure

status. Active status licensees choosing inactive status at any other time than at the time of license renewal must pay the fee to change licensure status.

(b)An active status licensee or an inactive status licensee who chooses retired status at the time of license renewal must pay the retired status fee, which may not exceed $50 as established by rule of the board or the department if there is no board. An active status licensee or inactive status licensee who chooses retired status at any time other than at the time of license renewal must pay the retired status fee plus a change-of-status fee.

(c)An inactive status licensee may change to active status at any time, if the licensee meets all requirements for active status. Inactive status licensees choosing active status at the time of license renewal must pay the active status renewal fee, any applicable reactivation fees as set by the board, or the department if there is no board, and, if applicable, the delinquency fee and the fee to change licensure status. Inactive status licensees choosing active status at any other time than at the time of license renewal must pay the difference between the inactive status renewal fee and the active status renewal fee, if any exists, any applicable reactivation fees as set by the board, or the department if there is no board, and the fee to change licensure status.

(5)A licensee must apply with a complete application, as defined by rule of the board, or the department if there is no board, to renew an active or inactive status license before the license expires. If a licensee fails to renew before the license expires, the license becomes delinquent in the license cycle following expiration.

(6)A delinquent licensee must affirmatively apply with a complete application, as defined by rule of the board, or the department if there is no board, for active or inactive status during the licensure cycle in which a licensee becomes delinquent. Failure by a delinquent licensee to become active or inactive before the expiration of the current licensure cycle renders the license null without any further action by the board or the department. Any subsequent licensure shall be as a result of applying for and meeting all requirements imposed on an applicant for new licensure.

(7)Each board, or the department if there is no board, shall by rule impose an additional delinquency fee, not to exceed the biennial renewal fee for an active status license, on a delinquent licensee when such licensee applies for active or inactive status.

(8)Each board, or the department if there is no board, shall by rule impose an additional fee, not to exceed the biennial renewal fee for an active status license, for processing a licensee's request to change licensure status at any time other than at the beginning of a licensure cycle.

(9)Each board, or the department if there is no board, may by rule impose reasonable conditions, excluding full reexamination but including part of a national examination or a special purpose examination to assess current competency, necessary to ensure that a licensee who has been on inactive status for more than two consecutive biennial licensure cycles and who applies for active status can practice with the care and skill sufficient to protect the health, safety, and welfare of the public. Reactivation requirements may differ depending on the length of time licensees are inactive.

The costs to meet reactivation requirements shall be borne by licensees requesting reactivation.

(10)Each board, or the department if there is no board, may by rule impose reasonable conditions, including full reexamination to assess current competency, in order to ensure that a licensee who has been on retired status for more than 5 years, or a licensee from another state who has not been in active practice within the past 5 years, and who applies for active status is able to practice with the care and skill sufficient to protect the health, safety, and welfare of the public. Requirements for reactivation of a license may differ depending on the length of time a licensee has been retired.

(11)Before reactivation, an inactive status licensee or a delinquent licensee who was inactive prior to becoming delinquent must meet the same continuing education requirements, if any, imposed on an active status licensee for all biennial licensure periods in which the licensee was inactive or delinquent.

(12)Before the license of a retired status licensee is reactivated, the licensee must meet the same requirements for continuing education, if any, and pay any renewal fees imposed on an active status licensee for all biennial licensure periods during which the licensee was on retired status.

(13)The status or a change in status of a licensee does not alter in any way the right of the board, or of the department if there is no board, to impose discipline or to enforce discipline previously imposed on a licensee for acts or omissions committed by the licensee while holding a license, whether active, inactive, retired, or delinquent.

(14)A person who has been denied renewal of licensure, certification, or registration under s. 456.0635(3) may regain licensure, certification, or registration only by meeting the qualifications and completing the application process for initial licensure as defined by the board, or the department if there is no board. However, a person who was denied renewal of licensure, certification, or registration under s. 24, chapter 2009-223, Laws of Florida, between July 1, 2009, and June 30, 2012, is not required to retake and pass examinations applicable for initial licensure, certification, or registration.

(15)This section does not apply to a business establishment registered, permitted, or licensed by the department to do business.

(16)The board, or the department when there is no board, may adopt rules pursuant to ss. 120.536(1) and 120.54 as necessary to implement this section.

History.—s. 95, ch. 97-261; s. 63, ch. 2000-160; s. 31, ch. 2000-318; s. 3, ch. 2005-62; s. 2, ch. 2012-64.

Note.—Former s. 455.711.

456.037Business establishments; requirements for active status licenses; delinquency; discipline; applicability.—

(1)A business establishment regulated by the Division of Medical Quality Assurance pursuant to this chapter may provide regulated services only if the business establishment has an active status license. A business establishment that provides regulated services without an active status license is in violation

of this section and s. 456.072, and the board, or the department if there is no board, may impose discipline on the business establishment.

(2)A business establishment must apply with a complete application, as defined by rule of the board, or the department if there is no board, to renew an active status license before the license expires. If a business establishment fails to renew before the license expires, the license becomes delinquent, except as otherwise provided in statute, in the license cycle following expiration.

(3)A delinquent business establishment must apply with a complete application, as defined by rule of the board, or the department if there is no board, for active status within 6 months after becoming delinquent. Failure of a delinquent business establishment to renew the license within the 6 months after the expiration date of the license renders the license null without any further action by the board or the department. Any subsequent licensure shall be as a result of applying for and meeting all requirements imposed on a business establishment for new licensure.

(4)The status or a change in status of a business establishment license does not alter in any way the right of the board, or of the department if there is no board, to impose discipline or to enforce discipline previously imposed on a business establishment for acts or omissions committed by the business establishment while holding a license, whether active or null.

(5)This section applies to any business establishment registered, permitted, or licensed by the department to do business. Business establishments include, but are not limited to, dental laboratories, electrology facilities, massage establishments, pharmacies, and pain-management clinics required to be registered under s. 458.3265 or s. 459.0137.

History.—s. 89, ch. 99-397; s. 64, ch. 2000-160; s. 27, ch. 2000-318; s. 102, ch. 2000-349; s. 1, ch. 2010-211.

Note.—Former s. 455.712.

456.038Renewal and cancellation notices.—

(1)At least 90 days before the end of a licensure cycle, the department shall:

(a)Forward a licensure renewal notification to an active or inactive status licensee at the licensee's last known address of record with the department.

(b)Forward a notice of pending cancellation of licensure to a delinquent licensee at the licensee's last known address of record with the department.

(2)Each licensure renewal notification and each notice of pending cancellation of licensure must state conspicuously that a licensee who remains on inactive status for more than two consecutive biennial licensure cycles and who wishes to reactivate the license may be required to demonstrate the competency to resume active practice by sitting for a special purpose examination or by completing other reactivation requirements, as defined by rule of the board or the department if there is no board.

History.—s. 96, ch. 97-261; s. 65, ch. 2000-160; s. 33, ch. 2000-318.

Note.—Former s. 455.714.

456.039Designated health care professionals; information required for licensure.—

(1)Each person who applies for initial licensure as a physician under chapter 458, chapter 459, chapter 460, or chapter 461, except a person applying for registration pursuant to ss. 458.345 and 459.021, must, at the time of application, and each physician who applies for license renewal under chapter 458, chapter 459, chapter 460, or chapter 461, except a person registered pursuant to ss. 458.345 and 459.021, must, in conjunction with the renewal of such license and under procedures adopted by the Department of Health, and in addition to any other information that may be required from the applicant, furnish the following information to the Department of Health:

(a)1.The name of each medical school that the applicant has attended, with the dates of attendance and the date of graduation, and a description of all graduate medical education completed by the applicant, excluding any coursework taken to satisfy medical licensure continuing education requirements.

2.The name of each hospital at which the applicant has privileges.

3.The address at which the applicant will primarily conduct his or her practice.

4.Any certification that the applicant has received from a specialty board that is recognized by the board to which the applicant is applying.

5.The year that the applicant began practicing medicine.

6.Any appointment to the faculty of a medical school which the applicant currently holds and an indication as to whether the applicant has had the responsibility for graduate medical education within the most recent 10 years.

7.A description of any criminal offense of which the applicant has been found guilty, regardless of whether adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony or misdemeanor if committed in this state must be reported. If the applicant indicates that a criminal offense is under appeal and submits a copy of the notice for appeal of that criminal offense, the department must state that the criminal offense is under appeal if the criminal offense is reported in the applicant's profile. If the applicant indicates to the department that a criminal offense is under appeal, the applicant must, upon disposition of the appeal, submit to the department a copy of the final written order of disposition.

8.A description of any final disciplinary action taken within the previous 10 years against the applicant by the agency regulating the profession that the applicant is or has been licensed to practice, whether in this state or in any other jurisdiction, by a specialty board that is recognized by the American Board of Medical Specialties, the American Osteopathic Association, or a similar national organization, or by a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home. Disciplinary action includes resignation from or nonrenewal of medical staff membership or the restriction of privileges at a licensed hospital, health

maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home taken in lieu of or in settlement of a pending disciplinary case related to competence or character. If the applicant indicates that the disciplinary action is under appeal and submits a copy of the document initiating an appeal of the disciplinary action, the department must state that the disciplinary action is under appeal if the disciplinary action is reported in the applicant's profile.

9.Relevant professional qualifications as defined by the applicable board.

(b)In addition to the information required under paragraph (a), each applicant who seeks licensure under chapter 458, chapter 459, or chapter 461, and who has practiced previously in this state or in another jurisdiction or a foreign country must provide the information required of licensees under those chapters pursuant to s. 456.049. An applicant for licensure under chapter 460 who has practiced previously in this state or in another jurisdiction or a foreign country must provide the same information as is required of licensees under chapter 458, pursuant to s. 456.049.

(2)Before the issuance of the licensure renewal notice required by s. 456.038, the Department of Health shall send a notice to each person licensed under chapter 458, chapter 459, chapter 460, or chapter 461, at the licensee's last known address of record with the department, regarding the requirements for information to be submitted by those practitioners pursuant to this section in conjunction with the renewal of such license and under procedures adopted by the department.

(3)Each person who has submitted information pursuant to subsection (1) must update that information in writing by notifying the Department of Health within 45 days after the occurrence of an event or the attainment of a status that is required to be reported by subsection (1). Failure to comply with the requirements of this subsection to update and submit information constitutes a ground for disciplinary action under each respective licensing chapter and s. 456.072(1)(k). For failure to comply with the requirements of this subsection to update and submit information, the department or board, as appropriate, may:

(a)Refuse to issue a license to any person applying for initial licensure who fails to submit and update the required information.

(b)Issue a citation to any licensee who fails to submit and update the required information and may fine the licensee up to $50 for each day that the licensee is not in compliance with this subsection. The citation must clearly state that the licensee may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the licensee disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the licensee does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the licensee's last known address.

(4)(a)An applicant for initial licensure must submit a set of fingerprints to the Department of Health in accordance with s. 458.311, s. 458.3115, s. 458.3124, s. 458.313, s. 459.0055, s. 460.406, or s. 461.006.

(b)An applicant for renewed licensure must submit a set of fingerprints for the initial renewal of his or her license after January 1, 2000, to the agency regulating that profession in accordance with procedures established under s. 458.319, s. 459.008, s. 460.407, or s. 461.007.

(c)The Department of Health shall submit the fingerprints provided by an applicant for initial licensure to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant. The department shall submit the fingerprints provided by an applicant for a renewed license to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check for the initial renewal of the applicant's license after January 1, 2000; for any subsequent renewal of the applicant's license, the department shall submit the required information for a statewide criminal history check of the applicant.

(5)Each person who is required to submit information pursuant to this section may submit additional information. Such information may include, but is not limited to:

(a)Information regarding publications in peer-reviewed medical literature within the previous 10 years.

(b)Information regarding professional or community service activities or awards.

(c)Languages, other than English, used by the applicant to communicate with patients and identification of any translating service that may be available at the place where the applicant primarily conducts his or her practice.

(d)An indication of whether the person participates in the Medicaid program.

History.—s. 127, ch. 97-237; s. 3, ch. 97-273; ss. 8, 34, ch. 98-166; s. 60, ch. 99-397; s. 66, ch. 2000-160; s. 21, ch. 2000-318; s. 74, ch. 2001-62; s. 13, ch. 2003-416; s. 57, ch. 2010-114.

Note.—Former s. 455.565.

456.0391Advanced registered nurse practitioners; information required for certification.—

(1)(a)Each person who applies for initial certification under s. 464.012 must, at the time of application, and each person certified under s. 464.012 who applies for certification renewal must, in conjunction with the renewal of such certification and under procedures adopted by the Department of Health, and in addition to any other information that may be required from the applicant, furnish the following information to the Department of Health:

1.The name of each school or training program that the applicant has attended, with the months and years of attendance and the month and year of graduation, and a description of all graduate professional education completed by the applicant, excluding any coursework taken to satisfy continuing education requirements.

2.The name of each location at which the applicant practices.

3.The address at which the applicant will primarily conduct his or her practice.

4.Any certification or designation that the applicant has received from a specialty or certification board that is recognized or approved by the regulatory board or department to which the applicant is applying.

5.The year that the applicant received initial certification and began practicing the profession in any jurisdiction and the year that the applicant received initial certification in this state.

6.Any appointment which the applicant currently holds to the faculty of a school related to the profession and an indication as to whether the applicant has had the responsibility for graduate education within the most recent 10 years.

7.A description of any criminal offense of which the applicant has been found guilty, regardless of whether adjudication of guilt was withheld, or to which the applicant has pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony or misdemeanor if committed in this state must be reported. If the applicant indicates that a criminal offense is under appeal and submits a copy of the notice for appeal of that criminal offense, the department must state that the criminal offense is under appeal if the criminal offense is reported in the applicant's profile. If the applicant indicates to the department that a criminal offense is under appeal, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

8.A description of any final disciplinary action taken within the previous 10 years against the applicant by a licensing or regulatory body in any jurisdiction, by a specialty board that is recognized by the board or department, or by a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home. Disciplinary action includes resignation from or nonrenewal of staff membership or the restriction of privileges at a licensed hospital, health maintenance organization, prepaid health clinic, ambulatory surgical center, or nursing home taken in lieu of or in settlement of a pending disciplinary case related to competence or character. If the applicant indicates that the disciplinary action is under appeal and submits a copy of the document initiating an appeal of the disciplinary action, the department must state that the disciplinary action is under appeal if the disciplinary action is reported in the applicant's profile.

(b)In addition to the information required under paragraph (a), each applicant for initial certification or certification renewal must provide the information required of licensees pursuant to s. 456.049.

(2)The Department of Health shall send a notice to each person certified under s. 464.012 at the certificateholder's last known address of record regarding the requirements for information to be submitted by advanced registered nurse practitioners pursuant to this section in conjunction with the renewal of such certificate.

(3)Each person certified under s. 464.012 who has submitted information pursuant to subsection (1) must update that information in writing by notifying the Department of Health within 45 days after the

occurrence of an event or the attainment of a status that is required to be reported by subsection (1). Failure to comply with the requirements of this subsection to update and submit information constitutes a ground for disciplinary action under chapter 464 and s. 456.072(1)(k). For failure to comply with the requirements of this subsection to update and submit information, the department or board, as appropriate, may:

(a)Refuse to issue a certificate to any person applying for initial certification who fails to submit and update the required information.

(b)Issue a citation to any certificateholder who fails to submit and update the required information and may fine the certificateholder up to $50 for each day that the certificateholder is not in compliance with this subsection. The citation must clearly state that the certificateholder may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the certificateholder disputes the matter in the citation, the procedures set forth in s. 456.073 must be followed. However, if the certificateholder does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a final order and constitutes discipline. Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the certificateholder's last known address.

(4)(a)An applicant for initial certification under s. 464.012 must submit a set of fingerprints to the Department of Health on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check of the applicant.

(b)An applicant for renewed certification who has not previously submitted a set of fingerprints to the Department of Health for purposes of certification must submit a set of fingerprints to the department as a condition of the initial renewal of his or her certificate after the effective date of this section. The applicant must submit the fingerprints on a form and under procedures specified by the department, along with payment in an amount equal to the costs incurred by the Department of Health for a national criminal history check. For subsequent renewals, the applicant for renewed certification must only submit information necessary to conduct a statewide criminal history check, along with payment in an amount equal to the costs incurred by the Department of Health for a statewide criminal history check.

(c)1.The Department of Health shall submit the fingerprints provided by an applicant for initial certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check of the applicant.

2.The department shall submit the fingerprints provided by an applicant for the initial renewal of certification to the Florida Department of Law Enforcement for a statewide criminal history check, and the Florida Department of Law Enforcement shall forward the fingerprints to the Federal Bureau of Investigation for a national criminal history check for the initial renewal of the applicant's certificate

after the effective date of this section.

3.For any subsequent renewal of the applicant's certificate, the department shall submit the required information for a statewide criminal history check of the applicant to the Florida Department of Law Enforcement.

(d)Any applicant for initial certification or renewal of certification as an advanced registered nurse practitioner who submits to the Department of Health a set of fingerprints and information required for the criminal history check required under this section shall not be required to provide a subsequent set of fingerprints or other duplicate information required for a criminal history check to the Agency for Health Care Administration, the Department of Juvenile Justice, or the Department of Children and Family Services for employment or licensure with such agency or department, if the applicant has undergone a criminal history check as a condition of initial certification or renewal of certification as an advanced registered nurse practitioner with the Department of Health, notwithstanding any other provision of law to the contrary. In lieu of such duplicate submission, the Agency for Health Care Administration, the Department of Juvenile Justice, and the Department of Children and Family Services shall obtain criminal history information for employment or licensure of persons certified under s. 464.012 by such agency or department from the Department of Health's health care practitioner credentialing system.

(5)Each person who is required to submit information pursuant to this section may submit additional information to the Department of Health. Such information may include, but is not limited to:

(a)Information regarding publications in peer-reviewed professional literature within the previous 10 years.

(b)Information regarding professional or community service activities or awards.

(c)Languages, other than English, used by the applicant to communicate with patients or clients and identification of any translating service that may be available at the place where the applicant primarily conducts his or her practice.

(d)An indication of whether the person participates in the Medicaid program.

History.—s. 152, ch. 2000-318.

456.0392Prescription labeling.—

(1)A prescription written by a practitioner who is authorized under the laws of this state to write prescriptions for drugs that are not listed as controlled substances in chapter 893 but who is not eligible for a federal Drug Enforcement Administration number shall include that practitioner's name and professional license number. The pharmacist or dispensing practitioner must include the practitioner's name on the container of the drug that is dispensed. A pharmacist shall be permitted, upon verification by the prescriber, to document any information required by this section.

(2)A prescription for a drug that is not listed as a controlled substance in chapter 893 which is

written by an advanced registered nurse practitioner certified under s. 464.012 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by a practitioner licensed under chapter 458, chapter 459, or chapter 466.

(3)A prescription for a drug that is not listed as a controlled substance in chapter 893 which is written by a physician assistant licensed under chapter 458 or chapter 459 is presumed, subject to rebuttal, to be valid and within the parameters of the prescriptive authority delegated by the physician assistant's supervising physician.

History.—s. 1, ch. 2004-8.

456.041Practitioner profile; creation.—

(1)(a)The Department of Health shall compile the information submitted pursuant to s. 456.039 into a practitioner profile of the applicant submitting the information, except that the Department of Health shall develop a format to compile uniformly any information submitted under s. 456.039(4)(b). Beginning July 1, 2001, the Department of Health may compile the information submitted pursuant to s. 456.0391 into a practitioner profile of the applicant submitting the information. The protocol submitted pursuant to s. 464.012(3) must be included in the practitioner profile of the advanced registered nurse practitioner.

(b)Beginning July 1, 2005, the department shall verify the information submitted by the applicant under s. 456.039 concerning disciplinary history and medical malpractice claims at the time of initial licensure and license renewal using the National Practitioner Data Bank. The physician profiles shall reflect the disciplinary action and medical malpractice claims as reported by the National Practitioner Data Bank, and shall include information relating to liability and disciplinary actions obtained as a result of a search of the National Practitioner Data Bank.

(c)Within 30 calendar days after receiving an update of information required for the practitioner's profile, the department shall update the practitioner's profile in accordance with the requirements of subsection (8).

(2)On the profile published under subsection (1), the department shall indicate if the information provided under s. 456.039(1)(a)7. or s. 456.0391(1)(a)7. is or is not corroborated by a criminal history check conducted according to this subsection. The department, or the board having regulatory authority over the practitioner acting on behalf of the department, shall investigate any information received by the department or the board.

(3)The Department of Health shall include in each practitioner's practitioner profile that criminal information that directly relates to the practitioner's ability to competently practice his or her profession. The department must include in each practitioner's practitioner profile the following statement: "The criminal history information, if any exists, may be incomplete; federal criminal history information is not available to the public." The department shall provide in each practitioner profile, for every final disciplinary action taken against the practitioner, an easy-to-read narrative description

that explains the administrative complaint filed against the practitioner and the final disciplinary action imposed on the practitioner. The department shall include a hyperlink to each final order listed in its website report of dispositions of recent disciplinary actions taken against practitioners.

(4)The Department of Health shall include, with respect to a practitioner licensed under chapter 458 or chapter 459, a statement of how the practitioner has elected to comply with the financial responsibility requirements of s. 458.320 or s. 459.0085. The department shall include, with respect to practitioners subject to s. 456.048, a statement of how the practitioner has elected to comply with the financial responsibility requirements of that section. The department shall include, with respect to practitioners licensed under chapter 461, information relating to liability actions which has been reported under s. 456.049 or s. 627.912 within the previous 10 years for any paid claim that exceeds $5,000. The department shall include, with respect to practitioners licensed under chapter 458 or chapter 459, information relating to liability actions which has been reported under ss. 456.049 and 627.912 within the previous 10 years for any paid claim that exceeds $100,000. Such claims information shall be reported in the context of comparing an individual practitioner's claims to the experience of other practitioners within the same specialty, or profession if the practitioner is not a specialist. The department must provide a hyperlink in such practitioner's profile to all such comparison reports. If information relating to a liability action is included in a practitioner's practitioner profile, the profile must also include the following statement: "Settlement of a claim may occur for a variety of reasons that do not necessarily reflect negatively on the professional competence or conduct of the practitioner. A payment in settlement of a medical malpractice action or claim should not be construed as creating a presumption that medical malpractice has occurred."

(5)The Department of Health shall include the date of a hospital or ambulatory surgical center disciplinary action taken by a licensed hospital or an ambulatory surgical center, in accordance with the requirements of s. 395.0193, in the practitioner profile. The department shall state whether the action related to professional competence and whether it related to the delivery of services to a patient.

(6)The Department of Health shall provide in each practitioner profile for every physician or advanced registered nurse practitioner terminated for cause from participating in the Medicaid program, pursuant to s. 409.913, or sanctioned by the Medicaid program a statement that the practitioner has been terminated from participating in the Florida Medicaid program or sanctioned by the Medicaid program.

(7)The Department of Health may include in the practitioner's practitioner profile any other information that is a public record of any governmental entity and that relates to a practitioner's ability to competently practice his or her profession.

(8)Upon the completion of a practitioner profile under this section, the Department of Health shall furnish the practitioner who is the subject of the profile a copy of it for review and verification. The practitioner has a period of 30 days in which to review and verify the contents of the profile and to

correct any factual inaccuracies in it. The Department of Health shall make the profile available to the public at the end of the 30-day period regardless of whether the practitioner has provided verification of the profile content. A practitioner shall be subject to a fine of up to $100 per day for failure to verify the profile contents and to correct any factual errors in his or her profile within the 30-day period. The department shall make the profiles available to the public through the World Wide Web and other commonly used means of distribution. The department must include the following statement, in boldface type, in each profile that has not been reviewed by the practitioner to which it applies: "The practitioner has not verified the information contained in this profile."

(9)The Department of Health must provide in each profile an easy-to-read explanation of any disciplinary action taken and the reason the sanction or sanctions were imposed.

(10)The Department of Health may provide one link in each profile to a practitioner's professional website if the practitioner requests that such a link be included in his or her profile.

(11)Making a practitioner profile available to the public under this section does not constitute agency action for which a hearing under s. 120.57 may be sought.

History.—s. 128, ch. 97-237; s. 4, ch. 97-273; s. 35, ch. 98-166; s. 77, ch. 99-397; s. 111, ch. 2000-153; s. 67, ch. 2000-160; ss. 22, 153, ch. 2000-318; s. 14, ch. 2003-416; s. 7, ch. 2005-62; s. 1, ch. 2005-266; s. 3, ch. 2006-251; s. 22, ch. 2009-223; s. 103, ch. 2010-5.

Note.—Former s. 455.5651.

456.042Practitioner profiles; update.—A practitioner must submit updates of required information within 15 days after the final activity that renders such information a fact. The Department of Health shall update each practitioner's practitioner profile periodically. An updated profile is subject to the same requirements as an original profile.

History.—s. 129, ch. 97-237; s. 5, ch. 97-273; s. 68, ch. 2000-160; s. 15, ch. 2003-416.

Note.—Former s. 455.5652.

456.043Practitioner profiles; data storage.—Effective upon this act becoming a law, the Department of Health must develop or contract for a computer system to accommodate the new data collection and storage requirements under this act pending the development and operation of a computer system by the Department of Health for handling the collection, input, revision, and update of data submitted by physicians as a part of their initial licensure or renewal to be compiled into individual practitioner profiles. The Department of Health must incorporate any data required by this act into the computer system used in conjunction with the regulation of health care professions under its jurisdiction. The Department of Health is authorized to contract with and negotiate any interagency agreement necessary to develop and implement the practitioner profiles. The Department of Health shall have access to any information or record maintained by the Agency for Health Care Administration, including any information or record that is otherwise confidential and exempt from the provisions of chapter 119 and s. 24(a), Art. I of the State Constitution, so that the Department of

Health may corroborate any information that practitioners are required to report under s. 456.039 or s. 456.0391.

History.—s. 130, ch. 97-237; s. 6, ch. 97-273; s. 112, ch. 2000-153; s. 69, ch. 2000-160; ss. 23, 154, ch. 2000-318.

Note.—Former s. 455.5653.

456.044Practitioner profiles; rules; workshops.—Effective upon this act becoming a law, the Department of Health shall adopt rules for the form of a practitioner profile that the agency is required to prepare. The Department of Health, pursuant to chapter 120, must hold public workshops for purposes of rule development to implement this section. An agency to which information is to be submitted under this act may adopt by rule a form for the submission of the information required under s. 456.039 or s. 456.0391.

History.—s. 131, ch. 97-237; s. 7, ch. 97-273; s. 113, ch. 2000-153; s. 70, ch. 2000-160; ss. 24, 155, ch. 2000-318.

Note.—Former s. 455.5654.

456.045Practitioner profiles; maintenance of superseded information.—Information in superseded practitioner profiles must be maintained by the Department of Health, in accordance with general law and the rules of the Department of State.

History.—s. 132, ch. 97-237; s. 8, ch. 97-273; s. 71, ch. 2000-160.

Note.—Former s. 455.5655.

456.046Practitioner profiles; confidentiality.—Any patient name or other information that identifies a patient which is in a record obtained by the Department of Health or its agent for the purpose of compiling a practitioner profile pursuant to s. 456.041 is confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution. Other data received by the department or its agent as a result of its duty to compile and promulgate practitioner profiles are confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the profile into which the data are incorporated or with respect to which the data are submitted is made public pursuant to the requirements of s. 456.041. Any information or record that the Department of Health obtains from the Agency for Health Care Administration or any other governmental entity for the purpose of compiling a practitioner profile or substantiating other information or records submitted for that purpose which is otherwise exempt from public disclosure shall remain exempt as otherwise provided by law.

History.—s. 1, ch. 97-175; s. 71, ch. 2000-160; s. 1, ch. 2002-198.

Note.—Former s. 455.5656.

456.048Financial responsibility requirements for certain health care practitioners.—

(1)As a prerequisite for licensure or license renewal, the Board of Acupuncture, the Board of Chiropractic Medicine, the Board of Podiatric Medicine, and the Board of Dentistry shall, by rule,

require that all health care practitioners licensed under the respective board, and the Board of Medicine and the Board of Osteopathic Medicine shall, by rule, require that all anesthesiologist assistants licensed pursuant to s. 458.3475 or s. 459.023, and the Board of Nursing shall, by rule, require that advanced registered nurse practitioners certified under s. 464.012, and the department shall, by rule, require that midwives maintain medical malpractice insurance or provide proof of financial responsibility in an amount and in a manner determined by the board or department to be sufficient to cover claims arising out of the rendering of or failure to render professional care and services in this state.

(2)The board or department may grant exemptions upon application by practitioners meeting any of the following criteria:

(a)Any person licensed under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who practices exclusively as an officer, employee, or agent of the Federal Government or of the state or its agencies or its subdivisions. For the purposes of this subsection, an agent of the state, its agencies, or its subdivisions is a person who is eligible for coverage under any self-insurance or insurance program authorized by the provisions of s. 768.28(16) or who is a volunteer under s. 110.501(1).

(b)Any person whose license or certification has become inactive under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, part I of chapter 464, chapter 466, or chapter 467 and who is not practicing in this state. Any person applying for reactivation of a license must show either that such licensee maintained tail insurance coverage which provided liability coverage for incidents that occurred on or after October 1, 1993, or the initial date of licensure in this state, whichever is later, and incidents that occurred before the date on which the license became inactive; or such licensee must submit an affidavit stating that such licensee has no unsatisfied medical malpractice judgments or settlements at the time of application for reactivation.

(c)Any person holding a limited license pursuant to s. 456.015, and practicing under the scope of such limited license.

(d)Any person licensed or certified under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who practices only in conjunction with his or her teaching duties at an accredited school or in its main teaching hospitals. Such person may engage in the practice of medicine to the extent that such practice is incidental to and a necessary part of duties in connection with the teaching position in the school.

(e)Any person holding an active license or certification under chapter 457, s. 458.3475, s. 459.023, chapter 460, chapter 461, s. 464.012, chapter 466, or chapter 467 who is not practicing in this state. If such person initiates or resumes practice in this state, he or she must notify the department of such activity.

(f)Any person who can demonstrate to the board or department that he or she has no malpractice exposure in the state.

(3)Notwithstanding the provisions of this section, the financial responsibility requirements of ss. 458.320 and 459.0085 shall continue to apply to practitioners licensed under those chapters, except for anesthesiologist assistants licensed pursuant to s. 458.3475 or s. 459.023 who must meet the requirements of this section.

History.—s. 1, ch. 93-41; s. 193, ch. 97-103; s. 90, ch. 97-261; s. 266, ch. 98-166; s. 88, ch. 99-397; s. 73, ch. 2000-160; s. 116, ch. 2000-318; s. 73, ch. 2004-5; s. 1, ch. 2004-303.

Note.—Former s. 455.2456; s. 455.694.

456.049Health care practitioners; reports on professional liability claims and actions.—Any practitioner of medicine licensed pursuant to the provisions of chapter 458, practitioner of osteopathic medicine licensed pursuant to the provisions of chapter 459, podiatric physician licensed pursuant to the provisions of chapter 461, or dentist licensed pursuant to the provisions of chapter 466 shall report to the Office of Insurance Regulation any claim or action for damages for personal injury alleged to have been caused by error, omission, or negligence in the performance of such licensee's professional services or based on a claimed performance of professional services without consent pursuant to s. 627.912.

History.—s. 13, ch. 88-1; s. 7, ch. 91-140; s. 309, ch. 96-406; s. 91, ch. 97-261; s. 193, ch. 98-166; s. 74, ch. 2000-160; s. 16, ch. 2003-416.

Note.—Former s. 455.247; s. 455.697.

456.051Reports of professional liability actions; bankruptcies; Department of Health's responsibility to provide.—

(1)The report of a claim or action for damages for personal injury which is required to be provided to the Department of Health under s. 456.049 or s. 627.912 is public information except for the name of the claimant or injured person, which remains confidential as provided in s. 627.912(2)(e). The Department of Health shall, upon request, make such report available to any person. The department shall make such report available as a part of the practitioner's profile within 30 calendar days after receipt.

(2)Any information in the possession of the Department of Health which relates to a bankruptcy proceeding by a practitioner of medicine licensed under chapter 458, a practitioner of osteopathic medicine licensed under chapter 459, a podiatric physician licensed under chapter 461, or a dentist licensed under chapter 466 is public information. The Department of Health shall, upon request, make such information available to any person. The department shall make such report available as a part of the practitioner's profile within 30 calendar days after receipt.

History.—s. 146, ch. 97-237; s. 22, ch. 97-273; ss. 38, 194, ch. 98-166; s. 75, ch. 2000-160; s. 17, ch. 2003-416; s. 74, ch. 2004-5.

Note.—Former s. 455.698.

456.052Disclosure of financial interest by production.—

(1)A health care provider shall not refer a patient to an entity in which such provider is an investor unless, prior to the referral, the provider furnishes the patient with a written disclosure form, informing the patient of:

(a)The existence of the investment interest.

(b)The name and address of each applicable entity in which the referring health care provider is an investor.

(c)The patient's right to obtain the items or services for which the patient has been referred at the location or from the provider or supplier of the patient's choice, including the entity in which the referring provider is an investor.

(d)The names and addresses of at least two alternative sources of such items or services available to the patient.

(2)The physician or health care provider shall post a copy of the disclosure forms in a conspicuous public place in his or her office.

(3)A violation of this section shall constitute a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083. In addition to any other penalties or remedies provided, a violation of this section shall be grounds for disciplinary action by the respective board.

History.—s. 1, ch. 86-31; s. 84, ch. 91-224; s. 13, ch. 92-178; s. 92, ch. 97-261; s. 76, ch. 2000-160.

Note.—Former s. 455.25; s. 455.701.

456.053Financial arrangements between referring health care providers and providers of health care services.—

(1)SHORT TITLE.—This section may be cited as the "Patient Self-Referral Act of 1992."

(2)LEGISLATIVE INTENT.—It is recognized by the Legislature that the referral of a patient by a health care provider to a provider of health care services in which the referring health care provider has an investment interest represents a potential conflict of interest. The Legislature finds these referral practices may limit or eliminate competitive alternatives in the health care services market, may result in overutilization of health care services, may increase costs to the health care system, and may adversely affect the quality of health care. The Legislature also recognizes, however, that it may be appropriate for providers to own entities providing health care services, and to refer patients to such entities, as long as certain safeguards are present in the arrangement. It is the intent of the Legislature to provide guidance to health care providers regarding prohibited patient referrals between health care providers and entities providing health care services and to protect the people of Florida from unnecessary and costly health care expenditures.

(3)DEFINITIONS.—For the purpose of this section, the word, phrase, or term:

(a)"Board" means any of the following boards relating to the respective professions: the Board of Medicine as created in s. 458.307; the Board of Osteopathic Medicine as created in s. 459.004; the

Board of Chiropractic Medicine as created in s. 460.404; the Board of Podiatric Medicine as created in s. 461.004; the Board of Optometry as created in s. 463.003; the Board of Pharmacy as created in s. 465.004; and the Board of Dentistry as created in s. 466.004.

(b)"Comprehensive rehabilitation services" means services that are provided by health care professionals licensed under part I or part III of chapter 468 or chapter 486 to provide speech, occupational, or physical therapy services on an outpatient or ambulatory basis.

(c)"Designated health services" means, for purposes of this section, clinical laboratory services, physical therapy services, comprehensive rehabilitative services, diagnostic-imaging services, and radiation therapy services.

(d)"Diagnostic imaging services" means magnetic resonance imaging, nuclear medicine, angiography, arteriography, computed tomography, positron emission tomography, digital vascular imaging, bronchography, lymphangiography, splenography, ultrasound, EEG, EKG, nerve conduction studies, and evoked potentials.

(e)"Direct supervision" means supervision by a physician who is present in the office suite and immediately available to provide assistance and direction throughout the time services are being performed.

(f)"Entity" means any individual, partnership, firm, corporation, or other business entity.

(g)"Fair market value" means value in arms length transactions, consistent with the general market value, and, with respect to rentals or leases, the value of rental property for general commercial purposes, not taking into account its intended use, and, in the case of a lease of space, not adjusted to reflect the additional value the prospective lessee or lessor would attribute to the proximity or convenience to the lessor where the lessor is a potential source of patient referrals to the lessee.

(h)"Group practice" means a group of two or more health care providers legally organized as a partnership, professional corporation, or similar association:

1.In which each health care provider who is a member of the group provides substantially the full range of services which the health care provider routinely provides, including medical care, consultation, diagnosis, or treatment, through the joint use of shared office space, facilities, equipment, and personnel;

2.For which substantially all of the services of the health care providers who are members of the group are provided through the group and are billed in the name of the group and amounts so received are treated as receipts of the group; and

3.In which the overhead expenses of and the income from the practice are distributed in accordance with methods previously determined by members of the group.

(i)"Health care provider" means any physician licensed under chapter 458, chapter 459, chapter 460, or chapter 461, or any health care provider licensed under chapter 463 or chapter 466.

(j)"Immediate family member" means a health care provider's spouse, child, child's spouse,

grandchild, grandchild's spouse, parent, parent-in-law, or sibling.

(k)"Investment interest" means an equity or debt security issued by an entity, including, without limitation, shares of stock in a corporation, units or other interests in a partnership, bonds, debentures, notes, or other equity interests or debt instruments. The following investment interests shall be excepted from this definition:

1.An investment interest in an entity that is the sole provider of designated health services in a rural area;

2.An investment interest in notes, bonds, debentures, or other debt instruments issued by an entity which provides designated health services, as an integral part of a plan by such entity to acquire such investor's equity investment interest in the entity, provided that the interest rate is consistent with fair market value, and that the maturity date of the notes, bonds, debentures, or other debt instruments issued by the entity to the investor is not later than October 1, 1996.

3.An investment interest in real property resulting in a landlord-tenant relationship between the health care provider and the entity in which the equity interest is held, unless the rent is determined, in whole or in part, by the business volume or profitability of the tenant or exceeds fair market value; or

4.An investment interest in an entity which owns or leases and operates a hospital licensed under chapter 395 or a nursing home facility licensed under chapter 400.

(l)"Investor" means a person or entity owning a legal or beneficial ownership or investment interest, directly or indirectly, including, without limitation, through an immediate family member, trust, or another entity related to the investor within the meaning of 42 C.F.R. s. 413.17, in an entity.

(m)"Outside referral for diagnostic imaging services" means a referral of a patient to a group practice or sole provider for diagnostic imaging services by a physician who is not a member of the group practice or of the sole provider's practice and who does not have an investment interest in the group practice or sole provider's practice, for which the group practice or sole provider billed for both the technical and the professional fee for the patient, and the patient did not become a patient of the group practice or sole provider's practice.

(n)"Patient of a group practice" or "patient of a sole provider" means a patient who receives a physical examination, evaluation, diagnosis, and development of a treatment plan if medically necessary by a physician who is a member of the group practice or the sole provider's practice.

(o)"Referral" means any referral of a patient by a health care provider for health care services, including, without limitation:

1.The forwarding of a patient by a health care provider to another health care provider or to an entity which provides or supplies designated health services or any other health care item or service; or

2.The request or establishment of a plan of care by a health care provider, which includes the provision of designated health services or other health care item or service.

3.The following orders, recommendations, or plans of care shall not constitute a referral by a health care provider:

a.By a radiologist for diagnostic-imaging services.

b.By a physician specializing in the provision of radiation therapy services for such services.

c.By a medical oncologist for drugs and solutions to be prepared and administered intravenously to such oncologist's patient, as well as for the supplies and equipment used in connection therewith to treat such patient for cancer and the complications thereof.

d.By a cardiologist for cardiac catheterization services.

e.By a pathologist for diagnostic clinical laboratory tests and pathological examination services, if furnished by or under the supervision of such pathologist pursuant to a consultation requested by another physician.

f.By a health care provider who is the sole provider or member of a group practice for designated health services or other health care items or services that are prescribed or provided solely for such referring health care provider's or group practice's own patients, and that are provided or performed by or under the direct supervision of such referring health care provider or group practice; provided, however, that effective July 1, 1999, a physician licensed pursuant to chapter 458, chapter 459, chapter 460, or chapter 461 may refer a patient to a sole provider or group practice for diagnostic imaging services, excluding radiation therapy services, for which the sole provider or group practice billed both the technical and the professional fee for or on behalf of the patient, if the referring physician has no investment interest in the practice. The diagnostic imaging service referred to a group practice or sole provider must be a diagnostic imaging service normally provided within the scope of practice to the patients of the group practice or sole provider. The group practice or sole provider may accept no more than 15 percent of their patients receiving diagnostic imaging services from outside referrals, excluding radiation therapy services.

g.By a health care provider for services provided by an ambulatory surgical center licensed under chapter 395.

h.By a urologist for lithotripsy services.

i.By a dentist for dental services performed by an employee of or health care provider who is an independent contractor with the dentist or group practice of which the dentist is a member.

j.By a physician for infusion therapy services to a patient of that physician or a member of that physician's group practice.

k.By a nephrologist for renal dialysis services and supplies, except laboratory services.

l.By a health care provider whose principal professional practice consists of treating patients in their private residences for services to be rendered in such private residences, except for services rendered by a home health agency licensed under chapter 400. For purposes of this sub-subparagraph, the term "private residences" includes patients' private homes, independent living centers, and assisted living facilities, but does not include skilled nursing facilities.

m.By a health care provider for sleep-related testing.

(p)"Present in the office suite" means that the physician is actually physically present; provided, however, that the health care provider is considered physically present during brief unexpected absences as well as during routine absences of a short duration if the absences occur during time periods in which the health care provider is otherwise scheduled and ordinarily expected to be present and the absences do not conflict with any other requirement in the Medicare program for a particular level of health care provider supervision.

(q)"Rural area" means a county with a population density of no greater than 100 persons per square mile, as defined by the United States Census.

(r)"Sole provider" means one health care provider licensed under chapter 458, chapter 459, chapter 460, or chapter 461, who maintains a separate medical office and a medical practice separate from any other health care provider and who bills for his or her services separately from the services provided by any other health care provider. A sole provider shall not share overhead expenses or professional income with any other person or group practice.

(4)REQUIREMENTS FOR ACCEPTING OUTSIDE REFERRALS FOR DIAGNOSTIC IMAGING.—

(a)A group practice or sole provider accepting outside referrals for diagnostic imaging services is required to comply with the following conditions:

1.Diagnostic imaging services must be provided exclusively by a group practice physician or by a full-time or part-time employee of the group practice or of the sole provider's practice.

2.All equity in the group practice or sole provider's practice accepting outside referrals for diagnostic imaging must be held by the physicians comprising the group practice or the sole provider's practice, each of whom must provide at least 75 percent of his or her professional services to the group. Alternatively, the group must be incorporated under chapter 617 and must be exempt under the provisions of s. 501(c)(3) of the Internal Revenue Code and be part of a foundation in existence prior to January 1, 1999, that is created for the purpose of patient care, medical education, and research.

3.A group practice or sole provider may not enter into, extend or renew any contract with a practice management company that provides any financial incentives, directly or indirectly, based on an increase in outside referrals for diagnostic imaging services from any group or sole provider managed by the same practice management company.

4.The group practice or sole provider accepting outside referrals for diagnostic imaging services must bill for both the professional and technical component of the service on behalf of the patient, and no portion of the payment, or any type of consideration, either directly or indirectly, may be shared with the referring physician.

5.Group practices or sole providers that have a Medicaid provider agreement with the Agency for Health Care Administration must furnish diagnostic imaging services to their Medicaid patients and may not refer a Medicaid recipient to a hospital for outpatient diagnostic imaging services unless the physician furnishes the hospital with documentation demonstrating the medical necessity for such a

referral. If necessary, the Agency for Health Care Administration may apply for a federal waiver to implement this subparagraph.

6.All group practices and sole providers accepting outside referrals for diagnostic imaging shall report annually to the Agency for Health Care Administration providing the number of outside referrals accepted for diagnostic imaging services and the total number of all patients receiving diagnostic imaging services.

(b)If a group practice or sole provider accepts an outside referral for diagnostic imaging services in violation of this subsection or if a group practice or sole provider accepts outside referrals for diagnostic imaging services in excess of the percentage limitation established in subparagraph (a)2., the group practice or the sole provider shall be subject to the penalties in subsection (5).

(c)Each managing physician member of a group practice and each sole provider who accepts outside referrals for diagnostic imaging services shall submit an annual attestation signed under oath to the Agency for Health Care Administration which shall include the annual report required under subparagraph (a)6. and which shall further confirm that each group practice or sole provider is in compliance with the percentage limitations for accepting outside referrals and the requirements for accepting outside referrals listed in paragraph (a). The agency may verify the report submitted by group practices and sole providers.

(5)PROHIBITED REFERRALS AND CLAIMS FOR PAYMENT.—Except as provided in this section:

(a)A health care provider may not refer a patient for the provision of designated health services to an entity in which the health care provider is an investor or has an investment interest.

(b)A health care provider may not refer a patient for the provision of any other health care item or service to an entity in which the health care provider is an investor unless:

1.The provider's investment interest is in registered securities purchased on a national exchange or over-the-counter market and issued by a publicly held corporation:

a.Whose shares are traded on a national exchange or on the over-the-counter market; and

b.Whose total assets at the end of the corporation's most recent fiscal quarter exceeded $50 million; or

2.With respect to an entity other than a publicly held corporation described in subparagraph 1., and a referring provider's investment interest in such entity, each of the following requirements are met:

a.No more than 50 percent of the value of the investment interests are held by investors who are in a position to make referrals to the entity.

b.The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are no different from the terms offered to investors who are not in a position to make such referrals.

c.The terms under which an investment interest is offered to an investor who is in a position to make referrals to the entity are not related to the previous or expected volume of referrals from that

investor to the entity.

d.There is no requirement that an investor make referrals or be in a position to make referrals to the entity as a condition for becoming or remaining an investor.

3.With respect to either such entity or publicly held corporation:

a.The entity or corporation does not loan funds to or guarantee a loan for an investor who is in a position to make referrals to the entity or corporation if the investor uses any part of such loan to obtain the investment interest.

b.The amount distributed to an investor representing a return on the investment interest is directly proportional to the amount of the capital investment, including the fair market value of any preoperational services rendered, invested in the entity or corporation by that investor.

4.Each board and, in the case of hospitals, the Agency for Health Care Administration, shall encourage the use by licensees of the declaratory statement procedure to determine the applicability of this section or any rule adopted pursuant to this section as it applies solely to the licensee. Boards shall submit to the Agency for Health Care Administration the name of any entity in which a provider investment interest has been approved pursuant to this section, and the Agency for Health Care Administration shall adopt rules providing for periodic quality assurance and utilization review of such entities.

(c)No claim for payment may be presented by an entity to any individual, third-party payor, or other entity for a service furnished pursuant to a referral prohibited under this section.

(d)If an entity collects any amount that was billed in violation of this section, the entity shall refund such amount on a timely basis to the payor or individual, whichever is applicable.

(e)Any person that presents or causes to be presented a bill or a claim for service that such person knows or should know is for a service for which payment may not be made under paragraph (c), or for which a refund has not been made under paragraph (d), shall be subject to a civil penalty of not more than $15,000 for each such service to be imposed and collected by the appropriate board.

(f)Any health care provider or other entity that enters into an arrangement or scheme, such as a cross-referral arrangement, which the physician or entity knows or should know has a principal purpose of assuring referrals by the physician to a particular entity which, if the physician directly made referrals to such entity, would be in violation of this section, shall be subject to a civil penalty of not more than $100,000 for each such circumvention arrangement or scheme to be imposed and collected by the appropriate board.

(g)A violation of this section by a health care provider shall constitute grounds for disciplinary action to be taken by the applicable board pursuant to s. 458.331(2), s. 459.015(2), s. 460.413(2), s. 461.013(2), s. 463.016(2), or s. 466.028(2). Any hospital licensed under chapter 395 found in violation of this section shall be subject to the rules adopted by the Agency for Health Care Administration pursuant to s. 395.0185(2).

(h)Any hospital licensed under chapter 395 that discriminates against or otherwise penalizes a

health care provider for compliance with this act.

(i)The provision of paragraph (a) shall not apply to referrals to the offices of radiation therapy centers managed by an entity or subsidiary or general partner thereof, which performed radiation therapy services at those same offices prior to April 1, 1991, and shall not apply also to referrals for radiation therapy to be performed at no more than one additional office of any entity qualifying for the foregoing exception which, prior to February 1, 1992, had a binding purchase contract on and a nonrefundable deposit paid for a linear accelerator to be used at the additional office. The physical site of the radiation treatment centers affected by this provision may be relocated as a result of the following factors: acts of God; fire; strike; accident; war; eminent domain actions by any governmental body; or refusal by the lessor to renew a lease. A relocation for the foregoing reasons is limited to relocation of an existing facility to a replacement location within the county of the existing facility upon written notification to the Office of Licensure and Certification.

(j)A health care provider who meets the requirements of paragraphs (b) and (i) must disclose his or her investment interest to his or her patients as provided in s. 456.052.

History.—s. 7, ch. 92-178; s. 89, ch. 94-218; s. 60, ch. 95-144; s. 35, ch. 95-146; s. 8, ch. 96-296; s. 1083, ch. 97-103; s. 78, ch. 97-261; s. 70, ch. 97-264; s. 263, ch. 98-166; s. 62, ch. 98-171; s. 1, ch. 99-356; s. 10, ch. 2000-159; s. 77, ch. 2000-160; s. 14, ch. 2002-389; s. 23, ch. 2009-223.

Note.—Former s. 455.236; s. 455.654.

456.054Kickbacks prohibited.—

(1)As used in this section, the term "kickback" means a remuneration or payment, by or on behalf of a provider of health care services or items, to any person as an incentive or inducement to refer patients for past or future services or items, when the payment is not tax deductible as an ordinary and necessary expense.

(2)It is unlawful for any health care provider or any provider of health care services to offer, pay, solicit, or receive a kickback, directly or indirectly, overtly or covertly, in cash or in kind, for referring or soliciting patients.

(3)Violations of this section shall be considered patient brokering and shall be punishable as provided in s. 817.505.

History.—s. 8, ch. 92-178; s. 2, ch. 96-152; s. 79, ch. 97-261; s. 8, ch. 99-204; s. 78, ch. 2000-160; s. 6, ch. 2006-305.

Note.—Former s. 455.237; s. 455.657.

456.055Chiropractic and podiatric health care; denial of payment; limitation.—A chiropractic physician licensed under chapter 460 or a podiatric physician licensed under chapter 461 shall not be denied payment for treatment rendered solely on the basis that the chiropractic physician or podiatric physician is not a member of a particular preferred provider organization or exclusive provider organization which is composed only of physicians licensed under the same chapter.

History.—s. 43, ch. 85-167; s. 87, ch. 97-261; ss. 191, 264, ch. 98-166; s. 78, ch. 2000-160.

Note.—Former s. 455.244; s. 455.684.

456.056Treatment of Medicare beneficiaries; refusal, emergencies, consulting physicians.—

(1)Effective as of January 1, 1993, as used in this section, the term:

(a)"Physician" means a physician licensed under chapter 458, an osteopathic physician licensed under chapter 459, a chiropractic physician licensed under chapter 460, a podiatric physician licensed under chapter 461, or an optometrist licensed under chapter 463.

(b)"Beneficiary" means a beneficiary of health insurance under Title XVIII of the federal Social Security Act.

(c)"Consulting physician" means any physician to whom a primary physician refers a Medicare beneficiary for treatment.

(2)A physician may refuse to treat a beneficiary. However, nothing contained in this section shall be construed to limit a physician's obligation under state or federal law to treat a patient for an emergency medical condition, regardless of the patient's ability to pay.

(3)If treatment is provided to a beneficiary for an emergency medical condition as defined in [1]s. 395.0142(2)(c), the physician must accept Medicare assignment provided that the requirement to accept Medicare assignment for an emergency medical condition shall not apply to treatment rendered after the patient is stabilized, or the treatment is unrelated to the original emergency medical condition. For the purpose of this subsection "stabilized" is defined to mean with respect to an emergency medical condition, that no material deterioration of the condition is likely within reasonable medical probability.

(4)If treatment provided to a beneficiary is not for such emergency medical condition, and the primary physician accepts assignment, all consulting physicians must accept assignment unless the patient agrees in writing, before receiving the treatment, that the physician need not accept assignment.

(5)Any attempt by a primary physician or a consulting physician to collect from a Medicare beneficiary any amount of charges for medical services in excess of those authorized under this section, other than the unmet deductible and the 20 percent of charges that Medicare does not pay, shall be deemed null, void, and of no merit.

History.—s. 1, ch. 92-118; s. 160, ch. 92-149; s. 89, ch. 97-261; ss. 192, 265, ch. 98-166; s. 78, ch. 2000-160.

[1]**Note.**—"Emergency medical condition" is no longer defined in s. 395.0142, which was amended and transferred to s. 395.1041 by s. 24, ch. 92-289.

Note.—Former s. 455.2455; s. 455.691.

456.057Ownership and control of patient records; report or copies of records to be furnished.—

(1)As used in this section, the term "records owner" means any health care practitioner who generates a medical record after making a physical or mental examination of, or administering

treatment or dispensing legend drugs to, any person; any health care practitioner to whom records are transferred by a previous records owner; or any health care practitioner's employer, including, but not limited to, group practices and staff-model health maintenance organizations, provided the employment contract or agreement between the employer and the health care practitioner designates the employer as the records owner.

(2)As used in this section, the terms "records owner," "health care practitioner," and "health care practitioner's employer" do not include any of the following persons or entities; furthermore, the following persons or entities are not authorized to acquire or own medical records, but are authorized under the confidentiality and disclosure requirements of this section to maintain those documents required by the part or chapter under which they are licensed or regulated:

(a)Certified nursing assistants regulated under part II of chapter 464.

(b)Pharmacists and pharmacies licensed under chapter 465.

(c)Dental hygienists licensed under s. 466.023.

(d)Nursing home administrators licensed under part II of chapter 468.

(e)Respiratory therapists regulated under part V of chapter 468.

(f)Athletic trainers licensed under part XIII of chapter 468.

(g)Electrologists licensed under chapter 478.

(h)Clinical laboratory personnel licensed under part III of chapter 483.

(i)Medical physicists licensed under part IV of chapter 483.

(j)Opticians and optical establishments licensed or permitted under part I of chapter 484.

(k)Persons or entities practicing under s. 627.736(7).

(3)As used in this section, the term "records custodian" means any person or entity that:

(a)Maintains documents that are authorized in subsection (2); or

(b)Obtains medical records from a records owner.

(4)Any health care practitioner's employer who is a records owner and any records custodian shall maintain records or documents as provided under the confidentiality and disclosure requirements of this section.

(5)This section does not apply to facilities licensed under chapter 395.

(6)Any health care practitioner licensed by the department or a board within the department who makes a physical or mental examination of, or administers treatment or dispenses legend drugs to, any person shall, upon request of such person or the person's legal representative, furnish, in a timely manner, without delays for legal review, copies of all reports and records relating to such examination or treatment, including X rays and insurance information. However, when a patient's psychiatric, chapter 490 psychological, or chapter 491 psychotherapeutic records are requested by the patient or the patient's legal representative, the health care practitioner may provide a report of examination and treatment in lieu of copies of records. Upon a patient's written request, complete copies of the patient's psychiatric records shall be provided directly to a subsequent treating psychiatrist. The

furnishing of such report or copies shall not be conditioned upon payment of a fee for services rendered.

(7)(a)Except as otherwise provided in this section and in s. 440.13(4)(c), such records may not be furnished to, and the medical condition of a patient may not be discussed with, any person other than the patient or the patient's legal representative or other health care practitioners and providers involved in the care or treatment of the patient, except upon written authorization of the patient. However, such records may be furnished without written authorization under the following circumstances:

1.To any person, firm, or corporation that has procured or furnished such examination or treatment with the patient's consent.

2.When compulsory physical examination is made pursuant to Rule 1.360, Florida Rules of Civil Procedure, in which case copies of the medical records shall be furnished to both the defendant and the plaintiff.

3.In any civil or criminal action, unless otherwise prohibited by law, upon the issuance of a subpoena from a court of competent jurisdiction and proper notice to the patient or the patient's legal representative by the party seeking such records.

4.For statistical and scientific research, provided the information is abstracted in such a way as to protect the identity of the patient or provided written permission is received from the patient or the patient's legal representative.

5.To a regional poison control center for purposes of treating a poison episode under evaluation, case management of poison cases, or compliance with data collection and reporting requirements of s. 395.1027 and the professional organization that certifies poison control centers in accordance with federal law.

(b)Absent a specific written release or authorization permitting utilization of patient information for solicitation or marketing the sale of goods or services, any use of that information for those purposes is prohibited.

(8)Except in a medical negligence action or administrative proceeding when a health care practitioner or provider is or reasonably expects to be named as a defendant, information disclosed to a health care practitioner by a patient in the course of the care and treatment of such patient is confidential and may be disclosed only to other health care practitioners and providers involved in the care or treatment of the patient, or if permitted by written authorization from the patient or compelled by subpoena at a deposition, evidentiary hearing, or trial for which proper notice has been given.

(9)(a)1.The department may obtain patient records pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has excessively or inappropriately prescribed any controlled substance specified in chapter 893 in violation of this chapter

or any professional practice act or that a health care practitioner has practiced his or her profession below that level of care, skill, and treatment required as defined by this chapter or any professional practice act and also find that appropriate, reasonable attempts were made to obtain a patient release. Notwithstanding the foregoing, the department need not attempt to obtain a patient release when investigating an offense involving the inappropriate prescribing, overprescribing, or diversion of controlled substances and the offense involves a pain-management clinic. The department may obtain patient records without patient authorization or subpoena from any pain-management clinic required to be licensed if the department has probable cause to believe that a violation of any provision of s. 458.3265 or s. 459.0137 is occurring or has occurred and reasonably believes that obtaining such authorization is not feasible due to the volume of the dispensing and prescribing activity involving controlled substances and that obtaining patient authorization or the issuance of a subpoena would jeopardize the investigation.

2.The department may obtain patient records and insurance information pursuant to a subpoena without written authorization from the patient if the department and the probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has provided inadequate medical care based on termination of insurance and also find that appropriate, reasonable attempts were made to obtain a patient release.

3.The department may obtain patient records, billing records, insurance information, provider contracts, and all attachments thereto pursuant to a subpoena without written authorization from the patient if the department and probable cause panel of the appropriate board, if any, find reasonable cause to believe that a health care practitioner has submitted a claim, statement, or bill using a billing code that would result in payment greater in amount than would be paid using a billing code that accurately describes the services performed, requested payment for services that were not performed by that health care practitioner, used information derived from a written report of an automobile accident generated pursuant to chapter 316 to solicit or obtain patients personally or through an agent regardless of whether the information is derived directly from the report or a summary of that report or from another person, solicited patients fraudulently, received a kickback as defined in s. 456.054, violated the patient brokering provisions of s. 817.505, or presented or caused to be presented a false or fraudulent insurance claim within the meaning of s. 817.234(1)(a), and also find that, within the meaning of s. 817.234(1)(a), patient authorization cannot be obtained because the patient cannot be located or is deceased, incapacitated, or suspected of being a participant in the fraud or scheme, and if the subpoena is issued for specific and relevant records.

4.Notwithstanding subparagraphs 1.-3., when the department investigates a professional liability claim or undertakes action pursuant to s. 456.049 or s. 627.912, the department may obtain patient records pursuant to a subpoena without written authorization from the patient if the patient refuses to cooperate or if the department attempts to obtain a patient release and the failure to obtain the patient records would be detrimental to the investigation.

(b)Patient records, billing records, insurance information, provider contracts, and all attachments thereto obtained by the department pursuant to this subsection shall be used solely for the purpose of the department and the appropriate regulatory board in disciplinary proceedings. This section does not limit the assertion of the psychotherapist-patient privilege under s. 90.503 in regard to records of treatment for mental or nervous disorders by a medical practitioner licensed pursuant to chapter 458 or chapter 459 who has primarily diagnosed and treated mental and nervous disorders for a period of not less than 3 years, inclusive of psychiatric residency. However, the health care practitioner shall release records of treatment for medical conditions even if the health care practitioner has also treated the patient for mental or nervous disorders. If the department has found reasonable cause under this section and the psychotherapist-patient privilege is asserted, the department may petition the circuit court for an in camera review of the records by expert medical practitioners appointed by the court to determine if the records or any part thereof are protected under the psychotherapist-patient privilege.

(10)(a)All patient records obtained by the department and any other documents maintained by the department which identify the patient by name are confidential and exempt from s. 119.07(1) and shall be used solely for the purpose of the department and the appropriate regulatory board in its investigation, prosecution, and appeal of disciplinary proceedings. The records shall not be available to the public as part of the record of investigation for and prosecution in disciplinary proceedings made available to the public by the department or the appropriate board.

(b)Notwithstanding paragraph (a), all patient records obtained by the department and any other documents maintained by the department which relate to a current or former Medicaid recipient shall be provided to the Medicaid Fraud Control Unit in the Department of Legal Affairs, upon request.

(11)All records owners shall develop and implement policies, standards, and procedures to protect the confidentiality and security of the medical record. Employees of records owners shall be trained in these policies, standards, and procedures.

(12)Records owners are responsible for maintaining a record of all disclosures of information contained in the medical record to a third party, including the purpose of the disclosure request. The record of disclosure may be maintained in the medical record. The third party to whom information is disclosed is prohibited from further disclosing any information in the medical record without the expressed written consent of the patient or the patient's legal representative.

(13)Notwithstanding the provisions of s. 456.058, records owners shall place an advertisement in the local newspaper or notify patients, in writing, when they are terminating practice, retiring, or relocating, and no longer available to patients, and offer patients the opportunity to obtain a copy of their medical record.

(14)Notwithstanding the provisions of s. 456.058, records owners shall notify the appropriate board office when they are terminating practice, retiring, or relocating, and no longer available to patients, specifying who the new records owner is and where medical records can be found.

(15)Whenever a records owner has turned records over to a new records owner, the new records owner shall be responsible for providing a copy of the complete medical record, upon written request, of the patient or the patient's legal representative.

(16)Licensees in violation of the provisions of this section shall be disciplined by the appropriate licensing authority.

(17)The Attorney General is authorized to enforce the provisions of this section for records owners not otherwise licensed by the state, through injunctive relief and fines not to exceed $5,000 per violation.

(18)A health care practitioner or records owner furnishing copies of reports or records or making the reports or records available for digital scanning pursuant to this section shall charge no more than the actual cost of copying, including reasonable staff time, or the amount specified in administrative rule by the appropriate board, or the department when there is no board.

(19)Nothing in this section shall be construed to limit health care practitioner consultations, as necessary.

(20)A records owner shall release to a health care practitioner who, as an employee of the records owner, previously provided treatment to a patient, those records that the health care practitioner actually created or generated when the health care practitioner treated the patient. Records released pursuant to this subsection shall be released only upon written request of the health care practitioner and shall be limited to the notes, plans of care, and orders and summaries that were actually generated by the health care practitioner requesting the record.

(21)The board, or department when there is no board, may temporarily or permanently appoint a person or entity as a custodian of medical records in the event of the death of a practitioner, the mental or physical incapacitation of the practitioner, or the abandonment of medical records by a practitioner. The custodian appointed shall comply with all provisions of this section, including the release of patient records.

History.—s. 1, ch. 79-302; s. 1, ch. 82-22; s. 1, ch. 83-108; s. 81, ch. 83-218; ss. 14, 119, ch. 83-329; s. 2, ch. 84-15; s. 41, ch. 85-175; s. 4, ch. 87-333; s. 9, ch. 88-1; s. 2, ch. 88-208; s. 14, ch. 88-219; s. 6, ch. 88-277; s. 10, ch. 88-392; s. 2, ch. 89-85; s. 14, ch. 89-124; s. 28, ch. 89-289; s. 1, ch. 90-263; s. 11, ch. 91-137; s. 6, ch. 91-140; s. 12, ch. 91-176; s. 4, ch. 91-269; s. 62, ch. 92-33; s. 32, ch. 92-149; s. 23, ch. 93-129; s. 315, ch. 94-119; ss. 90, 91, ch. 94-218; s. 308, ch. 96-406; s. 1084, ch. 97-103; s. 82, ch. 97-261; s. 6, ch. 98-166; s. 12, ch. 99-349; s. 86, ch. 99-397; s. 79, ch. 2000-160; s. 9, ch. 2000-163; s. 114, ch. 2000-318; s. 9, ch. 2001-222; ss. 69, 140, ch. 2001-277; s. 18, ch. 2003-416; s. 4, ch. 2005-256; s. 1, ch. 2006-271; s. 2, ch. 2010-211.

Note.—Former s. 455.241; s. 455.667.

456.0575Duty to notify patients.—Every licensed health care practitioner shall inform each patient, or an individual identified pursuant to s. 765.401(1), in person about adverse incidents that result in serious harm to the patient. Notification of outcomes of care that result in harm to the

patient under this section shall not constitute an acknowledgment of admission of liability, nor can such notifications be introduced as evidence.

History.—s. 8, ch. 2003-416.

456.058Disposition of records of deceased practitioners or practitioners relocating or terminating practice.—Each board created under the provisions of chapter 457, chapter 458, chapter 459, chapter 460, chapter 461, chapter 463, part I of chapter 464, chapter 465, chapter 466, part I of chapter 484, chapter 486, chapter 490, or chapter 491, and the department under the provisions of chapter 462, shall provide by rule for the disposition, under that chapter, of the medical records or records of a psychological nature of practitioners which are in existence at the time the practitioner dies, terminates practice, or relocates and is no longer available to patients and which records pertain to the practitioner's patients. The rules shall provide that the records be retained for at least 2 years after the practitioner's death, termination of practice, or relocation. In the case of the death of the practitioner, the rules shall provide for the disposition of such records by the estate of the practitioner.

History.—s. 85, ch. 97-261; s. 80, ch. 2000-160; s. 115, ch. 2000-318.

Note.—Former s. 455.677.

456.059Communications confidential; exceptions.—Communications between a patient and a psychiatrist, as defined in s. 394.455, shall be held confidential and shall not be disclosed except upon the request of the patient or the patient's legal representative. Provision of psychiatric records and reports shall be governed by s. 456.057. Notwithstanding any other provision of this section or s. 90.503, where:

(1)A patient is engaged in a treatment relationship with a psychiatrist;

(2)Such patient has made an actual threat to physically harm an identifiable victim or victims; and

(3)The treating psychiatrist makes a clinical judgment that the patient has the apparent capability to commit such an act and that it is more likely than not that in the near future the patient will carry out that threat,

the psychiatrist may disclose patient communications to the extent necessary to warn any potential victim or to communicate the threat to a law enforcement agency. No civil or criminal action shall be instituted, and there shall be no liability on account of disclosure of otherwise confidential communications by a psychiatrist in disclosing a threat pursuant to this section.

History.—s. 10, ch. 88-1; s. 33, ch. 92-149; s. 43, ch. 96-169; s. 83, ch. 97-261; s. 81, ch. 2000-160.

Note.—Former s. 455.2415; s. 455.671.

456.061Practitioner disclosure of confidential information; immunity from civil or criminal liability.—

(1)A practitioner regulated through the Division of Medical Quality Assurance of the department

shall not be civilly or criminally liable for the disclosure of otherwise confidential information to a sexual partner or a needle-sharing partner under the following circumstances:

(a)If a patient of the practitioner who has tested positive for human immunodeficiency virus discloses to the practitioner the identity of a sexual partner or a needle-sharing partner;

(b)The practitioner recommends the patient notify the sexual partner or the needle-sharing partner of the positive test and refrain from engaging in sexual or drug activity in a manner likely to transmit the virus and the patient refuses, and the practitioner informs the patient of his or her intent to inform the sexual partner or needle-sharing partner; and

(c)If pursuant to a perceived civil duty or the ethical guidelines of the profession, the practitioner reasonably and in good faith advises the sexual partner or the needle-sharing partner of the patient of the positive test and facts concerning the transmission of the virus.

However, any notification of a sexual partner or a needle-sharing partner pursuant to this section shall be done in accordance with protocols developed pursuant to rule of the Department of Health.

(2)Notwithstanding the foregoing, a practitioner regulated through the Division of Medical Quality Assurance of the department shall not be civilly or criminally liable for failure to disclose information relating to a positive test result for human immunodeficiency virus of a patient to a sexual partner or a needle-sharing partner.

History.—s. 43, ch. 88-380; s. 12, ch. 89-350; s. 191, ch. 97-103; s. 84, ch. 97-261; s. 220, ch. 99-8; s. 82, ch. 2000-160.

Note.—Former s. 455.2416; s. 455.674.

456.062Advertisement by a health care practitioner of free or discounted services; required statement.—In any advertisement for a free, discounted fee, or reduced fee service, examination, or treatment by a health care practitioner licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, chapter 467, chapter 478, chapter 483, part I of chapter 484, chapter 486, chapter 490, or chapter 491, the following statement shall appear in capital letters clearly distinguishable from the rest of the text: THE PATIENT AND ANY OTHER PERSON RESPONSIBLE FOR PAYMENT HAS A RIGHT TO REFUSE TO PAY, CANCEL PAYMENT, OR BE REIMBURSED FOR PAYMENT FOR ANY OTHER SERVICE, EXAMINATION, OR TREATMENT THAT IS PERFORMED AS A RESULT OF AND WITHIN 72 HOURS OF RESPONDING TO THE ADVERTISEMENT FOR THE FREE, DISCOUNTED FEE, OR REDUCED FEE SERVICE, EXAMINATION, OR TREATMENT. However, the required statement shall not be necessary as an accompaniment to an advertisement of a licensed health care practitioner defined by this section if the advertisement appears in a classified directory the primary purpose of which is to provide products and services at free, reduced, or discounted prices to consumers and in which the statement prominently appears in at least one place.

History.—s. 81, ch. 97-261; s. 85, ch. 99-397; s. 82, ch. 2000-160; s. 1, ch. 2006-215.

Note.—Former s. 455.664.

456.063Sexual misconduct; disqualification for license, certificate, or registration.—

(1)Sexual misconduct in the practice of a health care profession means violation of the professional relationship through which the health care practitioner uses such relationship to engage or attempt to engage the patient or client, or an immediate family member, guardian, or representative of the patient or client in, or to induce or attempt to induce such person to engage in, verbal or physical sexual activity outside the scope of the professional practice of such health care profession. Sexual misconduct in the practice of a health care profession is prohibited.

(2)Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant has:

(a)Had any license, certificate, or registration to practice any profession or occupation revoked or surrendered based on a violation of sexual misconduct in the practice of that profession under the laws of any other state or any territory or possession of the United States and has not had that license, certificate, or registration reinstated by the licensing authority of the jurisdiction that revoked the license, certificate, or registration; or

(b)Committed any act in any other state or any territory or possession of the United States which if committed in this state would constitute sexual misconduct.

For purposes of this subsection, a licensing authority's acceptance of a candidate's relinquishment of a license which is offered in response to or in anticipation of the filing of administrative charges against the candidate's license constitutes the surrender of the license.

(3)Licensed health care practitioners shall report allegations of sexual misconduct to the department, regardless of the practice setting in which the alleged sexual misconduct occurred.

History.—s. 1, ch. 95-183; s. 52, ch. 97-261; s. 78, ch. 99-397; s. 82, ch. 2000-160; s. 25, ch. 2000-318; s. 70, ch. 2001-277.

Note.—Former s. 455.2142; s. 455.567.

456.0635Health care fraud; disqualification for license, certificate, or registration.—

(1)Health care fraud in the practice of a health care profession is prohibited.

(2)Each board within the jurisdiction of the department, or the department if there is no board, shall refuse to admit a candidate to any examination and refuse to issue a license, certificate, or registration to any applicant if the candidate or applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the candidate or applicant has successfully completed a drug court program for that felony and provides proof that the plea has been withdrawn or the charges have been dismissed. Any such conviction or plea shall exclude the applicant or

candidate from licensure, examination, certification, or registration unless the sentence and any subsequent period of probation for such conviction or plea ended:

1.For felonies of the first or second degree, more than 15 years before the date of application.

2.For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3.For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of application;

(b)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application;

(c)Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the candidate or applicant has been in good standing with the Florida Medicaid program for the most recent 5 years;

(d)Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the candidate or applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application; or

(e)Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

This subsection does not apply to candidates or applicants for initial licensure or certification who were enrolled in an educational or training program on or before July 1, 2009, which was recognized by a board or, if there is no board, recognized by the department, and who applied for licensure after July 1, 2012.

(3)The department shall refuse to renew a license, certificate, or registration of any applicant if the applicant or any principal, officer, agent, managing employee, or affiliated person of the applicant:

(a)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under chapter 409, chapter 817, or chapter 893, or a similar felony offense committed in another state or jurisdiction, unless the applicant is currently enrolled in a drug court program that allows the withdrawal of the plea for that felony upon successful completion of that program. Any such conviction or plea excludes the applicant from licensure renewal unless the sentence and any subsequent period of probation for such conviction or plea ended:

1.For felonies of the first or second degree, more than 15 years before the date of application.

2.For felonies of the third degree, more than 10 years before the date of application, except for felonies of the third degree under s. 893.13(6)(a).

3.For felonies of the third degree under s. 893.13(6)(a), more than 5 years before the date of

application.

(b)Has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a felony under 21 U.S.C. ss. 801-970, or 42 U.S.C. ss. 1395-1396 since July 1, 2009, unless the sentence and any subsequent period of probation for such conviction or plea ended more than 15 years before the date of the application.

(c)Has been terminated for cause from the Florida Medicaid program pursuant to s. 409.913, unless the applicant has been in good standing with the Florida Medicaid program for the most recent 5 years.

(d)Has been terminated for cause, pursuant to the appeals procedures established by the state, from any other state Medicaid program, unless the applicant has been in good standing with a state Medicaid program for the most recent 5 years and the termination occurred at least 20 years before the date of the application.

(e)Is currently listed on the United States Department of Health and Human Services Office of Inspector General's List of Excluded Individuals and Entities.

(4)Licensed health care practitioners shall report allegations of health care fraud to the department, regardless of the practice setting in which the alleged health care fraud occurred.

(5)The acceptance by a licensing authority of a licensee's relinquishment of a license which is offered in response to or anticipation of the filing of administrative charges alleging health care fraud or similar charges constitutes the permanent revocation of the license.

History.—s. 24, ch. 2009-223; s. 1, ch. 2012-64.

456.065Unlicensed practice of a health care profession; intent; cease and desist notice; penalties; enforcement; citations; fees; allocation and disposition of moneys collected.—

(1)It is the intent of the Legislature that vigorous enforcement of licensure regulation for all health care professions is a state priority in order to protect Florida residents and visitors from the potentially serious and dangerous consequences of receiving medical and health care services from unlicensed persons whose professional education and training and other relevant qualifications have not been approved through the issuance of a license by the appropriate regulatory board or the department when there is no board. The unlicensed practice of a health care profession or the performance or delivery of medical or health care services to patients in this state without a valid, active license to practice that profession, regardless of the means of the performance or delivery of such services, is strictly prohibited.

(2)The penalties for unlicensed practice of a health care profession shall include the following:

(a)When the department has probable cause to believe that any person not licensed by the department, or the appropriate regulatory board within the department, has violated any provision of this chapter or any statute that relates to the practice of a profession regulated by the department, or any rule adopted pursuant thereto, the department may issue and deliver to such person a notice to cease and desist from such violation. In addition, the department may issue and deliver a notice to

cease and desist to any person who aids and abets the unlicensed practice of a profession by employing such unlicensed person. The issuance of a notice to cease and desist shall not constitute agency action for which a hearing under ss. 120.569 and 120.57 may be sought. For the purpose of enforcing a cease and desist order, the department may file a proceeding in the name of the state seeking issuance of an injunction or a writ of mandamus against any person who violates any provisions of such order.

(b)In addition to the remedies under paragraph (a), the department may impose by citation an administrative penalty not to exceed $5,000 per incident. The citation shall be issued to the subject and shall contain the subject's name and any other information the department determines to be necessary to identify the subject, a brief factual statement, the sections of the law allegedly violated, and the penalty imposed. If the subject does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation shall become a final order of the department. The department may adopt rules to implement this section. The penalty shall be a fine of not less than $500 nor more than $5,000 as established by rule of the department. Each day that the unlicensed practice continues after issuance of a notice to cease and desist constitutes a separate violation. The department shall be entitled to recover the costs of investigation and prosecution in addition to the fine levied pursuant to the citation. Service of a citation may be made by personal service or by mail to the subject at the subject's last known address or place of practice. If the department is required to seek enforcement of the cease and desist or agency order, it shall be entitled to collect its attorney's fees and costs.

(c)In addition to or in lieu of any other administrative remedy, the department may seek the imposition of a civil penalty through the circuit court for any violation for which the department may issue a notice to cease and desist. The civil penalty shall be no less than $500 and no more than $5,000 for each offense. The court may also award to the prevailing party court costs and reasonable attorney fees and, in the event the department prevails, may also award reasonable costs of investigation and prosecution.

(d)In addition to the administrative and civil remedies under paragraphs (b) and (c) and in addition to the criminal violations and penalties listed in the individual health care practice acts:

1.It is a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, to practice, attempt to practice, or offer to practice a health care profession without an active, valid Florida license to practice that profession. Practicing without an active, valid license also includes practicing on a suspended, revoked, or void license, but does not include practicing, attempting to practice, or offering to practice with an inactive or delinquent license for a period of up to 12 months which is addressed in subparagraph 3. Applying for employment for a position that requires a license without notifying the employer that the person does not currently possess a valid, active license to practice that profession shall be deemed to be an attempt or offer to practice that health care profession without a license. Holding oneself out, regardless of the means of communication, as able to practice a health care profession or as able to provide services that require a health care license shall

be deemed to be an attempt or offer to practice such profession without a license. The minimum penalty for violating this subparagraph shall be a fine of $1,000 and a minimum mandatory period of incarceration of 1 year.

2.It is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, to practice a health care profession without an active, valid Florida license to practice that profession when such practice results in serious bodily injury. For purposes of this section, "serious bodily injury" means death; brain or spinal damage; disfigurement; fracture or dislocation of bones or joints; limitation of neurological, physical, or sensory function; or any condition that required subsequent surgical repair. The minimum penalty for violating this subparagraph shall be a fine of $1,000 and a minimum mandatory period of incarceration of 1 year.

3.It is a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, to practice, attempt to practice, or offer to practice a health care profession with an inactive or delinquent license for any period of time up to 12 months. However, practicing, attempting to practice, or offering to practice a health care profession when that person's license has been inactive or delinquent for a period of time of 12 months or more shall be a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. The minimum penalty for violating this subparagraph shall be a term of imprisonment of 30 days and a fine of $500.

(3)Because all enforcement costs should be covered by professions regulated by the department, the department shall impose, upon initial licensure and each licensure renewal, a special fee of $5 per licensee to fund efforts to combat unlicensed activity. Such fee shall be in addition to all other fees collected from each licensee. The department shall make direct charges to the Medical Quality Assurance Trust Fund by profession. The department shall seek board advice regarding enforcement methods and strategies. The department shall directly credit the Medical Quality Assurance Trust Fund, by profession, with the revenues received from the department's efforts to enforce licensure provisions. The department shall include all financial and statistical data resulting from unlicensed activity enforcement as a separate category in the quarterly management report provided for in s. 456.025. For an unlicensed activity account, a balance which remains at the end of a renewal cycle may, with concurrence of the applicable board and the department, be transferred to the operating fund account of that profession. The department shall also use these funds to inform and educate consumers generally on the importance of using licensed health care practitioners.

(4)The provisions of this section apply only to health care professional practice acts administered by the department.

(5)Nothing herein shall be construed to limit or restrict the sale, use, or recommendation of the use of a dietary supplement, as defined by the Food, Drug, and Cosmetic Act, 21 U.S.C. s. 321, so long as the person selling, using, or recommending the dietary supplement does so in compliance with federal and state law.

History.—s. 73, ch. 97-261; s. 84, ch. 2000-160; s. 35, ch. 2000-318; s. 54, ch. 2001-277.

Note.—Former s. 455.637.

456.066Prosecution of criminal violations.—The department or the appropriate board shall report any criminal violation of any statute relating to the practice of a profession regulated by the department or appropriate board to the proper prosecuting authority for prompt prosecution.

History.—s. 72, ch. 97-261; s. 85, ch. 2000-160.

Note.—Former s. 455.634.

456.067Penalty for giving false information.—In addition to, or in lieu of, any other discipline imposed pursuant to s. 456.072, the act of knowingly giving false information in the course of applying for or obtaining a license from the department, or any board thereunder, with intent to mislead a public servant in the performance of his or her official duties, or the act of attempting to obtain or obtaining a license from the department, or any board thereunder, to practice a profession by knowingly misleading statements or knowing misrepresentations constitutes a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—s. 71, ch. 97-261; s. 24, ch. 99-7; s. 86, ch. 2000-160; s. 27, ch. 2000-318.

Note.—Former s. 455.631.

456.068Toll-free telephone number for reporting of complaints.—The Agency for Health Care Administration shall establish a toll-free telephone number for public reporting of complaints relating to medical treatment or services provided by health care professionals.

History.—s. 148, ch. 97-237; s. 24, ch. 97-273; s. 87, ch. 2000-160.

Note.—Former s. 455.699.

456.069Authority to inspect.—In addition to the authority specified in s. 465.017, duly authorized agents and employees of the department shall have the power to inspect in a lawful manner at all reasonable hours:

(1)Any pharmacy; or

(2)Any establishment at which the services of a licensee authorized to prescribe controlled substances specified in chapter 893 are offered,

for the purpose of determining if any of the provisions of this chapter or any practice act of a profession or any rule adopted thereunder is being violated; or for the purpose of securing such other evidence as may be needed for prosecution.

History.—s. 86, ch. 97-261; s. 88, ch. 2000-160.

Note.—Former s. 455.681.

456.071Power to administer oaths, take depositions, and issue subpoenas.—For the purpose of any investigation or proceeding conducted by the department, the department shall have the power to administer oaths, take depositions, make inspections when authorized by statute, issue subpoenas

which shall be supported by affidavit, serve subpoenas and other process, and compel the attendance of witnesses and the production of books, papers, documents, and other evidence. The department shall exercise this power on its own initiative or whenever requested by a board or the probable cause panel of any board. Challenges to, and enforcement of, the subpoenas and orders shall be handled as provided in s. 120.569.

History.—s. 65, ch. 97-261; s. 89, ch. 2000-160.

Note.—Former s. 455.611.

456.072Grounds for discipline; penalties; enforcement.—

(1)The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:

(a)Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.

(b)Intentionally violating any rule adopted by the board or the department, as appropriate.

(c)Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.

(d)Using a Class III or a Class IV laser device or product, as defined by federal regulations, without having complied with the rules adopted under s. 501.122(2) governing the registration of the devices.

(e)Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome.

(f)Having a license or the authority to practice any regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.

(g)Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the department against another licensee.

(h)Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the department or the board.

(i)Except as provided in s. 465.016, failing to report to the department any person who the licensee knows is in violation of this chapter, the chapter regulating the alleged violator, or the rules of the department or the board.

(j)Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this chapter, the chapter regulating the profession, or the rules of the department or the board.

(k)Failing to perform any statutory or legal obligation placed upon a licensee. For purposes of this section, failing to repay a student loan issued or guaranteed by the state or the Federal Government in accordance with the terms of the loan or failing to comply with service scholarship obligations shall be considered a failure to perform a statutory or legal obligation, and the minimum disciplinary action imposed shall be a suspension of the license until new payment terms are agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount. Fines collected shall be deposited into the Medical Quality Assurance Trust Fund.

(l)Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee.

(m)Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or scheme in or related to the practice of a profession.

(n)Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.

(o)Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.

(p)Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of the responsibilities knows, or has reason to know, the person is not qualified by training, experience, and authorization when required to perform them.

(q)Violating a lawful order of the department or the board, or failing to comply with a lawfully issued subpoena of the department.

(r)Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding.

(s)Failing to comply with the educational course requirements for domestic violence.

(t)Failing to identify through written notice, which may include the wearing of a name tag, or orally to a patient the type of license under which the practitioner is practicing. Any advertisement for health care services naming the practitioner must identify the type of license the practitioner holds. This paragraph does not apply to a practitioner while the practitioner is providing services in a facility licensed under chapter 394, chapter 395, chapter 400, or chapter 429. Each board, or the department where there is no board, is authorized by rule to determine how its practitioners may comply with this disclosure requirement.

(u)Failing to comply with the requirements of ss. 381.026 and 381.0261 to provide patients with information about their patient rights and how to file a patient complaint.

(v)Engaging or attempting to engage in sexual misconduct as defined and prohibited in s. 456.063(1).

(w)Failing to comply with the requirements for profiling and credentialing, including, but not limited to, failing to provide initial information, failing to timely provide updated information, or making misleading, untrue, deceptive, or fraudulent representations on a profile, credentialing, or initial or renewal licensure application.

(x)Failing to report to the board, or the department if there is no board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction. Convictions, findings, adjudications, and pleas entered into prior to the enactment of this paragraph must be reported in writing to the board, or department if there is no board, on or before October 1, 1999.

(y)Using information about people involved in motor vehicle accidents which has been derived from accident reports made by law enforcement officers or persons involved in accidents under s. 316.066, or using information published in a newspaper or other news publication or through a radio or television broadcast that has used information gained from such reports, for the purposes of commercial or any other solicitation whatsoever of the people involved in the accidents.

(z)Being unable to practice with reasonable skill and safety to patients by reason of illness or use of alcohol, drugs, narcotics, chemicals, or any other type of material or as a result of any mental or physical condition. In enforcing this paragraph, the department shall have, upon a finding of the State Surgeon General or the State Surgeon General's designee that probable cause exists to believe that the licensee is unable to practice because of the reasons stated in this paragraph, the authority to issue an order to compel a licensee to submit to a mental or physical examination by physicians designated by the department. If the licensee refuses to comply with the order, the department's order directing the examination may be enforced by filing a petition for enforcement in the circuit court where the licensee resides or does business. The department shall be entitled to the summary procedure provided in s. 51.011. A licensee or certificateholder affected under this paragraph shall at reasonable intervals be afforded an opportunity to demonstrate that he or she can resume the competent practice of his or her profession with reasonable skill and safety to patients.

(aa)Testing positive for any drug, as defined in s. 112.0455, on any confirmed preemployment or employer-ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using the drug.

(bb)Performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient.

(cc)Leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other

paraphernalia commonly used in surgical, examination, or other diagnostic procedures. For the purposes of this paragraph, it shall be legally presumed that retention of a foreign body is not in the best interest of the patient and is not within the standard of care of the profession, regardless of the intent of the professional.

(dd)Violating any provision of this chapter, the applicable practice act, or any rules adopted pursuant thereto.

(ee)With respect to making a personal injury protection claim as required by s. 627.736, intentionally submitting a claim, statement, or bill that has been "upcoded" as defined in s. 627.732.

(ff)With respect to making a personal injury protection claim as required by s. 627.736, intentionally submitting a claim, statement, or bill for payment of services that were not rendered.

(gg)Engaging in a pattern of practice when prescribing medicinal drugs or controlled substances which demonstrates a lack of reasonable skill or safety to patients, a violation of any provision of this chapter, a violation of the applicable practice act, or a violation of any rules adopted under this chapter or the applicable practice act of the prescribing practitioner. Notwithstanding s. 456.073(13), the department may initiate an investigation and establish such a pattern from billing records, data, or any other information obtained by the department.

(hh)Being terminated from a treatment program for impaired practitioners, which is overseen by an impaired practitioner consultant as described in s. 456.076, for failure to comply, without good cause, with the terms of the monitoring or treatment contract entered into by the licensee, or for not successfully completing any drug treatment or alcohol treatment program.

(ii)Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program.

(jj)Failing to remit the sum owed to the state for an overpayment from the Medicaid program pursuant to a final order, judgment, or stipulation or settlement.

(kk)Being terminated from the state Medicaid program pursuant to s. 409.913, any other state Medicaid program, or the federal Medicare program, unless eligibility to participate in the program from which the practitioner was terminated has been restored.

(ll)Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud.

(mm)Failure to comply with controlled substance prescribing requirements of s. 456.44.

(nn)Violating any of the provisions of s. 790.338.

(2)When the board, or the department when there is no board, finds any person guilty of the grounds set forth in subsection (1) or of any grounds set forth in the applicable practice act, including conduct constituting a substantial violation of subsection (1) or a violation of the applicable practice act which occurred prior to obtaining a license, it may enter an order imposing one or more of the following penalties:

(a)Refusal to certify, or to certify with restrictions, an application for a license.

(b)Suspension or permanent revocation of a license.

(c)Restriction of practice or license, including, but not limited to, restricting the licensee from practicing in certain settings, restricting the licensee to work only under designated conditions or in certain settings, restricting the licensee from performing or providing designated clinical and administrative services, restricting the licensee from practicing more than a designated number of hours, or any other restriction found to be necessary for the protection of the public health, safety, and welfare.

(d)Imposition of an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.

(e)Issuance of a reprimand or letter of concern.

(f)Placement of the licensee on probation for a period of time and subject to such conditions as the board, or the department when there is no board, may specify. Those conditions may include, but are not limited to, requiring the licensee to undergo treatment, attend continuing education courses, submit to be reexamined, work under the supervision of another licensee, or satisfy any terms which are reasonably tailored to the violations found.

(g)Corrective action.

(h)Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights.

(i)Refund of fees billed and collected from the patient or a third party on behalf of the patient.

(j)Requirement that the practitioner undergo remedial education.

In determining what action is appropriate, the board, or department when there is no board, must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the practitioner. All costs associated with compliance with orders issued under this subsection are the obligation of the practitioner.

(3)(a)Notwithstanding subsection (2), if the ground for disciplinary action is the first-time failure of the licensee to satisfy continuing education requirements established by the board, or by the department if there is no board, the board or department, as applicable, shall issue a citation in accordance with s. 456.077 and assess a fine, as determined by the board or department by rule. In addition, for each hour of continuing education not completed or completed late, the board or department, as applicable, may require the licensee to take 1 additional hour of continuing education for each hour not completed or completed late.

(b)Notwithstanding subsection (2), if the ground for disciplinary action is the first-time violation of a practice act for unprofessional conduct, as used in ss. 464.018(1)(h), 467.203(1)(f), 468.365(1)(f), and 478.52(1)(f), and no actual harm to the patient occurred, the board or department, as applicable, shall

issue a citation in accordance with s. 456.077 and assess a penalty as determined by rule of the board or department.

(4)In addition to any other discipline imposed through final order, or citation, entered on or after July 1, 2001, under this section or discipline imposed through final order, or citation, entered on or after July 1, 2001, for a violation of any practice act, the board, or the department when there is no board, shall assess costs related to the investigation and prosecution of the case. The costs related to the investigation and prosecution include, but are not limited to, salaries and benefits of personnel, costs related to the time spent by the attorney and other personnel working on the case, and any other expenses incurred by the department for the case. The board, or the department when there is no board, shall determine the amount of costs to be assessed after its consideration of an affidavit of itemized costs and any written objections thereto. In any case where the board or the department imposes a fine or assessment and the fine or assessment is not paid within a reasonable time, the reasonable time to be prescribed in the rules of the board, or the department when there is no board, or in the order assessing the fines or costs, the department or the Department of Legal Affairs may contract for the collection of, or bring a civil action to recover, the fine or assessment.

(5)In addition to, or in lieu of, any other remedy or criminal prosecution, the department may file a proceeding in the name of the state seeking issuance of an injunction or a writ of mandamus against any person who violates any of the provisions of this chapter, or any provision of law with respect to professions regulated by the department, or any board therein, or the rules adopted pursuant thereto.

(6)If the board, or the department when there is no board, determines that revocation of a license is the appropriate penalty, the revocation shall be permanent. However, the board may establish by rule requirements for reapplication by applicants whose licenses have been permanently revoked. The requirements may include, but are not limited to, satisfying current requirements for an initial license.

(7)Notwithstanding subsection (2), upon a finding that a physician has prescribed or dispensed a controlled substance, or caused a controlled substance to be prescribed or dispensed, in a manner that violates the standard of practice set forth in s. 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o) or (s), or s. 466.028(1)(p) or (x), the physician shall be suspended for a period of not less than 6 months and pay a fine of not less than $10,000 per count. Repeated violations shall result in increased penalties.

(8)The purpose of this section is to facilitate uniform discipline for those actions made punishable under this section and, to this end, a reference to this section constitutes a general reference under the doctrine of incorporation by reference.

History.—s. 69, ch. 97-261; s. 84, ch. 99-397; s. 90, ch. 2000-160; s. 26, ch. 2000-318; s. 71, ch. 2001-277; s. 2, ch. 2002-254; s. 6, ch. 2003-411; s. 19, ch. 2003-416; s. 10, ch. 2004-344; s. 1, ch. 2005-240; s. 2, ch. 2006-207; s. 111, ch. 2007-5; s. 64, ch. 2008-6; s. 25, ch. 2009-223; s. 3, ch. 2011-112; s. 1, ch. 2011-141.

Note.—Former s. 455.624.

456.0721Practitioners in default on student loan or scholarship obligations; investigation; report.—The Department of Health shall obtain from the United States Department of Health and Human Services information necessary to investigate and prosecute health care practitioners for failing to repay a student loan or comply with scholarship service obligations pursuant to s. 456.072(1)(k). The department shall obtain from the United States Department of Health and Human Services a list of default health care practitioners each month, along with the information necessary to investigate a complaint in accordance with s. 456.073. The department may obtain evidence to support the investigation and prosecution from any financial institution or educational institution involved in providing the loan or education to the practitioner. The department shall report to the Legislature as part of the annual report required by s. 456.026, the number of practitioners in default, along with the results of the department's investigations and prosecutions, and the amount of fines collected from practitioners prosecuted for violating s. 456.072(1)(k).

History.—s. 3, ch. 2002-254.

456.073Disciplinary proceedings.—Disciplinary proceedings for each board shall be within the jurisdiction of the department.

(1)The department, for the boards under its jurisdiction, shall cause to be investigated any complaint that is filed before it if the complaint is in writing, signed by the complainant, and legally sufficient. A complaint filed by a state prisoner against a health care practitioner employed by or otherwise providing health care services within a facility of the Department of Corrections is not legally sufficient unless there is a showing that the prisoner complainant has exhausted all available administrative remedies within the state correctional system before filing the complaint. However, if the Department of Health determines after a preliminary inquiry of a state prisoner's complaint that the practitioner may present a serious threat to the health and safety of any individual who is not a state prisoner, the Department of Health may determine legal sufficiency and proceed with discipline. The Department of Health shall be notified within 15 days after the Department of Corrections disciplines or allows a health care practitioner to resign for an offense related to the practice of his or her profession. A complaint is legally sufficient if it contains ultimate facts that show that a violation of this chapter, of any of the practice acts relating to the professions regulated by the department, or of any rule adopted by the department or a regulatory board in the department has occurred. In order to determine legal sufficiency, the department may require supporting information or documentation. The department may investigate, and the department or the appropriate board may take appropriate final action on, a complaint even though the original complainant withdraws it or otherwise indicates a desire not to cause the complaint to be investigated or prosecuted to completion. The department may investigate an anonymous complaint if the complaint is in writing and is legally sufficient, if the alleged violation of law or rules is substantial, and if the department has reason to believe, after preliminary inquiry, that the violations alleged in the complaint are true. The department may

investigate a complaint made by a confidential informant if the complaint is legally sufficient, if the alleged violation of law or rule is substantial, and if the department has reason to believe, after preliminary inquiry, that the allegations of the complainant are true. The department may initiate an investigation if it has reasonable cause to believe that a licensee or a group of licensees has violated a Florida statute, a rule of the department, or a rule of a board. Notwithstanding subsection (13), the department may investigate information filed pursuant to s. 456.041(4) relating to liability actions with respect to practitioners licensed under chapter 458 or chapter 459 which have been reported under s. 456.049 or s. 627.912 within the previous 6 years for any paid claim that exceeds $50,000. Except as provided in ss. 458.331(9), 459.015(9), 460.413(5), and 461.013(6), when an investigation of any subject is undertaken, the department shall promptly furnish to the subject or the subject's attorney a copy of the complaint or document that resulted in the initiation of the investigation. The subject may submit a written response to the information contained in such complaint or document within 20 days after service to the subject of the complaint or document. The subject's written response shall be considered by the probable cause panel. The right to respond does not prohibit the issuance of a summary emergency order if necessary to protect the public. However, if the State Surgeon General, or the State Surgeon General's designee, and the chair of the respective board or the chair of its probable cause panel agree in writing that such notification would be detrimental to the investigation, the department may withhold notification. The department may conduct an investigation without notification to any subject if the act under investigation is a criminal offense.

(2)The department shall allocate sufficient and adequately trained staff to expeditiously and thoroughly determine legal sufficiency and investigate all legally sufficient complaints. For purposes of this section, it is the intent of the Legislature that the term "expeditiously" means that the department complete the report of its initial investigative findings and recommendations concerning the existence of probable cause within 6 months after its receipt of the complaint. The failure of the department, for disciplinary cases under its jurisdiction, to comply with the time limits of this section while investigating a complaint against a licensee constitutes harmless error in any subsequent disciplinary action unless a court finds that either the fairness of the proceeding or the correctness of the action may have been impaired by a material error in procedure or a failure to follow prescribed procedure. When its investigation is complete and legally sufficient, the department shall prepare and submit to the probable cause panel of the appropriate regulatory board the investigative report of the department. The report shall contain the investigative findings and the recommendations of the department concerning the existence of probable cause. The department shall not recommend a letter of guidance in lieu of finding probable cause if the subject has already been issued a letter of guidance for a related offense. At any time after legal sufficiency is found, the department may dismiss any case, or any part thereof, if the department determines that there is insufficient evidence to support the prosecution of allegations contained therein. The department shall provide a detailed report to the appropriate probable cause panel prior to dismissal of any case or part thereof, and to the subject of

the complaint after dismissal of any case or part thereof, under this section. For cases dismissed prior to a finding of probable cause, such report is confidential and exempt from s. 119.07(1). The probable cause panel shall have access, upon request, to the investigative files pertaining to a case prior to dismissal of such case. If the department dismisses a case, the probable cause panel may retain independent legal counsel, employ investigators, and continue the investigation and prosecution of the case as it deems necessary.

(3)As an alternative to the provisions of subsections (1) and (2), when a complaint is received, the department may provide a licensee with a notice of noncompliance for an initial offense of a minor violation. Each board, or the department if there is no board, shall establish by rule those minor violations under this provision which do not endanger the public health, safety, and welfare and which do not demonstrate a serious inability to practice the profession. Failure of a licensee to take action in correcting the violation within 15 days after notice may result in the institution of regular disciplinary proceedings.

(4)The determination as to whether probable cause exists shall be made by majority vote of a probable cause panel of the board, or by the department, as appropriate. Each regulatory board shall provide by rule that the determination of probable cause shall be made by a panel of its members or by the department. Each board may provide by rule for multiple probable cause panels composed of at least two members. Each board may provide by rule that one or more members of the panel or panels may be a former board member. The length of term or repetition of service of any such former board member on a probable cause panel may vary according to the direction of the board when authorized by board rule. Any probable cause panel must include one of the board's former or present consumer members, if one is available, is willing to serve, and is authorized to do so by the board chair. Any probable cause panel must include a present board member. Any probable cause panel must include a former or present professional board member. However, any former professional board member serving on the probable cause panel must hold an active valid license for that profession. All proceedings of the panel are exempt from s. 286.011 until 10 days after probable cause has been found to exist by the panel or until the subject of the investigation waives his or her privilege of confidentiality. The probable cause panel may make a reasonable request, and upon such request the department shall provide such additional investigative information as is necessary to the determination of probable cause. A request for additional investigative information shall be made within 15 days from the date of receipt by the probable cause panel of the investigative report of the department or the agency. The probable cause panel or the department, as may be appropriate, shall make its determination of probable cause within 30 days after receipt by it of the final investigative report of the department. The State Surgeon General may grant extensions of the 15-day and the 30-day time limits. In lieu of a finding of probable cause, the probable cause panel, or the department if there is no board, may issue a letter of guidance to the subject. If, within the 30-day time limit, as may be extended, the probable cause panel does not make a determination regarding the existence of probable cause or does not issue

a letter of guidance in lieu of a finding of probable cause, the department must make a determination regarding the existence of probable cause within 10 days after the expiration of the time limit. If the probable cause panel finds that probable cause exists, it shall direct the department to file a formal complaint against the licensee. The department shall follow the directions of the probable cause panel regarding the filing of a formal complaint. If directed to do so, the department shall file a formal complaint against the subject of the investigation and prosecute that complaint pursuant to chapter 120. However, the department may decide not to prosecute the complaint if it finds that probable cause has been improvidently found by the panel. In such cases, the department shall refer the matter to the board. The board may then file a formal complaint and prosecute the complaint pursuant to chapter 120. The department shall also refer to the board any investigation or disciplinary proceeding not before the Division of Administrative Hearings pursuant to chapter 120 or otherwise completed by the department within 1 year after the filing of a complaint. The department, for disciplinary cases under its jurisdiction, must establish a uniform reporting system to quarterly refer to each board the status of any investigation or disciplinary proceeding that is not before the Division of Administrative Hearings or otherwise completed by the department within 1 year after the filing of the complaint. Annually, the department, in consultation with the applicable probable cause panel, must establish a plan to expedite or otherwise close any investigation or disciplinary proceeding that is not before the Division of Administrative Hearings or otherwise completed by the department within 1 year after the filing of the complaint. A probable cause panel or a board may retain independent legal counsel, employ investigators, and continue the investigation as it deems necessary; all costs thereof shall be paid from a trust fund used by the department to implement this chapter. All proceedings of the probable cause panel are exempt from s. 120.525.

(5)A formal hearing before an administrative law judge from the Division of Administrative Hearings shall be held pursuant to chapter 120 if there are any disputed issues of material fact. The determination of whether or not a licensee has violated the laws and rules regulating the profession, including a determination of the reasonable standard of care, is a conclusion of law to be determined by the board, or department when there is no board, and is not a finding of fact to be determined by an administrative law judge. The administrative law judge shall issue a recommended order pursuant to chapter 120. Notwithstanding s. 120.569(2), the department shall notify the division within 45 days after receipt of a petition or request for a formal hearing.

(6)The appropriate board, with those members of the panel, if any, who reviewed the investigation pursuant to subsection (4) being excused, or the department when there is no board, shall determine and issue the final order in each disciplinary case. Such order shall constitute final agency action. Any consent order or agreed-upon settlement shall be subject to the approval of the department.

(7)The department shall have standing to seek judicial review of any final order of the board, pursuant to s. 120.68.

(8)Any proceeding for the purpose of summary suspension of a license, or for the restriction of the

license, of a licensee pursuant to s. 120.60(6) shall be conducted by the State Surgeon General or his or her designee, as appropriate, who shall issue the final summary order.

(9)(a)The department shall periodically notify the person who filed the complaint, as well as the patient or the patient's legal representative, of the status of the investigation, indicating whether probable cause has been found and the status of any civil action or administrative proceeding or appeal.

(b)In any disciplinary case for which probable cause has been found, the department shall provide to the person who filed the complaint a copy of the administrative complaint and:

1.A written explanation of how an administrative complaint is resolved by the disciplinary process.

2.A written explanation of how and when the person may participate in the disciplinary process.

3.A written notice of any hearing before the Division of Administrative Hearings or the regulatory board at which final agency action may be taken.

(c)In any disciplinary case for which probable cause is not found, the department shall so inform the person who filed the complaint and notify that person that he or she may, within 60 days, provide any additional information to the department which may be relevant to the decision. To facilitate the provision of additional information, the person who filed the complaint may receive, upon request, a copy of the department's expert report that supported the recommendation for closure, if such a report was relied upon by the department. In no way does this require the department to procure an expert opinion or report if none was used. Additionally, the identity of the expert shall remain confidential. In any administrative proceeding under s. 120.57, the person who filed the disciplinary complaint shall have the right to present oral or written communication relating to the alleged disciplinary violations or to the appropriate penalty.

(10)The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) until 10 days after probable cause has been found to exist by the probable cause panel or by the department, or until the regulated professional or subject of the investigation waives his or her privilege of confidentiality, whichever occurs first. Upon completion of the investigation and a recommendation by the department to find probable cause, and pursuant to a written request by the subject or the subject's attorney, the department shall provide the subject an opportunity to inspect the investigative file or, at the subject's expense, forward to the subject a copy of the investigative file. Notwithstanding s. 456.057, the subject may inspect or receive a copy of any expert witness report or patient record connected with the investigation if the subject agrees in writing to maintain the confidentiality of any information received under this subsection until 10 days after probable cause is found and to maintain the confidentiality of patient records pursuant to s. 456.057. The subject may file a written response to the information contained in the investigative file. Such response must be filed within 20 days of mailing by the department, unless an extension of time has been granted by the department. This subsection does not prohibit the department from providing such information to any law enforcement agency or to any other regulatory agency.

(11)A privilege against civil liability is hereby granted to any complainant or any witness with regard to information furnished with respect to any investigation or proceeding pursuant to this section, unless the complainant or witness acted in bad faith or with malice in providing such information.

(12)(a)No person who reports in any capacity, whether or not required by law, information to the department with regard to the incompetence, impairment, or unprofessional conduct of any health care provider licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, or chapter 466 shall be held liable in any civil action for reporting against such health care provider if such person acts without intentional fraud or malice.

(b)No facility licensed under chapter 395, health maintenance organization certificated under part I of chapter 641, physician licensed under chapter 458, or osteopathic physician licensed under chapter 459 shall discharge, threaten to discharge, intimidate, or coerce any employee or staff member by reason of such employee's or staff member's report to the department about a physician licensed under chapter 458, chapter 459, chapter 460, chapter 461, or chapter 466 who may be guilty of incompetence, impairment, or unprofessional conduct so long as such report is given without intentional fraud or malice.

(c)In any civil suit brought outside the protections of paragraphs (a) and (b) in which intentional fraud or malice is alleged, the person alleging intentional fraud or malice shall be liable for all court costs and for the other party's reasonable attorney's fees if intentional fraud or malice is not proved.

(13)Notwithstanding any provision of law to the contrary, an administrative complaint against a licensee shall be filed within 6 years after the time of the incident or occurrence giving rise to the complaint against the licensee. If such incident or occurrence involved criminal actions, diversion of controlled substances, sexual misconduct, or impairment by the licensee, this subsection does not apply to bar initiation of an investigation or filing of an administrative complaint beyond the 6-year timeframe. In those cases covered by this subsection in which it can be shown that fraud, concealment, or intentional misrepresentation of fact prevented the discovery of the violation of law, the period of limitations is extended forward, but in no event to exceed 12 years after the time of the incident or occurrence.

History.—s. 68, ch. 97-261; s. 23, ch. 99-7; s. 114, ch. 2000-153; s. 91, ch. 2000-160; ss. 14, 72, ch. 2001-277; s. 5, ch. 2002-254; s. 1, ch. 2003-27; s. 20, ch. 2003-416; s. 65, ch. 2008-6.

Note.—Former s. 455.621.

456.074Certain health care practitioners; immediate suspension of license.—

(1)The department shall issue an emergency order suspending the license of any person licensed under chapter 458, chapter 459, chapter 460, chapter 461, chapter 462, chapter 463, chapter 464, chapter 465, chapter 466, or chapter 484 who pleads guilty to, is convicted or found guilty of, or who enters a plea of nolo contendere to, regardless of adjudication, to:

(a)A felony under chapter 409, chapter 817, or chapter 893 or under 21 U.S.C. ss. 801-970 or under 42 U.S.C. ss. 1395-1396; or

(b)A misdemeanor or felony under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518 or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program.

(2)If the board has previously found any physician or osteopathic physician in violation of the provisions of s. 458.331(1)(t) or s. 459.015(1)(x), in regard to her or his treatment of three or more patients, and the probable cause panel of the board finds probable cause of an additional violation of that section, then the State Surgeon General shall review the matter to determine if an emergency suspension or restriction order is warranted. Nothing in this section shall be construed so as to limit the authority of the State Surgeon General to issue an emergency order.

(3)The department may issue an emergency order suspending or restricting the license of any health care practitioner as defined in s. 456.001(4) who tests positive for any drug on any government or private sector preemployment or employer-ordered confirmed drug test, as defined in s. 112.0455, when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug. The practitioner shall be given 48 hours from the time of notification to the practitioner of the confirmed test result to produce a lawful prescription for the drug before an emergency order is issued.

(4)Upon receipt of information that a Florida-licensed health care practitioner has defaulted on a student loan issued or guaranteed by the state or the Federal Government, the department shall notify the licensee by certified mail that he or she shall be subject to immediate suspension of license unless, within 45 days after the date of mailing, the licensee provides proof that new payment terms have been agreed upon by all parties to the loan. The department shall issue an emergency order suspending the license of any licensee who, after 45 days following the date of mailing from the department, has failed to provide such proof. Production of such proof shall not prohibit the department from proceeding with disciplinary action against the licensee pursuant to s. 456.073.

History.—s. 88, ch. 97-261; s. 25, ch. 99-7; s. 87, ch. 99-397; s. 92, ch. 2000-160; s. 73, ch. 2001-277; s. 1, ch. 2002-254; s. 66, ch. 2008-6; s. 26, ch. 2009-223.

Note.—Former s. 455.687.

456.075Criminal proceedings against licensees; appearances by department representatives.—In any criminal proceeding against a person licensed by the department to practice a health care profession in this state, a representative of the department may voluntarily appear and furnish pertinent information, make recommendations regarding specific conditions of probation, or provide any other assistance necessary to promote justice or protect the public. The court may order a representative of the department to appear in any criminal proceeding if the crime charged is substantially related to the qualifications, functions, or duties of a health care professional licensed by the department.

History.—s. 1, ch. 2002-81.

456.076Treatment programs for impaired practitioners.—

(1)For professions that do not have impaired practitioner programs provided for in their practice acts, the department shall, by rule, designate approved impaired practitioner programs under this section. The department may adopt rules setting forth appropriate criteria for approval of treatment providers. The rules may specify the manner in which the consultant, retained as set forth in subsection (2), works with the department in intervention, requirements for evaluating and treating a professional, requirements for continued care of impaired professionals by approved treatment providers, continued monitoring by the consultant of the care provided by approved treatment providers regarding the professionals under their care, and requirements related to the consultant's expulsion of professionals from the program.

(2)The department shall retain one or more impaired practitioner consultants. The consultant shall be a licensee under the jurisdiction of the Division of Medical Quality Assurance within the department who must be a practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464, or an entity employing a medical director who must be a practitioner or recovered practitioner licensed under chapter 458, chapter 459, or part I of chapter 464. The consultant shall assist the probable cause panel and department in carrying out the responsibilities of this section. This shall include working with department investigators to determine whether a practitioner is, in fact, impaired. The consultant may contract for services to be provided, for appropriate compensation, if requested by the school, for students enrolled in schools for licensure as allopathic physicians or physician assistants under chapter 458, osteopathic physicians or physician assistants under chapter 459, nurses under chapter 464, or pharmacists under chapter 465 who are alleged to be impaired as a result of the misuse or abuse of alcohol or drugs, or both, or due to a mental or physical condition. The department is not responsible under any circumstances for paying the costs of care provided by approved treatment providers, and the department is not responsible for paying the costs of consultants' services provided for students. A medical school accredited by the Liaison Committee on Medical Education of the Commission on Osteopathic College Accreditation, or other school providing for the education of students enrolled in preparation for licensure as allopathic physicians under chapter 458 or osteopathic physicians under chapter 459, which is governed by accreditation standards requiring notice and the provision of due process procedures to students, is not liable in any civil action for referring a student to the consultant retained by the department or for disciplinary actions that adversely affect the status of a student when the disciplinary actions are instituted in reasonable reliance on the recommendations, reports, or conclusions provided by such consultant, if the school, in referring the student or taking disciplinary action, adheres to the due process procedures adopted by the applicable accreditation entities and if the school committed no intentional fraud in carrying out the provisions of this section.

(3)(a)Whenever the department receives a written or oral legally sufficient complaint alleging that a licensee under the jurisdiction of the Division of Medical Quality Assurance within the department is impaired as a result of the misuse or abuse of alcohol or drugs, or both, or due to a mental or physical condition which could affect the licensee's ability to practice with skill and safety, and no complaint against the licensee other than impairment exists, the reporting of such information shall not constitute grounds for discipline pursuant to s. 456.072 or the corresponding grounds for discipline within the applicable practice act if the probable cause panel of the appropriate board, or the department when there is no board, finds:

1.The licensee has acknowledged the impairment problem.

2.The licensee has voluntarily enrolled in an appropriate, approved treatment program.

3.The licensee has voluntarily withdrawn from practice or limited the scope of practice as required by the consultant, in each case, until such time as the panel, or the department when there is no board, is satisfied the licensee has successfully completed an approved treatment program.

4.The licensee has executed releases for medical records, authorizing the release of all records of evaluations, diagnoses, and treatment of the licensee, including records of treatment for emotional or mental conditions, to the consultant. The consultant shall make no copies or reports of records that do not regard the issue of the licensee's impairment and his or her participation in a treatment program.

(b)If, however, the department has not received a legally sufficient complaint and the licensee agrees to withdraw from practice until such time as the consultant determines the licensee has satisfactorily completed an approved treatment program or evaluation, the probable cause panel, or the department when there is no board, shall not become involved in the licensee's case.

(c)Inquiries related to impairment treatment programs designed to provide information to the licensee and others and which do not indicate that the licensee presents a danger to the public shall not constitute a complaint within the meaning of s. 456.073 and shall be exempt from the provisions of this subsection.

(d)Whenever the department receives a legally sufficient complaint alleging that a licensee is impaired as described in paragraph (a) and no complaint against the licensee other than impairment exists, the department shall forward all information in its possession regarding the impaired licensee to the consultant. For the purposes of this section, a suspension from hospital staff privileges due to the impairment does not constitute a complaint.

(e)The probable cause panel, or the department when there is no board, shall work directly with the consultant, and all information concerning a practitioner obtained from the consultant by the panel, or the department when there is no board, shall remain confidential and exempt from the provisions of s. 119.07(1), subject to the provisions of subsections (5) and (6).

(f)A finding of probable cause shall not be made as long as the panel, or the department when there is no board, is satisfied, based upon information it receives from the consultant and the department, that the licensee is progressing satisfactorily in an approved impaired practitioner

program and no other complaint against the licensee exists.

(4)In any disciplinary action for a violation other than impairment in which a licensee establishes the violation for which the licensee is being prosecuted was due to or connected with impairment and further establishes the licensee is satisfactorily progressing through or has successfully completed an approved treatment program pursuant to this section, such information may be considered by the board, or the department when there is no board, as a mitigating factor in determining the appropriate penalty. This subsection does not limit mitigating factors the board may consider.

(5)(a)An approved treatment provider shall, upon request, disclose to the consultant all information in its possession regarding the issue of a licensee's impairment and participation in the treatment program. All information obtained by the consultant and department pursuant to this section is confidential and exempt from the provisions of s. 119.07(1), subject to the provisions of this subsection and subsection (6). Failure to provide such information to the consultant is grounds for withdrawal of approval of such program or provider.

(b)If in the opinion of the consultant, after consultation with the treatment provider, an impaired licensee has not progressed satisfactorily in a treatment program, all information regarding the issue of a licensee's impairment and participation in a treatment program in the consultant's possession shall be disclosed to the department. Such disclosure shall constitute a complaint pursuant to the general provisions of s. 456.073. Whenever the consultant concludes that impairment affects a licensee's practice and constitutes an immediate, serious danger to the public health, safety, or welfare, that conclusion shall be communicated to the State Surgeon General.

(6)A consultant, licensee, or approved treatment provider who makes a disclosure pursuant to this section is not subject to civil liability for such disclosure or its consequences. The provisions of s. 766.101 apply to any officer, employee, or agent of the department or the board and to any officer, employee, or agent of any entity with which the department has contracted pursuant to this section.

(7)(a)A consultant retained pursuant to subsection (2), a consultant's officers and employees, and those acting at the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention shall be considered agents of the department for purposes of s. 768.28 while acting within the scope of the consultant's duties under the contract with the department if the contract complies with the requirements of this section. The contract must require that:

1.The consultant indemnify the state for any liabilities incurred up to the limits set out in chapter 768.

2.The consultant establish a quality assurance program to monitor services delivered under the contract.

3.The consultant's quality assurance program, treatment, and monitoring records be evaluated quarterly.

4.The consultant's quality assurance program be subject to review and approval by the

department.

5.The consultant operate under policies and procedures approved by the department.

6.The consultant provide to the department for approval a policy and procedure manual that comports with all statutes, rules, and contract provisions approved by the department.

7.The department be entitled to review the records relating to the consultant's performance under the contract for the purpose of management audits, financial audits, or program evaluation.

8.All performance measures and standards be subject to verification and approval by the department.

9.The department be entitled to terminate the contract with the consultant for noncompliance with the contract.

(b)In accordance with s. 284.385, the Department of Financial Services shall defend any claim, suit, action, or proceeding against the consultant, the consultant's officers or employees, or those acting at the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention which is brought as a result of any act or omission by any of the consultant's officers and employees and those acting under the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention when such act or omission arises out of and in the scope of the consultant's duties under its contract with the department.

(c)If the consultant retained pursuant to subsection (2) is retained by any other state agency, and if the contract between such state agency and the consultant complies with the requirements of this section, the consultant, the consultant's officers and employees, and those acting under the direction of the consultant for the limited purpose of an emergency intervention on behalf of a licensee or student as described in subsection (2) when the consultant is unable to perform such intervention shall be considered agents of the state for the purposes of this section while acting within the scope of and pursuant to guidelines established in the contract between such state agency and the consultant.

History.—s. 38, ch. 92-149; s. 1, ch. 95-139; s. 310, ch. 96-406; s. 1085, ch. 97-103; s. 3, ch. 97-209; s. 94, ch. 97-261; s. 2, ch. 98-130; s. 94, ch. 2000-160; ss. 29, 117, ch. 2000-318; s. 67, ch. 2008-6; s. 1, ch. 2008-63.

Note.—Former s. 455.261; s. 455.707.

456.077Authority to issue citations.—

(1)Notwithstanding s. 456.073, the board, or the department if there is no board, shall adopt rules to permit the issuance of citations. The citation shall be issued to the subject and shall contain the subject's name and address, the subject's license number if applicable, a brief factual statement, the sections of the law allegedly violated, and the penalty imposed. The citation must clearly state that the subject may choose, in lieu of accepting the citation, to follow the procedure under s. 456.073. If the subject disputes the matter in the citation, the procedures set forth in s. 456.073 must be

followed. However, if the subject does not dispute the matter in the citation with the department within 30 days after the citation is served, the citation becomes a public final order and does not constitute discipline for a first offense, but does constitute discipline for a second or subsequent offense. The penalty shall be a fine or other conditions as established by rule.

(2)The board, or the department if there is no board, shall adopt rules designating violations for which a citation may be issued. Such rules shall designate as citation violations those violations for which there is no substantial threat to the public health, safety, and welfare or no violation of standard of care involving injury to a patient. Violations for which a citation may be issued shall include violations of continuing education requirements; failure to timely pay required fees and fines; failure to comply with the requirements of ss. 381.026 and 381.0261 regarding the dissemination of information regarding patient rights; failure to comply with advertising requirements; failure to timely update practitioner profile and credentialing files; failure to display signs, licenses, and permits; failure to have required reference books available; and all other violations that do not pose a direct and serious threat to the health and safety of the patient or involve a violation of standard of care that has resulted in injury to a patient.

(3)The department shall be entitled to recover the costs of investigation, in addition to any penalty provided according to board or department rule, as part of the penalty levied pursuant to the citation.

(4)A citation must be issued within 6 months after the filing of the complaint that is the basis for the citation.

(5)Service of a citation may be made by personal service or certified mail, restricted delivery, to the subject at the subject's last known address.

(6)A board has 6 months in which to enact rules designating violations and penalties appropriate for citation offenses. Failure to enact such rules gives the department exclusive authority to adopt rules as required for implementing this section. A board has continuous authority to amend its rules adopted pursuant to this section.

History.—s. 67, ch. 97-261; s. 95, ch. 2000-160; s. 74, ch. 2001-277; s. 21, ch. 2003-416.

Note.—Former s. 455.617.

456.078Mediation.—

(1)Notwithstanding the provisions of s. 456.073, the board, or the department when there is no board, shall adopt rules to designate which violations of the applicable professional practice act are appropriate for mediation. The board, or the department when there is no board, shall designate as mediation offenses those complaints where harm caused by the licensee:

(a)Is economic in nature except any act or omission involving intentional misconduct;

(b)Can be remedied by the licensee;

(c)Is not a standard of care violation involving any type of injury to a patient; or

(d)Does not result in an adverse incident.

(2)For the purposes of this section, an "adverse incident" means an event that results in:

(a)The death of a patient;

(b)Brain or spinal damage to a patient;

(c)The performance of a surgical procedure on the wrong patient;

(d)The performance of a wrong-site surgical procedure;

(e)The performance of a surgical procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition;

(f)The surgical repair of damage to a patient resulting from a planned surgical procedure, which damage is not a recognized specific risk as disclosed to the patient and documented through the informed-consent process;

(g)The performance of a procedure to remove unplanned foreign objects remaining from a surgical procedure; or

(h)The performance of any other surgical procedure that breached the standard of care.

(3)After the department determines a complaint is legally sufficient and the alleged violations are defined as mediation offenses, the department or any agent of the department may conduct informal mediation to resolve the complaint. If the complainant and the subject of the complaint agree to a resolution of a complaint within 14 days after contact by the mediator, the mediator shall notify the department of the terms of the resolution. The department or board shall take no further action unless the complainant and the subject each fail to record with the department an acknowledgment of satisfaction of the terms of mediation within 60 days of the mediator's notification to the department. A successful mediation shall not constitute discipline. In the event the complainant and subject fail to reach settlement terms or to record the required acknowledgment, the department shall process the complaint according to the provisions of s. 456.073.

(4)Conduct or statements made during mediation are inadmissible in any proceeding pursuant to s. 456.073. Further, any information relating to the mediation of a case shall be subject to the confidentiality provisions of s. 456.073.

(5)No licensee shall go through the mediation process more than three times without approval of the department. The department may consider the subject and dates of the earlier complaints in rendering its decision. Such decision shall not be considered a final agency action for purposes of chapter 120.

(6)Any board created on or after January 1, 1995, shall have 6 months to adopt rules designating which violations are appropriate for mediation, after which time the department shall have exclusive authority to adopt rules pursuant to this section. A board shall have continuing authority to amend its rules adopted pursuant to this section.

History.—s. 66, ch. 97-261; s. 96, ch. 2000-160; s. 22, ch. 2003-416.

Note.—Former s. 455.614.

456.079Disciplinary guidelines.—

(1)Each board, or the department if there is no board, shall adopt by rule and periodically review the disciplinary guidelines applicable to each ground for disciplinary action which may be imposed by the board, or the department if there is no board, pursuant to this chapter, the respective practice acts, and any rule of the board or department.

(2)The disciplinary guidelines shall specify a meaningful range of designated penalties based upon the severity and repetition of specific offenses, it being the legislative intent that minor violations be distinguished from those which endanger the public health, safety, or welfare; that such guidelines provide reasonable and meaningful notice to the public of likely penalties which may be imposed for proscribed conduct; and that such penalties be consistently applied by the board.

(3)A specific finding in the final order of mitigating or aggravating circumstances shall allow the board to impose a penalty other than that provided for in such guidelines. If applicable, the board, or the department if there is no board, shall adopt by rule disciplinary guidelines to designate possible mitigating and aggravating circumstances and the variation and range of penalties permitted for such circumstances.

(4)The department must review such disciplinary guidelines for compliance with the legislative intent as set forth herein to determine whether the guidelines establish a meaningful range of penalties and may also challenge such rules pursuant to s. 120.56.

(5)The administrative law judge, in recommending penalties in any recommended order, must follow the penalty guidelines established by the board or department and must state in writing the mitigating or aggravating circumstances upon which the recommended penalty is based.

History.—s. 70, ch. 97-261; s. 97, ch. 2000-160; s. 16, ch. 2001-277.

Note.—Former s. 455.627.

456.081Publication of information.—The department and the boards shall have the authority to advise licensees periodically, through the publication of a newsletter on the department's website, about information that the department or the board determines is of interest to the industry. The department and the boards shall maintain a website which contains copies of the newsletter; information relating to adverse incident reports without identifying the patient, practitioner, or facility in which the adverse incident occurred until 10 days after probable cause is found, at which time the name of the practitioner and facility shall become public as part of the investigative file; information about error prevention and safety strategies; and information concerning best practices. Unless otherwise prohibited by law, the department and the boards shall publish on the website a summary of final orders entered after July 1, 2001, resulting in disciplinary action, and any other information the department or the board determines is of interest to the public. In order to provide useful and timely information at minimal cost, the department and boards may consult with, and include information provided by, professional associations and national organizations.

History.—s. 44, ch. 97-261; s. 98, ch. 2000-160; ss. 15, 75, ch. 2001-277.

Note.—Former s. 455.537.

456.082Disclosure of confidential information.—

(1)No officer, employee, or person under contract with the department, or any board therein, or any subject of an investigation shall convey knowledge or information to any person who is not lawfully entitled to such knowledge or information about any public meeting or public record, which at the time such knowledge or information is conveyed is exempt from the provisions of s. 119.01, s. 119.07(1), or s. 286.011.

(2)Any person who willfully violates any provision of this section is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, and may be subject to discipline pursuant to s. 456.072, and, if applicable, shall be removed from office, employment, or the contractual relationship.

(3)Any person injured as a result of a willful violation of this section shall have a civil cause of action for treble damages, reasonable attorney fees, and costs.

History.—s. 77, ch. 97-261; s. 37, ch. 98-166; s. 7, ch. 99-356; s. 188, ch. 99-397; s. 99, ch. 2000-160; s. 27, ch. 2000-318.

Note.—Former s. 455.651.

456.36Health care professionals; exemption from disqualification from employment or contracting.—Any other provision of law to the contrary notwithstanding, only the appropriate regulatory board, or the department when there is no board, may grant an exemption from disqualification from employment or contracting as provided in s. 435.07 to a person under the licensing jurisdiction of that board or the department, as applicable.

History.—s. 34, ch. 2000-318.

456.38Practitioner registry for disasters and emergencies.—The Department of Health may include on its forms for the licensure or certification of health care practitioners, as defined in s. 456.001, who could assist the department in the event of a disaster a question asking if the practitioner would be available to provide health care services in special needs shelters or to help staff disaster medical assistance teams during times of emergency or major disaster. The names of practitioners who answer affirmatively shall be maintained by the department as a health care practitioner registry for disasters and emergencies.

History.—s. 20, ch. 2000-140.

456.41Complementary or alternative health care treatments.—

(1)LEGISLATIVE INTENT.—It is the intent of the Legislature that citizens be able to make informed choices for any type of health care they deem to be an effective option for treating human disease,

pain, injury, deformity, or other physical or mental condition. It is the intent of the Legislature that citizens be able to choose from all health care options, including the prevailing or conventional treatment methods as well as other treatments designed to complement or substitute for the prevailing or conventional treatment methods. It is the intent of the Legislature that health care practitioners be able to offer complementary or alternative health care treatments with the same requirements, provisions, and liabilities as those associated with the prevailing or conventional treatment methods.

(2)DEFINITIONS.—As used in this section, the term:

(a)"Complementary or alternative health care treatment" means any treatment that is designed to provide patients with an effective option to the prevailing or conventional treatment methods associated with the services provided by a health care practitioner. Such a treatment may be provided in addition to or in place of other treatment options.

(b)"Health care practitioner" means any health care practitioner as defined in s. 456.001(4).

(3)COMMUNICATION OF TREATMENT ALTERNATIVES.—A health care practitioner who offers to provide a patient with a complementary or alternative health care treatment must inform the patient of the nature of the treatment and must explain the benefits and risks associated with the treatment to the extent necessary for the patient to make an informed and prudent decision regarding such treatment option. In compliance with this subsection:

(a)The health care practitioner must inform the patient of the practitioner's education, experience, and credentials in relation to the complementary or alternative health care treatment option.

(b)The health care practitioner may, in his or her discretion, communicate the information orally or in written form directly to the patient or to the patient's legal representative.

(c)The health care practitioner may, in his or her discretion and without restriction, recommend any mode of treatment that is, in his or her judgment, in the best interests of the patient, including complementary or alternative health care treatments, in accordance with the provisions of his or her license.

(4)RECORDS.—Every health care practitioner providing a patient with a complementary or alternative health care treatment must indicate in the patient's care record the method by which the requirements of subsection (3) were met.

(5)EFFECT.—This section does not modify or change the scope of practice of any licensees of the department, nor does it alter in any way the provisions of the individual practice acts for those licensees, which require licensees to practice within their respective standards of care and which prohibit fraud and exploitation of patients.

History.—s. 1, ch. 2001-116.

456.42Written prescriptions for medicinal drugs.—

(1)A written prescription for a medicinal drug issued by a health care practitioner licensed by law

to prescribe such drug must be legibly printed or typed so as to be capable of being understood by the pharmacist filling the prescription; must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed, and the directions for use of the drug; must be dated; and must be signed by the prescribing practitioner on the day when issued. However, a prescription that is electronically generated and transmitted must contain the name of the prescribing practitioner, the name and strength of the drug prescribed, the quantity of the drug prescribed in numerical format, and the directions for use of the drug and must be dated and signed by the prescribing practitioner only on the day issued, which signature may be in an electronic format as defined in s. 668.003(4).

(2)A written prescription for a controlled substance listed in chapter 893 must have the quantity of the drug prescribed in both textual and numerical formats, must be dated with the abbreviated month written out on the face of the prescription, and must be either written on a standardized counterfeit-proof prescription pad produced by a vendor approved by the department or electronically prescribed as that term is used in s. 408.0611. As a condition of being an approved vendor, a prescription pad vendor must submit a monthly report to the department which, at a minimum, documents the number of prescription pads sold and identifies the purchasers. The department may, by rule, require the reporting of additional information.

History.—s. 1, ch. 2003-41; s. 2, ch. 2006-271; s. 2, ch. 2009-202; s. 2, ch. 2011-141.

456.43Electronic prescribing for medicinal drugs.—

(1)Electronic prescribing shall not interfere with a patient's freedom to choose a pharmacy.

(2)Electronic prescribing software shall not use any means or permit any other person to use any means, including, but not limited to, advertising, instant messaging, and pop-up ads, to influence or attempt to influence, through economic incentives or otherwise, the prescribing decision of a prescribing practitioner at the point of care. Such means shall not be triggered or in specific response to the input, selection, or act of a prescribing practitioner or his or her agent in prescribing a certain pharmaceutical or directing a patient to a certain pharmacy.

(a)The term "prescribing decision" means a prescribing practitioner's decision to prescribe a certain pharmaceutical.

(b)The term "point of care" means the time that a prescribing practitioner or his or her agent is in the act of prescribing a certain pharmaceutical.

(3)Electronic prescribing software may show information regarding a payor's formulary as long as nothing is designed to preclude or make more difficult the act of a prescribing practitioner or patient selecting any particular pharmacy or pharmaceutical.

History.—s. 3, ch. 2006-271.

456.44Controlled substance prescribing.—

(1)DEFINITIONS.—

(a)“Addiction medicine specialist” means a board-certified psychiatrist with a subspecialty certification in addiction medicine or who is eligible for such subspecialty certification in addiction medicine, an addiction medicine physician certified or eligible for certification by the American Society of Addiction Medicine, or an osteopathic physician who holds a certificate of added qualification in Addiction Medicine through the American Osteopathic Association.

(b)“Adverse incident” means any incident set forth in s. 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

(c)“Board-certified pain management physician” means a physician who possesses board certification in pain medicine by the American Board of Pain Medicine, board certification by the American Board of Interventional Pain Physicians, or board certification or subcertification in pain management or pain medicine by a specialty board recognized by the American Association of Physician Specialists or the American Board of Medical Specialties or an osteopathic physician who holds a certificate in Pain Management by the American Osteopathic Association.

(d)“Board eligible” means successful completion of an anesthesia, physical medicine and rehabilitation, rheumatology, or neurology residency program approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association for a period of 6 years from successful completion of such residency program.

(e)“Chronic nonmalignant pain” means pain unrelated to cancer which persists beyond the usual course of disease or the injury that is the cause of the pain or more than 90 days after surgery.

(f)“Mental health addiction facility” means a facility licensed under chapter 394 or chapter 397.

(2)REGISTRATION.—Effective January 1, 2012, a physician licensed under chapter 458, chapter 459, chapter 461, or chapter 466 who prescribes any controlled substance, listed in Schedule II, Schedule III, or Schedule IV as defined in s. 893.03, for the treatment of chronic nonmalignant pain, must:

(a)Designate himself or herself as a controlled substance prescribing practitioner on the physician’s practitioner profile.

(b)Comply with the requirements of this section and applicable board rules.

(3)STANDARDS OF PRACTICE.—The standards of practice in this section do not supersede the level of care, skill, and treatment recognized in general law related to health care licensure.

(a)A complete medical history and a physical examination must be conducted before beginning any treatment and must be documented in the medical record. The exact components of the physical examination shall be left to the judgment of the clinician who is expected to perform a physical examination proportionate to the diagnosis that justifies a treatment. The medical record must, at a minimum, document the nature and intensity of the pain, current and past treatments for pain, underlying or coexisting diseases or conditions, the effect of the pain on physical and psychological function, a review of previous medical records, previous diagnostic studies, and history of alcohol and substance abuse. The medical record shall also document the presence of one or more recognized medical indications for the use of a controlled substance. Each registrant must develop a written plan for assessing each patient’s risk of aberrant drug-related behavior, which may include patient drug

testing. Registrants must assess each patient's risk for aberrant drug-related behavior and monitor that risk on an ongoing basis in accordance with the plan.

(b)Each registrant must develop a written individualized treatment plan for each patient. The treatment plan shall state objectives that will be used to determine treatment success, such as pain relief and improved physical and psychosocial function, and shall indicate if any further diagnostic evaluations or other treatments are planned. After treatment begins, the physician shall adjust drug therapy to the individual medical needs of each patient. Other treatment modalities, including a rehabilitation program, shall be considered depending on the etiology of the pain and the extent to which the pain is associated with physical and psychosocial impairment. The interdisciplinary nature of the treatment plan shall be documented.

(c)The physician shall discuss the risks and benefits of the use of controlled substances, including the risks of abuse and addiction, as well as physical dependence and its consequences, with the patient, persons designated by the patient, or the patient's surrogate or guardian if the patient is incompetent. The physician shall use a written controlled substance agreement between the physician and the patient outlining the patient's responsibilities, including, but not limited to:

1.Number and frequency of controlled substance prescriptions and refills.

2.Patient compliance and reasons for which drug therapy may be discontinued, such as a violation of the agreement.

3.An agreement that controlled substances for the treatment of chronic nonmalignant pain shall be prescribed by a single treating physician unless otherwise authorized by the treating physician and documented in the medical record.

(d)The patient shall be seen by the physician at regular intervals, not to exceed 3 months, to assess the efficacy of treatment, ensure that controlled substance therapy remains indicated, evaluate the patient's progress toward treatment objectives, consider adverse drug effects, and review the etiology of the pain. Continuation or modification of therapy shall depend on the physician's evaluation of the patient's progress. If treatment goals are not being achieved, despite medication adjustments, the physician shall reevaluate the appropriateness of continued treatment. The physician shall monitor patient compliance in medication usage, related treatment plans, controlled substance agreements, and indications of substance abuse or diversion at a minimum of 3-month intervals.

(e)The physician shall refer the patient as necessary for additional evaluation and treatment in order to achieve treatment objectives. Special attention shall be given to those patients who are at risk for misusing their medications and those whose living arrangements pose a risk for medication misuse or diversion. The management of pain in patients with a history of substance abuse or with a comorbid psychiatric disorder requires extra care, monitoring, and documentation and requires consultation with or referral to an addiction medicine specialist or psychiatrist.

(f)A physician registered under this section must maintain accurate, current, and complete records that are accessible and readily available for review and comply with the requirements of this section,

the applicable practice act, and applicable board rules. The medical records must include, but are not limited to:

1.The complete medical history and a physical examination, including history of drug abuse or dependence.

2.Diagnostic, therapeutic, and laboratory results.

3.Evaluations and consultations.

4.Treatment objectives.

5.Discussion of risks and benefits.

6.Treatments.

7.Medications, including date, type, dosage, and quantity prescribed.

8.Instructions and agreements.

9.Periodic reviews.

10.Results of any drug testing.

11.A photocopy of the patient's government-issued photo identification.

12.If a written prescription for a controlled substance is given to the patient, a duplicate of the prescription.

13.The physician's full name presented in a legible manner.

(g)Patients with signs or symptoms of substance abuse shall be immediately referred to a board-certified pain management physician, an addiction medicine specialist, or a mental health addiction facility as it pertains to drug abuse or addiction unless the physician is board-certified or board-eligible in pain management. Throughout the period of time before receiving the consultant's report, a prescribing physician shall clearly and completely document medical justification for continued treatment with controlled substances and those steps taken to ensure medically appropriate use of controlled substances by the patient. Upon receipt of the consultant's written report, the prescribing physician shall incorporate the consultant's recommendations for continuing, modifying, or discontinuing controlled substance therapy. The resulting changes in treatment shall be specifically documented in the patient's medical record. Evidence or behavioral indications of diversion shall be followed by discontinuation of controlled substance therapy, and the patient shall be discharged, and all results of testing and actions taken by the physician shall be documented in the patient's medical record.

This subsection does not apply to a board-eligible or board-certified anesthesiologist, physiatrist, rheumatologist, or neurologist, or to a board-certified physician who has surgical privileges at a hospital or ambulatory surgery center and primarily provides surgical services. This subsection does not apply to a board-eligible or board-certified medical specialist who has also completed a fellowship in pain medicine approved by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association, or who is board eligible or board certified in pain medicine by the American Board of Pain Medicine or a board approved by the American Board of Medical Specialties or the

American Osteopathic Association and performs interventional pain procedures of the type routinely billed using surgical codes. This subsection does not apply to a physician who prescribes medically necessary controlled substances for a patient during an inpatient stay in a hospital licensed under chapter 395.

History.—s. 3, ch. 2011-141; s. 31, ch. 2012-160.

456.50Repeated medical malpractice.—

(1)For purposes of s. 26, Art. X of the State Constitution and ss. 458.331(1)(t), (4), and (5) and 459.015(1)(x), (4), and (5):

(a)"Board" means the Board of Medicine, in the case of a physician licensed pursuant to chapter 458, or the Board of Osteopathic Medicine, in the case of an osteopathic physician licensed pursuant to chapter 459.

(b)"Final administrative agency decision" means a final order of the licensing board following a hearing as provided in s. 120.57(1) or (2) or s. 120.574 finding that the licensee has violated s. 458.331(1)(t) or s. 459.015(1)(x).

(c)"Found to have committed" means the malpractice has been found in a final judgment of a court of law, final administrative agency decision, or decision of binding arbitration.

(d)"Incident" means the wrongful act or occurrence from which the medical malpractice arises, regardless of the number of claimants or findings. For purposes of this section:

1.A single act of medical malpractice, regardless of the number of claimants, shall count as only one incident.

2.Multiple findings of medical malpractice arising from the same wrongful act or series of wrongful acts associated with the treatment of the same patient shall count as only one incident.

(e)"Level of care, skill, and treatment recognized in general law related to health care licensure" means the standard of care specified in s. 766.102.

(f)"Medical doctor" means a physician licensed pursuant to chapter 458 or chapter 459.

(g)"Medical malpractice" means the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure. Only for the purpose of finding repeated medical malpractice pursuant to this section, any similar wrongful act, neglect, or default committed in another state or country which, if committed in this state, would have been considered medical malpractice as defined in this paragraph, shall be considered medical malpractice if the standard of care and burden of proof applied in the other state or country equaled or exceeded that used in this state.

(h)"Repeated medical malpractice" means three or more incidents of medical malpractice found to have been committed by a medical doctor. Only an incident occurring on or after November 2, 2004, shall be considered an incident for purposes of finding repeated medical malpractice under this section.

(2)For purposes of implementing s. 26, Art. X of the State Constitution, the board shall not license or continue to license a medical doctor found to have committed repeated medical malpractice, the finding of which was based upon clear and convincing evidence. In order to rely on an incident of medical malpractice to determine whether a license must be denied or revoked under this section, if the facts supporting the finding of the incident of medical malpractice were determined on a standard less stringent than clear and convincing evidence, the board shall review the record of the case and determine whether the finding would be supported under a standard of clear and convincing evidence. Section 456.073 applies. The board may verify on a biennial basis an out-of-state licensee's medical malpractice history using federal, state, or other databases. The board may require licensees and applicants for licensure to provide a copy of the record of the trial of any medical malpractice judgment, which may be required to be in an electronic format, involving an incident that occurred on or after November 2, 2004. For purposes of implementing s. 26, Art. X of the State Constitution, the 90-day requirement for granting or denying a complete allopathic or osteopathic licensure application in s. 120.60(1) is extended to 180 days.

History.—s. 2, ch. 2005-266

2012 Florida Statutes

Chapter 499

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499.001 Florida Drug and Cosmetic Act; short title.—Sections 499.001-499.081 may be cited as the "Florida Drug and Cosmetic Act."

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 1, ch. 86-133; ss. 1, 52, ch. 92-69.

499.002Purpose, administration, and enforcement of and exemption from this part.—

(1)This part is intended to:

(a)Safeguard the public health and promote the public welfare by protecting the public from injury by product use and by merchandising deceit involving drugs, devices, and cosmetics.

(b)Provide uniform legislation to be administered so far as practicable in conformity with the provisions of, and regulations issued under the authority of, the Federal Food, Drug, and Cosmetic Act and that portion of the Federal Trade Commission Act which expressly prohibits the false advertisement of drugs, devices, and cosmetics.

(c)Promote thereby uniformity of such state and federal laws, and their administration and enforcement, throughout the United States.

(2)The department shall administer and enforce this part to prevent fraud, adulteration, misbranding, or false advertising in the preparation, manufacture, repackaging, or distribution of drugs, devices, and cosmetics.

(3)For the purpose of any investigation or proceeding conducted by the department under this part, the department may administer oaths, take depositions, issue and serve subpoenas, and compel the attendance of witnesses and the production of books, papers, documents, or other evidence. The department shall exercise this power on its own initiative. Challenges to, and enforcement of, the subpoenas and orders shall be handled as provided in s. 120.569.

(4)Each state attorney, county attorney, or municipal attorney to whom the department or its designated agent reports any violation of this part shall cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

(5)This part does not require the department to report, for the institution of proceedings under this part, minor violations of this part when it believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

(6)Common carriers engaged in interstate commerce are not subject to this part if they are engaged in the usual course of business as common carriers.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 2, 3, ch. 86-133; s. 2, ch. 87-50; ss. 2, 4, 6, 48, 49, 50, 52, ch. 92-69; s. 240, ch. 96-410; s. 236, ch. 99-8; s. 1, ch. 2008-207.

Note.—Subsection (2) former s. 499.004; subsection (3) former s. 499.0053; subsection (4) former s. 499.07; subsection (5) former s. 499.071; subsection (6) former s. 499.081.

499.003Definitions of terms used in this part.—As used in this part, the term:

(1)"Advertisement" means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

(2)"Affiliated group" means an affiliated group as defined by s. 1504 of the Internal Revenue Code of 1986, as amended, which is composed of chain drug entities, including at least 50 retail pharmacies, warehouses, or repackagers, which are members of the same affiliated group. The affiliated group must disclose the names of all its members to the department.

(3)"Affiliated party" means:

(a)A director, officer, trustee, partner, or committee member of a permittee or applicant or a subsidiary or service corporation of the permittee or applicant;

(b)A person who, directly or indirectly, manages, controls, or oversees the operation of a permittee or applicant, regardless of whether such person is a partner, shareholder, manager, member, officer, director, independent contractor, or employee of the permittee or applicant;

(c)A person who has filed or is required to file a personal information statement pursuant to s. 499.012(9) or is required to be identified in an application for a permit or to renew a permit pursuant to s. 499.012(8); or

(d)The five largest natural shareholders that own at least 5 percent of the permittee or applicant.

(4)"Applicant" means a person applying for a permit or certification under this part.

(5)"Authenticate" means to affirmatively verify upon receipt of a prescription drug that each transaction listed on the pedigree paper has occurred.

(a)A wholesale distributor is not required to open a sealed, medical convenience kit to authenticate a pedigree paper for a prescription drug contained within the kit.

(b)Authentication of a prescription drug included in a sealed, medical convenience kit shall be limited to verifying the transaction and pedigree information received.

(6)"Certificate of free sale" means a document prepared by the department which certifies a drug, device, or cosmetic, that is registered with the department, as one that can be legally sold in the state.

(7)"Chain pharmacy warehouse" means a wholesale distributor permitted pursuant to s. 499.01 that maintains a physical location for prescription drugs that functions solely as a central warehouse to perform intracompany transfers of such drugs to a member of its affiliated group.

(8)"Closed pharmacy" means a pharmacy that is licensed under chapter 465 and purchases prescription drugs for use by a limited patient population and not for wholesale distribution or sale to the public. The term does not include retail pharmacies.

(9)"Color" includes black, white, and intermediate grays.

(10)"Color additive" means, with the exception of any material that has been or hereafter is exempt under the federal act, a material that:

(a)Is a dye pigment, or other substance, made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity from a vegetable, animal, mineral, or other source; or

(b)When added or applied to a drug or cosmetic or to the human body, or any part thereof, is capable alone, or through reaction with other substances, of imparting color thereto.

(11)"Compressed medical gas" means any liquefied or vaporized gas that is a prescription drug, whether it is alone or in combination with other gases.

(12)"Contraband prescription drug" means any adulterated drug, as defined in s. 499.006, any counterfeit drug, as defined in this section, and also means any prescription drug for which a pedigree paper does not exist, or for which the pedigree paper in existence has been forged, counterfeited, falsely created, or contains any altered, false, or misrepresented matter.

(13)"Cosmetic" means an article, with the exception of soap, that is:

(a)Intended to be rubbed, poured, sprinkled, or sprayed on; introduced into; or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance; or

(b)Intended for use as a component of any such article.

(14)"Counterfeit drug," "counterfeit device," or "counterfeit cosmetic" means a drug, device, or cosmetic which, or the container, seal, or labeling of which, without authorization, bears the trademark, trade name, or other identifying mark, imprint,

or device, or any likeness thereof, of a drug, device, or cosmetic manufacturer, processor, packer, or distributor other than the person that in fact manufactured, processed, packed, or distributed that drug, device, or cosmetic and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, that other drug, device, or cosmetic manufacturer, processor, packer, or distributor.

(15)"Department" means the Department of Business and Professional Regulation.

(16)"Device" means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including its components, parts, or accessories, which is:

(a)Recognized in the current edition of the United States Pharmacopoeia and National Formulary, or any supplement thereof,

(b)Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or

(c)Intended to affect the structure or any function of the body of humans or other animals,

and that does not achieve any of its principal intended purposes through chemical action within or on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

(17)"Distribute" or "distribution" means to sell; offer to sell; give away; transfer, whether by passage of title, physical movement, or both; deliver; or offer to deliver. The term does not mean to administer or dispense and does not include the billing and invoicing activities that commonly follow a wholesale distribution transaction.

(18)"Drop shipment" means the sale of a prescription drug from a manufacturer to a wholesale distributor, where the wholesale distributor takes title to, but not possession of, the prescription drug, and the manufacturer of the prescription drug ships the prescription drug directly to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003.

(19)"Drug" means an article that is:

(a)Recognized in the current edition of the United States Pharmacopoeia and National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to any of those publications;

(b)Intended for use in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals;

(c)Intended to affect the structure or any function of the body of humans or other animals; or

(d)Intended for use as a component of any article specified in paragraph (a), paragraph (b), or paragraph (c), and includes active pharmaceutical ingredients, but does not include devices or their nondrug components, parts, or accessories. For purposes of this paragraph, an "active pharmaceutical ingredient" includes any substance or mixture of substances intended, represented, or labeled for use in drug manufacturing that furnishes or is intended to furnish, in a finished dosage form, any pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, therapy, or prevention of disease in humans or other animals, or to affect the structure or any function of the body of humans or other animals.

(20)"Establishment" means a place of business which is at one general physical location and may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common exclusive ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the

buildings. For purposes of permitting, each suite, unit, floor, or building must be identified in the most recent permit application.

(21)"Federal act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. ss. 301 et seq.; 52 Stat. 1040 et seq.

(22)"Freight forwarder" means a person who receives prescription drugs which are owned by another person and designated by that person for export, and exports those prescription drugs.

(23)"Health care entity" means a closed pharmacy or any person, organization, or business entity that provides diagnostic, medical, surgical, or dental treatment or care, or chronic or rehabilitative care, but does not include any wholesale distributor or retail pharmacy licensed under state law to deal in prescription drugs. However, a blood establishment is a health care entity that may engage in the wholesale distribution of prescription drugs under s. 499.01(2)(g)1.c.

(24)"Health care facility" means a health care facility licensed under chapter 395.

(25)"Hospice" means a corporation licensed under part IV of chapter 400.

(26)"Hospital" means a facility as defined in s. 395.002 and licensed under chapter 395.

(27)"Immediate container" does not include package liners.

(28)"Label" means a display of written, printed, or graphic matter upon the immediate container of any drug, device, or cosmetic. A requirement made by or under authority of this part or rules adopted under this part that any word, statement, or other information appear on the label is not complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any, of the retail package of such drug, device, or cosmetic or is easily legible through the outside container or wrapper.

(29)"Labeling" means all labels and other written, printed, or graphic matters:

(a)Upon a drug, device, or cosmetic, or any of its containers or wrappers; or

(b)Accompanying or related to such drug, device, or cosmetic.

(30)"Manufacture" means the preparation, deriving, compounding, propagation, processing, producing, or fabrication of any drug, device, or cosmetic.

(31)"Manufacturer" means:

(a)A person who prepares, derives, manufactures, or produces a drug, device, or cosmetic;

(b)The holder or holders of a New Drug Application (NDA), an Abbreviated New Drug Application (ANDA), a Biologics License Application (BLA), or a New Animal Drug Application (NADA), provided such application has become effective or is otherwise approved consistent with s. 499.023;

(c)A private label distributor for whom the private label distributor's prescription drugs are originally manufactured and labeled for the distributor and have not been repackaged;

(d)A person registered under the federal act as a manufacturer of a prescription drug, who is described in paragraph (a), paragraph (b), or paragraph (c), who has entered into a written agreement with another prescription drug manufacturer that authorizes either manufacturer to distribute the prescription drug identified in the agreement as the manufacturer of that drug consistent with the federal act and its implementing regulations;

(e)A member of an affiliated group that includes, but is not limited to, persons described in paragraph (a), paragraph (b), paragraph (c), or paragraph (d), which member distributes prescription drugs, whether or not obtaining title to the drugs, only for the manufacturer of the drugs who is also a member of the affiliated group. As used in this paragraph, the term "affiliated group" means an affiliated group as defined in s. 1504 of the Internal Revenue Code of 1986, as amended. The

manufacturer must disclose the names of all of its affiliated group members to the department; or

(f)A person permitted as a third party logistics provider, only while providing warehousing, distribution, or other logistics services on behalf of a person described in paragraph (a), paragraph (b), paragraph (c), paragraph (d), or paragraph (e).

The term does not include a pharmacy that is operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(32)"Medical convenience kit" means packages or units that contain combination products as defined in 21 C.F.R. s. 3.2(e)(2).

(33)"New drug" means:

(a)Any drug the composition of which is such that the drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling of that drug; or

(b)Any drug the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under certain conditions, has been recognized for use under such conditions, but which drug has not, other than in those investigations, been used to a material extent or for a material time under such conditions.

(34)"Normal distribution chain" means a wholesale distribution of a prescription drug in which the wholesale distributor or its wholly owned subsidiary purchases and receives the specific unit of the prescription drug directly from the manufacturer and distributes the prescription drug directly, or through up to two intracompany transfers, to a chain pharmacy warehouse or a person authorized by law to purchase prescription drugs for the purpose of administering or dispensing the drug, as defined in s. 465.003. For purposes of this subsection, the term "intracompany" means any transaction or transfer between any parent, division, or subsidiary wholly owned by a corporate entity.

(35)"Nursing home" means a facility licensed under part II of chapter 400.

(36)"Official compendium" means the current edition of the official United States Pharmacopoeia and National Formulary, or any supplement thereto.

(37)"Pedigree paper" means a document in written or electronic form approved by the department which contains information required by s. 499.01212 regarding the sale and distribution of any given prescription drug.

(38)"Permittee" means any person holding a permit issued pursuant to s. 499.012.

(39)"Person" means any individual, child, joint venture, syndicate, fiduciary, partnership, corporation, division of a corporation, firm, trust, business trust, company, estate, public or private institution, association, organization, group, city, county, city and county, political subdivision of this state, other governmental agency within this state, and any representative, agent, or agency of any of the foregoing, or any other group or combination of the foregoing.

(40)"Pharmacist" means a person licensed under chapter 465.

(41)"Pharmacy" means an entity licensed under chapter 465.

(42)"Prepackaged drug product" means a drug that originally was in finished packaged form sealed by a manufacturer and that is placed in a properly labeled container by a pharmacy or practitioner authorized to dispense pursuant to chapter 465 for the purpose of dispensing in the establishment in which the prepackaging occurred.

(43)"Prescription drug" means a prescription, medicinal, or legend drug, including, but not limited to, finished dosage forms or active pharmaceutical ingredients subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act

or s. 465.003(8), s. 499.007(13), or subsection (11), subsection (46), or subsection (53), except that an active pharmaceutical ingredient is a prescription drug only if substantially all finished dosage forms in which it may be lawfully dispensed or administered in this state are also prescription drugs.

(44)"Prescription drug label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug prior to its dispensing to an individual patient pursuant to a prescription of a practitioner authorized by law to prescribe.

(45)"Prescription label" means any display of written, printed, or graphic matter upon the immediate container of any prescription drug dispensed pursuant to a prescription of a practitioner authorized by law to prescribe.

(46)"Prescription medical oxygen" means oxygen USP which is a drug that can only be sold on the order or prescription of a practitioner authorized by law to prescribe. The label of prescription medical oxygen must comply with current labeling requirements for oxygen under the Federal Food, Drug, and Cosmetic Act.

(47)"Primary wholesale distributor" means any wholesale distributor that:

(a)Purchased 90 percent or more of the total dollar volume of its purchases of prescription drugs directly from manufacturers in the previous year; and

(b)1.Directly purchased prescription drugs from not fewer than 50 different prescription drug manufacturers in the previous year; or

2.Has, or the affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member has, not fewer than 250 employees.

(c)For purposes of this subsection, "directly from manufacturers" means:

1.Purchases made by the wholesale distributor directly from the manufacturer of prescription drugs; and

2.Transfers from a member of an affiliated group, as defined in s. 1504 of the Internal Revenue Code, of which the wholesale distributor is a member, if:

a.The affiliated group purchases 90 percent or more of the total dollar volume of its purchases of prescription drugs from the manufacturer in the previous year; and

b.The wholesale distributor discloses to the department the names of all members of the affiliated group of which the wholesale distributor is a member and the affiliated group agrees in writing to provide records on prescription drug purchases by the members of the affiliated group not later than 48 hours after the department requests access to such records, regardless of the location where the records are stored.

(48)"Proprietary drug," or "OTC drug," means a patent or over-the-counter drug in its unbroken, original package, which drug is sold to the public by, or under the authority of, the manufacturer or primary distributor thereof, is not misbranded under the provisions of this part, and can be purchased without a prescription.

(49)"Repackage" includes repacking or otherwise changing the container, wrapper, or labeling to further the distribution of the drug, device, or cosmetic.

(50)"Repackager" means a person who repackages. The term excludes pharmacies that are operating in compliance with pharmacy practice standards as defined in chapter 465 and rules adopted under that chapter.

(51)"Retail pharmacy" means a community pharmacy licensed under chapter 465 that purchases prescription drugs at fair market prices and provides prescription services to the public.

(52)"Secondary wholesale distributor" means a wholesale distributor that is not a primary wholesale distributor.

(53)"Veterinary prescription drug" means a prescription drug intended solely for veterinary use. The label of the drug must bear the statement, "Caution: Federal law restricts this drug to sale by or on the order of a licensed veterinarian."

(54)"Wholesale distribution" means distribution of prescription drugs to persons other than a consumer or patient, but does not include:

(a)Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with s. 499.01(2)(g):

1.The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization of a prescription drug for its own use from the group purchasing organization or from other hospitals or health care entities that are members of that organization.

2.The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug by a charitable organization described in s. 501(c)(3) of the Internal Revenue Code of 1986, as amended and revised, to a nonprofit affiliate of the organization to the extent otherwise permitted by law.

3.The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug among hospitals or other health care entities that are under common control. For purposes of this subparagraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, by voting rights, by contract, or otherwise.

4.The sale, purchase, trade, or other transfer of a prescription drug from or for any federal, state, or local government agency or any entity eligible to purchase prescription drugs at public health services prices pursuant to Pub. L. No. 102-585, s. 602 to a contract provider or its subcontractor for eligible patients of the agency or entity under the following conditions:

a.The agency or entity must obtain written authorization for the sale, purchase, trade, or other transfer of a prescription drug under this subparagraph from the Secretary of Business and Professional Regulation or his or her designee.

b.The contract provider or subcontractor must be authorized by law to administer or dispense prescription drugs.

c.In the case of a subcontractor, the agency or entity must be a party to and execute the subcontract.

d.The contract provider and subcontractor must maintain and produce immediately for inspection all records of movement or transfer of all the prescription drugs belonging to the agency or entity, including, but not limited to, the records of receipt and disposition of prescription drugs. Each contractor and subcontractor dispensing or administering these drugs must maintain and produce records documenting the dispensing or administration. Records that are required to be maintained include, but are not limited to, a perpetual inventory itemizing drugs received and drugs dispensed by prescription number or administered by patient identifier, which must be submitted to the agency or entity quarterly.

e.The contract provider or subcontractor may administer or dispense the prescription drugs only to the eligible patients of the agency or entity or must return the prescription drugs for or to the agency or entity. The contract provider or subcontractor must require proof from each person seeking to fill a prescription or obtain treatment that the person is an eligible patient of the agency or entity and must, at a minimum, maintain a copy of this proof as part of the records of the contractor or subcontractor required under sub-subparagraph d.

f.In addition to the departmental inspection authority set forth in s. 499.051, the establishment of the contract provider and subcontractor and all records pertaining to prescription drugs subject to this subparagraph shall be subject to inspection by the agency or entity. All records relating to prescription drugs of a manufacturer under this subparagraph shall be subject to audit by the manufacturer of those drugs, without identifying individual patient information.

(b)Any of the following activities, which is not a violation of s. 499.005(21) if such activity is conducted in accordance with rules established by the department:

1.The sale, purchase, or trade of a prescription drug among federal, state, or local government health care entities that are under common control and are authorized to purchase such prescription drug.

2.The sale, purchase, or trade of a prescription drug or an offer to sell, purchase, or trade a prescription drug for emergency medical reasons. For purposes of this subparagraph, the term "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage.

3.The transfer of a prescription drug acquired by a medical director on behalf of a licensed emergency medical services provider to that emergency medical services provider and its transport vehicles for use in accordance with the provider's license under chapter 401.

4.The revocation of a sale or the return of a prescription drug to the person's prescription drug wholesale supplier.

5.The donation of a prescription drug by a health care entity to a charitable organization that has been granted an exemption under s. 501(c)(3) of the Internal Revenue Code of 1986, as amended, and that is authorized to possess prescription drugs.

6.The transfer of a prescription drug by a person authorized to purchase or receive prescription drugs to a person licensed or permitted to handle reverse distributions or destruction under the laws of the jurisdiction in which the person handling the reverse distribution or destruction receives the drug.

7.The transfer of a prescription drug by a hospital or other health care entity to a person licensed under this part to repackage prescription drugs for the purpose of repackaging the prescription drug for use by that hospital, or other health care entity and other health care entities that are under common control, if ownership of the prescription drugs remains with the hospital or other health care entity at all times. In addition to the recordkeeping requirements of s. 499.0121(6), the hospital or health care entity that transfers prescription drugs pursuant to this subparagraph must reconcile all drugs transferred and returned and resolve any discrepancies in a timely manner.

(c)The distribution of prescription drug samples by manufacturers' representatives or distributors' representatives conducted in accordance with s. 499.028.

(d)The sale, purchase, or trade of blood and blood components intended for transfusion. As used in this paragraph, the term "blood" means whole blood collected from a single donor and processed for transfusion or further manufacturing, and the term "blood components" means that part of the blood separated by physical or mechanical means.

(e)The lawful dispensing of a prescription drug in accordance with chapter 465.

(f)The sale, purchase, or trade of a prescription drug between pharmacies as a result of a sale, transfer, merger, or consolidation of all or part of the business of the pharmacies from or with another pharmacy, whether accomplished as a purchase and sale of stock or of business assets.

(55)"Wholesale distributor" means any person engaged in wholesale distribution of prescription drugs in or into this state, including, but not limited to, manufacturers; repackagers; own-label distributors; jobbers; private-label distributors; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; independent wholesale drug traders; exporters; retail pharmacies; and the agents thereof that conduct wholesale distributions.

History.—s. 34, ch. 82-225; s. 105, ch. 83-218; s. 1, ch. 83-265; s. 1, ch. 84-115; s. 1, ch. 87-57; s. 3, ch. 88-159; ss. 3, 15, 52, ch. 92-69; s. 584, ch. 97-103; s. 31, ch. 98-151; s. 235, ch. 99-8; ss. 124, 172, ch. 99-397; s. 34, ch. 2000-242; s. 10, ch. 2000-326; s. 38, ch. 2002-400; ss. 3, 13, 14, 25, ch. 2003-155; s. 1, ch. 2004-328; ss. 1, 2, ch. 2005-248; ss. 1, 3, ch. 2006-310; s. 122, ch. 2007-5; s. 20, ch. 2007-6; s. 104, ch. 2008-6; s. 2, ch. 2008-207; s. 60, ch. 2009-21; s. 1, ch. 2009-221; s. 22, ch. 2010-161; s. 2, ch. 2012-37; s. 33, ch. 2012-61; s. 3, ch. 2012-143; s. 122, ch. 2012-184.
Note.—Subsection (24) former s. 499.029(3)(f); subsection (25) former s. 499.029(3)(h); subsection (26) former s. 499.029(3)(i); subsection (34) former s. 499.029(3)(j); subsection (37) former s. 499.0661(1); subsection (39) former s. 499.029(3)(l); subsection (40) former s. 499.029(3)(m); subsection (46) intro., paragraphs (a), (b) former s. 499.012(1)(d); paragraph (46)(c) former s. 499.012(1)(e); subsection (50) former s. 499.012(1)(c); subsection (51) former s. 499.012(1)(f); subsection (53) former s. 499.012(1)(a); subsection (54) former s. 499.012(1)(b).

499.005Prohibited acts.—It is unlawful for a person to perform or cause the performance of any of the following acts in this state:

(1)The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug, device, or cosmetic that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(2)The adulteration or misbranding of any drug, device, or cosmetic.

(3)The receipt of any drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery of such drug, device, or cosmetic, for pay or otherwise.

(4)The sale, distribution, purchase, trade, holding, or offering of any drug, device, or cosmetic in violation of this part.

(5)The dissemination of any false or misleading advertisement of a drug, device, or cosmetic.

(6)The refusal or constructive refusal:

(a)To allow the department to enter or inspect an establishment in which drugs, devices, or cosmetics are manufactured, processed, repackaged, sold, brokered, or held;

(b)To allow inspection of any record of that establishment;

(c)To allow the department to enter and inspect any vehicle that is being used to transport drugs, devices, or cosmetics; or

(d)To allow the department to take samples of any drug, device, or cosmetic.

(7)The purchase or sale of prescription drugs for wholesale distribution in exchange for currency, as defined in s. 560.103.

(8)Committing any act that causes a drug, device, or cosmetic to be a counterfeit drug, device, or cosmetic; or selling, dispensing, or holding for sale a counterfeit drug, device, or cosmetic.

(9)The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of a drug, device, or cosmetic, or the doing of any other act with respect to a drug, device, or cosmetic, if the act is done while the drug, device, or cosmetic is held for sale and the act results in the drug, device, or cosmetic being misbranded.

(10)Forging; counterfeiting; simulating; falsely representing any drug, device, or cosmetic; or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.

(11)The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(12)The possession of any drug in violation of this part.

(13)The sale, delivery, holding, or offering for sale of any self-testing kits designed to tell persons their status concerning human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions. This prohibition shall not apply to home access HIV test kits approved for distribution and sale by the United States Food and Drug Administration.

(14)The purchase or receipt of a prescription drug from a person that is not authorized under this chapter to distribute prescription drugs to that purchaser or recipient.

(15)The sale or transfer of a prescription drug to a person that is not authorized under the law of the jurisdiction in which the person receives the drug to purchase or possess prescription drugs from the person selling or transferring the prescription drug.

(16)The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(17)The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(18)Failure to maintain records as required by this part and rules adopted under this part.

(19)Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part.

(20)The importation of a prescription drug except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(21)The wholesale distribution of any prescription drug that was:

(a)Purchased by a public or private hospital or other health care entity; or

(b)Donated or supplied at a reduced price to a charitable organization,

unless the wholesale distribution of the prescription drug is authorized in s. 499.01(2)(g)1.c.

(22)Failure to obtain a permit or registration, or operating without a valid permit when a permit or registration is required by this part for that activity.

(23)Obtaining or attempting to obtain a prescription drug or device by fraud, deceit, misrepresentation or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug or device.

(24)The distribution of a prescription device to the patient or ultimate consumer without a prescription or order from a practitioner licensed by law to use or prescribe the device.

(25)Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(26)Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(27)Distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(28)Failure to acquire or deliver a pedigree paper as required under this part.

(29)The receipt of a prescription drug pursuant to a wholesale distribution without having previously received or simultaneously receiving a pedigree paper that was attested to as accurate and complete by the wholesale distributor as required under this part.

History.—s. 34, ch. 82-225; s. 106, ch. 83-218; s. 1, ch. 83-265; s. 24, ch. 88-380; ss. 5, 52, ch. 92-69; s. 3, ch. 95-308; s. 585, ch. 97-103; s. 29, ch. 98-151; s. 37, ch. 99-397; s. 35, ch. 2000-242; s. 17, ch. 2001-63; s. 32, ch. 2001-89; s. 4, ch. 2003-155; s. 4, ch. 2006-310; s. 21, ch. 2007-6; s. 48, ch. 2008-177; s. 3, ch. 2008-207; s. 3, ch. 2012-37.

499.0051Criminal acts.—

(1)FAILURE TO MAINTAIN OR DELIVER PEDIGREE PAPERS.—

(a)A person, other than a manufacturer, engaged in the wholesale distribution of prescription drugs who fails to deliver to another person complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the transfer of the prescription drug or contraband prescription drug to another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A person engaged in the wholesale distribution of prescription drugs who fails to acquire complete and accurate pedigree papers concerning a prescription drug or contraband prescription drug prior to, or simultaneous with, the receipt of the prescription drug or contraband prescription drug from another person commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(c)Any person who knowingly destroys, alters, conceals, or fails to maintain complete and accurate pedigree papers concerning any prescription drug or contraband prescription drug in his or her possession commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)FAILURE TO AUTHENTICATE PEDIGREE PAPERS.—Effective July 1, 2006:

(a)A person engaged in the wholesale distribution of prescription drugs who is in possession of pedigree papers concerning prescription drugs or contraband prescription drugs and who fails to authenticate the matters contained in the pedigree papers and who nevertheless attempts to further distribute prescription drugs or contraband prescription drugs commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(b)A person in possession of pedigree papers concerning prescription drugs or contraband prescription drugs who falsely swears or certifies that he or she has authenticated the matters contained in the pedigree papers commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)KNOWING FORGERY OF PEDIGREE PAPERS.—A person who knowingly forges, counterfeits, or falsely creates any pedigree paper; who falsely represents any factual matter contained on any pedigree paper; or who knowingly omits to record material information required to be recorded in a pedigree paper, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4)KNOWING PURCHASE OR RECEIPT OF PRESCRIPTION DRUG FROM UNAUTHORIZED PERSON.—A person who knowingly purchases or receives from a person not authorized to distribute prescription drugs under this chapter a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5)KNOWING SALE OR TRANSFER OF PRESCRIPTION DRUG TO UNAUTHORIZED PERSON.—A person who knowingly sells or transfers to a person not authorized to purchase or possess prescription drugs, under the law of the jurisdiction in which the person receives the drug, a prescription drug in a wholesale distribution transaction commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6)KNOWING SALE OR DELIVERY, OR POSSESSION WITH INTENT TO SELL, CONTRABAND PRESCRIPTION DRUGS.—A person who is knowingly in actual or

constructive possession of any amount of contraband prescription drugs, who knowingly sells or delivers, or who possesses with intent to sell or deliver any amount of contraband prescription drugs, commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(7)KNOWING TRAFFICKING IN CONTRABAND PRESCRIPTION DRUGS.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs valued at $25,000 or more commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a)Upon conviction, each defendant shall be ordered to pay a mandatory fine according to the following schedule:

1.If the value of contraband prescription drugs involved is $25,000 or more, but less than $100,000, the defendant shall pay a mandatory fine of $25,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $75,000.

2.If the value of contraband prescription drugs involved is $100,000 or more, but less than $250,000, the defendant shall pay a mandatory fine of $100,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $300,000.

3.If the value of contraband prescription drugs involved is $250,000 or more, the defendant shall pay a mandatory fine of $200,000. If the defendant is a corporation or other person that is not a natural person, it shall pay a mandatory fine of $600,000.

(b)As used in this subsection, the term "value" means the market value of the property at the time and place of the offense or, if such cannot be satisfactorily ascertained, the cost of replacement of the property within a reasonable time after the offense. Amounts of value of separate contraband prescription drugs involved in distinct transactions for the distribution of the contraband prescription drugs committed pursuant to one scheme or course of conduct, whether involving the same person or several persons, may be aggregated in determining the punishment of the offense.

(8)KNOWING FORGERY OF PRESCRIPTION OR PRESCRIPTION DRUG LABELS.—A person who knowingly forges, counterfeits, or falsely creates any prescription label or prescription drug label, or who falsely represents any factual matter contained on any prescription label or prescription drug label, commits a felony of the first degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(9)KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN GREAT BODILY HARM.—A person who knowingly sells, purchases, manufactures, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in great bodily harm to a person, commits a felony of the first degree, as provided in s. 775.082, s. 775.083, or s. 775.084.

(10)KNOWING SALE OR PURCHASE OF CONTRABAND PRESCRIPTION DRUGS RESULTING IN DEATH.—A person who knowingly manufactures, sells, purchases, delivers, or brings into this state, or who is knowingly in actual or constructive possession of any amount of contraband prescription drugs, and whose acts in violation of this subsection result in the death of a person, commits a felony of the first degree, punishable by a term of years not exceeding life, as provided in s. 775.082, s. 775.083, or s. 775.084.

(11)VIOLATIONS OF S. 499.005 RELATED TO DEVICES AND COSMETICS; DISSEMINATION OF FALSE ADVERTISEMENT.—

(a)Any person who violates any of the provisions of s. 499.005 with respect to a device or cosmetic commits a misdemeanor of the second degree, punishable as

provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083 or as otherwise provided in this part, except that any person who violates s. 499.005(8) or (10) with respect to a device or cosmetic commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part.

(b)A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, wholesaler, or seller of the article to which a false advertisement relates, is not liable under this subsection by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, wholesaler, seller, or advertising agency that asked him or her to disseminate such advertisement.

(12)ADULTERATED AND MISBRANDED DRUGS; FALSE ADVERTISEMENT; FAILURE TO MAINTAIN RECORDS RELATING TO DRUGS.—Any person who violates any of the following provisions commits a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083; but, if the violation is committed after a conviction of such person under this subsection has become final, such person commits a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083, or as otherwise provided in this part:

(a)The manufacture, repackaging, sale, delivery, or holding or offering for sale of any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b)The adulteration or misbranding of any drug intended for further distribution.

(c)The receipt of any drug that is adulterated or misbranded, and the delivery or proffered delivery of such drug, for pay or otherwise.

(d)The dissemination of any false or misleading advertisement of a drug.

(e)The use, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application of the drug is effective when it is not or that the drug complies with this part when it does not.

(f)The purchase or receipt of a compressed medical gas from a person that is not authorized under this chapter to distribute compressed medical gases.

(g)Charging a dispensing fee for dispensing, administering, or distributing a prescription drug sample.

(h)The failure to maintain records related to a drug as required by this part and rules adopted under this part, except for pedigree papers, invoices, or shipping documents related to prescription drugs.

(i)The possession of any drug in violation of this part, except if the violation relates to a deficiency in pedigree papers.

(13)REFUSAL TO ALLOW INSPECTION; SELLING, PURCHASING, OR TRADING DRUG SAMPLES; FAILURE TO MAINTAIN RECORDS RELATING TO PRESCRIPTION DRUGS.—Any person who violates any of the following provisions commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a)The refusal or constructive refusal to allow:

1.The department to enter or inspect an establishment in which drugs are manufactured, processed, repackaged, sold, brokered, or held;

2.Inspection of any record of that establishment;

3.The department to enter and inspect any vehicle that is being used to transport drugs; or

4.The department to take samples of any drug.

(b)The sale, purchase, or trade, or the offer to sell, purchase, or trade, a drug sample as defined in s. 499.028; the distribution of a drug sample in violation of s. 499.028; or the failure to otherwise comply with s. 499.028.

(c)Providing the department with false or fraudulent records, or making false or fraudulent statements, regarding any matter within the provisions of this part related to a drug.

(d)The failure to receive, maintain, or provide invoices and shipping documents, other than pedigree papers, if applicable, related to the distribution of a prescription drug.

(e)The importation of a prescription drug for wholesale distribution, except as provided by s. 801(d) of the Federal Food, Drug, and Cosmetic Act.

(f)The wholesale distribution of a prescription drug that was:

1.Purchased by a public or private hospital or other health care entity; or

2.Donated or supplied at a reduced price to a charitable organization.

(g)The failure to obtain a permit as a prescription drug wholesale distributor when a permit is required by this part for that activity.

(h)Knowingly possessing any adulterated or misbranded prescription drug outside of a designated quarantine area.

(i)The purchase or sale of a prescription drug for wholesale distribution in exchange for currency, as defined in s. 560.103.

(14)OTHER VIOLATIONS.—Any person who violates any of the following provisions commits a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084, or as otherwise provided in this part:

(a)Knowingly manufacturing, repackaging, selling, delivering, or holding or offering for sale any drug that is adulterated or misbranded or has otherwise been rendered unfit for human or animal use.

(b)Knowingly adulterating a drug that is intended for further distribution.

(c)Knowingly receiving a drug that is adulterated and delivering or proffering delivery of such drug for pay or otherwise.

(d)Committing any act that causes a drug to be a counterfeit drug, or selling, dispensing, or knowingly holding for sale a counterfeit drug.

(e)Forging, counterfeiting, simulating, or falsely representing any drug, or, without the authority of the manufacturer, using any mark, stamp, tag, label, or other identification device authorized or required by rules adopted under this part.

(f)Knowingly obtaining or attempting to obtain a prescription drug for wholesale distribution by fraud, deceit, misrepresentation, or subterfuge, or engaging in misrepresentation or fraud in the distribution of a drug.

(g)Removing a pharmacy's dispensing label from a dispensed prescription drug with the intent to further distribute the prescription drug.

(h)Knowingly distributing a prescription drug that was previously dispensed by a licensed pharmacy, unless such distribution was authorized in chapter 465 or the rules adopted under chapter 465.

(15)FALSE ADVERTISEMENT.—A publisher, radio broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, repackager, wholesale distributor, or seller of the article to which a false advertisement relates, is not liable under subsection (12), subsection (13), or subsection (14) by reason of the dissemination by him or her of such false advertisement, unless he or she has refused, on the request of the department, to furnish to the department the name and post office address of the manufacturer, repackager, wholesale distributor, seller, or advertising agency that asked him or her to disseminate such advertisement.

(16)FALSE REPORT.—Any person who submits a report required by s. 499.0121(14) knowing that such report contains a false statement commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(17)CONTROLLED SUBSTANCE DISTRIBUTION.—Any person who engages in the wholesale distribution of prescription drugs and who knowingly distributes controlled substances in violation of s. 499.0121(14) commits a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084. In addition to any other fine that may be imposed, a person convicted of such a violation may be sentenced to pay a fine that does not exceed three times the gross monetary value gained from such violation, plus court costs and the reasonable costs of investigation and prosecution.

History.—s. 34, ch. 82-225; s. 118, ch. 83-218; s. 1, ch. 83-265; ss. 47, 52, ch. 92-69; s. 595, ch. 97-103; s. 40, ch. 99-397; ss. 5, 6, 7, 8, 27, 28, ch. 2003-155; s. 16, ch. 2007-6; s. 49, ch. 2008-177; s. 4, ch. 2008-207; s. 16, ch. 2011-141.

Note.—Subsection (7) former s. 499.0052; subsection (9) former s. 499.00535; subsection (10) former s. 499.00545; subsection (11) former s. 499.069; subsections (12)-(15) former s. 499.0691.

499.0054Advertising and labeling of drugs, devices, and cosmetics; exemptions.—

(1)It is a violation of the Florida Drug and Cosmetic Act to perform or cause the performance of any of the following acts:

(a)The dissemination of any false advertisement of any drug, device, or cosmetic. An advertisement is false if it is false or misleading in any way.

(b)The distribution in commerce of any drug, device, or cosmetic, if its labeling or advertising is in violation of this part.

(c)The manufacturing, repackaging, packaging, selling, delivery, holding, or offering for sale of any drug, device, or cosmetic for which the advertising or labeling is false or misleading.

(d)The advertising of any drug, device, or cosmetic that is adulterated or misbranded.

(e)The receiving in commerce of any drug, device, or cosmetic that is falsely advertised or labeled or the delivering or proffering for delivery of any such drug, device, or cosmetic.

(f)The advertising or labeling of any product containing ephedrine, a salt of ephedrine, an isomer of ephedrine, or a salt of an isomer of ephedrine, for the indication of stimulation, mental alertness, weight loss, appetite control, energy, or other indications not approved by the pertinent United States Food and Drug Administration Over-the-Counter Final or Tentative Final Monograph or approved new drug application under the federal act. In determining compliance with this requirement, the department may consider the following factors:

1.The packaging of the product.

2.The name and labeling of the product.

3.The manner of distribution, advertising, and promotion of the product, including verbal representations at the point of sale.

4.The duration, scope, and significance of abuse of the particular product.

(g)The advertising of any drug or device represented to have any effect in any of the following conditions, disorders, diseases, or processes:

1.Blood disorders.

2.Bone or joint diseases.

3.Kidney diseases or disorders.

4.Cancer.

5.Diabetes.

6.Gall bladder diseases or disorders.

7.Heart and vascular diseases.

8.High blood pressure.
9.Diseases or disorders of the ear or auditory apparatus, including hearing loss or deafness.
10.Mental disease or mental retardation.
11.Paralysis.
12.Prostate gland disorders.
13.Conditions of the scalp affecting hair loss.
14.Baldness.
15.Endocrine disorders.
16.Sexual impotence.
17.Tumors.
18.Venereal diseases.
19.Varicose ulcers.
20.Breast enlargement.
21.Purifying blood.
22.Metabolic disorders.
23.Immune system disorders or conditions affecting the immune system.
24.Extension of life expectancy.
25.Stress and tension.
26.Brain stimulation or performance.
27.The body's natural defense mechanisms.
28.Blood flow.
29.Depression.
30.Human immunodeficiency virus or acquired immune deficiency syndrome or related disorders or conditions.

(h)The representation or suggestion in labeling or advertising that an article is approved under this part, when such is not the case.

(2)In determining whether an advertisement is false or misleading, the department shall review the representations made or suggested by statement, word, design, device, sound, or any combination thereof within the advertisement and the extent to which the advertisement fails to reveal material facts with respect to consequences that can result from the use of the drug, device, or cosmetic to which the advertisement relates under the conditions of use prescribed in the labeling or advertisement.

(3)(a)An advertisement that is not prohibited under paragraph (1)(a) is not prohibited under paragraph (1)(g) if it is disseminated:

1.To the public solely to advertise the product for those indications that are safe and effective indications and the product is safe and effective for self-medication, as established by the United States Food and Drug Administration; or

2.Only to members of the medical, dental, pharmaceutical, or veterinary professions or appears only in the scientific periodicals of these professions.

(b)Compliance with this part and the rules adopted under this part creates no legal presumption that a drug or device is safe or effective.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 1, 2, 4, ch. 86-271; s. 5, ch. 88-172; s. 25, ch. 88-380; ss. 7, 8, 9, 52, ch. 92-69; ss. 2, 3, ch. 95-415; s. 36, ch. 2000-242; s. 5, ch. 2008-207.

Note.—Subsection (2) former s. 499.0055; subsection (3) former s. 499.0057.

499.006Adulterated drug or device.—A drug or device is adulterated:

(1)If it consists in whole or in part of any filthy, putrid, or decomposed substance;

(2)If it has been produced, prepared, packed, or held under conditions whereby it could have been contaminated with filth or rendered injurious to health;

(3)If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to, or are not operated

or administered in conformity with, current good manufacturing practices to assure that the drug meets the requirements of this part and that the drug has the identity and strength, and meets the standard of quality and purity, which it purports or is represented to possess;

(4)If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which could render the contents injurious to health;

(5)If it is a drug and it bears or contains, for the purpose of coloring only, a color additive that is unsafe within the meaning of the federal act; or, if it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, and it is unsafe within the meaning of the federal act;

(6)If it purports to be, or is represented as, a drug the name of which is recognized in the official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. The determination as to strength, quality, or purity must be made in accordance with the tests or methods of assay set forth in such compendium, or, when such tests or methods of assay are absent or inadequate, in accordance with those tests or methods of assay prescribed under authority of the federal act. A drug defined in the official compendium is not adulterated under this subsection merely because it differs from the standard of strength, quality, or purity set forth for that drug in such compendium if its difference in strength, quality, or purity from such standard is plainly stated on its label;

(7)If it is not subject to subsection (6) and its strength differs from, or its purity or quality falls below the standard of, that which it purports or is represented to possess;

(8)If it is a drug:

(a)With which any substance has been mixed or packed so as to reduce the quality or strength of the drug; or

(b)For which any substance has been substituted wholly or in part;

(9)If it is a drug or device for which the expiration date has passed;

(10)If it is a prescription drug for which the required pedigree paper is nonexistent, fraudulent, or incomplete under the requirements of this part or applicable rules, or that has been purchased, held, sold, or distributed at any time by a person not authorized under federal or state law to do so; or

(11)If it is a prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian to a limited prescription drug veterinary wholesale distributor.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 10, 52, ch. 92-69; s. 9, ch. 2003-155; s. 1, ch. 2006-92; s. 6, ch. 2008-207.

499.007Misbranded drug or device.—A drug or device is misbranded:

(1)If its labeling is in any way false or misleading.

(2)If in package form, it does not bear a label containing:

(a)The name and place of business of the manufacturer, repackager, or distributor of the finished dosage form of the drug. For the purpose of this paragraph, the finished dosage form of a prescription drug is that form of the drug which is, or is intended to be, dispensed or administered to the patient and requires no further manufacturing or processing other than packaging, reconstitution, and labeling; and

(b)An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count. However, under this section, reasonable variations are permitted, and the department shall establish by rule exemptions for small packages.

(3)If it is an active pharmaceutical ingredient in bulk form and does not bear a label containing:

(a)The name and place of business of the manufacturer, repackager, or distributor; and

(b)An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count.

(4)If any word, statement, or other information required by or under this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood under customary conditions of purchase and use.

(5)If it is a drug and is not designated solely by a name recognized in an official compendium and its label does not bear:

(a)The common or usual name of the drug, if any; and

(b)In case it is fabricated from two or more ingredients, the common or usual name and quantity of each active ingredient.

(6)If its labeling does not bear:

(a)Adequate directions for use; and

(b)Adequate warnings against use in those pathological conditions in which its use may be dangerous to health or against use by children if its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form as are necessary for the protection of users.

(7)If it purports to be a drug the name of which is recognized in the official compendium and it is not packaged and labeled as prescribed therein. However, the method of packaging may be modified with the consent of the department.

(8)If it has been found by the department to be a drug liable to deterioration and it is not packaged in such form and manner, and its label bears a statement of such precautions, as the department by rule requires as necessary to protect the public health. Such rule may not be established for any drug recognized in an official compendium until the department has informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and that body has failed within a reasonable time to prescribe such requirements.

(9)If it is:

(a)A drug and its container or finished dosage form is so made, formed, or filled as to be misleading;

(b)An imitation of another drug; or

(c)Offered for sale under the name of another drug.

(10)If it is dangerous to health when used in the dosage or with the frequency or duration prescribed, recommended, or suggested in the labeling of the drug.

(11)If it is, purports to be, or is represented as a drug composed wholly or partly of insulin and it is not from a batch with respect to which a certificate has been issued pursuant to s. 506 of the federal act, which certificate is in effect with respect to the drug.

(12)If it is, purports to be, or is represented as a drug composed wholly or partly of any kind of antibiotic requiring certification under the federal act and it is not from a batch with respect to which a certificate has been issued pursuant to s. 507 of the federal act, which certificate is in effect with respect to the drug. However, this subsection does not apply to any drug or class of drugs exempted by regulations adopted under s. 507(c) or (d) of the federal act.

(13)If it is a drug intended for use by humans which is a habit-forming drug or which, because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs, or

which is limited by an effective application under s. 505 of the federal act to use under the professional supervision of a practitioner licensed by law to prescribe such drug, if it is not dispensed only:

(a)Upon the written prescription of a practitioner licensed by law to prescribe such drug;

(b)Upon an oral prescription of such practitioner, which is reduced promptly to writing and filled by the pharmacist; or

(c)By refilling any such written or oral prescription, if such refilling is authorized by the prescriber in the original prescription or by oral order which is reduced promptly to writing and filled by the pharmacist.

This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(14)If it is a drug that is subject to paragraph (13)(a), and if, at any time before it is dispensed, its label does not bear the statement:

(a)"Caution: Federal Law Prohibits Dispensing Without Prescription";

(b)"Rx Only";

(c)The prescription symbol followed by the word "Only"; or

(d)"Caution: State Law Prohibits Dispensing Without Prescription."

(15)If it is a drug that is not subject to paragraph (13)(a), if at any time before it is dispensed its label bears the statement of caution required in subsection (14).

(16)If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only and its packaging and labeling are not in conformity with the packaging and labeling requirements that apply to such color additive and are prescribed under the federal act.

(17)A drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to prescribe such drug is exempt from the requirements of this section, except subsections (1), (9), (11), and (12) and the packaging requirements of subsections (7) and (8), if the drug bears a label that contains the name and address of the dispenser or seller, the prescription number and the date the prescription was written or filled, the name of the prescriber and the name of the patient, and the directions for use and cautionary statements. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or to any drug dispensed in violation of subsection (13). The department may, by rule, exempt drugs subject to s. 499.062 from subsection (13) if compliance with that subsection is not necessary to protect the public health, safety, and welfare.

History.—s. 34, ch. 82-225; s. 107, ch. 83-218; s. 1, ch. 83-265; s. 2, ch. 84-115; ss. 11, 52, ch. 92-69; s. 586, ch. 97-103; s. 38, ch. 99-397; s. 10, ch. 2003-155; s. 84, ch. 2004-5; s. 7, ch. 2008-207.

499.008Adulterated cosmetics.—A cosmetic is adulterated:

(1)If it bears or contains any poisonous or deleterious substance that is injurious to users under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual; however, this subsection does not apply to coal-tar hair dye:

(a)The label of which bears the following legend conspicuously displayed thereon: "Caution: This product contains ingredients which may cause skin irritation on certain individuals, and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness"; and

(b)The labeling of which bears adequate directions for such preliminary testing.

(2)If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(3)If it has been produced, prepared, packed, or held under conditions whereby it could have become contaminated with filth or whereby it could have been rendered injurious to health.

(4)If it is not a hair dye and it is, or it bears or contains, a color additive that is unsafe within the meaning of the federal act.

(5)For the purposes of subsections (1) and (4), the term "hair dye" does not include eyelash dyes or eyebrow dyes.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 12, 52, ch. 92-69; s. 8, ch. 2008-207.

499.009Misbranded cosmetics.—A cosmetic is misbranded:

(1)If its labeling is false or misleading in any particular.

(2)If in package form, it does not bear a label containing:

(a)The name and place of business of the manufacturer, packer, or distributor;

(b)An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; however, under this paragraph reasonable variations are permitted, and the department shall establish by rule exemptions for small packages; and

(c)A declaration of ingredients in descending order of predominance, or as otherwise required by federal law.

(3)If any word, statement, or other information required by or under authority of this part to appear on the label or labeling is not prominently placed thereon with such conspicuousness as compared with other words, statements, designs, or devices in the labeling, and in such terms, as to render the word, statement, or other information likely to be read and understood by an individual under customary conditions of purchase and use.

(4)If its container is so made, formed, or filled as to be misleading.

(5)If it is a color additive, its packaging and labeling are not in conformity with the packaging and labeling requirements applicable to that color additive prescribed under the federal act. This subsection does not apply to packages of color additives that, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 13, 52, ch. 92-69; s. 9, ch. 2008-207.

499.01Permits.—

(1)Prior to operating, a permit is required for each person and establishment that intends to operate as:

(a)A prescription drug manufacturer;

(b)A prescription drug repackager;

(c)A nonresident prescription drug manufacturer;

(d)A prescription drug wholesale distributor;

(e)An out-of-state prescription drug wholesale distributor;

(f)A retail pharmacy drug wholesale distributor;

(g)A restricted prescription drug distributor;

(h)A complimentary drug distributor;

(i)A freight forwarder;

(j)A veterinary prescription drug retail establishment;

(k)A veterinary prescription drug wholesale distributor;

(l)A limited prescription drug veterinary wholesale distributor;

(m)A medical oxygen retail establishment;

(n)A compressed medical gas wholesale distributor;

(o)A compressed medical gas manufacturer;

(p)An over-the-counter drug manufacturer;

(q)A device manufacturer;

(r)A cosmetic manufacturer;

(s)A third party logistics provider; or

(t)A health care clinic establishment.

(2)The following permits are established:

(a)Prescription drug manufacturer permit.—A prescription drug manufacturer permit is required for any person that is a manufacturer of a prescription drug and that manufactures or distributes such prescription drugs in this state.

1.A person that operates an establishment permitted as a prescription drug manufacturer may engage in wholesale distribution of prescription drugs manufactured at that establishment and must comply with all of the provisions of this part, except s. 499.01212, and the rules adopted under this part, except s. 499.01212, which apply to a wholesale distributor.

2.A prescription drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

3.A blood establishment, as defined in s. 381.06014, operating in a manner consistent with the provisions of 21 C.F.R. parts 211 and 600-640, and manufacturing only the prescription drugs described in s. 499.003(54)(d) is not required to be permitted as a prescription drug manufacturer under this paragraph or to register products under s. 499.015.

(b)Prescription drug repackager permit.—A prescription drug repackager permit is required for any person that repackages a prescription drug in this state.

1.A person that operates an establishment permitted as a prescription drug repackager may engage in wholesale distribution of prescription drugs repackaged at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

2.A prescription drug repackager must comply with all appropriate state and federal good manufacturing practices.

(c)Nonresident prescription drug manufacturer permit.—A nonresident prescription drug manufacturer permit is required for any person that is a manufacturer of prescription drugs, unless permitted as a third party logistics provider, located outside of this state or outside the United States and that engages in the wholesale distribution in this state of such prescription drugs. Each such manufacturer must be permitted by the department and comply with all of the provisions required of a wholesale distributor under this part, except s. 499.01212.

1.A person that distributes prescription drugs for which the person is not the manufacturer must also obtain an out-of-state prescription drug wholesale distributor permit or third party logistics provider permit pursuant to this section to engage in the wholesale distribution of such prescription drugs. This subparagraph does not apply to a manufacturer as defined in s. 499.003(31)(e).

2.Any such person must comply with the licensing or permitting requirements of the jurisdiction in which the establishment is located and the federal act, and any product wholesaled into this state must comply with this part. If a person intends to import prescription drugs from a foreign country into this state, the nonresident prescription drug manufacturer must provide to the department a list identifying each prescription drug it intends to import and document approval by the United States Food and Drug Administration for such importation.

(d)Prescription drug wholesale distributor permit.—A prescription drug wholesale distributor is a wholesale distributor that may engage in the wholesale distribution of prescription drugs. A prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the

bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The department may adopt rules for issuing a prescription drug wholesale distributor-broker permit to a person who engages in the wholesale distribution of prescription drugs and does not take physical possession of any prescription drugs.

(e)Out-of-state prescription drug wholesale distributor permit.—An out-of-state prescription drug wholesale distributor is a wholesale distributor located outside this state which engages in the wholesale distribution of prescription drugs into this state and which must be permitted by the department and comply with all the provisions required of a wholesale distributor under this part. An out-of-state prescription drug wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $100,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later. The out-of-state prescription drug wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

(f)Retail pharmacy drug wholesale distributor permit.—A retail pharmacy drug wholesale distributor is a retail pharmacy engaged in wholesale distribution of prescription drugs within this state under the following conditions:

1.The pharmacy must obtain a retail pharmacy drug wholesale distributor permit pursuant to this part and the rules adopted under this part.

2.The wholesale distribution activity does not exceed 30 percent of the total annual purchases of prescription drugs. If the wholesale distribution activity exceeds the 30-percent maximum, the pharmacy must obtain a prescription drug wholesale distributor permit.

3.The transfer of prescription drugs that appear in any schedule contained in chapter 893 is subject to chapter 893 and the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

4.The transfer is between a retail pharmacy and another retail pharmacy, or a Modified Class II institutional pharmacy, or a health care practitioner licensed in this state and authorized by law to dispense or prescribe prescription drugs.

5.All records of sales of prescription drugs subject to this section must be maintained separate and distinct from other records and comply with the recordkeeping requirements of this part.

(g)Restricted prescription drug distributor permit.—

1.A restricted prescription drug distributor permit is required for:

a.Any person located in this state who engages in the distribution of a prescription drug, which distribution is not considered "wholesale distribution" under s. 499.003(54)(a).

b.Any person located in this state who engages in the receipt or distribution of a prescription drug in this state for the purpose of processing its return or its destruction if such person is not the person initiating the return, the prescription drug wholesale supplier of the person initiating the return, or the manufacturer of the drug.

c.A blood establishment located in this state which collects blood and blood components only from volunteer donors as defined in s. 381.06014 or pursuant to an authorized practitioner's order for medical treatment or therapy and engages in the wholesale distribution of a prescription drug not described in s. 499.003(54)(d) to a health care entity. A mobile blood unit operated by a blood establishment permitted under this sub-subparagraph is not required to be separately permitted. The health care entity receiving a prescription drug distributed under this sub-subparagraph must be licensed as a closed pharmacy or provide health care services at that establishment. The blood establishment must operate in accordance with s. 381.06014 and may distribute only:

(I)Prescription drugs indicated for a bleeding or clotting disorder or anemia;

(II)Blood-collection containers approved under s. 505 of the federal act;

(III)Drugs that are blood derivatives, or a recombinant or synthetic form of a blood derivative;

(IV)Prescription drugs that are identified in rules adopted by the department and that are essential to services performed or provided by blood establishments and authorized for distribution by blood establishments under federal law; or

(V)To the extent authorized by federal law, drugs necessary to collect blood or blood components from volunteer blood donors; for blood establishment personnel to perform therapeutic procedures under the direction and supervision of a licensed physician; and to diagnose, treat, manage, and prevent any reaction of a volunteer blood donor or a patient undergoing a therapeutic procedure performed under the direction and supervision of a licensed physician,

as long as all of the health care services provided by the blood establishment are related to its activities as a registered blood establishment or the health care services consist of collecting, processing, storing, or administering human hematopoietic stem cells or progenitor cells or performing diagnostic testing of specimens if such specimens are tested together with specimens undergoing routine donor testing. The blood establishment may purchase and possess the drugs described in this sub-subparagraph without a health care clinic establishment permit.

2.Storage, handling, and recordkeeping of these distributions by a person required to be permitted as a restricted prescription drug distributor must be in accordance with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212 if the distribution occurs pursuant to sub-subparagraph 1.a. or sub-subparagraph 1.b.

3.A person who applies for a permit as a restricted prescription drug distributor, or for the renewal of such a permit, must provide to the department the information required under s. 499.012.

4.The department may adopt rules regarding the distribution of prescription drugs by hospitals, health care entities, charitable organizations, other persons not involved in wholesale distribution, and blood establishments, which rules are necessary for the protection of the public health, safety, and welfare.

(h)Complimentary drug distributor permit.—A complimentary drug distributor permit is required for any person that engages in the distribution of a complimentary drug, subject to the requirements of s. 499.028.

(i)Freight forwarder permit.—A freight forwarder permit is required for any person that engages in the distribution of a prescription drug as a freight forwarder unless the person is a common carrier. The storage, handling, and recordkeeping of such distributions must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212. A freight forwarder must provide the source of the prescription drugs with a validated airway bill, bill of lading, or other appropriate documentation to evidence the exportation of the product.

(j)Veterinary prescription drug retail establishment permit.—A veterinary prescription drug retail establishment permit is required for any person that sells veterinary prescription drugs to the public but does not include a pharmacy licensed under chapter 465.

1.The sale to the public must be based on a valid written order from a veterinarian licensed in this state who has a valid client-veterinarian relationship with the purchaser's animal.

2.Veterinary prescription drugs may not be sold in excess of the amount clearly indicated on the order or beyond the date indicated on the order.

3.An order may not be valid for more than 1 year.

4.A veterinary prescription drug retail establishment may not purchase, sell, trade, or possess human prescription drugs or any controlled substance as defined in chapter 893.

5.A veterinary prescription drug retail establishment must sell a veterinary prescription drug in the original, sealed manufacturer's container with all labeling intact and legible. The department may adopt by rule additional labeling requirements for the sale of a veterinary prescription drug.

6.A veterinary prescription drug retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

7.Prescription drugs sold by a veterinary prescription drug retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(k)Veterinary prescription drug wholesale distributor permit.—A veterinary prescription drug wholesale distributor permit is required for any person that engages in the distribution of veterinary prescription drugs in or into this state. A veterinary prescription drug wholesale distributor that also distributes prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which it did not manufacture must obtain a permit as a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a limited prescription drug veterinary wholesale distributor in lieu of the veterinary prescription drug wholesale distributor permit. A veterinary prescription drug wholesale distributor must comply with the requirements for wholesale distributors under s. 499.0121, but not those set forth in s. 499.01212.

(l)Limited prescription drug veterinary wholesale distributor permit.—Unless engaging in the activities of and permitted as a prescription drug manufacturer, nonresident prescription drug manufacturer, prescription drug wholesale distributor, or out-of-state prescription drug wholesale distributor, a limited prescription drug veterinary wholesale distributor permit is required for any person that engages in the distribution in or into this state of veterinary prescription drugs and prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act under the following conditions:

1.The person is engaged in the business of wholesaling prescription and veterinary prescription drugs to persons:

a.Licensed as veterinarians practicing on a full-time basis;

b.Regularly and lawfully engaged in instruction in veterinary medicine;

c.Regularly and lawfully engaged in law enforcement activities;

d.For use in research not involving clinical use; or

e.For use in chemical analysis or physical testing or for purposes of instruction in law enforcement activities, research, or testing.

2.No more than 30 percent of total annual prescription drug sales may be prescription drugs approved for human use which are subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act.

3.The person does not distribute in any jurisdiction prescription drugs subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act to any person who is authorized to sell, distribute, purchase, trade, or use these drugs on or for humans.

4.A limited prescription drug veterinary wholesale distributor that applies to the department for a new permit or the renewal of a permit must submit a bond of $20,000, or other equivalent means of security acceptable to the department, such as an irrevocable letter of credit or a deposit in a trust account or financial institution, payable to the Professional Regulation Trust Fund. The purpose of the bond is to secure payment of any administrative penalties imposed by the department and any fees and costs incurred by the department regarding that permit which are authorized under state law and which the permittee fails to pay 30 days after the fine or costs become final. The department may make a claim against such bond or security until 1 year after the permittee's license ceases to be valid or until 60 days after any administrative or legal proceeding authorized in this part which involves the permittee is concluded, including any appeal, whichever occurs later.

5.A limited prescription drug veterinary wholesale distributor must maintain at all times a license or permit to engage in the wholesale distribution of prescription drugs in compliance with laws of the state in which it is a resident.

6.A limited prescription drug veterinary wholesale distributor must comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, except that a limited prescription drug veterinary wholesale distributor is not required to provide a pedigree paper as required by s. 499.01212 upon the wholesale distribution of a prescription drug to a veterinarian.

7.A limited prescription drug veterinary wholesale distributor may not return to inventory for subsequent wholesale distribution any prescription drug subject to, defined by, or described by s. 503(b) of the Federal Food, Drug, and Cosmetic Act which has been returned by a veterinarian.

8.A limited prescription drug veterinary wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed to engage in the wholesale distribution of prescription drugs in its state of residence to a licensed limited prescription drug veterinary wholesale distributor in this state if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for this transaction.

(m)Medical oxygen retail establishment permit.—A medical oxygen retail establishment permit is required for any person that sells medical oxygen to patients only. The sale must be based on an order from a practitioner authorized by law to prescribe. The term does not include a pharmacy licensed under chapter 465.

1.A medical oxygen retail establishment may not possess, purchase, sell, or trade any prescription drug other than medical oxygen.

2.A medical oxygen retail establishment may refill medical oxygen for an individual patient based on an order from a practitioner authorized by law to prescribe. A medical oxygen retail establishment that refills medical oxygen must comply with all appropriate state and federal good manufacturing practices.

3.A medical oxygen retail establishment must comply with all of the wholesale distribution requirements of s. 499.0121.

4.Prescription medical oxygen sold by a medical oxygen retail establishment pursuant to a practitioner's order may not be returned into the retail establishment's inventory.

(n)Compressed medical gas wholesale distributor permit.—A compressed medical gas wholesale distributor is a wholesale distributor that is limited to the wholesale distribution of compressed medical gases to other than the consumer or patient. The compressed medical gas must be in the original sealed container that was purchased by that wholesale distributor. A compressed medical gas wholesale distributor may not possess or engage in the wholesale distribution of any prescription drug other than compressed medical gases. The department shall adopt rules that govern the wholesale distribution of prescription medical oxygen for emergency use. With respect to the emergency use of prescription medical oxygen, those rules may not be inconsistent with rules and regulations of federal agencies unless the Legislature specifically directs otherwise.

(o)Compressed medical gas manufacturer permit.—A compressed medical gas manufacturer permit is required for any person that engages in the manufacture of compressed medical gases or repackages compressed medical gases from one container to another.

1.A compressed medical gas manufacturer may not manufacture or possess any prescription drug other than compressed medical gases.

2.A compressed medical gas manufacturer may engage in wholesale distribution of compressed medical gases manufactured at that establishment and must comply with all the provisions of this part and the rules adopted under this part that apply to a wholesale distributor.

3.A compressed medical gas manufacturer must comply with all appropriate state and federal good manufacturing practices.

(p)Over-the-counter drug manufacturer permit.—An over-the-counter drug manufacturer permit is required for any person that engages in the manufacture or repackaging of an over-the-counter drug.

1.An over-the-counter drug manufacturer may not possess or purchase prescription drugs.

2.A pharmacy is exempt from obtaining an over-the-counter drug manufacturer permit if it is operating in compliance with pharmacy practice standards as defined in chapter 465 and the rules adopted under that chapter.

3.An over-the-counter drug manufacturer must comply with all appropriate state and federal good manufacturing practices.

(q)Device manufacturer permit.—

1.A device manufacturer permit is required for any person that engages in the manufacture, repackaging, or assembly of medical devices for human use in this state, except that a permit is not required if:

a.The person is engaged only in manufacturing, repackaging, or assembling a medical device pursuant to a practitioner's order for a specific patient; or

b.The person does not manufacture, repackage, or assemble any medical devices or components for such devices, except those devices or components which are exempt from registration pursuant to s. 499.015(8).

2.A manufacturer or repackager of medical devices in this state must comply with all appropriate state and federal good manufacturing practices and quality system rules.

3.The department shall adopt rules related to storage, handling, and recordkeeping requirements for manufacturers of medical devices for human use.

(r)Cosmetic manufacturer permit.—A cosmetic manufacturer permit is required for any person that manufactures or repackages cosmetics in this state. A person that only labels or changes the labeling of a cosmetic but does not open the container sealed by the manufacturer of the product is exempt from obtaining a permit under this paragraph.

(s)Third party logistics provider permit.—A third party logistics provider permit is required for any person that contracts with a prescription drug wholesale distributor or prescription drug manufacturer to provide warehousing, distribution, or other logistics services on behalf of a manufacturer or wholesale distributor, but who does not take title to the prescription drug or have responsibility to direct the sale or disposition of the prescription drug. Each third party logistics provider permittee shall comply with the requirements for wholesale distributors under ss. 499.0121 and 499.01212, with the exception of those wholesale distributions described in s. 499.01212(3)(a), and other rules that the department requires.

(t)Health care clinic establishment permit.—Effective January 1, 2009, a health care clinic establishment permit is required for the purchase of a prescription drug by a place of business at one general physical location that provides health care or veterinary services, which is owned and operated by a business entity that has been issued a federal employer tax identification number. For the purpose of this paragraph, the term "qualifying practitioner" means a licensed health care practitioner defined in s. 456.001, or a veterinarian licensed under chapter 474, who is authorized under the appropriate practice act to prescribe and administer a prescription drug.

1.An establishment must provide, as part of the application required under s. 499.012, designation of a qualifying practitioner who will be responsible for complying with all legal and regulatory requirements related to the purchase, recordkeeping, storage, and handling of the prescription drugs. In addition, the designated qualifying practitioner shall be the practitioner whose name, establishment address, and license number is used on all distribution documents for prescription drugs purchased or returned by the health care clinic establishment. Upon initial appointment of a qualifying practitioner, the qualifying practitioner and the health care clinic establishment shall notify the department on a form furnished by the department within 10 days after such employment. In addition, the qualifying practitioner and health care clinic establishment shall notify the department within 10 days after any subsequent change.

2.The health care clinic establishment must employ a qualifying practitioner at each establishment.

3.In addition to the remedies and penalties provided in this part, a violation of this chapter by the health care clinic establishment or qualifying practitioner constitutes grounds for discipline of the qualifying practitioner by the appropriate regulatory board.

4.The purchase of prescription drugs by the health care clinic establishment is prohibited during any period of time when the establishment does not comply with this paragraph.

5.A health care clinic establishment permit is not a pharmacy permit or otherwise subject to chapter 465. A health care clinic establishment that meets the criteria of a modified Class II institutional pharmacy under s. 465.019 is not eligible to be permitted under this paragraph.

6.This paragraph does not apply to the purchase of a prescription drug by a licensed practitioner under his or her license.

(3)A nonresident prescription drug manufacturer permit is not required for a manufacturer to distribute a prescription drug active pharmaceutical ingredient that it manufactures to a prescription drug manufacturer permitted in this state in limited

quantities intended for research and development and not for resale or human use other than lawful clinical trials and biostudies authorized and regulated by federal law. A manufacturer claiming to be exempt from the permit requirements of this subsection and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212. The prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall maintain on file a record of the FDA registration number; if available, the out-of-state license, permit, or registration number; and, if available, a copy of the most current FDA inspection report, for all manufacturers from whom they purchase active pharmaceutical ingredients under this section. The department shall define the term "limited quantities" by rule, and may include the allowable number of transactions within a given period of time and the amount of prescription drugs distributed into the state for purposes of this exemption. The failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, for the purchase of prescription drug active pharmaceutical ingredients is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(4)(a)A permit issued under this part is not required to distribute a prescription drug active pharmaceutical ingredient from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for use by the recipient in preparing, deriving, processing, producing, or fabricating a prescription drug finished dosage form at the establishment in this state where the product is received under an approved and otherwise valid New Drug Approval Application, Abbreviated New Drug Application, New Animal Drug Application, or Therapeutic Biologic Application, provided that the application, active pharmaceutical ingredient, or finished dosage form has not been withdrawn or removed from the market in this country for public health reasons.

1.Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2.Any distributor claiming exemption from permitting requirements pursuant to this paragraph and the prescription drug manufacturer purchasing and receiving the active pharmaceutical ingredient shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

(b)A permit issued under this part is not required to distribute limited quantities of a prescription drug that has not been repackaged from an establishment located in the United States to an establishment located in this state permitted as a prescription drug manufacturer under this part for research and development or to a holder of a letter of exemption issued by the department under s. 499.03(4) for research, teaching, or testing. The department shall define "limited quantities" by rule and may include the allowable number of transactions within a given period of time and the amounts of prescription drugs distributed into the state for purposes of this exemption.

1.Any distributor claiming exemption from permitting requirements pursuant to this paragraph shall maintain a license, permit, or registration to engage in the wholesale distribution of prescription drugs under the laws of the state from which the product is distributed.

2.All purchasers and recipients of any prescription drugs distributed pursuant to this paragraph shall ensure that the products are not resold or used, directly or indirectly, on humans except in lawful clinical trials and biostudies authorized and regulated by federal law.

3.Any distributor claiming exemption from permitting requirements pursuant to this paragraph, and the purchaser and recipient of the prescription drug, shall comply with the recordkeeping requirements of s. 499.0121(6), but not the requirements of s. 499.01212.

4.The immediate package or container of any active pharmaceutical ingredient distributed into the state that is intended for teaching, testing, research, and development shall bear a label prominently displaying the statement: "Caution: Research, Teaching, or Testing Only – Not for Manufacturing, Compounding, or Resale."

(c)An out-of-state prescription drug wholesale distributor permit is not required for an intracompany sale or transfer of a prescription drug from an out-of-state establishment that is duly licensed as a prescription drug wholesale distributor in its state of residence to a licensed prescription drug wholesale distributor in this state, if both wholesale distributors conduct wholesale distributions of prescription drugs under the same business name. The recordkeeping requirements of ss. 499.0121(6) and 499.01212 must be followed for such transactions.

(d)Persons receiving prescription drugs from a source claimed to be exempt from permitting requirements under this subsection shall maintain on file:

1.A record of the FDA establishment registration number, if any;

2.The resident state prescription drug wholesale distribution license, permit, or registration number; and

3.A copy of the most recent resident state or FDA inspection report, for all distributors and establishments [1]from whom they purchase or receive prescription drugs under this subsection.

(e)All persons claiming exemption from permitting requirements pursuant to this subsection who engage in the distribution of prescription drugs within or into the state are subject to this part, including ss. 499.005 and 499.0051, and shall make available, within 48 hours, to the department on request all records related to any prescription drugs distributed under this subsection, including those records described in s. 499.051(4), regardless of the location where the records are stored.

(f)A person purchasing and receiving a prescription drug from a person claimed to be exempt from licensing requirements pursuant to this subsection shall report to the department in writing within 14 days after receiving any product that is misbranded or adulterated or that fails to meet minimum standards set forth in the official compendium or state or federal good manufacturing practices for identity, purity, potency, or sterility, regardless of whether the product is thereafter rehabilitated, quarantined, returned, or destroyed.

(g)The department may adopt rules to administer this subsection which are necessary for the protection of the public health, safety, and welfare. Failure to comply with the requirements of this subsection, or rules adopted by the department to administer this subsection, is a violation of s. 499.005(14), and a knowing failure is a violation of s. 499.0051(4).

(h)This subsection does not relieve any person from any requirement prescribed by law with respect to controlled substances as defined in the applicable federal and state laws.

(5)A prescription drug repackager permit issued under this part is not required for a restricted prescription drug distributor permitholder that is a health care entity to repackage prescription drugs in this state for its own use or for distribution to hospitals or other health care entities in the state for their own use, pursuant to s. 499.003(54)(a)3., if:

(a)The prescription drug distributor notifies the department, in writing, of its intention to engage in repackaging under this exemption, 30 days before engaging in the repackaging of prescription drugs at the permitted establishment;

(b)The prescription drug distributor is under common control with the hospitals or other health care entities to which the prescription drug distributor is distributing prescription drugs. As used in this paragraph, "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, contract, or otherwise;

(c)The prescription drug distributor repackages the prescription drugs in accordance with current state and federal good manufacturing practices; and

(d)The prescription drug distributor labels the prescription drug it repackages in accordance with state and federal laws and rules.

The prescription drug distributor is exempt from the product registration requirements of s. 499.015 with regard to the prescription drugs that it repackages and distributes under this subsection.

History.—s. 34, ch. 82-225; s. 108, ch. 83-218; s. 1, ch. 83-265; ss. 14, 15, 18, 19, 52, ch. 92-69; ss. 30, 31, 34, 35, ch. 98-151; ss. 37, 40, ch. 2000-242; s. 20, ch. 2001-53; s. 138, ch. 2001-277; ss. 11, 12, 13, 14, 18, 19, ch. 2003-155; s. 85, ch. 2004-5; ss. 2, 3, ch. 2004-328; ss. 2, 3, ch. 2006-92; ss. 22, 25, ch. 2007-6; ss. 10, 11, ch. 2008-207; s. 2, ch. 2009-221; ss. 23, 39, ch. 2010-161; s. 4, ch. 2012-37; s. 34, ch. 2012-61; s. 11, ch. 2012-143.

[1]Note.—The word "from" was inserted by the editors.

Note.—Subsection (2) intro. former s. 499.012(2) intro.; paragraph (2)(c) former s. 499.012(2)(e); paragraph (2)(d) former s. 499.012(2)(a); paragraph (2)(e) former s. 499.012(2)(c); paragraph (2)(f) former s. 499.012(2)(d); paragraph (2)(g) former s. 499.014; paragraph (2)(i) former s. 499.012(2)(f); paragraph (2)(k) former s. 499.012(2)(g); paragraph (2)(l) former s. 499.012(2)(h); paragraph (2)(n) former s. 499.012(2)(b); paragraph (2)(o) former s. 499.013(2)(c); paragraph (2)(p) former s. 499.013(2)(b); paragraph (2)(q) former s. 499.013(2)(d); paragraph (2)(r) former s. 499.013(2)(e).

499.012Permit application requirements.—

(1)(a)A permit issued pursuant to this part may be issued only to a natural person who is at least 18 years of age or to an applicant that is not a natural person if each person who, directly or indirectly, manages, controls, or oversees the operation of that applicant is at least 18 years of age.

(b)An establishment that is a place of residence may not receive a permit and may not operate under this part.

(c)A person that applies for or renews a permit to manufacture or distribute prescription drugs may not use a name identical to the name used by any other establishment or licensed person authorized to purchase prescription drugs in this state, except that a restricted drug distributor permit issued to a health care entity will be issued in the name in which the institutional pharmacy permit is issued and a retail pharmacy drug wholesale distributor will be issued a permit in the name of its retail pharmacy permit.

(d)A permit for a prescription drug manufacturer, prescription drug repackager, prescription drug wholesale distributor, limited prescription drug veterinary wholesale distributor, or retail pharmacy drug wholesale distributor may not be issued to the address of a health care entity or to a pharmacy licensed under chapter 465, except as provided in this paragraph. The department may issue a prescription drug manufacturer permit to an applicant at the same address as a licensed nuclear pharmacy, which is a health care entity, for the purpose of manufacturing prescription drugs used in positron emission tomography or other radiopharmaceuticals, as listed in a rule adopted by the department pursuant to this paragraph. The purpose of this exemption is to assure availability of state-of-the-art

pharmaceuticals that would pose a significant danger to the public health if manufactured at a separate establishment address from the nuclear pharmacy from which the prescription drugs are dispensed. The department may also issue a retail pharmacy drug wholesale distributor permit to the address of a community pharmacy licensed under chapter 465 which does not meet the definition of a closed pharmacy in s. 499.003.

(e)A county or municipality may not issue an occupational license for any licensing period beginning on or after October 1, 2003, for any establishment that requires a permit pursuant to this part, unless the establishment exhibits a current permit issued by the department for the establishment. Upon presentation of the requisite permit issued by the department, an occupational license may be issued by the municipality or county in which application is made. The department shall furnish to local agencies responsible for issuing occupational licenses a current list of all establishments licensed pursuant to this part.

(2)Notwithstanding subsection (6), a permitted person in good standing may change the type of permit issued to that person by completing a new application for the requested permit, paying the amount of the difference in the permit fees if the fee for the new permit is more than the fee for the original permit, and meeting the applicable permitting conditions for the new permit type. The new permit expires on the expiration date of the original permit being changed; however, a new permit for a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a retail pharmacy drug wholesale distributor shall expire on the expiration date of the original permit or 1 year after the date of issuance of the new permit, whichever is earlier. A refund may not be issued if the fee for the new permit is less than the fee that was paid for the original permit.

(3)A written application for a permit or to renew a permit must be filed with the department on forms furnished by the department. The department shall establish, by rule, the form and content of the application to obtain or renew a permit. The applicant must submit to the department with the application a statement that swears or affirms that the information is true and correct.

(4)(a)Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor, an application for a permit must include:

1.The name, full business address, and telephone number of the applicant;

2.All trade or business names used by the applicant;

3.The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs;

4.The type of ownership or operation, such as a partnership, corporation, or sole proprietorship; and

5.The names of the owner and the operator of the establishment, including:

a.If an individual, the name of the individual;

b.If a partnership, the name of each partner and the name of the partnership;

c.If a corporation, the name and title of each corporate officer and director, the corporate names, and the name of the state of incorporation;

d.If a sole proprietorship, the full name of the sole proprietor and the name of the business entity;

e.If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company, and the name of the state in which the limited liability company was organized; and

f.Any other relevant information that the department requires.

(b)Upon approval of the application by the department and payment of the required fee, the department shall issue a permit to the applicant, if the applicant meets the requirements of this part and rules adopted under this part.

(c)Any change in information required under paragraph (a) must be submitted to the department before the change occurs.

(d)The department shall consider, at a minimum, the following factors in reviewing the qualifications of persons to be permitted under this part:

1.The applicant's having been found guilty, regardless of adjudication, in a court of this state or other jurisdiction, of a violation of a law that directly relates to a drug, device, or cosmetic. A plea of nolo contendere constitutes a finding of guilt for purposes of this subparagraph.

2.The applicant's having been disciplined by a regulatory agency in any state for any offense that would constitute a violation of this part.

3.Any felony conviction of the applicant under a federal, state, or local law;

4.The applicant's past experience in manufacturing or distributing drugs, devices, or cosmetics;

5.The furnishing by the applicant of false or fraudulent material in any application made in connection with manufacturing or distributing drugs, devices, or cosmetics;

6.Suspension or revocation by a federal, state, or local government of any permit currently or previously held by the applicant for the manufacture or distribution of any drugs, devices, or cosmetics;

7.Compliance with permitting requirements under any previously granted permits;

8.Compliance with requirements to maintain or make available to the state permitting authority or to federal, state, or local law enforcement officials those records required under this section; and

9.Any other factors or qualifications the department considers relevant to and consistent with the public health and safety.

(5)Except for a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:

(a)The department shall adopt rules for the biennial renewal of permits.

(b)The department shall renew a permit upon receipt of the renewal application and renewal fee if the applicant meets the requirements established under this part and the rules adopted under this part.

(c)A permit, unless sooner suspended or revoked, automatically expires 2 years after the last day of the anniversary month in which the permit was originally issued. A permit issued under this part may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after the expiration date of the permit, the permit may be renewed only upon payment of a late renewal delinquent fee of $100, plus the required renewal fee, not later than 60 days after the expiration date.

(d)Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this part has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit, pay the applicable application fee, the initial permit fee, and all applicable penalties, and be issued a new permit by the department.

(6)A permit issued by the department is nontransferable. Each permit is valid only for the person or governmental unit to which it is issued and is not subject to sale, assignment, or other transfer, voluntarily or involuntarily; nor is a permit valid for any establishment other than the establishment for which it was originally issued.

(a)A person permitted under this part must notify the department before making a change of address. The department shall set a change of location fee not to exceed $100.

(b)1.An application for a new permit is required when a majority of the ownership or controlling interest of a permitted establishment is transferred or assigned or when a lessee agrees to undertake or provide services to the extent that legal liability for operation of the establishment will rest with the lessee. The application for the new permit must be made before the date of the sale, transfer, assignment, or lease.

2.A permittee that is authorized to distribute prescription drugs may transfer such drugs to the new owner or lessee under subparagraph 1. only after the new owner or lessee has been approved for a permit to distribute prescription drugs.

(c)If an establishment permitted under this part closes, the owner must notify the department in writing before the effective date of closure and must:

1.Return the permit to the department;

2.If the permittee is authorized to distribute prescription drugs, indicate the disposition of such drugs, including the name, address, and inventory, and provide the name and address of a person to contact regarding access to records that are required to be maintained under this part. Transfer of ownership of prescription drugs may be made only to persons authorized to possess prescription drugs under this part.

The department may revoke the permit of any person that fails to comply with the requirements of this subsection.

(7)A permit must be posted in a conspicuous place on the licensed premises.

(8)An application for a permit or to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor submitted to the department must include:

(a)The name, full business address, and telephone number of the applicant.

(b)All trade or business names used by the applicant.

(c)The address, telephone numbers, and the names of contact persons for each facility used by the applicant for the storage, handling, and distribution of prescription drugs.

(d)The type of ownership or operation, such as a partnership, corporation, or sole proprietorship.

(e)The names of the owner and the operator of the establishment, including:

1.If an individual, the name of the individual.

2.If a partnership, the name of each partner and the name of the partnership.

3.If a corporation:

a.The name, address, and title of each corporate officer and director.

b.The name and address of the corporation, resident agent of the corporation, the resident agent's address, and the corporation's state of incorporation.

c.The name and address of each shareholder of the corporation that owns 5 percent or more of the outstanding stock of the corporation.

4.If a sole proprietorship, the full name of the sole proprietor and the name of the business entity.

5.If a limited liability company:

a.The name and address of each member.

b.The name and address of each manager.

c.The name and address of the limited liability company, the resident agent of the limited liability company, and the name of the state in which the limited liability company was organized.

(f)If applicable, the name and address of each member of the affiliated group of which the applicant is a member.

(g)1.For an application for a new permit, the estimated annual dollar volume of prescription drug sales of the applicant, the estimated annual percentage of the applicant's total company sales that are prescription drugs, the applicant's estimated annual total dollar volume of purchases of prescription drugs, and the applicant's estimated annual total dollar volume of prescription drug purchases directly from manufacturers.

2.For an application to renew a permit, the total dollar volume of prescription drug sales in the previous year, the total dollar volume of prescription drug sales made in the previous 6 months, the percentage of total company sales that were prescription drugs in the previous year, the total dollar volume of purchases of prescription drugs in the previous year, and the total dollar volume of prescription drug purchases directly from manufacturers in the previous year.

Such portions of the information required pursuant to this paragraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

(h)The tax year of the applicant.

(i)A copy of the deed for the property on which applicant's establishment is located, if the establishment is owned by the applicant, or a copy of the applicant's lease for the property on which applicant's establishment is located that has an original term of not less than 1 calendar year, if the establishment is not owned by the applicant.

(j)A list of all licenses and permits issued to the applicant by any other state which authorize the applicant to purchase or possess prescription drugs.

(k)The name of the manager of the establishment that is applying for the permit or to renew the permit, the next four highest ranking employees responsible for prescription drug wholesale operations for the establishment, and the name of all affiliated parties for the establishment, together with the personal information statement and fingerprints required pursuant to subsection (9) for each of such persons.

(l)The name of each of the applicant's designated representatives as required by subsection (16), together with the personal information statement and fingerprints required pursuant to subsection (9) for each such person.

(m)For an applicant that is a secondary wholesale distributor, each of the following:

1.A personal background information statement containing the background information and fingerprints required pursuant to subsection (9) for each person named in the applicant's response to paragraphs (k) and (l) and for each affiliated party of the applicant.

2.If any of the five largest shareholders of the corporation seeking the permit is a corporation, the name, address, and title of each corporate officer and director of each such corporation; the name and address of such corporation; the name of such corporation's resident agent, such corporation's resident agent's address, and such corporation's state of its incorporation; and the name and address of each shareholder of such corporation that owns 5 percent or more of the stock of such corporation.

3.The name and address of all financial institutions in which the applicant has an account which is used to pay for the operation of the establishment or to pay for drugs purchased for the establishment, together with the names of all persons that are authorized signatories on such accounts. The portions of the information required

pursuant to this subparagraph which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

4.The sources of all funds and the amounts of such funds used to purchase or finance purchases of prescription drugs or to finance the premises on which the establishment is to be located.

5.If any of the funds identified in subparagraph 4. were borrowed, copies of all promissory notes or loans used to obtain such funds.

(n)Any other relevant information that the department requires, including, but not limited to, any information related to whether the applicant satisfies the definition of a primary wholesale distributor or a secondary wholesale distributor.

(o)Documentation of the credentialing policies and procedures required by s. 499.0121(15).

(9)(a)Each person required by subsection (8) to provide a personal information statement and fingerprints shall provide the following information to the department on forms prescribed by the department:

1.The person's places of residence for the past 7 years.

2.The person's date and place of birth.

3.The person's occupations, positions of employment, and offices held during the past 7 years.

4.The principal business and address of any business, corporation, or other organization in which each such office of the person was held or in which each such occupation or position of employment was carried on.

5.Whether the person has been, during the past 7 years, the subject of any proceeding for the revocation of any license and, if so, the nature of the proceeding and the disposition of the proceeding.

6.Whether, during the past 7 years, the person has been enjoined, temporarily or permanently, by a court of competent jurisdiction from violating any federal or state law regulating the possession, control, or distribution of prescription drugs, together with details concerning any such event.

7.A description of any involvement by the person with any business, including any investments, other than the ownership of stock in a publicly traded company or mutual fund, during the past 7 years, which manufactured, administered, prescribed, distributed, or stored pharmaceutical products and any lawsuits in which such businesses were named as a party.

8.A description of any felony criminal offense of which the person, as an adult, was found guilty, regardless of whether adjudication of guilt was withheld or whether the person pled guilty or nolo contendere. A criminal offense committed in another jurisdiction which would have been a felony in this state must be reported. If the person indicates that a criminal conviction is under appeal and submits a copy of the notice of appeal of that criminal offense, the applicant must, within 15 days after the disposition of the appeal, submit to the department a copy of the final written order of disposition.

9.A photograph of the person taken in the previous 30 days.

10.A set of fingerprints for the person on a form and under procedures specified by the department, together with payment of an amount equal to the costs incurred by the department for the criminal record check of the person.

11.The name, address, occupation, and date and place of birth for each member of the person's immediate family who is 18 years of age or older. As used in this subparagraph, the term "member of the person's immediate family" includes the person's spouse, children, parents, siblings, the spouses of the person's children, and the spouses of the person's siblings.

12.Any other relevant information that the department requires.

(b)The information required pursuant to paragraph (a) shall be provided under oath.

(c)The department shall submit the fingerprints provided by a person for initial licensure to the Department of Law Enforcement for a statewide criminal record check and for forwarding to the Federal Bureau of Investigation for a national criminal record check of the person. The department shall submit the fingerprints provided by a person as a part of a renewal application to the Department of Law Enforcement for a statewide criminal record check, and for forwarding to the Federal Bureau of Investigation for a national criminal record check, for the initial renewal of a permit after January 1, 2004; for any subsequent renewal of a permit, the department shall submit the required information for a statewide and national criminal record check of the person. Any person who as a part of an initial permit application or initial permit renewal after January 1, 2004, submits to the department a set of fingerprints required for the criminal record check required in this paragraph shall not be required to provide a subsequent set of fingerprints for a criminal record check to the department, if the person has undergone a criminal record check as a condition of the issuance of an initial permit or the initial renewal of a permit of an applicant after January 1, 2004.

(10)The department may deny an application for a permit or refuse to renew a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor if:

(a)The applicant has not met the requirements for the permit.

(b)The management, officers, or directors of the applicant or any affiliated party are found by the department to be incompetent or untrustworthy.

(c)The applicant is so lacking in experience in managing a wholesale distributor as to make the issuance of the proposed permit hazardous to the public health.

(d)The applicant is so lacking in experience in managing a wholesale distributor as to jeopardize the reasonable promise of successful operation of the wholesale distributor.

(e)The applicant is lacking in experience in the distribution of prescription drugs.

(f)The applicant's past experience in manufacturing or distributing prescription drugs indicates that the applicant poses a public health risk.

(g)The applicant is affiliated directly or indirectly through ownership, control, or other business relations, with any person or persons whose business operations are or have been detrimental to the public health.

(h)The applicant, or any affiliated party, has been found guilty of or has pleaded guilty or nolo contendere to any felony or crime punishable by imprisonment for 1 year or more under the laws of the United States, any state, or any other country, regardless of whether adjudication of guilt was withheld.

(i)The applicant or any affiliated party has been charged with a felony in a state or federal court and the disposition of that charge is pending during the application review or renewal review period.

(j)The applicant has furnished false or fraudulent information or material in any application made in this state or any other state in connection with obtaining a permit or license to manufacture or distribute drugs, devices, or cosmetics.

(k)That a federal, state, or local government permit currently or previously held by the applicant, or any affiliated party, for the manufacture or distribution of any drugs, devices, or cosmetics has been disciplined, suspended, or revoked and has not been reinstated.

(l)The applicant does not possess the financial or physical resources to operate in compliance with the permit being sought, this chapter, and the rules adopted under this chapter.

(m)The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who was an affiliated party of a permittee whose permit was subject to discipline or was suspended or revoked, other than through the ownership of stock in a publicly traded company or a mutual fund.

(n)The applicant or any affiliated party receives, directly or indirectly, financial support and assistance from a person who has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, any federal or state drug law, or any felony where the underlying facts related to drugs, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld, other than through the ownership of stock in a publicly traded company or a mutual fund.

(o)The applicant for renewal of a permit under s. 499.01(2)(d) or (e) has not actively engaged in the wholesale distribution of prescription drugs, as demonstrated by the regular and systematic distribution of prescription drugs throughout the year as evidenced by not fewer than 12 wholesale distributions in the previous year and not fewer than three wholesale distributions in the previous 6 months.

(p)Information obtained in response to s. 499.01(2)(d) or (e) demonstrates it would not be in the best interest of the public health, safety, and welfare to issue a permit.

(q)The applicant does not possess the financial standing and business experience for the successful operation of the applicant.

(r)The applicant or any affiliated party has failed to comply with the requirements for manufacturing or distributing prescription drugs under this part, similar federal laws, similar laws in other states, or the rules adopted under such laws.

(11)Upon approval of the application by the department and payment of the required fee, the department shall issue or renew a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor permit to the applicant.

(12)For a permit for a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor:

(a)The department shall adopt rules for the annual renewal of permits. At least 90 days before the expiration of a permit, the department shall forward a permit renewal notification and renewal application to the prescription drug wholesale distributor or out-of-state prescription drug wholesale distributor at the mailing address of the permitted establishment on file with the department. The permit renewal notification must state conspicuously the date on which the permit for the establishment will expire and that the establishment may not operate unless the permit for the establishment is renewed timely.

(b)A permit, unless sooner suspended or revoked, automatically expires 1 year after the last day of the anniversary month in which the permit was originally issued. A permit may be renewed by making application for renewal on forms furnished by the department and paying the appropriate fees. If a renewal application and fee are submitted and postmarked after 45 days prior to the expiration date of the permit, the permit may be renewed only upon payment of a late renewal fee of $100, plus the required renewal fee. A permittee that has submitted a renewal application in accordance with this paragraph may continue to operate under its permit, unless the permit is suspended or revoked, until final disposition of the renewal application.

(c)Failure to renew a permit in accordance with this section precludes any future renewal of that permit. If a permit issued pursuant to this section has expired and cannot be renewed, before an establishment may engage in activities that require a permit under this part, the establishment must submit an application for a new permit; pay the applicable application fee, initial permit fee, and all applicable penalties; and be issued a new permit by the department.

(13)A person that engages in wholesale distribution of prescription drugs in this state must have a wholesale distributor's permit issued by the department, except as noted in this section. Each establishment must be separately permitted except as noted in this subsection.

(a)A separate establishment permit is not required when a permitted prescription drug wholesale distributor consigns a prescription drug to a pharmacy that is permitted under chapter 465 and located in this state, provided that:

1.The consignor wholesale distributor notifies the department in writing of the contract to consign prescription drugs to a pharmacy along with the identity and location of each consignee pharmacy;

2.The pharmacy maintains its permit under chapter 465;

3.The consignor wholesale distributor, which has no legal authority to dispense prescription drugs, complies with all wholesale distribution requirements of ss. 499.0121 and 499.01212 with respect to the consigned drugs and maintains records documenting the transfer of title or other completion of the wholesale distribution of the consigned prescription drugs;

4.The distribution of the prescription drug is otherwise lawful under this chapter and other applicable law;

5.Open packages containing prescription drugs within a pharmacy are the responsibility of the pharmacy, regardless of how the drugs are titled; and

6.The pharmacy dispenses the consigned prescription drug in accordance with the limitations of its permit under chapter 465 or returns the consigned prescription drug to the consignor wholesale distributor. In addition, a person who holds title to prescription drugs may transfer the drugs to a person permitted or licensed to handle the reverse distribution or destruction of drugs. Any other distribution by and means of the consigned prescription drug by any person, not limited to the consignor wholesale distributor or consignee pharmacy, to any other person is prohibited.

(b)A wholesale distributor's permit is not required for the one-time transfer of title of a pharmacy's lawfully acquired prescription drug inventory by a pharmacy with a valid permit issued under chapter 465 to a consignor prescription drug wholesale distributor, permitted under this chapter, in accordance with a written consignment agreement between the pharmacy and that wholesale distributor if the permitted pharmacy and the permitted prescription drug wholesale distributor comply with all of the provisions of paragraph (a) and the prescription drugs continue to be within the permitted pharmacy's inventory for dispensing in accordance with the limitations of the pharmacy permit under chapter 465. A consignor drug wholesale distributor may not use the pharmacy as a wholesale distributor through which it distributes the prescription drugs to other pharmacies. Nothing in this section is intended to prevent a wholesale distributor from obtaining this inventory in the event of nonpayment by the pharmacy.

(c)A separate establishment permit is not required when a permitted prescription drug wholesale distributor operates temporary transit storage facilities for the sole purpose of storage, for up to 16 hours, of a delivery of prescription drugs when the wholesale distributor was temporarily unable to complete the delivery to the recipient.

(d)The department shall require information from each wholesale distributor as part of the permit and renewal of such permit, as required under this section.

(14)Personnel employed in wholesale distribution must have appropriate education and experience to enable them to perform their duties in compliance with state permitting requirements.

(15)The name of a permittee or establishment on a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit may not include any indicia of attainment of any educational degree, any indicia that

the permittee or establishment possesses a professional license, or any name or abbreviation that the department determines is likely to cause confusion or mistake or that the department determines is deceptive, including that of any other entity authorized to purchase prescription drugs.

(16)(a)Each establishment that is issued an initial or renewal permit as a prescription drug wholesale distributor or an out-of-state prescription drug wholesale distributor must designate in writing to the department at least one natural person to serve as the designated representative of the wholesale distributor. Such person must have an active certification as a designated representative from the department.

(b)To be certified as a designated representative, a natural person must:

1.Submit an application on a form furnished by the department and pay the appropriate fees;

2.Be at least 18 years of age;

3.Have not less than 2 years of verifiable full-time work experience in a pharmacy licensed in this state or another state, where the person's responsibilities included, but were not limited to, recordkeeping for prescription drugs, or have not less than 2 years of verifiable full-time managerial experience with a prescription drug wholesale distributor licensed in this state or in another state;

4.Receive a passing score of at least 75 percent on an examination given by the department regarding federal laws governing distribution of prescription drugs and this part and the rules adopted by the department governing the wholesale distribution of prescription drugs. This requirement shall be effective 1 year after the results of the initial examination are mailed to the persons that took the examination. The department shall offer such examinations at least four times each calendar year; and

5.Provide the department with a personal information statement and fingerprints pursuant to subsection (9).

(c)The department may deny an application for certification as a designated representative or may suspend or revoke a certification of a designated representative pursuant to s. 499.067.

(d)A designated representative:

1.Must be actively involved in and aware of the actual daily operation of the wholesale distributor.

2.Must be employed full time in a managerial position by the wholesale distributor.

3.Must be physically present at the establishment during normal business hours, except for time periods when absent due to illness, family illness or death, scheduled vacation, or other authorized absence.

4.May serve as a designated representative for only one wholesale distributor at any one time.

(e)A wholesale distributor must notify the department when a designated representative leaves the employ of the wholesale distributor. Such notice must be provided to the department within 10 business days after the last day of designated representative's employment with the wholesale distributor.

(f)A wholesale distributor may not operate under a prescription drug wholesale distributor permit or an out-of-state prescription drug wholesale distributor permit for more than 10 business days after the designated representative leaves the employ of the wholesale distributor, unless the wholesale distributor employs another designated representative and notifies the department within 10 business days of the identity of the new designated representative.

History.—s. 34, ch. 82-225; s. 108, ch. 83-218; s. 1, ch. 83-265; ss. 14, 15, 52, ch. 92-69; s. 187, ch. 97-264; ss. 30, 31, ch. 98-151; s. 172, ch. 99-397; s. 37, ch. 2000-242; s. 20, ch. 2001-53; s. 138, ch. 2001-277; s. 38, ch. 2002-400; ss. 11,

12, 13, 14, ch. 2003-155; s. 85, ch. 2004-5; s. 3, ch. 2004-328; s. 2, ch. 2005-248; ss. 2, 3, ch. 2006-92; s. 22, ch. 2007-6; ss. 2, 10, 11, 28, ch. 2008-207; s. 61, ch. 2009-21; s. 17, ch. 2011-141; s. 67, ch. 2012-5.
Note.—Subsections (1)-(7) former s. 499.01(2)-(8).

499.01201Agency for Health Care Administration review and use of statute and rule violation or compliance data.—Notwithstanding any other provisions of law to the contrary, the Agency for Health Care Administration may not:

(1)Review or use any violation or alleged violation of s. 499.0121(6) or s. 499.01212, or any rules adopted under those sections, as a ground for denying or withholding any payment of a Medicaid reimbursement to a pharmacy licensed under chapter 465; or

(2)Review or use compliance with s. 499.0121(6) or s. 499.01212, or any rules adopted under those sections, as the subject of any audit of Medicaid-related records held by a pharmacy licensed under chapter 465.
History.—s. 4, ch. 2005-248; s. 12, ch. 2008-207.

499.0121Storage and handling of prescription drugs; recordkeeping.—The department shall adopt rules to implement this section as necessary to protect the public health, safety, and welfare. Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records.

(1)ESTABLISHMENTS.—An establishment at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed must:

(a)Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;

(b)Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;

(c)Have a quarantine area for storage of prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

(d)Be maintained in a clean and orderly condition; and

(e)Be free from infestation by insects, rodents, birds, or vermin of any kind.

(2)SECURITY.—

(a)An establishment that is used for wholesale drug distribution must be secure from unauthorized entry.

1.Access from outside the premises must be kept to a minimum and be well-controlled.

2.The outside perimeter of the premises must be well-lighted.

3.Entry into areas where prescription drugs are held must be limited to authorized personnel.

(b)An establishment that is used for wholesale drug distribution must be equipped with:

1.An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers and establishments that only handle medical oxygen; and

2.A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.

(c)Any vehicle that contains prescription drugs must be secure from unauthorized access to the prescription drugs in the vehicle.

(3)STORAGE.—All prescription drugs shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the official compendium.

(a)If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

(b)Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, or logs must be used to document proper storage of prescription drugs.

(c)The recordkeeping requirements in subsection (6) must be followed for all stored prescription drugs.

(4)EXAMINATION OF MATERIALS AND RECORDS.—

(a)Upon receipt, each outside shipping container must be visually examined for identity and to prevent the acceptance of contaminated prescription drugs that are otherwise unfit for distribution. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.

(b)Each outgoing shipment must be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have expired or been damaged in storage or held under improper conditions.

(c)The recordkeeping requirements in subsection (6) must be followed for all incoming and outgoing prescription drugs.

(d)Upon receipt, a wholesale distributor must review records required under this section for the acquisition of prescription drugs for accuracy and completeness, considering the total facts and circumstances surrounding the transactions and the wholesale distributors involved. This includes authenticating each transaction listed on a pedigree paper, as defined in s. 499.003(37).

(5)RETURNED, DAMAGED, OR OUTDATED PRESCRIPTION DRUGS.—

(a)1.Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs.

2.Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined.

(b)Any prescription drugs of which the immediate or sealed outer containers or sealed secondary containers have been opened or used must be identified as such and must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to the supplier.

(c)If the conditions under which a prescription drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the drug must be destroyed or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which a drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale distributor must consider, among other things, the conditions under which the drug has been held, stored, or shipped before or during its return and the conditions of the drug and its container, carton, or labeling, as a result of storage or shipping.

(d)The recordkeeping requirements in subsection (6) must be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(6)RECORDKEEPING.—The department shall adopt rules that require keeping such records of prescription drugs as are necessary for the protection of the public health.

(a)Wholesale distributors must establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records must provide a complete audit trail from receipt to sale or other disposition, be readily retrievable for inspection, and include, at a minimum, the following information:

1.The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs were shipped;

2.The name, principal address, and state license permit or registration number of the person authorized to purchase prescription drugs;

3.The name, strength, dosage form, and quantity of the drugs received and distributed or disposed of;

4.The dates of receipt and distribution or other disposition of the drugs; and

5.Any financial documentation supporting the transaction.

(b)Inventories and records must be made available for inspection and photocopying by authorized federal, state, or local officials for a period of 2 years following disposition of the drugs or 3 years after the creation of the records, whichever period is longer.

(c)Records described in this section that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means must be readily available for authorized inspection during the retention period. Records that are kept at a central location outside of this state and that are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records that are maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part and must be readily available.

(d)Each manufacturer or repackager of medical devices, over-the-counter drugs, or cosmetics must maintain records that include the name and principal address of the seller or transferor of the product, the address of the location from which the product was shipped, the date of the transaction, the name and quantity of the product involved, and the name and principal address of the person who purchased the product.

(e)When pedigree papers are required by this part, a wholesale distributor must maintain the pedigree papers separate and distinct from other records required under this part.

(7)PRESCRIPTION DRUG PURCHASE LIST.—Each wholesale distributor, except for a manufacturer, shall annually provide the department with a written list of all wholesale distributors and manufacturers from whom the wholesale distributor purchases prescription drugs. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. Such portions of the information required pursuant to this subsection which are a trade secret, as defined in s. 812.081, shall be maintained by the department as trade secret information is required to be maintained under s. 499.051.

(8)WRITTEN POLICIES AND PROCEDURES.—Wholesale distributors must establish, maintain, and adhere to written policies and procedures, which must be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying, recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale distributors must include in their written policies and procedures:

(a)A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate.

(b)A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure must be adequate to deal with recalls and withdrawals due to:

1.Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department.

2.Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or

3.Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design.

(c)A procedure to ensure that wholesale distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility if a strike, fire, flood, or other natural disaster, or a local, state, or national emergency, occurs.

(d)A procedure to ensure that any outdated prescription drugs are segregated from other drugs and returned to the manufacturer or repackager or destroyed. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs.

(9)RESPONSIBLE PERSONS.—Wholesale distributors must establish and maintain lists of officers, directors, managers, designated representatives, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10)COMPLIANCE WITH FEDERAL, STATE, AND LOCAL LAW.—A wholesale distributor must operate in compliance with applicable federal, state, and local laws and regulations.

(a)A wholesale distributor must allow the department and authorized federal, state, and local officials to enter and inspect its premises and delivery vehicles, and to audit its records and written operating procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b)A wholesale distributor that deals in controlled substances must register with the Drug Enforcement Administration and must comply with all applicable state, local, and federal laws. A wholesale distributor that distributes any substance controlled under chapter 893 must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number.

(11)SALVAGING AND REPROCESSING.—A wholesale distributor is subject to any applicable federal, state, or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

(12)SHIPPING AND TRANSPORTATION.—The person responsible for shipment and transportation of a prescription drug in a wholesale distribution may use a common carrier; its own vehicle or employee acting within the scope of employment if authorized under s. 499.03 for the possession of prescription drugs in this state; or, in the case of a prescription drug intended for domestic distribution, an independent contractor who must be the agent of the authorized seller or recipient responsible for shipping and transportation as set forth in a written contract between the parties. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department.

(13)DUE DILIGENCE OF SUPPLIERS.—Prior to purchasing any prescription drugs from another wholesale distributor, a prescription drug wholesale distributor, an out-of-state prescription drug wholesale distributor, or a prescription drug repackager must:

(a)Enter an agreement with the selling wholesale distributor by which the selling wholesale distributor will indemnify the purchasing wholesale distributor for any loss caused to the purchasing wholesale distributor related to the purchase of drugs from the selling wholesale distributor which are determined to be counterfeit or to have been distributed in violation of any federal or state law governing the distribution of drugs.

(b)Determine that the selling wholesale distributor has insurance coverage of not less than the greater of 1 percent of the amount of total dollar volume of the prescription drug sales reported to the department under s. 499.012(8)(g) or $500,000; however the coverage need not exceed $2 million.

(c)Obtain information from the selling wholesale distributor, including the length of time the selling wholesale distributor has been licensed in this state, a copy of the selling wholesale distributor's licenses or permits, and background information concerning the ownership of the selling wholesale distributor, including the experience of the wholesale distributor in the wholesale distribution of prescription drugs.

(d)Verify that the selling wholesale distributor's Florida permit is valid.

(e)Inspect the selling wholesale distributor's licensed establishment to document that it has a policies and procedures manual relating to the distribution of drugs, the appropriate temperature controlled environment for drugs requiring temperature control, an alarm system, appropriate access restrictions, and procedures to ensure that records related to the wholesale distribution of prescription drugs are maintained as required by law:

1.Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or

2.Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located.

(14)DISTRIBUTION REPORTING.—Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager that engages in the wholesale distribution of controlled substances as defined in s. 893.02 shall submit a report to the department of its receipts and distributions of controlled substances listed in Schedule II, Schedule III, Schedule IV, or Schedule V as provided in s. 893.03. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information:

(a)The federal Drug Enforcement Administration registration number of the wholesale distributing location.

(b)The federal Drug Enforcement Administration registration number of the entity to which the drugs are distributed or from which the drugs are received.

(c)The transaction code that indicates the type of transaction.

(d)The National Drug Code identifier of the product and the quantity distributed or received.

(e)The Drug Enforcement Administration Form 222 number or Controlled Substance Ordering System Identifier on all Schedule II transactions.

(f)The date of the transaction.

The department must share the reported data with the Department of Law Enforcement and local law enforcement agencies upon request and must monitor purchasing to identify purchasing levels that are inconsistent with the purchasing entity's clinical needs. The Department of Law Enforcement shall investigate purchases at levels that are inconsistent with the purchasing entity's clinical needs to determine whether violations of chapter 893 have occurred.

(15)DUE DILIGENCE OF PURCHASERS.—

(a)Each prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor must establish and maintain policies and procedures to credential physicians licensed under chapter 458, chapter 459, chapter 461, or chapter 466 and pharmacies that purchase or otherwise receive from the wholesale distributor controlled substances listed in Schedule II or Schedule III as provided in s. 893.03. The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include:

1.A determination of the clinical nature of the receiving entity, including any specialty practice area.

2.A review of the receiving entity's history of Schedule II and Schedule III controlled substance purchasing from the wholesale distributor.

3.A determination that the receiving entity's Schedule II and Schedule III controlled substance purchasing history, if any, is consistent with and reasonable for that entity's clinical business needs.

(b)A wholesale distributor must take reasonable measures to identify its customers, understand the normal and expected transactions conducted by those customers, and identify those transactions that are suspicious in nature. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for greater than 5,000 unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. In making such assessments, a wholesale distributor may consider the purchasing entity's clinical business needs, location, and population served, in addition to other factors established in the distributor's policies and procedures. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

(c)A wholesale distributor may not distribute controlled substances to an entity if any criminal history record check for any person associated with that entity shows that the person has been convicted of, or entered a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction related to controlled substances, the practice of pharmacy, or the dispensing of medicinal drugs.

(d)The department shall assess national data from the Automation of Reports and Consolidated Orders System of the federal Drug Enforcement Administration, excluding Florida data, and identify the national average of grams of hydrocodone, morphine, oxycodone, and methadone distributed per pharmacy registrant per month in the most recent year for which data is available. The department shall report the average for each of these drugs to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011. The department shall assess the data reported pursuant to subsection (14) and identify the statewide average of grams of each benzodiazepine distributed per community pharmacy per month. The department shall report the average for each benzodiazepine to the Governor, the President of the Senate, and the Speaker of the House of Representatives by November 1, 2011.

History.—s. 16, ch. 92-69; s. 32, ch. 98-151; ss. 38, 40, ch. 2000-242; ss. 15, 16, 18, ch. 2003-155; s. 86, ch. 2004-5; s. 4, ch. 2004-328; s. 10, ch. 2004-387; s. 3, ch. 2005-248; s. 5, ch. 2006-310; s. 17, ch. 2007-6; s. 13, ch. 2008-207; s. 62, ch. 2009-21; s. 3, ch. 2009-221; s. 40, ch. 2010-161; s. 18, ch. 2011-141.

Note.—Paragraph (6)(d) former s. 499.013(4).

499.01211Drug Wholesale Distributor Advisory Council.—

(1)There is created the Drug Wholesale Distributor Advisory Council within the department. The council shall meet at least once each calendar quarter. Staff for the council shall be provided by the department. The council shall consist of 11 members who shall serve without compensation. The council shall elect a chairperson and a vice chairperson annually.

(2)The Secretary of Business and Professional Regulation or his or her designee and the Secretary of Health Care Administration or her or his designee shall be members of the council. The Secretary of Business and Professional Regulation shall appoint nine additional members to the council who shall be appointed to a term of 4 years each, as follows:

(a)Three different persons each of whom is employed by a different prescription drug wholesale distributor licensed under this part which operates nationally and is a primary wholesale distributor, as defined in s. 499.003(47).

(b)One person employed by a prescription drug wholesale distributor licensed under this part which is a secondary wholesale distributor, as defined in s. 499.003(52).

(c)One person employed by a retail pharmacy chain located in this state.

(d)One person who is a member of the Board of Pharmacy and is a pharmacist licensed under chapter 465.

(e)One person who is a physician licensed pursuant to chapter 458 or chapter 459.

(f)One person who is an employee of a hospital licensed pursuant to chapter 395 and is a pharmacist licensed pursuant to chapter 465.

(g)One person who is an employee of a pharmaceutical manufacturer.

(3)The council shall review this part and the rules adopted to administer this part annually, provide input to the department regarding all proposed rules to administer this part, make recommendations to the department to improve the protection of the prescription drugs and public health, make recommendations to improve coordination with other states' regulatory agencies and the federal government concerning the wholesale distribution of drugs, and make recommendations to

minimize the impact of regulation of the wholesale distribution industry while ensuring protection of the public health.
History.—s. 17, ch. 2003-155; s. 23, ch. 2007-6; s. 105, ch. 2008-6; s. 14, ch. 2008-207; s. 41, ch. 2010-161; s. 4, ch. 2012-143.

499.01212Pedigree paper.—

(1)APPLICATION.—Each person who is engaged in the wholesale distribution of a prescription drug must, prior to or simultaneous with each wholesale distribution, provide a pedigree paper to the person who receives the drug.

(2)FORMAT.—A pedigree paper must contain the following information:

(a)For the wholesale distribution of a prescription drug within the normal distribution chain:

1.The following statement: "This wholesale distributor purchased the specific unit of the prescription drug directly from the manufacturer."

2.The manufacturer's national drug code identifier and the name and address of the wholesale distributor and the purchaser of the prescription drug.

3.The name of the prescription drug as it appears on the label.

4.The quantity, dosage form, and strength of the prescription drug.

The wholesale distributor must also maintain and make available to the department, upon request, the point of origin of the prescription drugs, including intracompany transfers, the date of the shipment from the manufacturer to the wholesale distributor, the lot numbers of such drugs, and the invoice numbers from the manufacturer.

(b)For all other wholesale distributions of prescription drugs:

1.The quantity, dosage form, and strength of the prescription drugs.

2.The lot numbers of the prescription drugs.

3.The name and address of each owner of the prescription drug and his or her signature.

4.Shipping information, including the name and address of each person certifying delivery or receipt of the prescription drug.

5.An invoice number, a shipping document number, or another number uniquely identifying the transaction.

6.A certification that the recipient wholesale distributor has authenticated the pedigree papers.

7.The unique serialization of the prescription drug, if the manufacturer or repackager has uniquely serialized the individual prescription drug unit.

8.The name, address, telephone number, and, if available, e-mail contact information of each wholesale distributor involved in the chain of the prescription drug's custody.

When an affiliated group member obtains title to a prescription drug before distributing the prescription drug as the manufacturer under s. 499.003(31)(e), information regarding the distribution between those affiliated group members may be omitted from a pedigree paper required under this paragraph for subsequent distributions of that prescription drug.

(3)EXCEPTIONS.—A pedigree paper is not required for:

(a)The wholesale distribution of a prescription drug by the manufacturer or by a third party logistics provider performing a wholesale distribution of a prescription drug for a manufacturer.

(b)The wholesale distribution of a prescription drug by a freight forwarder within the authority of a freight forwarder permit.

(c)The wholesale distribution of a prescription drug by a limited prescription drug veterinary wholesale distributor to a veterinarian.

(d)The wholesale distribution of a compressed medical gas.

(e)The wholesale distribution of a veterinary prescription drug.

(f)A drop shipment, provided:

1.The wholesale distributor delivers to the recipient of the prescription drug, within 14 days after the shipment notification from the manufacturer, an invoice and the following sworn statement: "This wholesale distributor purchased the specific unit of the prescription drug listed on the invoice directly from the manufacturer, and the specific unit of prescription drug was shipped by the manufacturer directly to a person authorized by law to administer or dispense the legend drug, as defined in s. 465.003, Florida Statutes, or a member of an affiliated group, with the exception of a repackager." The invoice must contain a unique cross-reference to the shipping document sent by the manufacturer to the recipient of the prescription drug.

2.The manufacturer of the prescription drug shipped directly to the recipient provides and the recipient of the prescription drug acquires, within 14 days after receipt of the prescription drug, a shipping document from the manufacturer that contains, at a minimum:

a.The name and address of the manufacturer, including the point of origin of the shipment, and the names and addresses of the wholesale distributor and the purchaser.

b.The name of the prescription drug as it appears on the label.

c.The quantity, dosage form, and strength of the prescription drug.

d.The date of the shipment from the manufacturer.

3.The wholesale distributor maintains and makes available to the department, upon request, the lot number of such drug if not contained in the shipping document acquired by the recipient.

4.The wholesale distributor that takes title to, but not possession of, the prescription drug is not a member of the affiliated group that receives the prescription drug directly from the manufacturer.

Failure of the manufacturer to provide, the recipient to acquire, or the wholesale distributor to deliver the documentation required under this paragraph shall constitute failure to acquire or deliver a pedigree paper under ss. 499.005(28) and 499.0051. Forgery by the manufacturer, the recipient, or the wholesale distributor of the documentation required to be acquired or delivered under this paragraph shall constitute forgery of a pedigree paper under s. 499.0051.

(g)The wholesale distribution of a prescription drug by a warehouse within an affiliated group to a warehouse or retail pharmacy within its affiliated group, provided:

1.Any affiliated group member that purchases or receives a prescription drug from outside the affiliated group must receive a pedigree paper if the prescription drug is distributed in or into this state and a pedigree paper is required under this section and must authenticate the documentation as required in s. 499.0121(4), regardless of whether the affiliated group member is directly subject to regulation under this part; and

2.The affiliated group makes available, within 48 hours, to the department on request to one or more of its members all records related to the purchase or acquisition of prescription drugs by members of the affiliated group, regardless of the location where the records are stored, if the prescription drugs were distributed in or into this state.

(h)The repackaging of prescription drugs by a repackager solely for distribution to its affiliated group members for the exclusive distribution to and among retail pharmacies that are members of the affiliated group to which the repackager is a member.

1.The repackager must:

a.For all repackaged prescription drugs distributed in or into this state, state in writing under oath with each distribution of a repackaged prescription drug to an affiliated group member warehouse or repackager: "All repackaged prescription drugs are purchased by the affiliated group directly from the manufacturer or from a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer."

b.Purchase all prescription drugs it repackages:

(I)Directly from the manufacturer; or

(II)From a prescription drug wholesale distributor that purchased the prescription drugs directly from the manufacturer.

c.Maintain records in accordance with this section to document that it purchased the prescription drugs directly from the manufacturer or that its prescription drug wholesale supplier purchased the prescription drugs directly from the manufacturer.

2.All members of the affiliated group must provide, within 48 hours, to agents of the department on request to one or more of its members records of purchases by all members of the affiliated group of prescription drugs that have been repackaged, regardless of the location at which the records are stored or at which the repackager is located.

(i)The wholesale distribution of prescription drugs within a medical convenience kit if:

1.The medical convenience kit is assembled in an establishment that is registered with the United States Food and Drug Administration as a medical device manufacturer;

2.The medical convenience kit manufacturer purchased the prescription drug directly from the manufacturer or from a wholesaler that purchased the prescription drug directly from the manufacturer;

3.The medical convenience kit manufacturer complies with federal law for the distribution of the prescription drugs within the kit; and

4.The drugs contained in the medical kit are:

a.Intravenous solutions intended for the replenishment of fluids and electrolytes;

b.Products intended to maintain the equilibrium of water and minerals in the body;

c.Products intended for irrigation or reconstitution;

d.Anesthetics; or

e.Anticoagulants.

This exemption does not apply to a convenience kit containing any controlled substance that appears in a schedule contained in or subject to chapter 893 or the federal Comprehensive Drug Abuse Prevention and Control Act of 1970.

History.—s. 15, ch. 2008-207; s. 4, ch. 2009-221; s. 24, ch. 2010-161.

499.015Registration of drugs, devices, and cosmetics; issuance of certificates of free sale.—

(1)(a)Except for those persons exempted from the definition of manufacturer in s. 499.003(31), any person who manufactures, packages, repackages, labels, or relabels a drug, device, or cosmetic in this state must register such drug, device, or cosmetic biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug, device, or cosmetic at the time of registration.

(b)The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2)The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs, devices, and cosmetics packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs, devices, and cosmetics, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug, device, or cosmetic product. This approval or denial must include written notification to the manufacturer.

(3)Except for those persons exempted from the definition of manufacturer in s. 499.003(31), a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug, device, or cosmetic product to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4)Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs, devices, or cosmetics covered by this part until he or she complies with the requirements of this section.

(5)A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6)The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7)A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8)Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a)The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b)The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9)However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01 and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a)For Class II devices, a copy of the premarket notification letter (510K);

(b)For Class III devices, a Federal Drug Administration premarket approval number;

(c)For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a Federal Drug Administration registration number; or

(d)For a manufacturer of medical devices whose devices are exempt from premarket approval by the Federal Drug Administration, a Federal Drug Administration registration number.

History.—s. 34, ch. 82-225; s. 110, ch. 83-218; s. 1, ch. 83-265; s. 3, ch. 84-115; ss. 20, 52, ch. 92-69; s. 587, ch. 97-103; s. 36, ch. 98-151; s. 1, ch. 99-165; s. 41, ch. 2000-242; s. 12, ch. 2000-326; s. 18, ch. 2001-63; s. 33, ch. 2001-89; s. 88, ch. 2004-5; s. 18, ch. 2008-207; s. 63, ch. 2009-21.

499.023New drugs; sale, manufacture, repackaging, distribution.—A person may not sell, offer for sale, hold for sale, manufacture, repackage, distribute, or give away any new drug unless an approved application has become effective under s. 505 of the federal act or unless otherwise permitted by the Secretary of the United States Department of Health and Human Services for shipment in interstate commerce.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 26, 52, ch. 92-69.

499.024Drug product classification.—The department shall adopt rules to classify drug products intended for use by humans which the United States Food and Drug Administration has not classified in the federal act or the Code of Federal Regulations.

(1)Drug products must be classified as proprietary, prescription, or investigational drugs.

(2)If a product is distributed without required labeling, it is misbranded while held for sale.

(3)Any product that falls under the definition of drug in s. 499.003(19) may be classified under the authority of this section. This section does not subject portable emergency oxygen inhalators to classification; however, this section does not exempt any person from ss. 499.01 and 499.015.

(4)Any product classified under the authority of this section reverts to the federal classification, if different, upon the federal regulation or act becoming effective.

(5)The department may by rule reclassify drugs subject to this part when such classification action is necessary to protect the public health.

(6)The department may adopt rules that exempt from any labeling or packaging requirements of this part drugs classified under this section if those requirements are not necessary to protect the public health.

History.—s. 9, ch. 88-159; s. 1, ch. 89-296; ss. 27, 52, ch. 92-69; s. 589, ch. 97-103; s. 42, ch. 2000-242; s. 13, ch. 2000-326; s. 61, ch. 2006-1; s. 106, ch. 2008-6; s. 19, ch. 2008-207; s. 5, ch. 2012-143.

499.025Drug products in finished, solid, oral dosage form; identification requirements.—

(1)A drug product in finished, solid, oral dosage form for which a prescription is required by federal or state law may not be manufactured or distributed within this state unless it is clearly and prominently marked or imprinted with an individual symbol, number, company name, words, letters, marking, or national drug code, or any combination thereof, that identifies the drug product and the manufacturer or distributor of the drug product which has the ability to respond to requests for information regarding the drug product.

(2)A manufacturer or distributor must make available to the department on request descriptive material that identifies each current imprint used by the manufacturer.

(3)The department, upon application by a manufacturer, may exempt a particular drug product from the requirements of subsection (1) on the ground that imprinting is not feasible because of the size, texture, or other unique characteristic of the drug product.

(4)This section does not apply to drug products compounded by a pharmacist licensed under chapter 465 in a pharmacy operating under a permit issued by the Board of Pharmacy.

(5)The department shall adopt rules for implementing this section.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 22, ch. 86-256; ss. 28, 52, ch. 92-69; s. 18, ch. 2000-326.

499.028Drug samples or complimentary drugs; starter packs; permits to distribute.—

(1)As used in this section, the term:

(a)"Drug sample," or "complimentary drug," means a human prescription drug that is labeled "sample," "not to be sold," "complimentary," or other words to that effect, that is provided as a courtesy, that is not intended to be sold, and that is intended to promote the sale of the drug.

(b)"Starter packs," also known as "stock samples," "trade packages," "initial dose packs," or "starter stocks," means human prescription drugs that are generally distributed without charge by manufacturers or distributors to pharmacies to be placed in stock and sold at retail. Although starter packs are generally given without charge to the pharmacy, they are not intended to be a free sample to the consumer nor are they labeled as such. Starter packs are subject to regulation as prescription drugs under the Florida Drug and Cosmetic Act in the same manner as stock shipments of prescription drugs. Starter packs are not drug samples.

(2)A person may not sell, purchase, or trade or offer to sell, purchase, or trade any drug sample. An officer or executive of a drug manufacturer or distributor is not subject to criminal liability solely because of a sale, purchase, trade, or offer to sell, purchase, or trade of a drug sample in violation of this subsection by other employees of the manufacturer or distributor.

(3)Except as provided in this section, a representative of a drug manufacturer or distributor may not distribute any drug sample.

(a)The manufacturer or distributor of a human prescription drug may, in accordance with this paragraph, distribute drug samples by mail or common carrier to practitioners licensed to prescribe such drugs or, at the request of a licensed practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. Such a distribution of drug samples may only be made:

1.In response to a written request for drug samples made on a form that meets the requirements of paragraph (b); and

2.Under a system that requires the recipient of the drug sample to execute a written receipt for the drug sample upon its delivery and to return the receipt to the manufacturer or distributor.

(b)A written request for a drug sample that is required by this section must contain:

1.The name, address, professional designation, and signature of the practitioner who makes the request;

2.The name, strength, and dosage form of the drug sample requested and the quantity requested;

3.The name of the manufacturer of the drug sample requested; and

4.The date of the request.

(c)Each drug manufacturer or distributor that makes distributions by mail or common carrier under this paragraph must maintain, for a period of 3 years, the request forms submitted for such distributions and the receipts submitted for such distributions and must maintain a record of distributions of drug samples which identifies the drugs distributed and the recipients of the distributions. Forms, receipts, and records required to be maintained under this paragraph must be made available by the drug manufacturer or distributor to the department for its review and inspection.

(d)The manufacturer or distributor of a drug subject to paragraph (1)(a) may, by means other than mail or common carrier, distribute drug samples only if the

manufacturer or distributor makes the distributions in accordance with paragraph (e) and carries out the activities described in subsections (4)-(9).

(e)Drug samples may only be distributed:

1.To a practitioner authorized by law to prescribe such drugs if the practitioner makes a written request for the drug samples; or

2.At the written request of such a practitioner, to pharmacies of hospitals or to pharmacies of other health care entities. The written request for drug samples must be made on a form that contains the practitioner's name, address, and professional designation, the name, strength, and dosage form of the drug sample requested, the quantity of drug samples requested, the name of the manufacturer or distributor of the drug sample, the date of the request, and the signature of the practitioner that makes the request.

(4)A drug manufacturer or distributor must store drug samples under the conditions described on their labels that will maintain the stability, integrity, and effectiveness of the drug samples and will assure that the drug samples remain free of contamination, deterioration, and adulteration.

(5)A drug manufacturer or distributor must conduct, at least annually, a complete and accurate inventory of all drug samples in the possession of representatives of the manufacturer or distributor. A drug manufacturer or distributor must maintain lists of the names and addresses of each of its representatives who distribute drug samples and of the sites where drug samples are stored. A drug manufacturer or distributor must maintain for at least 3 years records of all drug samples distributed, destroyed, or returned to the manufacturer or distributor, of all inventories maintained under this subsection, of all thefts or significant losses of drug samples, and of all requests made under [1]subparagraph 1. for drug samples. The drug manufacturer or distributor must make available to the department upon request any record or list maintained under this subsection. The department shall provide to the Department of Business and Professional Regulation the names of those practitioners who have received an excessive or inappropriate quantity of such drugs.

(6)A drug manufacturer or distributor must notify the department of any significant loss of drug samples and any known theft of drug samples.

(7)A drug manufacturer or distributor must report to the department any conviction of itself or of its assigns, agents, employees, or representatives for a violation of s. 503(c)(1) of the federal act or of this part because of the sale, purchase, or trade of a drug sample or the offer to sell, purchase, or trade a drug sample.

(8)Drug manufacturers or distributors must provide to the department the name and telephone number of the individual responsible for responding to a request for information regarding drug samples.

(9)All out-of-date drug samples must be returned to the manufacturer or distributor of that drug sample.

(10)A manufacturer or distributor may not directly or through its agents, employees, or independent contractors, hold, distribute, or otherwise dispose of any complimentary drugs or drug samples in this state without first obtaining a complimentary drug distributor permit pursuant to this section.

(11)(a)Application for a permit by a manufacturer or distributor to hold, distribute, or otherwise dispose of drugs pursuant to this section must be made on a form prescribed by the department and must be accompanied by an application fee in an amount not exceeding $250 per year, as is determined by the department.

(b)A permit issued under this section expires 2 years after the date of issuance, unless sooner suspended or revoked.

(c)A permit is renewable biennially upon the filing of an application for renewal and the payment of a renewal fee of not more than $250 per year, as determined by the

department, if the applicant meets the requirements established by this section and the rules adopted under this section.

(12)The department may suspend or revoke a permit issued under this section, after giving notice and an opportunity to be heard pursuant to chapter 120, when:

(a)Such permit was obtained by misrepresentation or fraud or through a mistake of the department.

(b)The holder of the permit has distributed or disposed of any prescription drug, directly or through its agents, employees, or independent contractors, to any person not authorized to possess such drug.

(c)The holder of the permit, or its agents, employees, or independent contractors, has distributed or possessed any prescription drug except in the usual course of its business.

(d)The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug that is misbranded or adulterated under this part.

(e)The holder of the permit, or its agents, employees, or independent contractors, has distributed any prescription drug without written request, when a written request is required by this section.

(f)The holder of the permit has in its employ, or uses as agent or independent contractor for the purpose of distributing or disposing of drugs, any person who has:

1.Violated the requirements of this section or any rule adopted under this section.

2.Been convicted in any of the courts of this state, the United States, or any other state of a felony or any other crime involving moral turpitude or involving those drugs named or described in chapter 893.

(13)The department may, pursuant to chapter 120, impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of this section or rules adopted under this section. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. All amounts collected under this section shall be deposited into the Professional Regulation Trust Fund. In determining the amount of fine to be levied for a violation, the following factors must be considered:

(a)The severity of the violation.

(b)Any actions taken by the permittee to correct the violation or to remedy complaints.

(c)Any previous violations.

(14)Chapter 893 applies to all drug samples that are controlled substances.

(15)A person may not possess a prescription drug sample unless:

(a)The drug sample was prescribed to her or him as evidenced by the label required in s. 465.0276(5).

(b)She or he is the employee of a complimentary drug distributor that holds a permit issued under this part.

(c)She or he is a person to whom prescription drug samples may be distributed pursuant to this section.

(d)He or she is an officer or employee of a federal, state, or local government acting within the scope of his or her employment.

History.—s. 34, ch. 82-225; s. 114, ch. 83-218; s. 1, ch. 83-265; s. 8, ch. 84-115; s. 23, ch. 86-256; ss. 29, 52, ch. 92-69; s. 198, ch. 94-218; s. 23, ch. 97-98; s. 590, ch. 97-103; s. 39, ch. 99-397; s. 20, ch. 2008-207; s. 12, ch. 2012-143.

[1]Note.—Subsection (5) does not contain subparagraphs.

499.029Cancer Drug Donation Program.—

(1)This section may be cited as the "Cancer Drug Donation Program Act."

(2)There is created a Cancer Drug Donation Program within the department for the purpose of authorizing and facilitating the donation of cancer drugs and supplies to eligible patients.

(3)As used in this section:

(a)"Cancer drug" means a prescription drug that has been approved under s. 505 of the federal Food, Drug, and Cosmetic Act and is used to treat cancer or its side effects or is used to treat the side effects of a prescription drug used to treat cancer or its side effects. "Cancer drug" does not include a substance listed in Schedule II, Schedule III, Schedule IV, or Schedule V of s. 893.03.

(b)"Closed drug delivery system" means a system in which the actual control of the unit-dose medication package is maintained by the facility rather than by the individual patient.

(c)"Donor" means a patient or patient representative who donates cancer drugs or supplies needed to administer cancer drugs that have been maintained within a closed drug delivery system; health care facilities, nursing homes, hospices, or hospitals with closed drug delivery systems; or pharmacies, drug manufacturers, medical device manufacturers or suppliers, or wholesalers of drugs or supplies, in accordance with this section. "Donor" includes a physician licensed under chapter 458 or chapter 459 who receives cancer drugs or supplies directly from a drug manufacturer, wholesale distributor, or pharmacy.

(d)"Eligible patient" means a person who the department determines is eligible to receive cancer drugs from the program.

(e)"Participant facility" means a class II hospital pharmacy that has elected to participate in the program and that accepts donated cancer drugs and supplies under the rules adopted by the department for the program.

(f)"Prescribing practitioner" means a physician licensed under chapter 458 or chapter 459 or any other medical professional with authority under state law to prescribe cancer medication.

(g)"Program" means the Cancer Drug Donation Program created by this section.

(h)"Supplies" means any supplies used in the administration of a cancer drug.

(4)Any donor may donate cancer drugs or supplies to a participant facility that elects to participate in the program and meets criteria established by the department for such participation. Cancer drugs or supplies may not be donated to a specific cancer patient, and donated drugs or supplies may not be resold by the program. Cancer drugs billed to and paid for by Medicaid in long-term care facilities that are eligible for return to stock under federal Medicaid regulations shall be credited to Medicaid and are not eligible for donation under the program. A participant facility may provide dispensing and consulting services to individuals who are not patients of the hospital.

(5)The cancer drugs or supplies donated to the program may be prescribed only by a prescribing practitioner for use by an eligible patient and may be dispensed only by a pharmacist.

(6)(a)A cancer drug may only be accepted or dispensed under the program if the drug is in its original, unopened, sealed container, or in a tamper-evident unit-dose packaging, except that a cancer drug packaged in single-unit doses may be accepted and dispensed if the outside packaging is opened but the single-unit-dose packaging is unopened with tamper-resistant packaging intact.

(b)A cancer drug may not be accepted or dispensed under the program if the drug bears an expiration date that is less than 6 months after the date the drug was donated or if the drug appears to have been tampered with or mislabeled as determined in paragraph (c).

(c)Prior to being dispensed to an eligible patient, the cancer drug or supplies donated under the program shall be inspected by a pharmacist to determine that the drug and supplies do not appear to have been tampered with or mislabeled.

(d)A dispenser of donated cancer drugs or supplies may not submit a claim or otherwise seek reimbursement from any public or private third-party payor for donated cancer drugs or supplies dispensed to any patient under the program, and a public or private third-party payor is not required to provide reimbursement to a dispenser for donated cancer drugs or supplies dispensed to any patient under the program.

(7)(a)A donation of cancer drugs or supplies shall be made only at a participant facility. A participant facility may decline to accept a donation. A participant facility that accepts donated cancer drugs or supplies under the program shall comply with all applicable provisions of state and federal law relating to the storage and dispensing of the donated cancer drugs or supplies.

(b)A participant facility that voluntarily takes part in the program may charge a handling fee sufficient to cover the cost of preparation and dispensing of cancer drugs or supplies under the program. The fee shall be established in rules adopted by the department.

(8)The department, upon the recommendation of the Board of Pharmacy, shall adopt rules to carry out the provisions of this section. Initial rules under this section shall be adopted no later than 90 days after the effective date of this act. The rules shall include, but not be limited to:

(a)Eligibility criteria, including a method to determine priority of eligible patients under the program.

(b)Standards and procedures for participant facilities that accept, store, distribute, or dispense donated cancer drugs or supplies.

(c)Necessary forms for administration of the program, including, but not limited to, forms for use by entities that donate, accept, distribute, or dispense cancer drugs or supplies under the program.

(d)The maximum handling fee that may be charged by a participant facility that accepts and distributes or dispenses donated cancer drugs or supplies.

(e)Categories of cancer drugs and supplies that the program will accept for dispensing; however, the department may exclude any drug based on its therapeutic effectiveness or high potential for abuse or diversion.

(f)Maintenance and distribution of the participant facility registry established in subsection (10).

(9)A person who is eligible to receive cancer drugs or supplies under the state Medicaid program or under any other prescription drug program funded in whole or in part by the state, by any other prescription drug program funded in whole or in part by the Federal Government, or by any other prescription drug program offered by a third-party insurer, unless benefits have been exhausted, or a certain cancer drug or supply is not covered by the prescription drug program, is ineligible to participate in the program created under this section.

(10)The department shall establish and maintain a participant facility registry for the program. The participant facility registry shall include the participant facility's name, address, and telephone number. The department shall make the participant facility registry available on the department's website to any donor wishing to donate cancer drugs or supplies to the program. The department's website shall also contain links to cancer drug manufacturers that offer drug assistance programs or free medication.

(11)Any donor of cancer drugs or supplies, or any participant in the program, who exercises reasonable care in donating, accepting, distributing, or dispensing cancer drugs or supplies under the program and the rules adopted under this section shall

be immune from civil or criminal liability and from professional disciplinary action of any kind for any injury, death, or loss to person or property relating to such activities.

(12)A pharmaceutical manufacturer is not liable for any claim or injury arising from the transfer of any cancer drug under this section, including, but not limited to, liability for failure to transfer or communicate product or consumer information regarding the transferred drug, as well as the expiration date of the transferred drug.

(13)If any conflict exists between the provisions in this section and the provisions in this chapter or chapter 465, the provisions in this section shall control the operation of the Cancer Drug Donation Program.

History.—s. 1, ch. 2006-310; s. 122, ch. 2007-5; ss. 2, 21, ch. 2008-207.

499.03Possession of certain drugs without prescriptions unlawful; exemptions and exceptions.—

(1)A person may not possess, or possess with intent to sell, dispense, or deliver, any habit-forming, toxic, harmful, or new drug subject to s. 499.003(33), or prescription drug as defined in s. 499.003(43), unless the possession of the drug has been obtained by a valid prescription of a practitioner licensed by law to prescribe the drug. However, this section does not apply to the delivery of such drugs to persons included in any of the classes named in this subsection, or to the agents or employees of such persons, for use in the usual course of their businesses or practices or in the performance of their official duties, as the case may be; nor does this section apply to the possession of such drugs by those persons or their agents or employees for such use:

(a)A licensed pharmacist or any person under the licensed pharmacist's supervision while acting within the scope of the licensed pharmacist's practice;

(b)A licensed practitioner authorized by law to prescribe prescription drugs or any person under the licensed practitioner's supervision while acting within the scope of the licensed practitioner's practice;

(c)A qualified person who uses prescription drugs for lawful research, teaching, or testing, and not for resale;

(d)A licensed hospital or other institution that procures such drugs for lawful administration or dispensing by practitioners;

(e)An officer or employee of a federal, state, or local government; or

(f)A person that holds a valid permit issued by the department pursuant to this part which authorizes that person to possess prescription drugs.

(2)The possession of a drug under subsection (1) by any person not exempted under this section, which drug is not properly labeled to indicate that possession is by a valid prescription of a practitioner licensed by law to prescribe such drug, is prima facie evidence that such possession is unlawful.

(3)Violation of subsection (1) is a misdemeanor of the second degree, punishable as provided in s. 775.082 or s. 775.083, except that possession with the intent to sell, dispense, or deliver is a third degree felony, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(4)The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess prescription drugs and may issue letters of exemption to facilitate the lawful possession of prescription drugs under this section.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 5, ch. 84-115; s. 75, ch. 87-243; ss. 30, 52, ch. 92-69; s. 37, ch. 98-151; s. 43, ch. 2000-242; s. 14, ch. 2000-326; s. 19, ch. 2001-63; s. 89, ch. 2004-5; s. 22, ch. 2008-207; s. 42, ch. 2010-161.

499.032Phenylalanine; prescription required.—Phenylalanine restricted formula is declared to be a prescription drug and may be dispensed only upon the prescription of a practitioner authorized by law to prescribe prescription drugs.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 31, 52, ch. 92-69; s. 23, ch. 2008-207.

499.033Ephedrine; prescription required.—Ephedrine is declared to be a prescription drug.

(1)Except as provided in subsection (2), any product that contains any quantity of ephedrine, a salt of ephedrine, an optical isomer of ephedrine, or a salt of an optical isomer of ephedrine may be dispensed only upon the prescription of a duly licensed practitioner authorized by the laws of the state to prescribe prescription drugs.

(2)A product containing ephedrine described in paragraphs (a)-(e) is exempt from subsection (1) if it may lawfully be sold over the counter without a prescription under the federal act; is labeled and marketed in a manner consistent with the pertinent United States Food and Drug Administration Over-the-Counter Tentative Final or Final Monograph; and is manufactured and distributed for legitimate medicinal use in a manner that reduces or eliminates the likelihood of abuse, when considered in the context with: the package sizes and the manner of packaging of the drug product; the name and labeling of the product; the manner of distribution, advertising, and promotion of the product; the duration, scope, health significance, and societal cost of abuse of the particular product; the need to provide medically important ephedrine-containing therapies to the public for United States Food and Drug Administration approved indications on an unrestricted, over-the-counter basis; and other facts as may be relevant to and consistent with public health and safety.

(a)Solid oral dosage forms that combine active ingredients in the following ranges for each dosage unit:

1.Theophylline (100-130mg), ephedrine (12.5-24mg).

2.Theophylline (60-100mg), ephedrine (12.5-24mg), guaifenesin (200-400mg).

3.Ephedrine (12.5-25mg), guaifenesin (200-400mg).

4.Phenobarbital (not greater than 8mg) in combination with the ingredients of subparagraph 1. or subparagraph 2.

(b)Liquid oral dosage forms that combine active ingredients in the following ranges for each (5ml) dose:

1.Theophylline (not greater than 45mg), ephedrine (not greater than 36mg), guaifenesin (not greater than 100mg), phenobarbital (not greater than 12mg).

2.Phenylephrine (not greater than 5mg), ephedrine (not greater than 5mg), chlorpheniramine (not greater than 2mg), dextromethorphan (not greater than 10mg), ammonium chloride (not greater than 40mg), ipecac fluid extract (not greater than 0.005ml).

(c)Anorectal preparations containing less than 5 percent ephedrine.

(d)Nasal decongestant compounds, mixtures, or preparations containing 0.5 percent or less ephedrine.

(e)Any drug product containing ephedrine that is marketed pursuant to an approved new drug application or legal equivalent under the federal act.

(3)The department may implement this section by rule.

History.—s. 7, ch. 94-309; s. 1, ch. 95-415; s. 61, ch. 2003-1; s. 24, ch. 2008-207.

499.035Dimethyl sulfoxide (DMSO); labeling and advertising.—

(1)Dimethyl sulfoxide (DMSO) not approved for drug use must be clearly marked in at least 12-point boldfaced type: "May be unsafe. Not approved for human use."

(2)All advertisements for the sale of dimethyl sulfoxide (DMSO) not approved for drug use must contain, within the advertisement and in bold lettering, the following statement: "Warning. May be unsafe. Not approved for human use."

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-265; ss. 32, 52, ch. 92-69; ss. 1, 5, 8, ch. 94-309.

499.039Sale, distribution, or transfer of harmful chemical substances; penalties; authority for enforcement.—It is unlawful for a person to sell, deliver, or give to a

person under the age of 18 years any compound, liquid, or chemical containing toluol, hexane, trichloroethylene, acetone, toluene, ethyl acetate, methyl ethyl ketone, trichloroethane, isopropanol, methyl isobutyl ketone, ethylene glycol monomethyl ether acetate, cyclohexanone, nitrous oxide, diethyl ether, alkyl nitrites (butyl nitrite), or any similar substance for the purpose of inducing by breathing, inhaling, or ingesting a condition of intoxication or which is intended to distort or disturb the auditory, visual, or other physical or mental processes.

(1)On the first violation of this section, the department may issue a warning according to s. 499.002(5), if the violation has not caused temporary or permanent physical or mental injury to the user.

(2)If any violation of this section has caused temporary or permanent physical or mental injury to the user, the department may, pursuant to chapter 120, impose fines according to s. 499.066 and may report any violation to the appropriate state attorney for prosecution.

(3)The department shall adopt rules to implement this section.

History.—s. 12, ch. 86-133; s. 1, ch. 89-296; ss. 33, 52, ch. 92-69; s. 239, ch. 99-8; s. 25, ch. 2008-207.

499.04Fee authority.—The department may collect fees for all drug, device, and cosmetic applications, permits, product registrations, and free-sale certificates. The total amount of fees collected from all permits, applications, product registrations, and free-sale certificates must be adequate to fund the expenses incurred by the department in carrying out this part. The department shall, by rule, establish a schedule of fees that are within the ranges provided in this section and shall adjust those fees from time to time based on the costs associated with administering this part. The fees are payable to the department to be deposited into the Professional Regulation Trust Fund for the sole purpose of carrying out this part.

History.—s. 34, ch. 82-225; s. 115, ch. 83-218; s. 1, ch. 83-265; ss. 34, 52, ch. 92-69; s. 15, ch. 2000-326; s. 26, ch. 2008-207; s. 13, ch. 2012-143.

499.041Schedule of fees for drug, device, and cosmetic applications and permits, product registrations, and free-sale certificates.—

(1)The department shall assess applicants requiring a manufacturing permit an annual fee within the ranges established in this section for the specific type of manufacturer.

(a)The fee for a prescription drug manufacturer permit may not be less than $500 or more than $750 annually.

(b)The fee for a device manufacturer permit may not be less than $500 or more than $600 annually.

(c)The fee for a cosmetic manufacturer permit may not be less than $250 or more than $400 annually.

(d)The fee for an over-the-counter drug manufacturer permit may not be less than $300 or more than $400 annually.

(e)The fee for a compressed medical gas manufacturer permit may not be less than $400 or more than $500 annually.

(f)The fee for a prescription drug repackager permit may not be less than $500 or more than $750 annually.

(g)A manufacturer may not be required to pay more than one fee per establishment to obtain an additional manufacturing permit, but each manufacturer must pay the highest fee applicable to his or her operation in each establishment.

(2)The department shall assess an applicant that is required to have a wholesaling permit an annual fee within the ranges established in this section for the specific type of wholesaling.

(a)The fee for a prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(b)The fee for a compressed medical gas wholesale distributor permit may not be less than $200 or more than $300 annually.

(c)The fee for an out-of-state prescription drug wholesale distributor permit may not be less than $300 or more than $800 annually.

(d)The fee for a nonresident prescription drug manufacturer permit may not be less than $300 or more than $500 annually.

(e)The fee for a retail pharmacy drug wholesale distributor permit may not be less than $35 or more than $50 annually.

(f)The fee for a freight forwarder permit may not be less than $200 or more than $300 annually.

(g)The fee for a veterinary prescription drug wholesale distributor permit may not be less than $300 or more than $500 annually.

(h)The fee for a limited prescription drug veterinary wholesale distributor permit may not be less than $300 or more than $500 annually.

(i)The fee for a third party logistics provider permit may not be less than $200 or more than $300 annually.

(3)The department shall assess an applicant that is required to have a retail establishment permit an annual fee within the ranges established in this section for the specific type of retail establishment.

(a)The fee for a veterinary prescription drug retail establishment permit may not be less than $200 or more than $300 annually.

(b)The fee for a medical oxygen retail establishment permit may not be less than $200 or more than $300 annually.

(c)The fee for a health care clinic establishment permit may not be less than $125 or more than $250 annually.

(4)The department shall assess an applicant that is required to have a restricted prescription drug distributor permit an annual fee of not less than $200 or more than $300.

(5)In addition to the fee charged for a permit required by this part, the department shall assess applicants an initial application fee of $150 for each new permit issued by the department which requires an onsite inspection.

(6)A person that is required to register drugs, devices, or cosmetic products under s. 499.015 shall pay an annual product registration fee of not less than $5 or more than $15 for each separate and distinct product in package form. The registration fee is in addition to the fee charged for a free-sale certificate.

(7)The department shall assess an applicant that requests a free-sale certificate a fee of $25. A fee of $2 will be charged for each signature copy of a free-sale certificate that is obtained at the same time the free-sale certificate is issued.

(8)The department shall assess an out-of-state prescription drug wholesale distributor applicant or permittee an onsite inspection fee of not less than $1,000 or more than $3,000 annually, to be based on the actual cost of the inspection if an onsite inspection is performed by agents of the department.

(9)The department shall assess each person applying for certification as a designated representative a fee of $150, plus the cost of processing the criminal history record check.

(10)The department shall assess other fees as provided in this part.

History.—s. 34, ch. 82-225; s. 116, ch. 83-218; s. 1, ch. 83-265; ss. 10, 14, ch. 88-159; s. 4, ch. 89-296; ss. 35, 52, ch. 92-69; s. 591, ch. 97-103; s. 16, ch. 2000-326; s. 20, ch. 2003-155; s. 5, ch. 2004-328; s. 5, ch. 2006-92; s. 27, ch. 2008-207.

499.05Rules.—

(1)The department shall adopt rules to implement and enforce this part with respect to:

(a)The definition of terms used in this part, and used in the rules adopted under this part, when the use of the term is not its usual and ordinary meaning.

(b)Labeling requirements for drugs, devices, and cosmetics.

(c)The establishment of fees authorized in this part.

(d)The identification of permits that require an initial application and onsite inspection or other prerequisites for permitting which demonstrate that the establishment and person are in compliance with the requirements of this part.

(e)The application processes and forms for product registration.

(f)Procedures for requesting and issuing certificates of free sale.

(g)Inspections and investigations conducted under s. 499.051, and the identification of information claimed to be a trade secret and exempt from the public records law as provided in s. 499.051(7).

(h)The establishment of a range of penalties, as provided in s. 499.066; requirements for notifying persons of the potential impact of a violation of this part; and a process for the uncontested settlement of alleged violations.

(i)Additional conditions that qualify as an emergency medical reason under s. 499.003(54)(b)2.

(j)Procedures and forms relating to the pedigree paper requirement of s. 499.01212.

(k)The protection of the public health, safety, and welfare regarding good manufacturing practices that manufacturers and repackagers must follow to ensure the safety of the products.

(l)Information required from each retail establishment pursuant to s. 499.012(3), including requirements for prescriptions or orders.

(m)The recordkeeping, storage, and handling with respect to each of the distributions of prescription drugs specified in s. 499.003(54)(a)-(d).

(n)Alternatives to compliance with s. 499.01212 for a prescription drug in the inventory of a permitted prescription drug wholesale distributor as of June 30, 2006, and the return of a prescription drug purchased prior to July 1, 2006. The department may specify time limits for such alternatives.

(o)Wholesale distributor reporting requirements of s. 499.0121(14).

(p)Wholesale distributor credentialing and distribution requirements of s. 499.0121(15).

(2)With respect to products in interstate commerce, those rules must not be inconsistent with rules and regulations of federal agencies unless specifically otherwise directed by the Legislature.

(3)The department shall adopt rules regulating recordkeeping for and the storage, handling, and distribution of medical devices and over-the-counter drugs to protect the public from adulterated products.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 6, ch. 84-115; s. 88, ch. 85-81; s. 4, ch. 86-133; ss. 17, 18, 36, ch. 92-69; ss. 2, 5, 8, ch. 94-309; ss. 31, 34, 38, ch. 98-151; s. 172, ch. 99-397; ss. 39, 44, ch. 2000-242; s. 20, ch. 2001-63; s. 32, ch. 2001-89; ss. 13, 14, 18, ch. 2003-155; ss. 87, 90, ch. 2004-5; s. 28, ch. 2008-207; s. 43, ch. 2010-161; s. 19, ch. 2011-141.

Note.—Paragraph (1)(k) former s. 499.013(3); paragraph (1)(l) former s. 499.0122(2)(b); paragraph (1)(m) former s. 499.012(12).

499.051Inspections and investigations.—

(1)The agents of the department and of the Department of Law Enforcement, after they present proper identification, may inspect, monitor, and investigate any establishment permitted pursuant to this part during business hours for the purpose of enforcing this part, chapters 465, 501, and 893, and the rules of the department that protect the public health, safety, and welfare.

(2)In addition to the authority set forth in subsection (1), the department and any duly designated officer or employee of the department may enter and inspect any other establishment for the purpose of determining compliance with this part and rules adopted under this part regarding any drug, device, or cosmetic product.

(3)Any application for a permit or product registration or for renewal of such permit or registration made pursuant to this part and rules adopted under this part constitutes permission for any entry or inspection of the premises in order to verify compliance with this part and rules; to discover, investigate, and determine the existence of compliance; or to elicit, receive, respond to, and resolve complaints and violations.

(4)Any application for a permit made pursuant to s. 499.012 and rules adopted under that section constitutes permission for agents of the department and the Department of Law Enforcement, after presenting proper identification, to inspect, review, and copy any financial document or record related to the manufacture, repackaging, or distribution of a drug as is necessary to verify compliance with this part and the rules adopted by the department to administer this part, in order to discover, investigate, and determine the existence of compliance, or to elicit, receive, respond to, and resolve complaints and violations.

(5)The authority to inspect under this section includes the authority to access, review, and copy any and all financial documents related to the activity of manufacturing, repackaging, or distributing prescription drugs.

(6)The authority to inspect under this section includes the authority to secure:

(a)Samples or specimens of any drug, device, or cosmetic; or

(b)Such other evidence as is needed for any action to enforce this part and the rules adopted under this part.

(7)The complaint and all information obtained pursuant to the investigation by the department are confidential and exempt from s. 119.07(1) and s. 24(a), Art. I of the State Constitution until the investigation and the enforcement action are completed. However, trade secret information contained therein as defined by s. 812.081(1)(c) shall remain confidential and exempt from the provisions of s. 119.07(1) and s. 24(a), Art. I of the State Constitution, as long as the information is retained by the department. This subsection does not prohibit the department from using such information for regulatory or enforcement proceedings under this chapter or from providing such information to any law enforcement agency or any other regulatory agency. However, the receiving agency shall keep such records confidential and exempt as provided in this subsection. In addition, this subsection is not intended to prevent compliance with the provisions of s. 499.01212, and the pedigree papers required in that section shall not be deemed a trade secret.

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 1, ch. 83-265; s. 5, ch. 86-133; s. 11, ch. 88-159; ss. 37, 52, ch. 92-69; s. 199, ch. 94-218; ss. 3, 5, 8, ch. 94-309; s. 7, ch. 95-366; s. 332, ch. 96-406; s. 240, ch. 99-8; s. 62, ch. 2003-1; s. 21, ch. 2003-155; s. 26, ch. 2007-6; s. 29, ch. 2008-207.

499.052Records of interstate shipment.—For the purpose of enforcing this part, carriers engaged in interstate commerce and persons receiving drugs, devices, or cosmetics in interstate commerce must, upon the request, in the manner set out below, by an officer or employee duly designated by the department, permit the officer or employee to have access to and to copy all records showing the movement in interstate commerce of any drug, device, or cosmetic, and the quantity, shipper, and consignee thereof.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 38, 52, ch. 92-69; s. 30, ch. 2008-207.

499.055Reports and dissemination of information by department.—

(1)The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders that have been rendered under ss. 499.001-499.79, including the nature of any charges and the dispositions of the charges.

(2)The department may also cause to be disseminated such information regarding drugs, devices, and cosmetics as considered necessary in the interest of public health and the protection of consumers against fraud.

(3)This section does not prohibit the department from collecting, reporting, and illustrating the results of its investigations.

(4)The department shall publish on the department's website and update at least monthly:

(a)A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors against whom the department has initiated enforcement action pursuant to this part to suspend or revoke a permit, seek an injunction, or otherwise file an administrative complaint and the permit number of each such wholesale distributor.

(b)A list of the prescription drug wholesale distributors, out-of-state prescription drug wholesale distributors, and retail pharmacy drug wholesale distributors to which the department has issued a permit, including the date on which each permit will expire.

(c)A list of the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, and retail pharmacy drug wholesale distributor permits that have been returned to the department, were suspended, were revoked, have expired, or were not renewed in the previous year.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 6, ch. 86-133; ss. 39, 52, ch. 92-69; s. 22, ch. 2003-155; s. 31, ch. 2008-207.

499.057Expenses and salaries.—Except as otherwise provided in the General Appropriations Act, all expenses and salaries shall be paid out of the Professional Regulation Trust Fund.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 40, 52, ch. 92-69; s. 564, ch. 2003-261; s. 14, ch. 2012-143.

499.06Embargoing, detaining, or destroying article or processing equipment which is in violation of law or rule.—

(1)When a duly authorized agent of the department finds, or has probable cause to believe, that any drug, device, or cosmetic is in violation of any provision of this part or any rule adopted under this part so as to be dangerous, unwholesome, or fraudulent within the meaning of this part, she or he may issue and enforce a stop-sale, stop-use, removal, or hold order, which order gives notice that such article or processing equipment is, or is suspected of being, in violation and has been detained or embargoed, and which order warns all persons not to remove, use, or dispose of such article or processing equipment by sale or otherwise until permission for removal, use, or disposal is given by such agent or the court. It is unlawful for any person to remove, use, or dispose of such detained or embargoed article or processing equipment by sale or otherwise without such permission; and such act is a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)When an article or processing equipment detained or embargoed under subsection (1) has been found by such agent to be in violation of law or rule, she or he shall, within 90 days after the issuance of such notice, petition the circuit court, in the jurisdiction of which the article or processing equipment is detained or embargoed, for an order for condemnation of such article or processing equipment. When such agent has found that an article or processing equipment so detained or

embargoed is not in violation, she or he shall rescind the stop-sale, stop-use, removal, or hold order.

(3)If the court finds that the detained or embargoed article or processing equipment is in violation, such article or processing equipment shall, after entry of the court order, be destroyed or made sanitary at the expense of the claimant thereof, under the supervision of such agent; and all court costs, fees, and storage and other proper expenses shall be taxed against the claimant of such article or processing equipment or her or his agent. However, when the violation can be corrected by proper labeling of the article or sanitizing of the processing equipment, and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article be so labeled or processed or such processing equipment be so sanitized, has been executed, the court may by order direct that such article or processing equipment be delivered to the claimant thereof for such labeling, processing, or sanitizing, under the supervision of an agent of the department. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article or processing equipment upon representation to the court by the department that the article or processing equipment is no longer in violation of this part and that the expenses of such supervision have been paid.

(4)When the department or any of its authorized agents finds in any room, building, vehicle of transportation, or other structure any perishable articles that are unsound or contain any filthy, decomposed, or putrid substances, or which may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the department, or its authorized agent, shall forthwith condemn or destroy such articles or in any other manner render such articles unsalable.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 41, 52, ch. 92-69; s. 592, ch. 97-103; s. 32, ch. 2008-207.

499.062Seizure and condemnation of drugs, devices, or cosmetics.—

(1)Any article of any drug, device, or cosmetic that is adulterated or misbranded under this part is subject to seizure and condemnation by the department or by its duly authorized agents designated for that purpose in regard to drugs, devices, or cosmetics.

(2)Whenever a duly authorized officer or employee of the department finds cause, or has probable cause to believe that cause exists, for the seizure of any drug, device, or cosmetic, as set out in this part, he or she shall affix to the article a tag, stamp, or other appropriate marking, giving notice that the article is, or is suspected of being, subject to seizure under this part and that the article has been detained and seized by the department. Such officer or employee shall also warn all persons not to remove or dispose of the article, by sale or otherwise, until permission is given by the department or the court. Any person who violates this subsection is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(a)When any article detained or seized under this subsection has been found by the department to be subject to seizure and condemnation, the department shall petition the court for an order of condemnation or sale, as the court directs. The proceeds of the sale of drugs, devices, and cosmetics, less the legal costs and charges, shall be deposited into the Professional Regulation Trust Fund.

(b)If the department finds that any article seized under this subsection was not subject to seizure, the department or the designated officer or employee shall remove the tag or marking.

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; ss. 42, 43, 44, 52, ch. 92-69; s. 593, ch. 97-103; s. 33, ch. 2008-207; s. 15, ch. 2012-143.

Note.—Subsection (2) intro. former s. 499.063; paragraphs (2)(a), (b) former s. 499.064.

499.065Inspections; imminent danger.—

(1)Notwithstanding s. 499.051, the department shall inspect each prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, and retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part as often as necessary to ensure compliance with applicable laws and rules. The department shall have the right of entry and access to these facilities at any reasonable time.

(2)To protect the public from prescription drugs that are adulterated or otherwise unfit for human or animal consumption, the department may examine, sample, seize, and stop the sale or use of prescription drugs to determine the condition of those drugs. The department may immediately seize and remove any prescription drugs if the Secretary of Business and Professional Regulation or his or her designee determines that the prescription drugs represent a threat to the public health. The owner of any property seized under this section may, within 10 days after the seizure, apply to a court of competent jurisdiction for whatever relief is appropriate. At any time after 10 days, the department may destroy the drugs as contraband.

(3)The department may determine that a prescription drug wholesale distributor establishment, prescription drug repackager establishment, veterinary prescription drug wholesale distributor establishment, limited prescription drug veterinary wholesale distributor establishment, or retail pharmacy drug wholesale distributor establishment that is required to be permitted under this part is an imminent danger to the public health and shall require its immediate closure if the establishment fails to comply with applicable laws and rules and, because of the failure, presents an imminent threat to the public's health, safety, or welfare. Any establishment so deemed and closed shall remain closed until allowed by the department or by judicial order to reopen.

(4)For purposes of this section, a refusal to allow entry to the department for inspection at reasonable times, or a failure or refusal to provide the department with required documentation for purposes of inspection, constitutes an imminent danger to the public health.

History.—s. 23, ch. 2003-155; s. 6, ch. 2004-328; s. 6, ch. 2006-92; s. 107, ch. 2008-6; s. 34, ch. 2008-207; s. 6, ch. 2012-143.

499.066Penalties; remedies.—In addition to other penalties and other enforcement provisions:

(1)The department may institute such suits or other legal proceedings as are required to enforce any provision of this part. If it appears that a person has violated any provision of this part for which criminal prosecution is provided, the department may provide the appropriate state attorney or other prosecuting agency having jurisdiction with respect to such prosecution with the relevant information in the department's possession.

(2)If any person engaged in any activity covered by this part violates any provision of this part, any rule adopted under this part, or a cease and desist order as provided by this part, the department may obtain an injunction in the circuit court of the county in which the violation occurred or in which the person resides or has its principal place of business, and may apply in that court for such temporary and permanent orders as the department considers necessary to restrain the person from engaging in any such activities until the person complies with this part, the rules adopted under this part, and the orders of the department authorized by this part or

to mandate compliance with this part, the rules adopted under this part, and any order or permit issued by the department under this part.

(3)The department may impose an administrative fine, not to exceed $5,000 per violation per day, for the violation of any provision of this part or rules adopted under this part. Each day a violation continues constitutes a separate violation, and each separate violation is subject to a separate fine. All amounts collected pursuant to this section shall be deposited into the Professional Regulation Trust Fund and are appropriated for the use of the department in administering this part. In determining the amount of the fine to be levied for a violation, the department shall consider:

(a)The severity of the violation;

(b)Any actions taken by the person to correct the violation or to remedy complaints; and

(c)Any previous violations.

(4)The department shall deposit any rewards, fines, or collections that are due the department and which derive from joint enforcement activities with other state and federal agencies which relate to this part, chapter 893, or the federal act, into the Professional Regulation Trust Fund. The proceeds of those rewards, fines, and collections are appropriated for the use of the department in administering this part.

(5)The department may issue an emergency order immediately suspending or revoking a permit if it determines that any condition in the establishment presents a danger to the public health, safety, and welfare.

(6)The department may issue an emergency order to immediately remove from commerce and public access any drug, device, or cosmetic, if the department determines that the drug, device, or cosmetic presents a clear and present danger to the public health, safety, and welfare.

(7)Resignation or termination of an affiliated party does not affect the department's jurisdiction or discretion to proceed with action to suspend or revoke a permit or to impose other penalties or enforcement actions authorized by law.

History.—s. 34, ch. 82-225; s. 26, ch. 82-402; s. 117, ch. 83-218; s. 1, ch. 83-265; s. 7, ch. 86-133; s. 3, ch. 86-271; ss. 45, 52, ch. 92-69; ss. 4, 5, 8, ch. 94-309; s. 24, ch. 2003-155; s. 35, ch. 2008-207; s. 16, ch. 2012-143.

499.0661Cease and desist orders; removal of certain persons.—

(1)CEASE AND DESIST ORDERS.—

(a)In addition to any authority otherwise provided in this chapter, the department may issue and serve a complaint stating charges upon any permittee or upon any affiliated party, whenever the department has reasonable cause to believe that the person or individual named therein is engaging in or has engaged in conduct that is:

1.An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this part, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2.A violation of any provision of this part;

3.A violation of any rule of the department;

4.A violation of any order of the department; or

5.A breach of any written agreement with the department.

(b)The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c)If a hearing is not requested within the time allowed by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges are proven, the department may enter an order directing the permittee or the affiliated party named in the complaint to cease and desist from engaging in the conduct complained of and take corrective action to remedy the effects of past improper conduct and assure future compliance.

(d)A contested or default cease and desist order is effective when reduced to writing and served upon the permittee or affiliated party named therein. An uncontested cease and desist order is effective as agreed.

(e)Whenever the department finds that conduct described in paragraph (a) is likely to cause an immediate threat to the public health, it may issue an emergency cease and desist order requiring the permittee or any affiliated party to immediately cease and desist from engaging in the conduct complained of and to take corrective and remedial action. The emergency order is effective immediately upon service of a copy of the order upon the permittee or affiliated party named therein and remains effective for 90 days. If the department begins nonemergency cease and desist proceedings under this subsection, the emergency order remains effective until the conclusion of the proceedings under ss. 120.569 and 120.57.

(2)REMOVAL OF AFFILIATED PARTIES BY THE DEPARTMENT.—

(a)The department may issue and serve a complaint stating charges upon any affiliated party and upon the permittee involved whenever the department has reason to believe that an affiliated party is engaging in or has engaged in conduct that constitutes:

1.An act that demonstrates a lack of fitness or trustworthiness to engage in the business authorized under the permit issued pursuant to this part, is hazardous to the public health, or constitutes business operations that are a detriment to the public health;

2.A willful violation of this part; however, if the violation constitutes a misdemeanor, a complaint may not be served as provided in this section until the affiliated party is notified in writing of the matter of the violation and has been afforded a reasonable period of time, as set forth in the notice, to correct the violation and has failed to do so;

3.A violation of any other law involving fraud or moral turpitude which constitutes a felony;

4.A willful violation of any rule of the department;

5.A willful violation of any order of the department; or

6.A material misrepresentation of fact, made knowingly and willfully or made with reckless disregard for the truth of the matter.

(b)The complaint must contain a statement of facts and notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57.

(c)If a hearing is not requested within the time allotted by ss. 120.569 and 120.57, or if a hearing is held and the department finds that any of the charges in the complaint are proven true, the department may enter an order removing the affiliated party or restricting or prohibiting participation by the person in the affairs of that permittee or of any other permittee.

(d)A contested or default order of removal, restriction, or prohibition is effective when reduced to writing and served on the permittee and the affiliated party. An uncontested order of removal, restriction, or prohibition is effective as agreed.

(e)1.The chief executive officer, designated representative, or the person holding the equivalent office, of a permittee shall promptly notify the department if she or he has actual knowledge that any affiliated party is charged with a felony in a state or federal court.

2.Whenever any affiliated party is charged with a felony in a state or federal court or with the equivalent of a felony in the courts of any foreign country with which the United States maintains diplomatic relations, and the charge alleges violation of any law involving prescription drugs, pharmaceuticals, fraud, theft, or moral turpitude, the department may enter an emergency order suspending the affiliated party or restricting or prohibiting participation by the affiliated party in the affairs of the particular permittee or of any other permittee upon service of the order upon the

permittee and the affiliated party charged. The order must contain notice of opportunity for a hearing pursuant to ss. 120.569 and 120.57, where the affiliated party may request a postsuspension hearing to show that continued service to or participation in the affairs of the permittee does not pose a threat to the public health or the interests of the permittee and does not threaten to impair public confidence in the permittee. In accordance with applicable departmental rules, the department shall notify the affiliated party whether the order suspending or prohibiting the person from participation in the affairs of a permittee will be rescinded or otherwise modified. The emergency order remains in effect, unless otherwise modified by the department, until the criminal charge is disposed of. The acquittal of the person charged, or the final, unappealed dismissal of all charges against the person, dissolves the emergency order but does not prohibit the department from instituting proceedings under paragraph (a). If the person charged is convicted or pleads guilty or nolo contendere, whether or not an adjudication of guilt is entered by the court, the emergency order shall become final.

(f)Any affiliated party removed pursuant to this section is not eligible for reemployment by the permittee or to be an affiliated party of any permittee except upon the written consent of the department. Any affiliated party who is removed, restricted, or prohibited from participating in the affairs of a permittee pursuant to this section may petition the department for modification or termination of the removal, restriction, or prohibition.

History.—s. 25, ch. 2003-155; ss. 2, 36, ch. 2008-207.

499.067Denial, suspension, or revocation of permit, certification, or registration.—

(1)(a)The department may deny, suspend, or revoke a permit if it finds that there has been a substantial failure to comply with this part or chapter 465, chapter 501, or chapter 893, the rules adopted under this part or those chapters, any final order of the department, or applicable federal laws or regulations or other state laws or rules governing drugs, devices, or cosmetics.

(b)The department may deny an application for a permit or certification, or suspend or revoke a permit or certification, if the department finds that:

1.The applicant is not of good moral character or that it would be a danger or not in the best interest of the public health, safety, and welfare if the applicant were issued a permit or certification.

2.The applicant has not met the requirements for the permit or certification.

3.The applicant is not eligible for a permit or certification for any of the reasons enumerated in s. 499.012.

4.The applicant, permittee, or person certified under s. 499.012(16) demonstrates any of the conditions enumerated in s. 499.012.

5.The applicant, permittee, or person certified under s. 499.012(16) has committed any violation of ss. 499.005-499.0054.

(2)The department may deny, suspend, or revoke any registration required by the provisions of this part for the violation of any provision of this part or of any rules adopted under this part.

(3)The department may revoke or suspend a permit:

(a)If the permit was obtained by misrepresentation or fraud or through a mistake of the department;

(b)If the permit was procured, or attempted to be procured, for any other person by making or causing to be made any false representation; or

(c)If the permittee has violated any provision of this part or rules adopted under this part.

(4)If any permit issued under this part is revoked or suspended, the owner, manager, operator, or proprietor of the establishment shall cease to operate as the permit authorized, from the effective date of the suspension or revocation until the

person is again registered with the department and possesses the required permit. If a permit is revoked or suspended, the owner, manager, or proprietor shall remove all signs and symbols that identify the operation as premises permitted as a drug wholesaling establishment; drug, device, or cosmetic manufacturing establishment; or retail establishment. The department shall determine the length of time for which the permit is to be suspended. If a permit is revoked, the person that owns or operates the establishment may not apply for any permit under this part for a period of 1 year after the date of the revocation. A revocation of a permit may be permanent if the department considers that to be in the best interest of the public health.

(5)The department may deny, suspend, or revoke a permit issued under this part which authorizes the permittee to purchase prescription drugs if any owner, officer, employee, or other person who participates in administering or operating the establishment has been found guilty of any violation of this part or chapter 465, chapter 501, or chapter 893, any rules adopted under this part or those chapters, or any federal or state drug law, regardless of whether the person has been pardoned, had her or his civil rights restored, or had adjudication withheld.

(6)The department shall deny, suspend, or revoke the permit of any person or establishment if the assignment, sale, transfer, or lease of an establishment permitted under this part will avoid an administrative penalty, civil action, or criminal prosecution.

(7)Notwithstanding s. 120.60(5), if a permittee fails to comply with s. 499.012(6), the department may revoke the permit of the permittee and shall provide notice of the intended agency action by posting a notice at the department's headquarters and by mailing a copy of the notice of intended agency action by certified mail to the most recent mailing address on record with the department and, if the permittee is not a natural person, to the permittee's registered agent on file with the Department of State.

(8)The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the credentialing requirements of s. 499.0121(15).

(9)The department may deny, suspend, or revoke a permit if it finds the permittee has not complied with the reporting requirements of, or knowingly made a false statement in a report required by, s. 499.0121(14).

History.—s. 34, ch. 82-225; s. 1, ch. 83-265; s. 8, ch. 86-133; ss. 12, 14, ch. 88-159; s. 4, ch. 89-296; ss. 46, 52, ch. 92-69; s. 44, ch. 95-144; s. 594, ch. 97-103; s. 17, ch. 2000-326; s. 26, ch. 2003-155; s. 37, ch. 2008-207; s. 20, ch. 2011-141.

PART II

ETHER

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499.601Legislative intent; construction.—

(1)The Legislature finds that the unregulated possession of bulk quantities of ether poses a substantial risk to the health, safety, and welfare of the citizens of this state, and it is the intent of the Legislature that this part be liberally construed to provide all protection necessary for the citizens of this state.

(2)The provisions of this part are cumulative and shall not be construed as repealing or affecting any powers, duties, or authority of the department under any other law of this state; except that, with respect to the regulation of ether as herein provided, in instances in which the provisions of this part may conflict with any other such law, the provisions of this part shall control.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 241, ch. 99-8; s. 7, ch. 2012-143; s. 123, ch. 2012-184.

499.61Definitions.—As used in this part:

(1)"Dealer" means any person, firm, corporation, or other entity selling, brokering, or transferring ether to anyone other than a licensed ether manufacturer, distributor, or dealer.

(2)"Department" means the Department of Business and Professional Regulation.

(3)"Distributor" means any person, firm, corporation, or other entity distributing, selling, marketing, transferring, or otherwise supplying ether to retailers, dealers, or any other entity in the primary channel of trade, but does not include retailers.

(4)"Ether" means diethyl ether in any form.

(5)"Manufacturer" means any person, firm, corporation, or other entity preparing, deriving, producing, synthesizing, or otherwise making ether in any form or repacking, relabeling, or manipulating ether.

(6)"Purchaser" means any person, firm, corporation, or other entity who purchases ether in quantities of 2.5 gallons, or equivalent by weight, or more for any purpose whatsoever, but does not include a dealer, distributor, or manufacturer.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 242, ch. 99-8; s. 8, ch. 2012-143; s. 124, ch. 2012-184.

499.62License or permit required of manufacturer, distributor, dealer, or purchaser of ether.—

(1)It shall be unlawful for any person to engage in the business of manufacturing, distributing, or dealing in ether in this state, except when done in conformity with the provisions of this part. No person shall be required to obtain more than one license under this part to handle ether, but each person shall pay the highest fee applicable to her or his operation in each location.

(2)Any person who manufactures, distributes, or deals in ether in this state must possess a current valid license issued by the department, except that a manufacturer, distributor, or dealer who also purchases ether in this state shall not be required to obtain an additional permit as a purchaser of ether.

(3)Any person who manufactures, distributes, or deals in ether at or from more than one location must possess a current valid license for each location.

(4)Any person who purchases ether in this state must possess a current valid permit issued by the department, except that no permit shall be required of any

person who purchases ether in quantities of less than 2.5 gallons, or equivalent by weight.

(5)Annual fees for licenses and permits shall be specified by rule of the department, but shall not exceed the following amounts:

(a)Manufacturer's license.....$700

(b)Distributor's license.....$700

(c)Dealer's license.....$350

(d)Purchaser's permit.....$150

(6)Licenses and permits issued by the department shall be valid beginning on October 1 of the year for which they are issued and shall expire on the following September 30.

(7)A licensed or permitted facility shall renew its license or permit prior to its expiration date. If a renewal application and fee are not filed by the expiration date of any year, the permit may be reinstated only upon payment of a delinquent fee of $50, plus the required renewal fee, within 30 days after the date of expiration. If any person who is subject to the requirements of this part fails to comply with the renewal, the department shall have the authority to seize all ether products and dispose of them as of November 1 of the year the license or permit expires. Any funds collected from the disposal shall be placed in the Professional Regulation Trust Fund.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 596, ch. 97-103; s. 17, ch. 2012-143.

499.63Forms for applications for licenses and permits.—

(1)The forms for applications for ether licenses and permits shall be prescribed by the department.

(2)Each application for a license or permit required by the provisions of this part shall be filed in writing with the department. Each application shall require, as a minimum, the full name, date of birth, place of birth, social security number, physical description of the applicant, residence address and telephone number, and business address and telephone number of the applicant. Each application must be accompanied by an accurate and current photograph of the applicant and a complete set of fingerprints of the applicant taken by an authorized law enforcement officer; however, a set of fingerprints shall not be required if the applicant has possessed a valid Florida license or permit under this part during the prior license or permit year and such Florida license or permit has not lapsed or been suspended or revoked. If fingerprints are required, the set of fingerprints shall be submitted by the department to the Department of Law Enforcement for state processing and to the Federal Bureau of Investigation for federal processing. If the application does not require a set of fingerprints, the department shall submit the name and other identifying data to the Department of Law Enforcement for processing. Each application shall be in such form as to provide that the data and other information set forth therein shall be sworn to by the applicant or, if the applicant is a corporation, by all officers of the corporation. The officers applying on behalf of a corporation shall provide all the data and other information required by this subsection and subsection (3), and shall meet all other requirements, which are required of a natural person.

(3)The department may require an applicant to furnish such other information or data not required by this section if the information or data is deemed necessary by the department.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.64Issuance of licenses and permits; prohibitions.—

(1)Each license and permit issued by the department shall set forth, as a minimum, the full name, date of birth, and physical description of the licensee or

permittee and shall have permanently affixed an accurate and current photograph of the licensee or permittee. A license or permit issued to a corporation shall set forth the full name, date of birth, and physical description of the chief executive officer and/or resident agent residing in this state and shall have permanently affixed an accurate and current photograph of the chief executive officer and/or resident agent residing in this state. Each license and permit shall also contain a license or permit number.

(2)The department may, in its discretion, include other data or information in the license or permit when deemed appropriate.

(3)No license or permit shall be issued, renewed, or allowed to remain in effect for any natural person, or for any corporation which has any corporate officer:

(a)Under 18 years of age.

(b)Who has been convicted of a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction, regardless of whether he or she has been pardoned or had his or her civil rights restored.

(c)Who has been convicted of any felony other than a felony under the prescription drug or controlled substance laws of this state or any other state or federal jurisdiction and has not been pardoned or had his or her civil rights restored.

(d)Who has been adjudicated mentally incompetent and has not had his or her civil rights restored.

(4)It is unlawful for any person to knowingly withhold information or present to the department any false, fictitious, or misrepresented application, identification, document, information, or data intended or likely to deceive the department for the purpose of obtaining a license or permit.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 597, ch. 97-103.

499.65Possession of ether without license or permit prohibited; confiscation and disposal; exceptions.—

(1)It is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether unless she or he is the holder of a current valid license or permit as provided by this part.

(2)Whenever the department has reason to believe that any person is or has been violating the provisions of this part or any rules adopted pursuant thereto, the department may, without further process of law, confiscate and dispose of the ether in question. The department is authorized to seize and dispose of any abandoned ether.

(3)The department is authorized to enter into contracts with private business entities for the purpose of confiscation and disposal of ether as authorized in subsection (2).

(4)The provisions of subsection (1) shall not apply to:

(a)Any common carrier transporting ether into this state or within the boundaries of this state by air, highway, railroad, or water;

(b)Any contract or private carrier transporting ether on highways into this state or within the boundaries of this state by motor vehicle when such contract or private carrier is engaged in such transport pursuant to certificate or permit, by whatever name, issued to them by any federal or state officer, agency, bureau, commission, or department;

(c)Pharmacists, for use in the usual course of their professional practice or in the performance of their official duties;

(d)Medical practitioners, for use in the usual course of their professional practice or in the performance of their official duties;

(e)Persons who procure ether for disposition by or under the supervision of pharmacists or medical practitioners employed by them or for the purpose of lawful research, teaching, or testing, and not for resale;

(f)Hospitals and other institutions which procure ether for lawful administration by practitioners;

(g)Officers or employees of federal, state, or local governments carrying out their official duties; and

(h)Law enforcement agencies of this state or any of its political subdivisions, and the employees thereof, so long as said agencies and employees are acting within the scope of their respective official capacities and in the performance of their duties.

(5)The department may adopt rules regarding persons engaged in lawful teaching, research, or testing who possess ether and may issue letters of exemption to facilitate the lawful possession of ether under this section.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 598, ch. 97-103; s. 39, ch. 98-151.

499.66Maintenance of records and sales of ether by manufacturers, distributors, and dealers; inspections.—

(1)It is unlawful for any manufacturer, distributor, or dealer to sell, distribute, or otherwise transfer ether to any person except a person presenting a current valid license or permit as provided by this part.

(2)Each sale or transfer of ether shall be evidenced by an invoice, receipt, sales ticket, or sales slip which shall bear the name, address, and license or permit number of the manufacturer, distributor, or dealer and the purchaser or transferee, the date of sale or transfer, and the quantity sold or transferred. All original invoices, receipts, sales tickets, and sales slips shall be retained by the manufacturer, distributor, or dealer, and a copy thereof provided to the purchaser or transferee.

(3)Each manufacturer, distributor, and dealer shall keep an accurate and current written account of all inventories, sales, and transfers of ether. Such records shall be maintained by the manufacturer, distributor, or dealer for a period of 5 years.

(4)Records and inventories as required by subsections (2) and (3) shall be made immediately accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

(5)It is unlawful for any person to knowingly withhold information or to make any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, or sales slip for the sale, distribution, or transfer of ether or upon any account of inventories of ether.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 40, ch. 98-151.

499.67Maintenance of records by purchasers; inspections.—

(1)It is unlawful for any person to purchase, receive, store, or use ether without maintaining an accurate and current written inventory of all ether purchased, received, stored, and used.

(2)Such records shall include, but not be limited to, invoices, receipts, sales tickets, and sales slips; locations, quantities, and dates of use; the names of any persons using the ether; and the names and license or permit numbers of all persons making such records. Such records shall be maintained by permittees for a period of 5 years.

(3)Such records shall be made accessible to, and subject to examination and copying by, the department and any law enforcement officer of this state without any requirement of probable cause or search warrant.

(4)It is unlawful for any person to knowingly withhold information or make any false or fictitious entry or misrepresentation upon any such records for the purchase, receipt, storage, or use of ether.

(5)It is unlawful for any person to refuse entry or inspection by the department of factories, warehouses, or establishments in which ether is manufactured, processed,

repackaged, or held; to refuse entry by the department into any vehicle being used to transport ether; or to refuse the taking of samples by the department.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 41, ch. 98-151.

499.68Reports of thefts, illegal use, or illegal possession.—

(1)Any sheriff, police department, or law enforcement officer of this state shall give immediate notice to the department of any theft, illegal use, or illegal possession of ether involving any person and shall forward a copy of his or her final written report to the department.

(2)Any licensee or permittee who incurs a loss, an unexplained shortage, or a theft of ether, or who has knowledge of a loss, an unexplained shortage, or a theft of ether, shall, within 12 hours after the discovery thereof, report such loss, theft, or unexplained shortage to the county sheriff or police chief of the jurisdiction in which the loss, theft, or unexplained shortage occurred. Such loss, theft, or unexplained shortage must also be reported to the department by the close of the next business day following the discovery thereof.

(3)Any law enforcement agency which investigates the causes and circumstances of any loss, theft, or unexplained shortage of ether shall forward a copy of its final written report to the department. The department shall retain all such reports in the respective files of the affected licensees and permittees.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 599, ch. 97-103.

499.69Possession in or near residential housing prohibited; legal entitlement to possession of premises not a defense.—

(1)Notwithstanding the possession of a current valid license or permit as provided in this part, it is unlawful for any person to possess 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure.

(2)A defendant's legal entitlement to possession of the property where the violation occurred shall not be a defense to a prosecution for a violation of subsection (1).
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.701Adoption of rules by the department.—

(1)The department shall adopt and enforce rules necessary to the administration of its authority under this part. The rules must be such as are reasonably necessary for the protection of the health, welfare, and safety of the public and persons manufacturing, distributing, dealing, and possessing ether, and must provide for application forms and procedures, recordkeeping requirements, and security. The rules must be in substantial conformity with generally accepted standards of safety concerning such subject matter.

(2)The department may adopt rules regarding recordkeeping and security for methyl ethyl ketone (MEK) or butyl acetate as needed. These products and records are open to inspection in the same manner as are ether products and records.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 2000-242.

499.71Procedure for cease and desist orders.—

(1)Whenever the department has reason to believe that any person is or has been violating any provision of this part or any rules adopted pursuant thereto, it shall proceed to determine the matter.

(2)If the department determines that any provision of this part or any rules adopted pursuant thereto have been violated, it shall issue to the person charged with such violation an order requiring such person to cease and desist from such violation or imposing an administrative fine, or both.
History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.72Administrative fines.—

(1)If any person violates any provision of this part or any rule adopted pursuant thereto, or violates a cease and desist order issued by the department, the

department may impose an administrative fine, not to exceed $5,000 for each violation per day, or may suspend or revoke the license or permit issued to such person, or both. Each day such violation continues constitutes a separate violation, and each such separate violation is subject to a separate fine. The department shall allow the licensee or permittee a reasonable period, not to exceed 30 days, within which to pay to the department the amount of the fine so imposed. If the licensee or permittee fails to pay the fine in its entirety to the department at its office in Tallahassee within the period so allowed, the licenses or permits of such person shall stand revoked upon expiration of such period.

(2)All such fines, monetary penalties, and costs received by the department in connection with this part shall be deposited in the Professional Regulation Trust Fund.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 18, ch. 2012-143.

499.73Suspension or revocation of license or permit.—

(1)The violation of any provision of this part, any rule adopted pursuant thereto, or any cease and desist order issued by the department by a licensee or permittee as provided in this part shall be cause for revocation or suspension of all licenses or permits held by such licensee or permittee after the department has determined the licensee or permittee to be guilty of such violation.

(2)If the department finds the licensee or permittee to be guilty of such violation, it shall enter its order suspending or revoking the license or permit of the person charged. An order of suspension shall state the period of time of such suspension, which period shall not be in excess of 1 year from the date of such order. An order of revocation may be entered for a period not exceeding 5 years; such order shall effect the revocation of all licenses or permits then held by the person charged, and during such period no license or permit shall be issued to said person. If, during the period between the beginning of proceedings and the entry of an order of suspension or revocation by the department, a new license or permit has been issued to the person charged, any order of suspension or revocation shall operate effectively with respect to the new license or permit held by such person.

(3)Any person or office of a corporation whose permit or license has been suspended or revoked shall not be issued a new permit or license under any other name or company name until the expiration of the suspension or revocation in which she or he has been involved.

(4)The provisions of this section are cumulative and shall not affect the administrative fine and injunction provisions of ss. 499.72 and 499.76.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 600, ch. 97-103.

499.74Conduct of hearings; review of orders of the department.—

(1)All hearings shall be conducted in accordance with the provisions of chapter 120.

(2)All review of orders of the department shall be in accordance with the provisions of chapter 120.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.75Penalties.—

(1)Any person who knowingly manufactures, distributes, or deals in ether without possessing a valid current license as required by s. 499.62(2) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(2)Any person who knowingly purchases 2.5 gallons, or equivalent by weight, or more of ether without possessing a valid current permit as required by s. 499.62(4) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(3)Any person who knowingly withholds information or presents to the department any false, fictitious, or misrepresented application, identification, document,

information, statement, or data intended or likely to deceive the department for the purpose of obtaining a license or permit as prohibited by s. 499.64(4) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(4)Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether and is not the holder of a valid current license or permit as prohibited by s. 499.65(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(5)Any person who knowingly sells or otherwise transfers 2.5 gallons, or equivalent by weight, or more of ether to any person who is not the holder of a valid current license or permit as prohibited by s. 499.66(1) is guilty of a felony of the third degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

(6)Any person who knowingly withholds information or makes any false or fictitious entry or misrepresentation upon any invoice, receipt, sales ticket, sales slip, or account of inventories as prohibited by s. 499.66(5) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(7)Any licensee who knowingly fails to maintain written accounts of inventories or records of sales or transfers as required by s. 499.66(3) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(8)Any permittee who knowingly fails to maintain written inventories and records as required by s. 499.67 is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(9)Any licensee or permittee who fails to report the loss, unexplained shortage, or theft of ether as required by s. 499.68(2) is guilty of a misdemeanor of the first degree, punishable as provided in s. 775.082 or s. 775.083.

(10)Any person who knowingly possesses 2.5 gallons, or equivalent by weight, or more of ether in, or within 500 feet of, any residential housing structure as prohibited by s. 499.69(1) is guilty of a felony of the second degree, punishable as provided in s. 775.082, s. 775.083, or s. 775.084.

History.—ss. 10, 11, ch. 86-133; s. 121, ch. 91-224; s. 4, ch. 91-429.

499.76Injunctive relief.—In addition to the penalties and other enforcement provisions of this part, in the event any person engaged in any of the activities covered by this part violates any provision of this part, any rule adopted pursuant thereto, or any cease and desist order as provided by this part, the department is authorized to resort to proceedings for injunction in the circuit court of the county in which the violation occurred or in which the person resides or has his or her principal place of business and may therein apply for such temporary and permanent orders as the department may deem necessary to restrain such person from engaging in any such activities until such person complies with the provisions of this part, the rules adopted pursuant thereto, and the orders of the department as authorized by this part.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 601, ch. 97-103.

499.77Exceptions.—Nothing contained in this part shall apply to the regular military and naval forces of the United States, or to the duly organized military forces of any state or territory thereof, provided that they are acting within their respective official capacities and in the performance of their duties.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.78County and municipal ordinances.—Nothing contained in this part shall affect any existing ordinance, rule, or regulation pertaining to ether in any county or municipality in this state, which ordinance, rule, or regulation is more restrictive than the provisions of this part and the rules adopted pursuant thereto; nor shall the provisions of this part limit the power of any county or municipality to make ordinances, rules, or regulations pertaining to ether which may be more restrictive than the provisions of this part and the rules adopted pursuant thereto.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429.

499.79Deposit of fees.—All fees collected for licenses and permits required by this part shall be deposited in the Professional Regulation Trust Fund, and all moneys collected under this part and deposited in the trust fund shall be used by the department in the administration of this part. The Department of Business and Professional Regulation shall maintain a separate account in the Professional Regulation Trust Fund for the Drugs, Devices, and Cosmetics program.

History.—ss. 10, 11, ch. 86-133; s. 4, ch. 91-429; s. 45, ch. 95-144; s. 19, ch. 2012-143.

CHAPTER 120

ADMINISTRATIVE PROCEDURE ACT

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120.50Exception to application of chapter.—This chapter shall not apply to:

(1)The Legislature.

(2)The courts.

History.—s. 1, ch. 74-310; s. 3, ch. 77-468; s. 1, ch. 78-162.

120.51Short title.—This chapter may be known and cited as the "Administrative Procedure Act."

History.—s. 1, ch. 74-310.

[1] **120.515Declaration of policy.**—This chapter provides uniform procedures for the exercise of specified authority. This chapter does not limit or impinge upon the assignment of executive power under Article IV of the State Constitution or the legal authority of an appointing authority to direct and supervise those appointees serving at the pleasure of the appointing authority. For purposes of this chapter, adherence to the direction and supervision of an appointing authority does not constitute delegation or transfer of statutory authority assigned to the appointee.

History.—s. 7, ch. 2012-116.

[1]**Note.**—Section 3, ch. 2012-116, provides that "[t]he Legislature intends that the amendments made by this act to ss. 20.02, 20.03, and 20.05, Florida Statutes, which apply to the organizational structure of the executive branch, and the creation of s. 120.515, Florida Statutes, which applies to administrative procedure, are to clarify that the placement of an executive department under the direct administration of an officer or board appointed by and serving at the pleasure of the Governor does not implicitly limit or restrict the Governor's prerogative, legal authority, and constitutional responsibility to direct and supervise the execution of the law and the exercise of lawful discretion."

120.52Definitions.—As used in this act:

(1)"Agency" means the following officers or governmental entities if acting pursuant to powers other

than those derived from the constitution:

(a)The Governor; each state officer and state department, and each departmental unit described in s. 20.04; the Board of Governors of the State University System; the Commission on Ethics; the Fish and Wildlife Conservation Commission; a regional water supply authority; a regional planning agency; a multicounty special district, but only when a majority of its governing board is comprised of nonelected persons; educational units; and each entity described in chapters 163, 373, 380, and 582 and s. 186.504.

(b)Each officer and governmental entity in the state having statewide jurisdiction or jurisdiction in more than one county.

(c)Each officer and governmental entity in the state having jurisdiction in one county or less than one county, to the extent they are expressly made subject to this act by general or special law or existing judicial decisions.

This definition does not include any municipality or legal entity created solely by a municipality; any legal entity or agency created in whole or in part pursuant to part II of chapter 361; any metropolitan planning organization created pursuant to s. 339.175; any separate legal or administrative entity created pursuant to s. 339.175 of which a metropolitan planning organization is a member; an expressway authority pursuant to chapter 348 or any transportation authority under chapter 343 or chapter 349; or any legal or administrative entity created by an interlocal agreement pursuant to s. 163.01(7), unless any party to such agreement is otherwise an agency as defined in this subsection.

(2)"Agency action" means the whole or part of a rule or order, or the equivalent, or the denial of a petition to adopt a rule or issue an order. The term also includes any denial of a request made under s. 120.54(7).

(3)"Agency head" means the person or collegial body in a department or other governmental unit statutorily responsible for final agency action. An agency head appointed by and serving at the pleasure of an appointing authority remains subject to the direction and supervision of the appointing authority, but actions taken by the agency head as authorized by statute are official acts.

(4)"Committee" means the Administrative Procedures Committee.

(5)"Division" means the Division of Administrative Hearings. Any document filed with the division by a party represented by an attorney shall be filed by electronic means through the division's website. Any document filed with the division by a party not represented by an attorney shall, whenever possible, be filed by electronic means through the division's website.

(6)"Educational unit" means a local school district, a community college district, the Florida School for the Deaf and the Blind, or a state university when the university is acting pursuant to statutory authority derived from the Legislature.

(7)"Final order" means a written final decision which results from a proceeding under s. 120.56, s.

120.565, s. 120.569, s. 120.57, s. 120.573, or s. 120.574 which is not a rule, and which is not excepted from the definition of a rule, and which has been filed with the agency clerk, and includes final agency actions which are affirmative, negative, injunctive, or declaratory in form. A final order includes all materials explicitly adopted in it. The clerk shall indicate the date of filing on the order.

(8)"Invalid exercise of delegated legislative authority" means action that goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:

(a)The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;

(b)The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;

(c)The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;

(d)The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;

(e)The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational; or

(f)The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the enabling statute.

(9)"Law implemented" means the language of the enabling statute being carried out or interpreted by an agency through rulemaking.

(10)"License" means a franchise, permit, certification, registration, charter, or similar form of authorization required by law, but it does not include a license required primarily for revenue purposes when issuance of the license is merely a ministerial act.

(11)"Licensing" means the agency process respecting the issuance, denial, renewal, revocation,

suspension, annulment, withdrawal, or amendment of a license or imposition of terms for the exercise of a license.

(12)"Official reporter" means the publication in which an agency publishes final orders, the index to final orders, and the list of final orders which are listed rather than published.

(13)"Party" means:

(a)Specifically named persons whose substantial interests are being determined in the proceeding.

(b)Any other person who, as a matter of constitutional right, provision of statute, or provision of agency regulation, is entitled to participate in whole or in part in the proceeding, or whose substantial interests will be affected by proposed agency action, and who makes an appearance as a party.

(c)Any other person, including an agency staff member, allowed by the agency to intervene or participate in the proceeding as a party. An agency may by rule authorize limited forms of participation in agency proceedings for persons who are not eligible to become parties.

(d)Any county representative, agency, department, or unit funded and authorized by state statute or county ordinance to represent the interests of the consumers of a county, when the proceeding involves the substantial interests of a significant number of residents of the county and the board of county commissioners has, by resolution, authorized the representative, agency, department, or unit to represent the class of interested persons. The authorizing resolution shall apply to a specific proceeding and to appeals and ancillary proceedings thereto, and it shall not be required to state the names of the persons whose interests are to be represented.

The term "party" does not include a member government of a regional water supply authority or a governmental or quasi-judicial board or commission established by local ordinance or special or general law where the governing membership of such board or commission is shared with, in whole or in part, or appointed by a member government of a regional water supply authority in proceedings under s. 120.569, s. 120.57, or s. 120.68, to the extent that an interlocal agreement under ss. 163.01 and 373.713 exists in which the member government has agreed that its substantial interests are not affected by the proceedings or that it is to be bound by alternative dispute resolution in lieu of participating in the proceedings. This exclusion applies only to those particular types of disputes or controversies, if any, identified in an interlocal agreement.

(14)"Person" means any person described in s. 1.01, any unit of government in or outside the state, and any agency described in subsection (1).

(15)"Recommended order" means the official recommendation of an administrative law judge assigned by the division or of any other duly authorized presiding officer, other than an agency head or member of an agency head, for the final disposition of a proceeding under ss. 120.569 and 120.57.

(16)"Rule" means each agency statement of general applicability that implements, interprets, or

prescribes law or policy or describes the procedure or practice requirements of an agency and includes any form which imposes any requirement or solicits any information not specifically required by statute or by an existing rule. The term also includes the amendment or repeal of a rule. The term does not include:

(a)Internal management memoranda which do not affect either the private interests of any person or any plan or procedure important to the public and which have no application outside the agency issuing the memorandum.

(b)Legal memoranda or opinions issued to an agency by the Attorney General or agency legal opinions prior to their use in connection with an agency action.

(c)The preparation or modification of:

1.Agency budgets.

2.Statements, memoranda, or instructions to state agencies issued by the Chief Financial Officer or Comptroller as chief fiscal officer of the state and relating or pertaining to claims for payment submitted by state agencies to the Chief Financial Officer or Comptroller.

3.Contractual provisions reached as a result of collective bargaining.

4.Memoranda issued by the Executive Office of the Governor relating to information resources management.

(17)"Rulemaking authority" means statutory language that explicitly authorizes or requires an agency to adopt, develop, establish, or otherwise create any statement coming within the definition of the term "rule."

(18)"Small city" means any municipality that has an unincarcerated population of 10,000 or less according to the most recent decennial census.

(19)"Small county" means any county that has an unincarcerated population of 75,000 or less according to the most recent decennial census.

(20)"Unadopted rule" means an agency statement that meets the definition of the term "rule," but that has not been adopted pursuant to the requirements of s. 120.54.

(21)"Variance" means a decision by an agency to grant a modification to all or part of the literal requirements of an agency rule to a person who is subject to the rule. Any variance shall conform to the standards for variances outlined in this chapter and in the uniform rules adopted pursuant to s. 120.54(5).

(22)"Waiver" means a decision by an agency not to apply all or part of a rule to a person who is subject to the rule. Any waiver shall conform to the standards for waivers outlined in this chapter and in the uniform rules adopted pursuant to s. 120.54(5).

History.—s. 1, ch. 74-310; s. 1, ch. 75-191; s. 1, ch. 76-131; s. 1, ch. 77-174; s. 12, ch. 77-290; s. 2, ch. 77-453; s. 1, ch. 78-28; s. 1, ch. 78-425; s. 1, ch. 79-20; s. 55, ch. 79-40; s. 1, ch. 79-299; s. 2, ch. 81-119; s. 1, ch. 81-180; s. 7, ch. 82-180; s. 1, ch. 83-78; s. 2, ch. 83-273; s. 10, ch. 84-170; s. 15, ch. 85-80; s. 1, ch. 85-168; s. 2, ch. 87-385; s. 1, ch. 88-367; s. 1, ch. 89-147; s. 1, ch. 91-46; s. 9, ch. 92-166; s. 50, ch. 92-279; s. 55, ch. 92-326; s. 3, ch. 96-159; s. 1, ch. 97-176; s. 2, ch. 97-286; s. 1, ch. 98-

402; s. 64, ch. 99-245; s. 2, ch. 99-379; s. 895, ch. 2002-387; s. 1, ch. 2003-94; s. 138, ch. 2003-261; s. 7, ch. 2003-286; s. 3, ch. 2007-196; s. 13, ch. 2007-217; s. 2, ch. 2008-104; s. 1, ch. 2009-85; s. 1, ch. 2009-187; s. 10, ch. 2010-5; s. 2, ch. 2010-205; s. 7, ch. 2011-208; s. 8, ch. 2012-116.

120.525Meetings, hearings, and workshops.—

(1)Except in the case of emergency meetings, each agency shall give notice of public meetings, hearings, and workshops by publication in the Florida Administrative Weekly and on the agency's website not less than 7 days before the event. The notice shall include a statement of the general subject matter to be considered.

(2)An agenda shall be prepared by the agency in time to ensure that a copy of the agenda may be received at least 7 days before the event by any person in the state who requests a copy and who pays the reasonable cost of the copy. The agenda, along with any meeting materials available in electronic form excluding confidential and exempt information, shall be published on the agency's website. The agenda shall contain the items to be considered in order of presentation. After the agenda has been made available, a change shall be made only for good cause, as determined by the person designated to preside, and stated in the record. Notification of such change shall be at the earliest practicable time.

(3)If an agency finds that an immediate danger to the public health, safety, or welfare requires immediate action, the agency may hold an emergency public meeting and give notice of such meeting by any procedure that is fair under the circumstances and necessary to protect the public interest, if:

(a)The procedure provides at least the procedural protection given by other statutes, the State Constitution, or the United States Constitution.

(b)The agency takes only that action necessary to protect the public interest under the emergency procedure.

(c)The agency publishes in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. The agency findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable.

History.—s. 4, ch. 96-159; s. 3, ch. 2009-187.

120.53Maintenance of orders; indexing; listing; organizational information.—

(1)(a)Each agency shall maintain:

1.All agency final orders.

2.a.A current hierarchical subject-matter index, identifying for the public any rule or order as specified in this subparagraph.

b.In lieu of the requirement for making available for public inspection and copying a hierarchical subject-matter index of its orders, an agency may maintain and make available for public use an electronic database

of its orders that allows users to research and retrieve the full texts of agency orders by devising an ad hoc indexing system employing any logical search terms in common usage which are composed by the user and which are contained in the orders of the agency or by descriptive information about the order which may not be specifically contained in the order.

c.The agency orders that must be indexed, unless excluded under paragraph (c) or paragraph (d), include:

(I)Each final agency order resulting from a proceeding under s. 120.57 or s. 120.573.

(II)Each final agency order rendered pursuant to s. 120.57(4) which contains a statement of agency policy that may be the basis of future agency decisions or that may otherwise contain a statement of precedential value.

(III)Each declaratory statement issued by an agency.

(IV)Each final order resulting from a proceeding under s. 120.56 or s. 120.574.

3.A list of all final orders rendered pursuant to s. 120.57(4) which have been excluded from the indexing requirement of this section, with the approval of the Department of State, because they do not contain statements of agency policy or statements of precedential value. The list must include the name of the parties to the proceeding and the number assigned to the final order.

4.All final orders listed pursuant to subparagraph 3.

(b)An agency final order that must be indexed or listed pursuant to paragraph (a) must be indexed or listed within 120 days after the order is rendered. Each final order that must be indexed or listed pursuant to paragraph (a) must have attached a copy of the complete text of any materials incorporated by reference; however, if the quantity of the materials incorporated makes attachment of the complete text of the materials impractical, the order may contain a statement of the location of such materials and the manner in which the public may inspect or obtain copies of the materials incorporated by reference. The Department of State shall establish by rule procedures for indexing final orders, and procedures of agencies for indexing orders must be approved by the department.

(c)Each agency must receive approval in writing from the Department of State for:

1.The specific types and categories of agency final orders that may be excluded from the indexing and public inspection requirements, as determined by the department pursuant to paragraph (d).

2.The method for maintaining indexes, lists, and final orders that must be indexed or listed and made available to the public.

3.The method by which the public may inspect or obtain copies of indexes, lists, and final orders.

4.A sequential numbering system which numbers all final orders required to be indexed or listed pursuant to paragraph (a), in the order rendered.

5.Proposed rules for implementing the requirements of this section for indexing and making final orders

available for public inspection.

(d)In determining which final orders may be excluded from the indexing and public inspection requirements, the Department of State may consider all factors specified by an agency, including precedential value, legal significance, and purpose. Only agency final orders that are of limited or no precedential value, that are of limited or no legal significance, or that are ministerial in nature may be excluded.

(e)Each agency shall specify the specific types or categories of agency final orders that are excluded from the indexing and public inspection requirements.

(f)Each agency shall specify the location or locations where agency indexes, lists, and final orders that are required to be indexed or listed are maintained and shall specify the method or procedure by which the public may inspect or obtain copies of indexes, lists, and final orders.

(g)Each agency shall specify all systems in use by the agency to search and locate agency final orders that are required to be indexed or listed, including, but not limited to, any automated system. An agency shall make the search capabilities employed by the agency available to the public subject to reasonable terms and conditions, including a reasonable charge, as provided by s. 119.07. The agency shall specify how assistance and information pertaining to final orders may be obtained.

(h)Each agency shall specify the numbering system used to identify agency final orders.

(2)(a)An agency may comply with subparagraphs (1)(a)1. and 2. by designating an official reporter to publish and index by subject matter each agency order that must be indexed and made available to the public, or by electronically transmitting to the division a copy of such orders for posting on the division's website. An agency is in compliance with subparagraph (1)(a)3. if it publishes in its designated reporter a list of each agency final order that must be listed and preserves each listed order and makes it available for public inspection and copying.

(b)An agency may publish its official reporter or may contract with a publishing firm to publish its official reporter; however, if an agency contracts with a publishing firm to publish its reporter, the agency is responsible for the quality, timeliness, and usefulness of the reporter. The Department of State may publish an official reporter for an agency or may contract with a publishing firm to publish the reporter for the agency; however, if the department contracts for publication of the reporter, the department is responsible for the quality, timeliness, and usefulness of the reporter. A reporter that is designated by an agency as its official reporter and approved by the Department of State constitutes the official compilation of the administrative final orders for that agency.

(c)A reporter that is published by the Department of State may be made available by annual subscription, and each agency that designates an official reporter published by the department may be charged a space rate payable to the department. The subscription rate and the space rate must be equitably apportioned to cover the costs of publishing the reporter.

(d)An agency that designates an official reporter need not publish the full text of an agency final order that is rendered pursuant to s. 120.57(4) and that must be indexed pursuant to paragraph (1)(a), if the final order is preserved by the agency and made available for public inspection and copying and the official reporter indexes the final order and includes a synopsis of the order. A synopsis must include the names of the parties to the order; any rule, statute, or constitutional provision pertinent to the order; a summary of the facts, if included in the order, which are pertinent to the final disposition; and a summary of the final disposition.

(3)Agency orders that must be indexed or listed are documents of continuing legal value and must be permanently preserved and made available to the public. Each agency to which this chapter applies shall provide, under the direction of the Department of State, for the preservation of orders as required by this chapter and for maintaining an index to those orders.

(4)Each agency must provide any person who makes a request with a written description of its organization and the general course of its operations.

History.—s. 1, ch. 74-310; s. 2, ch. 75-191; s. 2, ch. 76-131; s. 2, ch. 79-299; s. 1, ch. 81-296; s. 2, ch. 81-309; s. 8, ch. 83-92; s. 34, ch. 83-217; s. 3, ch. 83-273; s. 1, ch. 84-203; s. 77, ch. 85-180; s. 2, ch. 87-100; s. 2, ch. 88-384; s. 44, ch. 90-136; s. 35, ch. 90-302; s. 2, ch. 91-30; s. 79, ch. 91-45; s. 1, ch. 91-191; s. 1, ch. 92-166; s. 143, ch. 92-279; s. 55, ch. 92-326; s. 757, ch. 95-147; s. 5, ch. 96-159; s. 2, ch. 96-423; s. 2, ch. 97-176; s. 3, ch. 2008-104.

120.533Coordination of indexing by Department of State.—The Department of State shall:

(1)Administer the coordination of the indexing, management, preservation, and availability of agency orders that must be indexed or listed pursuant to s. 120.53(1).

(2)Provide, by rule, guidelines for the indexing of agency orders. More than one system for indexing may be approved by the Department of State, including systems or methods in use, or proposed for use, by an agency. More than one system may be approved for use by a single agency as best serves the needs of that agency and the public.

(3)Provide, by rule, for storage and retrieval systems to be maintained by agencies for indexing, and making available, agency orders by subject matter. The Department of State may approve more than one system, including systems in use, or proposed for use, by an agency. Storage and retrieval systems that may be used by an agency include, without limitation, a designated reporter or reporters, a microfilming system, an automated system, or any other system considered appropriate by the Department of State.

(4)Determine which final orders must be indexed for each agency.

(5)Require each agency to report to the department concerning which types or categories of agency orders establish precedent for each agency.

History.—s. 9, ch. 91-30; s. 1, ch. 91-191; s. 7, ch. 96-159.

120.536Rulemaking authority; repeal; challenge.—

(1)A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the enabling statute.

(2)Unless otherwise expressly provided by law:

(a)The repeal of one or more provisions of law implemented by a rule that on its face implements only the provision or provisions repealed and no other provision of law nullifies the rule. Whenever notice of the nullification of a rule under this subsection is received from the committee or otherwise, the Department of State shall remove the rule from the Florida Administrative Code as of the effective date of the law effecting the nullification and update the historical notes for the code to show the rule repealed by operation of law.

(b)The repeal of one or more provisions of law implemented by a rule that on its face implements the provision or provisions repealed and one or more other provisions of law nullifies the rule or applicable portion of the rule to the extent that it implements the repealed law. The agency having authority to repeal or amend the rule shall, within 180 days after the effective date of the repealing law, publish a notice of rule development identifying all portions of rules affected by the repealing law, and if no notice is timely published the operation of each rule implementing a repealed provision of law shall be suspended until such notice is published.

(c)The repeal of one or more provisions of law that, other than as provided in paragraph (a) or paragraph (b), causes a rule or portion of a rule to be of uncertain enforceability requires the Department of State to treat the rule as provided by s. 120.555. A rule shall be considered to be of uncertain enforceability under this paragraph if the division notifies the Department of State that a rule or a portion of the rule has been invalidated in a division proceeding based upon a repeal of law, or the committee gives written notification to the Department of State and the agency having power to amend or repeal the rule that a law has been repealed creating doubt about whether the rule is still in full force and effect.

(3)The Administrative Procedures Committee or any substantially affected person may petition an agency to repeal any rule, or portion thereof, because it exceeds the rulemaking authority permitted by this section. Not later than 30 days after the date of filing the petition if the agency is headed by an individual, or not later than 45 days if the agency is headed by a collegial body, the agency shall initiate rulemaking proceedings

to repeal the rule, or portion thereof, or deny the petition, giving a written statement of its reasons for the denial.

(4)Nothing in this section shall be construed to change the legal status of a rule that has otherwise been judicially or administratively determined to be invalid.

History.—s. 9, ch. 96-159; s. 3, ch. 99-379; s. 15, ch. 2000-151; s. 15, ch. 2005-2; s. 4, ch. 2008-104; s. 1, ch. 2012-31.

120.54Rulemaking.—

(1)GENERAL PROVISIONS APPLICABLE TO ALL RULES OTHER THAN EMERGENCY RULES.—

(a)Rulemaking is not a matter of agency discretion. Each agency statement defined as a rule by s. 120.52 shall be adopted by the rulemaking procedure provided by this section as soon as feasible and practicable.

1.Rulemaking shall be presumed feasible unless the agency proves that:

a.The agency has not had sufficient time to acquire the knowledge and experience reasonably necessary to address a statement by rulemaking; or

b.Related matters are not sufficiently resolved to enable the agency to address a statement by rulemaking.

2.Rulemaking shall be presumed practicable to the extent necessary to provide fair notice to affected persons of relevant agency procedures and applicable principles, criteria, or standards for agency decisions unless the agency proves that:

a.Detail or precision in the establishment of principles, criteria, or standards for agency decisions is not reasonable under the circumstances; or

b.The particular questions addressed are of such a narrow scope that more specific resolution of the matter is impractical outside of an adjudication to determine the substantial interests of a party based on individual circumstances.

(b)Whenever an act of the Legislature is enacted which requires implementation of the act by rules of an agency within the executive branch of state government, such rules shall be drafted and formally proposed as provided in this section within 180 days after the effective date of the act, unless the act provides otherwise.

(c)No statutory provision shall be delayed in its implementation pending an agency's adoption of implementing rules unless there is an express statutory provision prohibiting its application until the adoption of implementing rules.

(d)In adopting rules, all agencies must, among the alternative approaches to any regulatory objective and to the extent allowed by law, choose the alternative that does not impose regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

(e)No agency has inherent rulemaking authority, nor has any agency authority to establish penalties for violation of a rule unless the Legislature, when establishing a penalty, specifically provides that the penalty

applies to rules.

(f)An agency may adopt rules authorized by law and necessary to the proper implementation of a statute prior to the effective date of the statute, but the rules may not be effective until the statute upon which they are based is effective. An agency may not adopt retroactive rules, including retroactive rules intended to clarify existing law, unless that power is expressly authorized by statute.

(g)Each rule adopted shall contain only one subject.

(h)In rulemaking proceedings, the agency may recognize any material which may be judicially noticed, and it may provide that materials so recognized be incorporated into the record of the proceeding. Before the record of any proceeding is completed, all parties shall be provided a list of these materials and given a reasonable opportunity to examine them and offer written comments or written rebuttal.

(i)1.A rule may incorporate material by reference but only as the material exists on the date the rule is adopted. For purposes of the rule, changes in the material are not effective unless the rule is amended to incorporate the changes.

2.An agency rule that incorporates by specific reference another rule of that agency automatically incorporates subsequent amendments to the referenced rule unless a contrary intent is clearly indicated in the referencing rule. A notice of amendments to a rule that has been incorporated by specific reference in other rules of that agency must explain the effect of those amendments on the referencing rules.

3.In rules adopted after December 31, 2010, material may not be incorporated by reference unless:

a.The material has been submitted in the prescribed electronic format to the Department of State and the full text of the material can be made available for free public access through an electronic hyperlink from the rule making the reference in the Florida Administrative Code; or

b.The agency has determined that posting the material on the Internet for purposes of public examination and inspection would constitute a violation of federal copyright law, in which case a statement to that effect, along with the address of locations at the Department of State and the agency at which the material is available for public inspection and examination, must be included in the notice required by subparagraph (3)(a)1.

4.A rule may not be amended by reference only. Amendments must set out the amended rule in full in the same manner as required by the State Constitution for laws.

5.Notwithstanding any contrary provision in this section, when an adopted rule of the Department of Environmental Protection or a water management district is incorporated by reference in the other agency's rule to implement a provision of part IV of chapter 373, subsequent amendments to the rule are not effective as to the incorporating rule unless the agency incorporating by reference notifies the committee and the Department of State of its intent to adopt the subsequent amendment, publishes notice of such intent in the Florida Administrative Weekly, and files with the Department of State a copy of the amended rule

incorporated by reference. Changes in the rule incorporated by reference are effective as to the other agency 20 days after the date of the published notice and filing with the Department of State. The Department of State shall amend the history note of the incorporating rule to show the effective date of such change. Any substantially affected person may, within 14 days after the date of publication of the notice of intent in the Florida Administrative Weekly, file an objection to rulemaking with the agency. The objection shall specify the portions of the rule incorporated by reference to which the person objects and the reasons for the objection. The agency shall not have the authority under this subparagraph to adopt those portions of the rule specified in such objection. The agency shall publish notice of the objection and of its action in response in the next available issue of the Florida Administrative Weekly.

6.The Department of State may adopt by rule requirements for incorporating materials pursuant to this paragraph.

(j)A rule published in the Florida Administrative Code must be indexed by the Department of State within 90 days after the rule is filed. The Department of State shall by rule establish procedures for indexing rules.

(k)An agency head may delegate the authority to initiate rule development under subsection (2); however, rulemaking responsibilities of an agency head under subparagraph (3)(a)1., subparagraph (3)(e)1., or subparagraph (3)(e)6. may not be delegated or transferred.

(2)RULE DEVELOPMENT; WORKSHOPS; NEGOTIATED RULEMAKING.—

(a)Except when the intended action is the repeal of a rule, agencies shall provide notice of the development of proposed rules by publication of a notice of rule development in the Florida Administrative Weekly before providing notice of a proposed rule as required by paragraph (3)(a). The notice of rule development shall indicate the subject area to be addressed by rule development, provide a short, plain explanation of the purpose and effect of the proposed rule, cite the specific legal authority for the proposed rule, and include the preliminary text of the proposed rules, if available, or a statement of how a person may promptly obtain, without cost, a copy of any preliminary draft, if available.

(b)All rules should be drafted in readable language. The language is readable if:

1.It avoids the use of obscure words and unnecessarily long or complicated constructions; and

2.It avoids the use of unnecessary technical or specialized language that is understood only by members of particular trades or professions.

(c)An agency may hold public workshops for purposes of rule development. An agency must hold public workshops, including workshops in various regions of the state or the agency's service area, for purposes of rule development if requested in writing by any affected person, unless the agency head explains in writing why a workshop is unnecessary. The explanation is not final agency action subject to review pursuant to ss. 120.569 and 120.57. The failure to provide the explanation when required may be a material error in procedure pursuant to s. 120.56(1)(c). When a workshop or public hearing is held, the agency must ensure

that the persons responsible for preparing the proposed rule are available to explain the agency's proposal and to respond to questions or comments regarding the rule being developed. The workshop may be facilitated or mediated by a neutral third person, or the agency may employ other types of dispute resolution alternatives for the workshop that are appropriate for rule development. Notice of a rule development workshop shall be by publication in the Florida Administrative Weekly not less than 14 days prior to the date on which the workshop is scheduled to be held and shall indicate the subject area which will be addressed; the agency contact person; and the place, date, and time of the workshop.

(d)1.An agency may use negotiated rulemaking in developing and adopting rules. The agency should consider the use of negotiated rulemaking when complex rules are being drafted or strong opposition to the rules is anticipated. The agency should consider, but is not limited to considering, whether a balanced committee of interested persons who will negotiate in good faith can be assembled, whether the agency is willing to support the work of the negotiating committee, and whether the agency can use the group consensus as the basis for its proposed rule. Negotiated rulemaking uses a committee of designated representatives to draft a mutually acceptable proposed rule.

2.An agency that chooses to use the negotiated rulemaking process described in this paragraph shall publish in the Florida Administrative Weekly a notice of negotiated rulemaking that includes a listing of the representative groups that will be invited to participate in the negotiated rulemaking process. Any person who believes that his or her interest is not adequately represented may apply to participate within 30 days after publication of the notice. All meetings of the negotiating committee shall be noticed and open to the public pursuant to the provisions of this chapter. The negotiating committee shall be chaired by a neutral facilitator or mediator.

3.The agency's decision to use negotiated rulemaking, its selection of the representative groups, and approval or denial of an application to participate in the negotiated rulemaking process are not agency action. Nothing in this subparagraph is intended to affect the rights of an affected person to challenge a proposed rule developed under this paragraph in accordance with s. 120.56(2).

(3)ADOPTION PROCEDURES.—

(a)*Notices.*—

1.Prior to the adoption, amendment, or repeal of any rule other than an emergency rule, an agency, upon approval of the agency head, shall give notice of its intended action, setting forth a short, plain explanation of the purpose and effect of the proposed action; the full text of the proposed rule or amendment and a summary thereof; a reference to the grant of rulemaking authority pursuant to which the rule is adopted; and a reference to the section or subsection of the Florida Statutes or the Laws of Florida being implemented or interpreted. The notice must include a summary of the agency's statement of the estimated regulatory costs, if one has been prepared, based on the factors set forth in s. 120.541(2); a statement that

any person who wishes to provide the agency with information regarding the statement of estimated regulatory costs, or to provide a proposal for a lower cost regulatory alternative as provided by s. 120.541(1), must do so in writing within 21 days after publication of the notice; and a statement as to whether, based on the statement of the estimated regulatory costs or other information expressly relied upon and described by the agency if no statement of regulatory costs is required, the proposed rule is expected to require legislative ratification pursuant to s. 120.541(3). The notice must state the procedure for requesting a public hearing on the proposed rule. Except when the intended action is the repeal of a rule, the notice must include a reference both to the date on which and to the place where the notice of rule development that is required by subsection (2) appeared.

2.The notice shall be published in the Florida Administrative Weekly not less than 28 days prior to the intended action. The proposed rule shall be available for inspection and copying by the public at the time of the publication of notice.

3.The notice shall be mailed to all persons named in the proposed rule and to all persons who, at least 14 days prior to such mailing, have made requests of the agency for advance notice of its proceedings. The agency shall also give such notice as is prescribed by rule to those particular classes of persons to whom the intended action is directed.

4.The adopting agency shall file with the committee, at least 21 days prior to the proposed adoption date, a copy of each rule it proposes to adopt; a copy of any material incorporated by reference in the rule; a detailed written statement of the facts and circumstances justifying the proposed rule; a copy of any statement of estimated regulatory costs that has been prepared pursuant to s. 120.541; a statement of the extent to which the proposed rule relates to federal standards or rules on the same subject; and the notice required by subparagraph 1.

(b)*Special matters to be considered in rule adoption.*—

1.Statement of estimated regulatory costs.—Before the adoption, amendment, or repeal of any rule other than an emergency rule, an agency is encouraged to prepare a statement of estimated regulatory costs of the proposed rule, as provided by s. 120.541. However, an agency must prepare a statement of estimated regulatory costs of the proposed rule, as provided by s. 120.541, if:

a.The proposed rule will have an adverse impact on small business; or

b.The proposed rule is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate in this state within 1 year after the implementation of the rule.

2.Small businesses, small counties, and small cities.—

a.Each agency, before the adoption, amendment, or repeal of a rule, shall consider the impact of the rule on small businesses as defined by s. 288.703 and the impact of the rule on small counties or small cities as defined by s. 120.52. Whenever practicable, an agency shall tier its rules to reduce disproportionate

impacts on small businesses, small counties, or small cities to avoid regulating small businesses, small counties, or small cities that do not contribute significantly to the problem the rule is designed to address. An agency may define "small business" to include businesses employing more than 200 persons, may define "small county" to include those with populations of more than 75,000, and may define "small city" to include those with populations of more than 10,000, if it finds that such a definition is necessary to adapt a rule to the needs and problems of small businesses, small counties, or small cities. The agency shall consider each of the following methods for reducing the impact of the proposed rule on small businesses, small counties, and small cities, or any combination of these entities:

(I)Establishing less stringent compliance or reporting requirements in the rule.

(II)Establishing less stringent schedules or deadlines in the rule for compliance or reporting requirements.

(III)Consolidating or simplifying the rule's compliance or reporting requirements.

(IV)Establishing performance standards or best management practices to replace design or operational standards in the rule.

(V)Exempting small businesses, small counties, or small cities from any or all requirements of the rule.

b.(I)If the agency determines that the proposed action will affect small businesses as defined by the agency as provided in sub-subparagraph a., the agency shall send written notice of the rule to the rules ombudsman in the Executive Office of the Governor at least 28 days before the intended action.

(II)Each agency shall adopt those regulatory alternatives offered by the rules ombudsman in the Executive Office of the Governor and provided to the agency no later than 21 days after the [1]council's receipt of the written notice of the rule which it finds are feasible and consistent with the stated objectives of the proposed rule and which would reduce the impact on small businesses. When regulatory alternatives are offered by the rules ombudsman in the Executive Office of the Governor, the 90-day period for filing the rule in subparagraph (e)2. is extended for a period of 21 days.

(III)If an agency does not adopt all alternatives offered pursuant to this sub-subparagraph, it shall, before rule adoption or amendment and pursuant to subparagraph (d)1., file a detailed written statement with the committee explaining the reasons for failure to adopt such alternatives. Within 3 working days after the filing of such notice, the agency shall send a copy of such notice to the rules ombudsman in the Executive Office of the Governor.

(c)*Hearings.*—

1.If the intended action concerns any rule other than one relating exclusively to procedure or practice, the agency shall, on the request of any affected person received within 21 days after the date of publication of the notice of intended agency action, give affected persons an opportunity to present evidence and argument on all issues under consideration. The agency may schedule a public hearing on the rule and, if requested by any affected person, shall schedule a public hearing on the rule. When a public hearing is held,

the agency must ensure that staff are available to explain the agency's proposal and to respond to questions or comments regarding the rule. If the agency head is a board or other collegial body created under s. 20.165(4) or s. 20.43(3)(g), and one or more requested public hearings is scheduled, the board or other collegial body shall conduct at least one of the public hearings itself and may not delegate this responsibility without the consent of those persons requesting the public hearing. Any material pertinent to the issues under consideration submitted to the agency within 21 days after the date of publication of the notice or submitted to the agency between the date of publication of the notice and the end of the final public hearing shall be considered by the agency and made a part of the record of the rulemaking proceeding.

2.Rulemaking proceedings shall be governed solely by the provisions of this section unless a person timely asserts that the person's substantial interests will be affected in the proceeding and affirmatively demonstrates to the agency that the proceeding does not provide adequate opportunity to protect those interests. If the agency determines that the rulemaking proceeding is not adequate to protect the person's interests, it shall suspend the rulemaking proceeding and convene a separate proceeding under the provisions of ss. 120.569 and 120.57. Similarly situated persons may be requested to join and participate in the separate proceeding. Upon conclusion of the separate proceeding, the rulemaking proceeding shall be resumed.

(d)*Modification or withdrawal of proposed rules.*—

1.After the final public hearing on the proposed rule, or after the time for requesting a hearing has expired, if the rule has not been changed from the rule as previously filed with the committee, or contains only technical changes, the adopting agency shall file a notice to that effect with the committee at least 7 days prior to filing the rule for adoption. Any change, other than a technical change that does not affect the substance of the rule, must be supported by the record of public hearings held on the rule, must be in response to written material submitted to the agency within 21 days after the date of publication of the notice of intended agency action or submitted to the agency between the date of publication of the notice and the end of the final public hearing, or must be in response to a proposed objection by the committee. In addition, when any change is made in a proposed rule, other than a technical change, the adopting agency shall provide a copy of a notice of change by certified mail or actual delivery to any person who requests it in writing no later than 21 days after the notice required in paragraph (a). The agency shall file the notice of change with the committee, along with the reasons for the change, and provide the notice of change to persons requesting it, at least 21 days prior to filing the rule for adoption. The notice of change shall be published in the Florida Administrative Weekly at least 21 days prior to filing the rule for adoption. This subparagraph does not apply to emergency rules adopted pursuant to subsection (4).

2.After the notice required by paragraph (a) and prior to adoption, the agency may withdraw the rule in whole or in part.

3.After adoption and before the rule becomes effective, a rule may be modified or withdrawn only in the

following circumstances:

a.When the committee objects to the rule;

b.When a final order, which is not subject to further appeal, is entered in a rule challenge brought pursuant to s. 120.56 after the date of adoption but before the rule becomes effective pursuant to subparagraph (e)6.;

c.If the rule requires ratification, when more than 90 days have passed since the rule was filed for adoption without the Legislature ratifying the rule, in which case the rule may be withdrawn but may not be modified; or

d.When the committee notifies the agency that an objection to the rule is being considered, in which case the rule may be modified to extend the effective date by not more than 60 days.

4.The agency shall give notice of its decision to withdraw or modify a rule in the first available issue of the publication in which the original notice of rulemaking was published, shall notify those persons described in subparagraph (a)3. in accordance with the requirements of that subparagraph, and shall notify the Department of State if the rule is required to be filed with the Department of State.

5.After a rule has become effective, it may be repealed or amended only through the rulemaking procedures specified in this chapter.

(e)*Filing for final adoption; effective date.*—

1.If the adopting agency is required to publish its rules in the Florida Administrative Code, the agency, upon approval of the agency head, shall file with the Department of State three certified copies of the rule it proposes to adopt; one copy of any material incorporated by reference in the rule, certified by the agency; a summary of the rule; a summary of any hearings held on the rule; and a detailed written statement of the facts and circumstances justifying the rule. Agencies not required to publish their rules in the Florida Administrative Code shall file one certified copy of the proposed rule, and the other material required by this subparagraph, in the office of the agency head, and such rules shall be open to the public.

2.A rule may not be filed for adoption less than 28 days or more than 90 days after the notice required by paragraph (a), until 21 days after the notice of change required by paragraph (d), until 14 days after the final public hearing, until 21 days after a statement of estimated regulatory costs required under s. 120.541 has been provided to all persons who submitted a lower cost regulatory alternative and made available to the public, or until the administrative law judge has rendered a decision under s. 120.56(2), whichever applies. When a required notice of change is published prior to the expiration of the time to file the rule for adoption, the period during which a rule must be filed for adoption is extended to 45 days after the date of publication. If notice of a public hearing is published prior to the expiration of the time to file the rule for adoption, the period during which a rule must be filed for adoption is extended to 45 days after adjournment of the final hearing on the rule, 21 days after receipt of all material authorized to be submitted at the hearing, or 21 days

after receipt of the transcript, if one is made, whichever is latest. The term "public hearing" includes any public meeting held by any agency at which the rule is considered. If a petition for an administrative determination under s. 120.56(2) is filed, the period during which a rule must be filed for adoption is extended to 60 days after the administrative law judge files the final order with the clerk or until 60 days after subsequent judicial review is complete.

3.At the time a rule is filed, the agency shall certify that the time limitations prescribed by this paragraph have been complied with, that all statutory rulemaking requirements have been met, and that there is no administrative determination pending on the rule.

4.At the time a rule is filed, the committee shall certify whether the agency has responded in writing to all material and timely written comments or written inquiries made on behalf of the committee. The department shall reject any rule that is not filed within the prescribed time limits; that does not comply with all statutory rulemaking requirements and rules of the department; upon which an agency has not responded in writing to all material and timely written inquiries or written comments; upon which an administrative determination is pending; or which does not include a statement of estimated regulatory costs, if required.

5.If a rule has not been adopted within the time limits imposed by this paragraph or has not been adopted in compliance with all statutory rulemaking requirements, the agency proposing the rule shall withdraw the rule and give notice of its action in the next available issue of the Florida Administrative Weekly.

6.The proposed rule shall be adopted on being filed with the Department of State and become effective 20 days after being filed, on a later date specified in the notice required by subparagraph (a)1., on a date required by statute, or upon ratification by the Legislature pursuant to s. 120.541(3). Rules not required to be filed with the Department of State shall become effective when adopted by the agency head, on a later date specified by rule or statute, or upon ratification by the Legislature pursuant to s. 120.541(3). If the committee notifies an agency that an objection to a rule is being considered, the agency may postpone the adoption of the rule to accommodate review of the rule by the committee. When an agency postpones adoption of a rule to accommodate review by the committee, the 90-day period for filing the rule is tolled until the committee notifies the agency that it has completed its review of the rule.

For the purposes of this paragraph, the term "administrative determination" does not include subsequent judicial review.

(4)EMERGENCY RULES.—

(a)If an agency finds that an immediate danger to the public health, safety, or welfare requires emergency action, the agency may adopt any rule necessitated by the immediate danger. The agency may adopt a rule by any procedure which is fair under the circumstances if:

1.The procedure provides at least the procedural protection given by other statutes, the State

Constitution, or the United States Constitution.

2.The agency takes only that action necessary to protect the public interest under the emergency procedure.

3.The agency publishes in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. In any event, notice of emergency rules, other than those of educational units or units of government with jurisdiction in only one or a part of one county, including the full text of the rules, shall be published in the first available issue of the Florida Administrative Weekly and provided to the committee along with any material incorporated by reference in the rules. The agency's findings of immediate danger, necessity, and procedural fairness shall be judicially reviewable.

(b)Rules pertaining to the public health, safety, or welfare shall include rules pertaining to perishable agricultural commodities or rules pertaining to the interpretation and implementation of the requirements of chapters 97-102 and chapter 105 of the Election Code.

(c)An emergency rule adopted under this subsection shall not be effective for a period longer than 90 days and shall not be renewable, except when the agency has initiated rulemaking to adopt rules addressing the subject of the emergency rule and either:

1.A challenge to the proposed rules has been filed and remains pending; or

2.The proposed rules are awaiting ratification by the Legislature pursuant to s. 120.541(3).

Nothing in this paragraph prohibits the agency from adopting a rule or rules identical to the emergency rule through the rulemaking procedures specified in subsection (3).

(d)Subject to applicable constitutional and statutory provisions, an emergency rule becomes effective immediately on filing, or on a date less than 20 days thereafter if specified in the rule, if the adopting agency finds that such effective date is necessary because of immediate danger to the public health, safety, or welfare.

(5)UNIFORM RULES.—

(a)1.By July 1, 1997, the Administration Commission shall adopt one or more sets of uniform rules of procedure which shall be reviewed by the committee and filed with the Department of State. Agencies must comply with the uniform rules by July 1, 1998. The uniform rules shall establish procedures that comply with the requirements of this chapter. On filing with the department, the uniform rules shall be the rules of procedure for each agency subject to this chapter unless the Administration Commission grants an exception to the agency under this subsection.

2.An agency may seek exceptions to the uniform rules of procedure by filing a petition with the Administration Commission. The Administration Commission shall approve exceptions to the extent necessary to implement other statutes, to the extent necessary to conform to any requirement imposed as a condition

precedent to receipt of federal funds or to permit persons in this state to receive tax benefits under federal law, or as required for the most efficient operation of the agency as determined by the Administration Commission. The reasons for the exceptions shall be published in the Florida Administrative Weekly.

3.Agency rules that provide exceptions to the uniform rules shall not be filed with the department unless the Administration Commission has approved the exceptions. Each agency that adopts rules that provide exceptions to the uniform rules shall publish a separate chapter in the Florida Administrative Code that delineates clearly the provisions of the agency's rules that provide exceptions to the uniform rules and specifies each alternative chosen from among those authorized by the uniform rules. Each chapter shall be organized in the same manner as the uniform rules.

(b)The uniform rules of procedure adopted by the commission pursuant to this subsection shall include, but are not limited to:

1.Uniform rules for the scheduling of public meetings, hearings, and workshops.

2.Uniform rules for use by each state agency that provide procedures for conducting public meetings, hearings, and workshops, and for taking evidence, testimony, and argument at such public meetings, hearings, and workshops, in person and by means of communications media technology. The rules shall provide that all evidence, testimony, and argument presented shall be afforded equal consideration, regardless of the method of communication. If a public meeting, hearing, or workshop is to be conducted by means of communications media technology, or if attendance may be provided by such means, the notice shall so state. The notice for public meetings, hearings, and workshops utilizing communications media technology shall state how persons interested in attending may do so and shall name locations, if any, where communications media technology facilities will be available. Nothing in this paragraph shall be construed to diminish the right to inspect public records under chapter 119. Limiting points of access to public meetings, hearings, and workshops subject to the provisions of s. 286.011 to places not normally open to the public shall be presumed to violate the right of access of the public, and any official action taken under such circumstances is void and of no effect. Other laws relating to public meetings, hearings, and workshops, including penal and remedial provisions, shall apply to public meetings, hearings, and workshops conducted by means of communications media technology, and shall be liberally construed in their application to such public meetings, hearings, and workshops. As used in this subparagraph, "communications media technology" means the electronic transmission of printed matter, audio, full-motion video, freeze-frame video, compressed video, and digital video by any method available.

3.Uniform rules of procedure for the filing of notice of protests and formal written protests. The Administration Commission may prescribe the form and substantive provisions of a required bond.

4.Uniform rules of procedure for the filing of petitions for administrative hearings pursuant to s. 120.569 or s. 120.57. Such rules shall require the petition to include:

a.The identification of the petitioner, including the petitioner's e-mail address, if any, for the

transmittal of subsequent documents by electronic means.

b.A statement of when and how the petitioner received notice of the agency's action or proposed action.

c.An explanation of how the petitioner's substantial interests are or will be affected by the action or proposed action.

d.A statement of all material facts disputed by the petitioner or a statement that there are no disputed facts.

e.A statement of the ultimate facts alleged, including a statement of the specific facts the petitioner contends warrant reversal or modification of the agency's proposed action.

f.A statement of the specific rules or statutes that the petitioner contends require reversal or modification of the agency's proposed action, including an explanation of how the alleged facts relate to the specific rules or statutes.

g.A statement of the relief sought by the petitioner, stating precisely the action petitioner wishes the agency to take with respect to the proposed action.

5.Uniform rules for the filing of request for administrative hearing by a respondent in agency enforcement and disciplinary actions. Such rules shall require a request to include:

a.The name, address, e-mail address, and telephone number of the party making the request and the name, address, and telephone number of the party's counsel or qualified representative upon whom service of pleadings and other papers shall be made;

b.A statement that the respondent is requesting an administrative hearing and disputes the material facts alleged by the petitioner, in which case the respondent shall identify those material facts that are in dispute, or that the respondent is requesting an administrative hearing and does not dispute the material facts alleged by the petitioner; and

c.A reference by file number to the administrative complaint that the party has received from the agency and the date on which the agency pleading was received.

The agency may provide an election-of-rights form for the respondent's use in requesting a hearing, so long as any form provided by the agency calls for the information in sub-subparagraphs a. through c. and does not impose any additional requirements on a respondent in order to request a hearing, unless such requirements are specifically authorized by law.

6.Uniform rules of procedure for the filing and prompt disposition of petitions for declaratory statements. The rules shall also describe the contents of the notices that must be published in the Florida Administrative Weekly under s. 120.565, including any applicable time limit for the filing of petitions to intervene or petitions for administrative hearing by persons whose substantial interests may be affected.

7.Provision of a method by which each agency head shall provide a description of the agency's organization and general course of its operations. The rules shall require that the statement concerning the

agency's organization and operations be published on the agency's website.

8.Uniform rules establishing procedures for granting or denying petitions for variances and waivers pursuant to s. 120.542.

(6)ADOPTION OF FEDERAL STANDARDS.—Notwithstanding any contrary provision of this section, in the pursuance of state implementation, operation, or enforcement of federal programs, an agency is empowered to adopt rules substantively identical to regulations adopted pursuant to federal law, in accordance with the following procedures:

(a)The agency shall publish notice of intent to adopt a rule pursuant to this subsection in the Florida Administrative Weekly at least 21 days prior to filing the rule with the Department of State. The agency shall provide a copy of the notice of intent to adopt a rule to the committee at least 21 days prior to the date of filing with the Department of State. Prior to filing the rule with the Department of State, the agency shall consider any written comments received within 14 days after the date of publication of the notice of intent to adopt a rule. The rule shall be adopted upon filing with the Department of State. Substantive changes from the rules as noticed shall require republishing of notice as required in this subsection.

(b)Any rule adopted pursuant to this subsection shall become effective upon the date designated by the agency in the notice of intent to adopt a rule; however, no such rule shall become effective earlier than the effective date of the substantively identical federal regulation.

(c)Any substantially affected person may, within 14 days after the date of publication of the notice of intent to adopt a rule, file an objection to rulemaking with the agency. The objection shall specify the portions of the proposed rule to which the person objects and the specific reasons for the objection. The agency shall not proceed pursuant to this subsection to adopt those portions of the proposed rule specified in an objection, unless the agency deems the objection to be frivolous, but may proceed pursuant to subsection (3). An objection to a proposed rule, which rule in no material respect differs from the requirements of the federal regulation upon which it is based, is deemed to be frivolous.

(d)Whenever any federal regulation adopted as an agency rule pursuant to this subsection is declared invalid or is withdrawn, revoked, repealed, remanded, or suspended, the agency shall, within 60 days thereafter, publish a notice of repeal of the substantively identical agency rule in the Florida Administrative Weekly. Such repeal is effective upon publication of the notice. Whenever any federal regulation adopted as an agency rule pursuant to this subsection is substantially amended, the agency may adopt the amended regulation as a rule. If the amended regulation is not adopted as a rule within 180 days after the effective date of the amended regulation, the original rule is deemed repealed and the agency shall publish a notice of repeal of the original agency rule in the next available Florida Administrative Weekly.

(e)Whenever all or part of any rule proposed for adoption by the agency is substantively identical to a regulation adopted pursuant to federal law, such rule shall be written in a manner so that the rule specifically

references the regulation whenever possible.

(7)PETITION TO INITIATE RULEMAKING.—

(a)Any person regulated by an agency or having substantial interest in an agency rule may petition an agency to adopt, amend, or repeal a rule or to provide the minimum public information required by this chapter. The petition shall specify the proposed rule and action requested. Not later than 30 calendar days following the date of filing a petition, the agency shall initiate rulemaking proceedings under this chapter, otherwise comply with the requested action, or deny the petition with a written statement of its reasons for the denial.

(b)If the petition filed under this subsection is directed to an unadopted rule, the agency shall, not later than 30 days following the date of filing a petition, initiate rulemaking, or provide notice in the Florida Administrative Weekly that the agency will hold a public hearing on the petition within 30 days after publication of the notice. The purpose of the public hearing is to consider the comments of the public directed to the agency rule which has not been adopted by the rulemaking procedures or requirements of this chapter, its scope and application, and to consider whether the public interest is served adequately by the application of the rule on a case-by-case basis, as contrasted with its adoption by the rulemaking procedures or requirements set forth in this chapter.

(c)Within 30 days following the public hearing provided for by paragraph (b), if the agency does not initiate rulemaking or otherwise comply with the requested action, the agency shall publish in the Florida Administrative Weekly a statement of its reasons for not initiating rulemaking or otherwise complying with the requested action, and of any changes it will make in the scope or application of the unadopted rule. The agency shall file the statement with the committee. The committee shall forward a copy of the statement to the substantive committee with primary oversight jurisdiction of the agency in each house of the Legislature. The committee or the committee with primary oversight jurisdiction may hold a hearing directed to the statement of the agency. The committee holding the hearing may recommend to the Legislature the introduction of legislation making the rule a statutory standard or limiting or otherwise modifying the authority of the agency.

(8)RULEMAKING RECORD.—In all rulemaking proceedings the agency shall compile a rulemaking record. The record shall include, if applicable, copies of:

(a)All notices given for the proposed rule.

(b)Any statement of estimated regulatory costs for the rule.

(c)A written summary of hearings on the proposed rule.

(d)The written comments and responses to written comments as required by this section and s. 120.541.

(e)All notices and findings made under subsection (4).

(f)All materials filed by the agency with the committee under subsection (3).

(g)All materials filed with the Department of State under subsection (3).

(h)All written inquiries from standing committees of the Legislature concerning the rule.

Each state agency shall retain the record of rulemaking as long as the rule is in effect. When a rule is no longer in effect, the record may be destroyed pursuant to the records-retention schedule developed under s. 257.36(6).

History.—s. 1, ch. 74-310; s. 3, ch. 75-191; s. 3, ch. 76-131; ss. 1, 2, ch. 76-276; s. 1, ch. 77-174; s. 13, ch. 77-290; s. 3, ch. 77-453; s. 2, ch. 78-28; s. 2, ch. 78-425; s. 7, ch. 79-3; s. 3, ch. 79-299; s. 69, ch. 79-400; s. 5, ch. 80-391; s. 1, ch. 81-309; s. 2, ch. 83-351; s. 1, ch. 84-173; s. 2, ch. 84-203; s. 7, ch. 85-104; s. 1, ch. 86-30; s. 3, ch. 87-385; s. 36, ch. 90-302; ss. 2, 4, 7, ch. 92-166; s. 63, ch. 93-187; s. 758, ch. 95-147; s. 6, ch. 95-295; s. 10, ch. 96-159; s. 6, ch. 96-320; s. 9, ch. 96-370; s. 3, ch. 97-176; s. 3, ch. 98-200; s. 4, ch. 99-379; s. 9, ch. 2001-75; s. 2, ch. 2003-94; s. 50, ch. 2005-278; s. 3, ch. 2006-82; ss. 5, 6, ch. 2008-104; s. 7, ch. 2008-149; s. 4, ch. 2009-187; ss. 1, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 49, ch. 2011-142; s. 8, ch. 2011-208; s. 1, ch. 2011-225; s. 2, ch. 2012-27; s. 1, ch. 2012-63.

[1]**Note.**—The word "council's" refers to the Small Business Regulatory Advisory Council. Section 5, ch. 2012-27, repealed s. 288.7001, which created the council, and other provisions in ch. 2012-27 reassigned the council's duties to the rules ombudsman in the Executive Office of the Governor.

120.541 Statement of estimated regulatory costs.—

(1)(a)Within 21 days after publication of the notice required under s. 120.54(3)(a), a substantially affected person may submit to an agency a good faith written proposal for a lower cost regulatory alternative to a proposed rule which substantially accomplishes the objectives of the law being implemented. The proposal may include the alternative of not adopting any rule if the proposal explains how the lower costs and objectives of the law will be achieved by not adopting any rule. If such a proposal is submitted, the 90-day period for filing the rule is extended 21 days. Upon the submission of the lower cost regulatory alternative, the agency shall prepare a statement of estimated regulatory costs as provided in subsection (2), or shall revise its prior statement of estimated regulatory costs, and either adopt the alternative or provide a statement of the reasons for rejecting the alternative in favor of the proposed rule.

(b)If a proposed rule will have an adverse impact on small business or if the proposed rule is likely to directly or indirectly increase regulatory costs in excess of $200,000 in the aggregate within 1 year after the implementation of the rule, the agency shall prepare a statement of estimated regulatory costs as required by s. 120.54(3)(b).

(c)The agency shall revise a statement of estimated regulatory costs if any change to the rule made under s. 120.54(3)(d) increases the regulatory costs of the rule.

(d)At least 21 days before filing the rule for adoption, an agency that is required to revise a statement of estimated regulatory costs shall provide the statement to the person who submitted the lower cost regulatory alternative and to the committee and shall provide notice on the agency's website that it is available to the

public.

(e)Notwithstanding s. 120.56(1)(c), the failure of the agency to prepare a statement of estimated regulatory costs or to respond to a written lower cost regulatory alternative as provided in this subsection is a material failure to follow the applicable rulemaking procedures or requirements set forth in this chapter.

(f)An agency's failure to prepare a statement of estimated regulatory costs or to respond to a written lower cost regulatory alternative may not be raised in a proceeding challenging the validity of a rule pursuant to s. 120.52(8)(a) unless:

1.Raised in a petition filed no later than 1 year after the effective date of the rule; and

2.Raised by a person whose substantial interests are affected by the rule's regulatory costs.

(g)A rule that is challenged pursuant to s. 120.52(8)(f) may not be declared invalid unless:

1.The issue is raised in an administrative proceeding within 1 year after the effective date of the rule;

2.The challenge is to the agency's rejection of a lower cost regulatory alternative offered under paragraph (a) or s. 120.54(3)(b)2.b.; and

3.The substantial interests of the person challenging the rule are materially affected by the rejection.

(2)A statement of estimated regulatory costs shall include:

(a)An economic analysis showing whether the rule directly or indirectly:

1.Is likely to have an adverse impact on economic growth, private sector job creation or employment, or private sector investment in excess of $1 million in the aggregate within 5 years after the implementation of the rule;

2.Is likely to have an adverse impact on business competitiveness, including the ability of persons doing business in the state to compete with persons doing business in other states or domestic markets, productivity, or innovation in excess of $1 million in the aggregate within 5 years after the implementation of the rule; or

3.Is likely to increase regulatory costs, including any transactional costs, in excess of $1 million in the aggregate within 5 years after the implementation of the rule.

(b)A good faith estimate of the number of individuals and entities likely to be required to comply with the rule, together with a general description of the types of individuals likely to be affected by the rule.

(c)A good faith estimate of the cost to the agency, and to any other state and local government entities, of implementing and enforcing the proposed rule, and any anticipated effect on state or local revenues.

(d)A good faith estimate of the transactional costs likely to be incurred by individuals and entities, including local government entities, required to comply with the requirements of the rule. As used in this section, "transactional costs" are direct costs that are readily ascertainable based upon standard business practices, and include filing fees, the cost of obtaining a license, the cost of equipment required to be installed or used or procedures required to be employed in complying with the rule, additional operating costs

incurred, the cost of monitoring and reporting, and any other costs necessary to comply with the rule.

(e)An analysis of the impact on small businesses as defined by s. 288.703, and an analysis of the impact on small counties and small cities as defined in s. 120.52. The impact analysis for small businesses must include the basis for the agency's decision not to implement alternatives that would reduce adverse impacts on small businesses.

(f)Any additional information that the agency determines may be useful.

(g)In the statement or revised statement, whichever applies, a description of any regulatory alternatives submitted under paragraph (1)(a) and a statement adopting the alternative or a statement of the reasons for rejecting the alternative in favor of the proposed rule.

(3)If the adverse impact or regulatory costs of the rule exceed any of the criteria established in paragraph (2)(a), the rule shall be submitted to the President of the Senate and Speaker of the House of Representatives no later than 30 days prior to the next regular legislative session, and the rule may not take effect until it is ratified by the Legislature.

[1] (4)This section does not apply to the adoption of emergency rules pursuant to s. 120.54(4) or the adoption of federal standards pursuant to s. 120.54(6).

History.—s. 11, ch. 96-159; s. 4, ch. 97-176; ss. 2, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 1, ch. 2011-222; s. 2, ch. 2011-225.

[1]**Note.**—As amended by s. 2, ch. 2011-225. For a description of multiple acts in the same session affecting a statutory provision, *see* preface to the *Florida Statutes*, "Statutory Construction." Subsection (4) was also amended by s. 1, ch. 2011-222, and that version reads:

Subsection (4) (3) does not apply to the adoption of:

Federal (a) standards pursuant to s. 120.54(6).

Triennial (b) updates of and amendments to the Florida Building Code which are expressly authorized by s. 553.73.

Triennial (c) updates of and amendments to the Florida Fire Prevention Code which are expressly authorized by s. 633.0215.

120.542Variances and waivers.—

(1)Strict application of uniformly applicable rule requirements can lead to unreasonable, unfair, and unintended results in particular instances. The Legislature finds that it is appropriate in such cases to adopt a procedure for agencies to provide relief to persons subject to regulation. A public employee is not a person subject to regulation under this section for the purpose of petitioning for a variance or waiver to a rule that affects that public employee in his or her capacity as a public employee. Agencies are authorized to grant variances and waivers to requirements of their rules consistent with this section and with rules adopted under the authority of this section. An agency may limit the duration of any grant of a variance or waiver or otherwise impose conditions on the grant only to the extent necessary for the purpose of the underlying statute to be achieved. This section does not authorize agencies to grant variances or waivers to statutes or to

rules required by the Federal Government for the agency's implementation or retention of any federally approved or delegated program, except as allowed by the program or when the variance or waiver is also approved by the appropriate agency of the Federal Government. This section is supplemental to, and does not abrogate, the variance and waiver provisions in any other statute.

(2)Variances and waivers shall be granted when the person subject to the rule demonstrates that the purpose of the underlying statute will be or has been achieved by other means by the person and when application of a rule would create a substantial hardship or would violate principles of fairness. For purposes of this section, "substantial hardship" means a demonstrated economic, technological, legal, or other type of hardship to the person requesting the variance or waiver. For purposes of this section, "principles of fairness" are violated when the literal application of a rule affects a particular person in a manner significantly different from the way it affects other similarly situated persons who are subject to the rule.

(3)The Governor and Cabinet, sitting as the Administration Commission, shall adopt uniform rules of procedure pursuant to the requirements of s. 120.54(5) establishing procedures for granting or denying petitions for variances and waivers. The uniform rules shall include procedures for the granting, denying, or revoking of emergency and temporary variances and waivers. Such provisions may provide for expedited timeframes, waiver of or limited public notice, and limitations on comments on the petition in the case of such temporary or emergency variances and waivers.

(4)Agencies shall advise persons of the remedies available through this section and shall provide copies of this section, the uniform rules on variances and waivers, and, if requested, the underlying statute, to persons who inquire about the possibility of relief from rule requirements.

(5)A person who is subject to regulation by an agency rule may file a petition with that agency, with a copy to the committee, requesting a variance or waiver from the agency's rule. In addition to any requirements mandated by the uniform rules, each petition shall specify:

(a)The rule from which a variance or waiver is requested.

(b)The type of action requested.

(c)The specific facts that would justify a waiver or variance for the petitioner.

(d)The reason why the variance or the waiver requested would serve the purposes of the underlying statute.

(6)Within 15 days after receipt of a petition for variance or waiver, an agency shall provide notice of the petition to the Department of State, which shall publish notice of the petition in the first available issue of the Florida Administrative Weekly. The notice shall contain the name of the petitioner, the date the petition was filed, the rule number and nature of the rule from which variance or waiver is sought, and an explanation of how a copy of the petition can be obtained. The uniform rules shall provide a means for interested persons to provide comments on the petition.

(7)Except for requests for emergency variances or waivers, within 30 days after receipt of a petition for a variance or waiver, an agency shall review the petition and request submittal of all additional information that the agency is permitted by this section to require. Within 30 days after receipt of such additional information, the agency shall review it and may request only that information needed to clarify the additional information or to answer new questions raised by or directly related to the additional information. If the petitioner asserts that any request for additional information is not authorized by law or by rule of the affected agency, the agency shall proceed, at the petitioner's written request, to process the petition.

(8)An agency shall grant or deny a petition for variance or waiver within 90 days after receipt of the original petition, the last item of timely requested additional material, or the petitioner's written request to finish processing the petition. A petition not granted or denied within 90 days after receipt of a completed petition is deemed approved. A copy of the order granting or denying the petition shall be filed with the committee and shall contain a statement of the relevant facts and reasons supporting the agency's action. The agency shall provide notice of the disposition of the petition to the Department of State, which shall publish the notice in the next available issue of the Florida Administrative Weekly. The notice shall contain the name of the petitioner, the date the petition was filed, the rule number and nature of the rule from which the waiver or variance is sought, a reference to the place and date of publication of the notice of the petition, the date of the order denying or approving the variance or waiver, the general basis for the agency decision, and an explanation of how a copy of the order can be obtained. The agency's decision to grant or deny the petition shall be supported by competent substantial evidence and is subject to ss. 120.569 and 120.57. Any proceeding pursuant to ss. 120.569 and 120.57 in regard to a variance or waiver shall be limited to the agency action on the request for the variance or waiver, except that a proceeding in regard to a variance or waiver may be consolidated with any other proceeding authorized by this chapter.

(9)Each agency shall maintain a record of the type and disposition of each petition, including temporary or emergency variances and waivers, filed pursuant to this section.

History.—s. 12, ch. 96-159; s. 5, ch. 97-176; s. 37, ch. 2010-102.

120.545Committee review of agency rules.—

(1)As a legislative check on legislatively created authority, the committee shall examine each proposed rule, except for those proposed rules exempted by s. 120.81(1)(e) and (2), and its accompanying material, and each emergency rule, and may examine any existing rule, for the purpose of determining whether:

(a)The rule is an invalid exercise of delegated legislative authority.

(b)The statutory authority for the rule has been repealed.

(c)The rule reiterates or paraphrases statutory material.

(d)The rule is in proper form.

(e)The notice given prior to its adoption was sufficient to give adequate notice of the purpose and effect

of the rule.

(f)The rule is consistent with expressed legislative intent pertaining to the specific provisions of law which the rule implements.

(g)The rule is necessary to accomplish the apparent or expressed objectives of the specific provision of law which the rule implements.

(h)The rule is a reasonable implementation of the law as it affects the convenience of the general public or persons particularly affected by the rule.

(i)The rule could be made less complex or more easily comprehensible to the general public.

(j)The rule's statement of estimated regulatory costs complies with the requirements of s. 120.541 and whether the rule does not impose regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.

(k)The rule will require additional appropriations.

(l)If the rule is an emergency rule, there exists an emergency justifying the adoption of such rule, the agency is within its statutory authority, and the rule was adopted in compliance with the requirements and limitations of s. 120.54(4).

(2)The committee may request from an agency such information as is reasonably necessary for examination of a rule as required by subsection (1). The committee shall consult with legislative standing committees having jurisdiction over the subject areas. If the committee objects to a rule, the committee shall, within 5 days after the objection, certify that fact to the agency whose rule has been examined and include with the certification a statement detailing its objections with particularity. The committee shall notify the Speaker of the House of Representatives and the President of the Senate of any objection to an agency rule concurrent with certification of that fact to the agency. Such notice shall include a copy of the rule and the statement detailing the committee's objections to the rule.

(3)Within 30 days after receipt of the objection, if the agency is headed by an individual, or within 45 days after receipt of the objection, if the agency is headed by a collegial body, the agency shall:

(a)If the rule is not yet in effect:

1.File notice pursuant to s. 120.54(3)(d) of only such modifications as are necessary to address the committee's objection;

2.File notice pursuant to s. 120.54(3)(d) of withdrawal of the rule; or

3.Notify the committee in writing that it refuses to modify or withdraw the rule.

(b)If the rule is in effect:

1.File notice pursuant to s. 120.54(3)(a), without prior notice of rule development, to amend the rule to address the committee's objection;

2.File notice pursuant to s. 120.54(3)(a) to repeal the rule; or

3.Notify the committee in writing that the agency refuses to amend or repeal the rule.

(c)If the objection is to the statement of estimated regulatory costs:

1.Prepare a corrected statement of estimated regulatory costs, give notice of the availability of the corrected statement in the first available issue of the Florida Administrative Weekly, and file a copy of the corrected statement with the committee; or

2.Notify the committee that it refuses to prepare a corrected statement of estimated regulatory costs.

(4)Failure of the agency to respond to a committee objection to a rule that is not yet in effect within the time prescribed in subsection (3) constitutes withdrawal of the rule in its entirety. In this event, the committee shall notify the Department of State that the agency, by its failure to respond to a committee objection, has elected to withdraw the rule. Upon receipt of the committee's notice, the Department of State shall publish a notice to that effect in the next available issue of the Florida Administrative Weekly. Upon publication of the notice, the rule shall be stricken from the files of the Department of State and the files of the agency.

(5)Failure of the agency to respond to a committee objection to a rule that is in effect within the time prescribed in subsection (3) constitutes a refusal to amend or repeal the rule.

(6)Failure of the agency to respond to a committee objection to a statement of estimated regulatory costs within the time prescribed in subsection (3) constitutes a refusal to prepare a corrected statement of estimated regulatory costs.

(7)If the committee objects to a rule and the agency refuses to modify, amend, withdraw, or repeal the rule, the committee shall file with the Department of State a notice of the objection, detailing with particularity the committee's objection to the rule. The Department of State shall publish this notice in the Florida Administrative Weekly. If the rule is published in the Florida Administrative Code, a reference to the committee's objection and to the issue of the Florida Administrative Weekly in which the full text thereof appears shall be recorded in a history note.

(8)(a)If the committee objects to a rule, or portion of a rule, and the agency fails to initiate administrative action to modify, amend, withdraw, or repeal the rule consistent with the objection within 60 days after the objection, or thereafter fails to proceed in good faith to complete such action, the committee may submit to the President of the Senate and the Speaker of the House of Representatives a recommendation that legislation be introduced to address the committee's objection.

(b)1.If the committee votes to recommend the introduction of legislation to address the committee's objection, the committee shall, within 5 days after this determination, certify that fact to the agency whose rule or proposed rule has been examined. The committee may request that the agency temporarily suspend the rule or suspend the adoption of the proposed rule, pending consideration of proposed legislation during the next regular session of the Legislature.

2.Within 30 days after receipt of the certification, if the agency is headed by an individual, or within 45 days after receipt of the certification, if the agency is headed by a collegial body, the agency shall:

a.Temporarily suspend the rule or suspend the adoption of the proposed rule; or

b.Notify the committee in writing that the agency refuses to temporarily suspend the rule or suspend the adoption of the proposed rule.

3.If the agency elects to temporarily suspend the rule or suspend the adoption of the proposed rule, the agency shall give notice of the suspension in the Florida Administrative Weekly. The rule or the rule adoption process shall be suspended upon publication of the notice. An agency may not base any agency action on a suspended rule or suspended proposed rule, or portion of such rule, prior to expiration of the suspension. A suspended rule or suspended proposed rule, or portion of such rule, continues to be subject to administrative determination and judicial review as provided by law.

4.Failure of an agency to respond to committee certification within the time prescribed by subparagraph 2. constitutes a refusal to suspend the rule or to suspend the adoption of the proposed rule.

(c)The committee shall prepare proposed legislation to address the committee's objection in accordance with the rules of the Senate and the House of Representatives for prefiling and introduction in the next regular session of the Legislature. The proposed legislation shall be presented to the President of the Senate and the Speaker of the House of Representatives with the committee recommendation.

(d)If proposed legislation addressing the committee's objection fails to become law, any temporary agency suspension shall expire.

History.—s. 4, ch. 76-131; s. 1, ch. 77-174; s. 6, ch. 80-391; s. 3, ch. 81-309; s. 4, ch. 87-385; s. 8, ch. 92-166; s. 20, ch. 95-280; s. 14, ch. 96-159; s. 16, ch. 2000-151; s. 18, ch. 2008-4; s. 7, ch. 2008-104.

120.55Publication.—

(1)The Department of State shall:

(a)1.Through a continuous revision and publication system, compile and publish electronically, on an Internet website managed by the department, the "Florida Administrative Code." The Florida Administrative Code shall contain all rules adopted by each agency, citing the grant of rulemaking authority and the specific law implemented pursuant to which each rule was adopted, all history notes as authorized in s. 120.545(7), complete indexes to all rules contained in the code, and any other material required or authorized by law or deemed useful by the department. The electronic code shall display each rule chapter currently in effect in browse mode and allow full text search of the code and each rule chapter. The department may contract with a publishing firm for a printed publication; however, the department shall retain responsibility for the code as provided in this section. The electronic publication shall be the official compilation of the administrative rules of this state. The Department of State shall retain the copyright over the Florida Administrative Code.

2.Rules general in form but applicable to only one school district, community college district, or county,

or a part thereof, or state university rules relating to internal personnel or business and finance shall not be published in the Florida Administrative Code. Exclusion from publication in the Florida Administrative Code shall not affect the validity or effectiveness of such rules.

3.At the beginning of the section of the code dealing with an agency that files copies of its rules with the department, the department shall publish the address and telephone number of the executive offices of each agency, the manner by which the agency indexes its rules, a listing of all rules of that agency excluded from publication in the code, and a statement as to where those rules may be inspected.

4.Forms shall not be published in the Florida Administrative Code; but any form which an agency uses in its dealings with the public, along with any accompanying instructions, shall be filed with the committee before it is used. Any form or instruction which meets the definition of "rule" provided in s. 120.52 shall be incorporated by reference into the appropriate rule. The reference shall specifically state that the form is being incorporated by reference and shall include the number, title, and effective date of the form and an explanation of how the form may be obtained. Each form created by an agency which is incorporated by reference in a rule notice of which is given under s. 120.54(3)(a) after December 31, 2007, must clearly display the number, title, and effective date of the form and the number of the rule in which the form is incorporated.

5.The department shall allow adopted rules and material incorporated by reference to be filed in electronic form as prescribed by department rule. When a rule is filed for adoption with incorporated material in electronic form, the department's publication of the Florida Administrative Code on its Internet website must contain a hyperlink from the incorporating reference in the rule directly to that material. The department may not allow hyperlinks from rules in the Florida Administrative Code to any material other than that filed with and maintained by the department, but may allow hyperlinks to incorporated material maintained by the department from the adopting agency's website or other sites.

(b)Electronically publish on an Internet website managed by the department a continuous revision and publication entitled the "Florida Administrative Register," which shall serve as the official publication and must contain:

1.All notices required by s. 120.54(3)(a), showing the text of all rules proposed for consideration.

2.All notices of public meetings, hearings, and workshops conducted in accordance with s. 120.525, including a statement of the manner in which a copy of the agenda may be obtained.

3.A notice of each request for authorization to amend or repeal an existing uniform rule or for the adoption of new uniform rules.

4.Notice of petitions for declaratory statements or administrative determinations.

5.A summary of each objection to any rule filed by the Administrative Procedures Committee.

6.Any other material required or authorized by law or deemed useful by the department.

The department may contract with a publishing firm for a printed publication of the Florida Administrative Register and make copies available on an annual subscription basis.

(c)Prescribe by rule the style and form required for rules, notices, and other materials submitted for filing.

(d)Charge each agency using the Florida Administrative Register a space rate to cover the costs related to the Florida Administrative Register and the Florida Administrative Code.

(e)Maintain a permanent record of all notices published in the Florida Administrative Register.

(2)The Florida Administrative Register Internet website must allow users to:

(a)Search for notices by type, publication date, rule number, word, subject, and agency.

(b)Search a database that makes available all notices published on the website for a period of at least 5 years.

(c)Subscribe to an automated e-mail notification of selected notices to be sent out before or concurrently with publication of the electronic Florida Administrative Register. Such notification must include in the text of the e-mail a summary of the content of each notice.

(d)View agency forms and other materials submitted to the department in electronic form and incorporated by reference in proposed rules.

(e)Comment on proposed rules.

(3)Publication of material required by paragraph (1)(b) on the Florida Administrative Register Internet website does not preclude publication of such material on an agency's website or by other means.

(4)Each agency shall provide copies of its rules upon request, with citations to the grant of rulemaking authority and the specific law implemented for each rule.

(5)Any publication of a proposed rule promulgated by an agency, whether published in the Florida Administrative Register or elsewhere, shall include, along with the rule, the name of the person or persons originating such rule, the name of the agency head who approved the rule, and the date upon which the rule was approved.

(6)Access to the Florida Administrative Register Internet website and its contents, including the e-mail notification service, shall be free for the public.

(7)(a)All fees and moneys collected by the Department of State under this chapter shall be deposited in the Records Management Trust Fund for the purpose of paying for costs incurred by the department in carrying out this chapter.

(b)The unencumbered balance in the Records Management Trust Fund for fees collected pursuant to this chapter may not exceed $300,000 at the beginning of each fiscal year, and any excess shall be transferred to the General Revenue Fund.

History.—s. 1, ch. 74-310; s. 1, ch. 75-107; s. 4, ch. 75-191; s. 5, ch. 76-131; s. 1, ch. 77-174; s. 4, ch. 77-453; s. 3, ch. 78-

425; s. 4, ch. 79-299; s. 7, ch. 80-391; s. 4, ch. 81-309; s. 1, ch. 82-19; s. 1, ch. 82-47; s. 3, ch. 83-351; s. 3, ch. 84-203; s. 17, ch. 87-224; s. 1, ch. 87-322; s. 20, ch. 91-45; s. 15, ch. 96-159; s. 896, ch. 2002-387; s. 5, ch. 2004-235; s. 14, ch. 2004-335; s. 4, ch. 2006-82; ss. 8, 9, ch. 2008-104; ss. 11, 12, ch. 2010-5; s. 2, ch. 2012-63.

120.555Summary removal of published rules no longer in force and effect.—When, as part of the continuous revision system authorized in s. 120.55(1)(a)1. or as otherwise provided by law, the Department of State is in doubt whether a rule published in the official version of the Florida Administrative Code is still in full force and effect, the procedure in this section shall be employed.

(1)The Department of State shall submit to the head of the agency with authority to repeal or amend the rule, if any, or if no such agency can be identified, to the Governor, a written request for a statement as to whether the rule is still in full force and effect. A copy of the request shall be promptly delivered to the committee and to the Attorney General. The Department of State shall publish a notice of the request together with a copy of the request in the Florida Administrative Weekly next available after delivery of the request to the head of the agency or the Governor.

(2)No later than 90 days after the date the notice required in subsection (1) is published, the agency or the Governor, notified pursuant to subsection (1), shall file a written response with the Department of State stating whether the rule is in full force and effect and under the jurisdiction of an agency with full authority to amend or repeal the rule. Failure to respond timely under this subsection constitutes an acknowledgment by the agency or the Governor that the rule is no longer in effect and is subject to summary repeal under this section.

(3)The Department of State shall publish a notice of the agency's or Governor's timely response or the acknowledgment determined under subsection (2) in the Florida Administrative Weekly next available after receipt of the response or the expiration of the response period, whichever occurs first.

(4)If the response states that the rule is no longer in effect, or if no response is filed timely with the Department of State, the notice required in subsection (3) shall also give notice of the following:

(a)Based on the agency's or Governor's written response or the acknowledgment determined under subsection (2), the rule will be repealed summarily pursuant to this section and removed from the Florida Administrative Code.

(b)Any objection to the summary repeal under this section must be filed as a petition challenging a proposed rule under s. 120.56 and must be filed no later than 21 days after the date the notice is published in the Florida Administrative Weekly.

(c)For purposes only of challenging a summary repeal under this section, the agency with current authority to repeal the rule under s. 120.54 shall be named as the respondent in the petition and shall be the proper party in interest. In such circumstances, the Department of State shall not be named as a party in a petition filed under paragraph (b) and this paragraph.

(d)If no agency currently has authority to repeal the rule under s. 120.54, the Department of State shall be named as the respondent in a petition filed under paragraph (b) and this paragraph. The Attorney General shall represent the Department of State in all proceedings under this paragraph.

(5)Upon the expiration of the 21-day period to file an objection to a notice of summary repeal published pursuant to subsection (4), if no timely objection is filed, or, if a timely objection is filed, on the date a decision finding the rule is no longer in effect becomes final, the Department of State shall update the Florida Administrative Code to remove the rule and shall provide historical notes identifying the manner in which the rule ceased to have effect, including the summary repeal pursuant to this section.

History.—s. 2, ch. 2012-31.

120.56Challenges to rules.—

(1)GENERAL PROCEDURES FOR CHALLENGING THE VALIDITY OF A RULE OR A PROPOSED RULE.—

(a)Any person substantially affected by a rule or a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority.

(b)The petition seeking an administrative determination must state with particularity the provisions alleged to be invalid with sufficient explanation of the facts or grounds for the alleged invalidity and facts sufficient to show that the person challenging a rule is substantially affected by it, or that the person challenging a proposed rule would be substantially affected by it.

(c)The petition shall be filed by electronic means with the division which shall, immediately upon filing, forward by electronic means copies to the agency whose rule is challenged, the Department of State, and the committee. Within 10 days after receiving the petition, the division director shall, if the petition complies with the requirements of paragraph (b), assign an administrative law judge who shall conduct a hearing within 30 days thereafter, unless the petition is withdrawn or a continuance is granted by agreement of the parties or for good cause shown. Evidence of good cause includes, but is not limited to, written notice of an agency's decision to modify or withdraw the proposed rule or a written notice from the chair of the committee stating that the committee will consider an objection to the rule at its next scheduled meeting. The failure of an agency to follow the applicable rulemaking procedures or requirements set forth in this chapter shall be presumed to be material; however, the agency may rebut this presumption by showing that the substantial interests of the petitioner and the fairness of the proceedings have not been impaired.

(d)Within 30 days after the hearing, the administrative law judge shall render a decision and state the reasons therefor in writing. The division shall forthwith transmit by electronic means copies of the administrative law judge's decision to the agency, the Department of State, and the committee.

(e)Hearings held under this section shall be de novo in nature. The standard of proof shall be the preponderance of the evidence. Hearings shall be conducted in the same manner as provided by ss. 120.569

and 120.57, except that the administrative law judge's order shall be final agency action. The petitioner and the agency whose rule is challenged shall be adverse parties. Other substantially affected persons may join the proceedings as intervenors on appropriate terms which shall not unduly delay the proceedings. Failure to proceed under this section shall not constitute failure to exhaust administrative remedies.

(2)CHALLENGING PROPOSED RULES; SPECIAL PROVISIONS.—

(a)A substantially affected person may seek an administrative determination of the invalidity of a proposed rule by filing a petition seeking such a determination with the division within 21 days after the date of publication of the notice required by s. 120.54(3)(a); within 10 days after the final public hearing is held on the proposed rule as provided by s. 120.54(3)(e)2.; within 20 days after the statement of estimated regulatory costs or revised statement of estimated regulatory costs, if applicable, has been prepared and made available as provided in s. 120.541(1)(d); or within 20 days after the date of publication of the notice required by s. 120.54(3)(d). The petition must state with particularity the objections to the proposed rule and the reasons that the proposed rule is an invalid exercise of delegated legislative authority. The petitioner has the burden of going forward. The agency then has the burden to prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority as to the objections raised. A person who is substantially affected by a change in the proposed rule may seek a determination of the validity of such change. A person who is not substantially affected by the proposed rule as initially noticed, but who is substantially affected by the rule as a result of a change, may challenge any provision of the rule and is not limited to challenging the change to the proposed rule.

(b)The administrative law judge may declare the proposed rule wholly or partly invalid. Unless the decision of the administrative law judge is reversed on appeal, the proposed rule or provision of a proposed rule declared invalid shall not be adopted. After a petition for administrative determination has been filed, the agency may proceed with all other steps in the rulemaking process, including the holding of a factfinding hearing. In the event part of a proposed rule is declared invalid, the adopting agency may, in its sole discretion, withdraw the proposed rule in its entirety. The agency whose proposed rule has been declared invalid in whole or part shall give notice of the decision in the first available issue of the Florida Administrative Weekly.

(c)When any substantially affected person seeks determination of the invalidity of a proposed rule pursuant to this section, the proposed rule is not presumed to be valid or invalid.

(3)CHALLENGING EXISTING RULES; SPECIAL PROVISIONS.—

(a)A substantially affected person may seek an administrative determination of the invalidity of an existing rule at any time during the existence of the rule. The petitioner has a burden of proving by a preponderance of the evidence that the existing rule is an invalid exercise of delegated legislative authority as to the objections raised.

(b)The administrative law judge may declare all or part of a rule invalid. The rule or part thereof declared invalid shall become void when the time for filing an appeal expires. The agency whose rule has been declared invalid in whole or part shall give notice of the decision in the Florida Administrative Weekly in the first available issue after the rule has become void.

(4)CHALLENGING AGENCY STATEMENTS DEFINED AS RULES; SPECIAL PROVISIONS.—

(a)Any person substantially affected by an agency statement may seek an administrative determination that the statement violates s. 120.54(1)(a). The petition shall include the text of the statement or a description of the statement and shall state with particularity facts sufficient to show that the statement constitutes a rule under s. 120.52 and that the agency has not adopted the statement by the rulemaking procedure provided by s. 120.54.

(b)The administrative law judge may extend the hearing date beyond 30 days after assignment of the case for good cause. Upon notification to the administrative law judge provided before the final hearing that the agency has published a notice of rulemaking under s. 120.54(3), such notice shall automatically operate as a stay of proceedings pending adoption of the statement as a rule. The administrative law judge may vacate the stay for good cause shown. A stay of proceedings pending rulemaking shall remain in effect so long as the agency is proceeding expeditiously and in good faith to adopt the statement as a rule. If a hearing is held and the petitioner proves the allegations of the petition, the agency shall have the burden of proving that rulemaking is not feasible or not practicable under s. 120.54(1)(a).

(c)The administrative law judge may determine whether all or part of a statement violates s. 120.54(1)(a). The decision of the administrative law judge shall constitute a final order. The division shall transmit a copy of the final order to the Department of State and the committee. The Department of State shall publish notice of the final order in the first available issue of the Florida Administrative Weekly.

(d)If an administrative law judge enters a final order that all or part of an agency statement violates s. 120.54(1)(a), the agency must immediately discontinue all reliance upon the statement or any substantially similar statement as a basis for agency action.

(e)If proposed rules addressing the challenged statement are determined to be an invalid exercise of delegated legislative authority as defined in s. 120.52(8)(b)-(f), the agency must immediately discontinue reliance on the statement and any substantially similar statement until rules addressing the subject are properly adopted, and the administrative law judge shall enter a final order to that effect.

(f)All proceedings to determine a violation of s. 120.54(1)(a) shall be brought pursuant to this subsection. A proceeding pursuant to this subsection may be consolidated with a proceeding under subsection (3) or under any other section of this chapter. This paragraph does not prevent a party whose substantial interests have been determined by an agency action from bringing a proceeding pursuant to s. 120.57(1)(e).

(5)CHALLENGING EMERGENCY RULES; SPECIAL PROVISIONS.—Challenges to the validity of an emergency

rule shall be subject to the following time schedules in lieu of those established by paragraphs (1)(c) and (d). Within 7 days after receiving the petition, the division director shall, if the petition complies with paragraph (1)(b), assign an administrative law judge, who shall conduct a hearing within 14 days, unless the petition is withdrawn. The administrative law judge shall render a decision within 14 days after the hearing.

History.—s. 1, ch. 74-310; s. 5, ch. 75-191; s. 6, ch. 76-131; s. 1, ch. 77-174; s. 4, ch. 78-425; s. 759, ch. 95-147; s. 16, ch. 96-159; s. 6, ch. 97-176; s. 5, ch. 99-379; s. 3, ch. 2003-94; s. 5, ch. 2006-82; ss. 10, 11, ch. 2008-104; ss. 3, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 10, ch. 2011-208; s. 3, ch. 2011-225.

120.565Declaratory statement by agencies.—

(1)Any substantially affected person may seek a declaratory statement regarding an agency's opinion as to the applicability of a statutory provision, or of any rule or order of the agency, as it applies to the petitioner's particular set of circumstances.

(2)The petition seeking a declaratory statement shall state with particularity the petitioner's set of circumstances and shall specify the statutory provision, rule, or order that the petitioner believes may apply to the set of circumstances.

(3)The agency shall give notice of the filing of each petition in the next available issue of the Florida Administrative Weekly and transmit copies of each petition to the committee. The agency shall issue a declaratory statement or deny the petition within 90 days after the filing of the petition. The declaratory statement or denial of the petition shall be noticed in the next available issue of the Florida Administrative Weekly. Agency disposition of petitions shall be final agency action.

History.—s. 6, ch. 75-191; s. 7, ch. 76-131; s. 5, ch. 78-425; s. 5, ch. 79-299; s. 760, ch. 95-147; s. 17, ch. 96-159.

120.569Decisions which affect substantial interests.—

(1)The provisions of this section apply in all proceedings in which the substantial interests of a party are determined by an agency, unless the parties are proceeding under s. 120.573 or s. 120.574. Unless waived by all parties, s. 120.57(1) applies whenever the proceeding involves a disputed issue of material fact. Unless otherwise agreed, s. 120.57(2) applies in all other cases. If a disputed issue of material fact arises during a proceeding under s. 120.57(2), then, unless waived by all parties, the proceeding under s. 120.57(2) shall be terminated and a proceeding under s. 120.57(1) shall be conducted. Parties shall be notified of any order, including a final order. Unless waived, a copy of the order shall be delivered or mailed to each party or the party's attorney of record at the address of record. Each notice shall inform the recipient of any administrative hearing or judicial review that is available under this section, s. 120.57, or s. 120.68; shall indicate the procedure which must be followed to obtain the hearing or judicial review; and shall state the time limits which apply.

(2)(a)Except for any proceeding conducted as prescribed in s. 120.56, a petition or request for a hearing

under this section shall be filed with the agency. If the agency requests an administrative law judge from the division, it shall so notify the division by electronic means through the division's website within 15 days after receipt of the petition or request. A request for a hearing shall be granted or denied within 15 days after receipt. On the request of any agency, the division shall assign an administrative law judge with due regard to the expertise required for the particular matter. The referring agency shall take no further action with respect to a proceeding under s. 120.57(1), except as a party litigant, as long as the division has jurisdiction over the proceeding under s. 120.57(1). Any party may request the disqualification of the administrative law judge by filing an affidavit with the division prior to the taking of evidence at a hearing, stating the grounds with particularity.

(b)All parties shall be afforded an opportunity for a hearing after reasonable notice of not less than 14 days; however, the 14-day notice requirement may be waived with the consent of all parties. The notice shall include:

1.A statement of the time, place, and nature of the hearing.

2.A statement of the legal authority and jurisdiction under which the hearing is to be held.

(c)Unless otherwise provided by law, a petition or request for hearing shall include those items required by the uniform rules adopted pursuant to s. 120.54(5)(b). Upon the receipt of a petition or request for hearing, the agency shall carefully review the petition to determine if it contains all of the required information. A petition shall be dismissed if it is not in substantial compliance with these requirements or it has been untimely filed. Dismissal of a petition shall, at least once, be without prejudice to petitioner's filing a timely amended petition curing the defect, unless it conclusively appears from the face of the petition that the defect cannot be cured. The agency shall promptly give written notice to all parties of the action taken on the petition, shall state with particularity its reasons if the petition is not granted, and shall state the deadline for filing an amended petition if applicable. This paragraph does not eliminate the availability of equitable tolling as a defense to the untimely filing of a petition.

(d)The agency may refer a petition to the division for the assignment of an administrative law judge only if the petition is in substantial compliance with the requirements of paragraph (c).

(e)All pleadings, motions, or other papers filed in the proceeding must be signed by the party, the party's attorney, or the party's qualified representative. The signature constitutes a certificate that the person has read the pleading, motion, or other paper and that, based upon reasonable inquiry, it is not interposed for any improper purposes, such as to harass or to cause unnecessary delay, or for frivolous purpose or needless increase in the cost of litigation. If a pleading, motion, or other paper is signed in violation of these requirements, the presiding officer shall impose upon the person who signed it, the represented party, or both, an appropriate sanction, which may include an order to pay the other party or parties the amount of reasonable expenses incurred because of the filing of the pleading, motion, or other paper, including a

reasonable attorney's fee.

(f)The presiding officer has the power to swear witnesses and take their testimony under oath, to issue subpoenas, and to effect discovery on the written request of any party by any means available to the courts and in the manner provided in the Florida Rules of Civil Procedure, including the imposition of sanctions, except contempt. However, no presiding officer has the authority to issue any subpoena or order directing discovery to any member or employee of the Legislature when the subpoena or order commands the production of documents or materials or compels testimony relating to the legislative duties of the member or employee. Any subpoena or order directing discovery directed to a member or an employee of the Legislature shall show on its face that the testimony sought does not relate to legislative duties.

(g)Irrelevant, immaterial, or unduly repetitious evidence shall be excluded, but all other evidence of a type commonly relied upon by reasonably prudent persons in the conduct of their affairs shall be admissible, whether or not such evidence would be admissible in a trial in the courts of Florida. Any part of the evidence may be received in written form, and all testimony of parties and witnesses shall be made under oath.

(h)Documentary evidence may be received in the form of a copy or excerpt. Upon request, parties shall be given an opportunity to compare the copy with the original, if available.

(i)When official recognition is requested, the parties shall be notified and given an opportunity to examine and contest the material.

(j)A party shall be permitted to conduct cross-examination when testimony is taken or documents are made a part of the record.

(k)1.Any person subject to a subpoena may, before compliance and on timely petition, request the presiding officer having jurisdiction of the dispute to invalidate the subpoena on the ground that it was not lawfully issued, is unreasonably broad in scope, or requires the production of irrelevant material.

2.A party may seek enforcement of a subpoena, order directing discovery, or order imposing sanctions issued under the authority of this chapter by filing a petition for enforcement in the circuit court of the judicial circuit in which the person failing to comply with the subpoena or order resides. A failure to comply with an order of the court shall result in a finding of contempt of court. However, no person shall be in contempt while a subpoena is being challenged under subparagraph 1. The court may award to the prevailing party all or part of the costs and attorney's fees incurred in obtaining the court order whenever the court determines that such an award should be granted under the Florida Rules of Civil Procedure.

3.Any public employee subpoenaed to appear at an agency proceeding shall be entitled to per diem and travel expenses at the same rate as that provided for state employees under s. 112.061 if travel away from such public employee's headquarters is required. All other witnesses appearing pursuant to a subpoena shall be paid such fees and mileage for their attendance as is provided in civil actions in circuit courts of this state. In the case of a public employee, such expenses shall be processed and paid in the manner provided for

agency employee travel expense reimbursement, and in the case of a witness who is not a public employee, payment of such fees and expenses shall accompany the subpoena.

(l)Unless the time period is waived or extended with the consent of all parties, the final order in a proceeding which affects substantial interests must be in writing and include findings of fact, if any, and conclusions of law separately stated, and it must be rendered within 90 days:

1.After the hearing is concluded, if conducted by the agency;

2.After a recommended order is submitted to the agency and mailed to all parties, if the hearing is conducted by an administrative law judge; or

3.After the agency has received the written and oral material it has authorized to be submitted, if there has been no hearing.

(m)Findings of fact, if set forth in a manner which is no more than mere tracking of the statutory language, must be accompanied by a concise and explicit statement of the underlying facts of record which support the findings.

(n)If an agency head finds that an immediate danger to the public health, safety, or welfare requires an immediate final order, it shall recite with particularity the facts underlying such finding in the final order, which shall be appealable or enjoinable from the date rendered.

(o)On the request of any party, the administrative law judge shall enter an initial scheduling order to facilitate the just, speedy, and inexpensive determination of the proceeding. The initial scheduling order shall establish a discovery period, including a deadline by which all discovery shall be completed, and the date by which the parties shall identify expert witnesses and their opinions. The initial scheduling order also may require the parties to meet and file a joint report by a date certain.

(p)For any proceeding arising under chapter 373, chapter 378, or chapter 403, if a nonapplicant petitions as a third party to challenge an agency's issuance of a license, permit, or conceptual approval, the order of presentation in the proceeding is for the permit applicant to present a prima facie case demonstrating entitlement to the license, permit, or conceptual approval, followed by the agency. This demonstration may be made by entering into evidence the application and relevant material submitted to the agency in support of the application, and the agency's staff report or notice of intent to approve the permit, license, or conceptual approval. Subsequent to the presentation of the applicant's prima facie case and any direct evidence submitted by the agency, the petitioner initiating the action challenging the issuance of the license, permit, or conceptual approval has the burden of ultimate persuasion and has the burden of going forward to prove the case in opposition to the license, permit, or conceptual approval through the presentation of competent and substantial evidence. The permit applicant and agency may on rebuttal present any evidence relevant to demonstrating that the application meets the conditions for issuance. Notwithstanding subsection (1), this paragraph applies to proceedings under s. 120.574.

History.—s. 18, ch. 96-159; s. 7, ch. 97-176; s. 4, ch. 98-200; s. 4, ch. 2003-94; s. 6, ch. 2006-82; s. 14, ch. 2008-104; s. 11, ch. 2011-208; s. 10, ch. 2011-225.

120.57Additional procedures for particular cases.—

(1)ADDITIONAL PROCEDURES APPLICABLE TO HEARINGS INVOLVING DISPUTED ISSUES OF MATERIAL FACT.—

(a)Except as provided in ss. 120.80 and 120.81, an administrative law judge assigned by the division shall conduct all hearings under this subsection, except for hearings before agency heads or a member thereof. If the administrative law judge assigned to a hearing becomes unavailable, the division shall assign another administrative law judge who shall use any existing record and receive any additional evidence or argument, if any, which the new administrative law judge finds necessary.

(b)All parties shall have an opportunity to respond, to present evidence and argument on all issues involved, to conduct cross-examination and submit rebuttal evidence, to submit proposed findings of facts and orders, to file exceptions to the presiding officer's recommended order, and to be represented by counsel or other qualified representative. When appropriate, the general public may be given an opportunity to present oral or written communications. If the agency proposes to consider such material, then all parties shall be given an opportunity to cross-examine or challenge or rebut the material.

(c)Hearsay evidence may be used for the purpose of supplementing or explaining other evidence, but it shall not be sufficient in itself to support a finding unless it would be admissible over objection in civil actions.

(d)Notwithstanding s. 120.569(2)(g), similar fact evidence of other violations, wrongs, or acts is admissible when relevant to prove a material fact in issue, such as proof of motive, opportunity, intent, preparation, plan, knowledge, identity, or absence of mistake or accident, but it is inadmissible when the evidence is relevant solely to prove bad character or propensity. When the state in an administrative proceeding intends to offer evidence of other acts or offenses under this paragraph, the state shall furnish to the party whose substantial interests are being determined and whose other acts or offenses will be the subject of such evidence, no fewer than 10 days before commencement of the proceeding, a written statement of the acts or offenses it intends to offer, describing them and the evidence the state intends to offer with particularity. Notice is not required for evidence of acts or offenses which is used for impeachment or on rebuttal.

(e)1.An agency or an administrative law judge may not base agency action that determines the substantial interests of a party on an unadopted rule. The administrative law judge shall determine whether an agency statement constitutes an unadopted rule. This subparagraph does not preclude application of adopted rules and applicable provisions of law to the facts.

2.Notwithstanding subparagraph 1., if an agency demonstrates that the statute being implemented directs it to adopt rules, that the agency has not had time to adopt those rules because the requirement was

so recently enacted, and that the agency has initiated rulemaking and is proceeding expeditiously and in good faith to adopt the required rules, then the agency's action may be based upon those unadopted rules, subject to de novo review by the administrative law judge. The agency action shall not be presumed valid or invalid. The agency must demonstrate that the unadopted rule:

a.Is within the powers, functions, and duties delegated by the Legislature or, if the agency is operating pursuant to authority derived from the State Constitution, is within that authority;

b.Does not enlarge, modify, or contravene the specific provisions of law implemented;

c.Is not vague, establishes adequate standards for agency decisions, or does not vest unbridled discretion in the agency;

d.Is not arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational;

e.Is not being applied to the substantially affected party without due notice; and

f.Does not impose excessive regulatory costs on the regulated person, county, or city.

3.The recommended and final orders in any proceeding shall be governed by the provisions of paragraphs (k) and (l), except that the administrative law judge's determination regarding an unadopted rule under subparagraph 1. or subparagraph 2. shall not be rejected by the agency unless the agency first determines from a review of the complete record, and states with particularity in the order, that such determination is clearly erroneous or does not comply with essential requirements of law. In any proceeding for review under s. 120.68, if the court finds that the agency's rejection of the determination regarding the unadopted rule does not comport with the provisions of this subparagraph, the agency action shall be set aside and the court shall award to the prevailing party the reasonable costs and a reasonable attorney's fee for the initial proceeding and the proceeding for review.

(f)The record in a case governed by this subsection shall consist only of:

1.All notices, pleadings, motions, and intermediate rulings.

2.Evidence admitted.

3.Those matters officially recognized.

4.Proffers of proof and objections and rulings thereon.

5.Proposed findings and exceptions.

6.Any decision, opinion, order, or report by the presiding officer.

7.All staff memoranda or data submitted to the presiding officer during the hearing or prior to its disposition, after notice of the submission to all parties, except communications by advisory staff as permitted under s. 120.66(1), if such communications are public records.

8.All matters placed on the record after an ex parte communication.

9.The official transcript.

(g)The agency shall accurately and completely preserve all testimony in the proceeding, and, on the request of any party, it shall make a full or partial transcript available at no more than actual cost.

(h)Any party to a proceeding in which an administrative law judge of the Division of Administrative Hearings has final order authority may move for a summary final order when there is no genuine issue as to any material fact. A summary final order shall be rendered if the administrative law judge determines from the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, that no genuine issue as to any material fact exists and that the moving party is entitled as a matter of law to the entry of a final order. A summary final order shall consist of findings of fact, if any, conclusions of law, a disposition or penalty, if applicable, and any other information required by law to be contained in the final order.

(i)When, in any proceeding conducted pursuant to this subsection, a dispute of material fact no longer exists, any party may move the administrative law judge to relinquish jurisdiction to the agency. An order relinquishing jurisdiction shall be rendered if the administrative law judge determines from the pleadings, depositions, answers to interrogatories, and admissions on file, together with supporting and opposing affidavits, if any, that no genuine issue as to any material fact exists. If the administrative law judge enters an order relinquishing jurisdiction, the agency may promptly conduct a proceeding pursuant to subsection (2), if appropriate, but the parties may not raise any issues of disputed fact that could have been raised before the administrative law judge. An order entered by an administrative law judge relinquishing jurisdiction to the agency based upon a determination that no genuine dispute of material fact exists, need not contain findings of fact, conclusions of law, or a recommended disposition or penalty.

(j)Findings of fact shall be based upon a preponderance of the evidence, except in penal or licensure disciplinary proceedings or except as otherwise provided by statute, and shall be based exclusively on the evidence of record and on matters officially recognized.

(k)The presiding officer shall complete and submit to the agency and all parties a recommended order consisting of findings of fact, conclusions of law, and recommended disposition or penalty, if applicable, and any other information required by law to be contained in the final order. All proceedings conducted under this subsection shall be de novo. The agency shall allow each party 15 days in which to submit written exceptions to the recommended order. The final order shall include an explicit ruling on each exception, but an agency need not rule on an exception that does not clearly identify the disputed portion of the recommended order by page number or paragraph, that does not identify the legal basis for the exception, or that does not include appropriate and specific citations to the record.

(l)The agency may adopt the recommended order as the final order of the agency. The agency in its final order may reject or modify the conclusions of law over which it has substantive jurisdiction and interpretation of administrative rules over which it has substantive jurisdiction. When rejecting or modifying such conclusion

of law or interpretation of administrative rule, the agency must state with particularity its reasons for rejecting or modifying such conclusion of law or interpretation of administrative rule and must make a finding that its substituted conclusion of law or interpretation of administrative rule is as or more reasonable than that which was rejected or modified. Rejection or modification of conclusions of law may not form the basis for rejection or modification of findings of fact. The agency may not reject or modify the findings of fact unless the agency first determines from a review of the entire record, and states with particularity in the order, that the findings of fact were not based upon competent substantial evidence or that the proceedings on which the findings were based did not comply with essential requirements of law. The agency may accept the recommended penalty in a recommended order, but may not reduce or increase it without a review of the complete record and without stating with particularity its reasons therefor in the order, by citing to the record in justifying the action.

(m)If a recommended order is submitted to an agency, the agency shall provide a copy of its final order and any exceptions to the division within 15 days after the order is filed with the agency clerk.

(n)Notwithstanding any law to the contrary, when statutes or rules impose conflicting time requirements for the scheduling of expedited hearings or issuance of recommended or final orders, the director of the division shall have the authority to set the proceedings for the orderly operation of this chapter.

(2)ADDITIONAL PROCEDURES APPLICABLE TO HEARINGS NOT INVOLVING DISPUTED ISSUES OF MATERIAL FACT.—In any case to which subsection (1) does not apply:

(a)The agency shall:

1.Give reasonable notice to affected persons of the action of the agency, whether proposed or already taken, or of its decision to refuse action, together with a summary of the factual, legal, and policy grounds therefor.

2.Give parties or their counsel the option, at a convenient time and place, to present to the agency or hearing officer written or oral evidence in opposition to the action of the agency or to its refusal to act, or a written statement challenging the grounds upon which the agency has chosen to justify its action or inaction.

3.If the objections of the parties are overruled, provide a written explanation within 7 days.

(b)The record shall only consist of:

1.The notice and summary of grounds.

2.Evidence received.

3.All written statements submitted.

4.Any decision overruling objections.

5.All matters placed on the record after an ex parte communication.

6.The official transcript.

7.Any decision, opinion, order, or report by the presiding officer.

(3)ADDITIONAL PROCEDURES APPLICABLE TO PROTESTS TO CONTRACT SOLICITATION OR AWARD.—Agencies subject to this chapter shall use the uniform rules of procedure, which provide procedures for the resolution of protests arising from the contract solicitation or award process. Such rules shall at least provide that:

(a)The agency shall provide notice of a decision or intended decision concerning a solicitation, contract award, or exceptional purchase by electronic posting. This notice shall contain the following statement: "Failure to file a protest within the time prescribed in section 120.57(3), Florida Statutes, or failure to post the bond or other security required by law within the time allowed for filing a bond shall constitute a waiver of proceedings under chapter 120, Florida Statutes."

(b)Any person who is adversely affected by the agency decision or intended decision shall file with the agency a notice of protest in writing within 72 hours after the posting of the notice of decision or intended decision. With respect to a protest of the terms, conditions, and specifications contained in a solicitation, including any provisions governing the methods for ranking bids, proposals, or replies, awarding contracts, reserving rights of further negotiation, or modifying or amending any contract, the notice of protest shall be filed in writing within 72 hours after the posting of the solicitation. The formal written protest shall be filed within 10 days after the date the notice of protest is filed. Failure to file a notice of protest or failure to file a formal written protest shall constitute a waiver of proceedings under this chapter. The formal written protest shall state with particularity the facts and law upon which the protest is based. Saturdays, Sundays, and state holidays shall be excluded in the computation of the 72-hour time periods provided by this paragraph.

(c)Upon receipt of the formal written protest that has been timely filed, the agency shall stop the solicitation or contract award process until the subject of the protest is resolved by final agency action, unless the agency head sets forth in writing particular facts and circumstances which require the continuance of the solicitation or contract award process without delay in order to avoid an immediate and serious danger to the public health, safety, or welfare.

(d)1.The agency shall provide an opportunity to resolve the protest by mutual agreement between the parties within 7 days, excluding Saturdays, Sundays, and state holidays, after receipt of a formal written protest.

2.If the subject of a protest is not resolved by mutual agreement within 7 days, excluding Saturdays, Sundays, and state holidays, after receipt of the formal written protest, and if there is no disputed issue of material fact, an informal proceeding shall be conducted pursuant to subsection (2) and applicable agency rules before a person whose qualifications have been prescribed by rules of the agency.

3.If the subject of a protest is not resolved by mutual agreement within 7 days, excluding Saturdays, Sundays, and state holidays, after receipt of the formal written protest, and if there is a disputed issue of material fact, the agency shall refer the protest to the division by electronic means through the division's

website for proceedings under subsection (1).

(e)Upon receipt of a formal written protest referred pursuant to this subsection, the director of the division shall expedite the hearing and assign an administrative law judge who shall commence a hearing within 30 days after the receipt of the formal written protest by the division and enter a recommended order within 30 days after the hearing or within 30 days after receipt of the hearing transcript by the administrative law judge, whichever is later. Each party shall be allowed 10 days in which to submit written exceptions to the recommended order. A final order shall be entered by the agency within 30 days of the entry of a recommended order. The provisions of this paragraph may be waived upon stipulation by all parties.

(f)In a protest to an invitation to bid or request for proposals procurement, no submissions made after the bid or proposal opening which amend or supplement the bid or proposal shall be considered. In a protest to an invitation to negotiate procurement, no submissions made after the agency announces its intent to award a contract, reject all replies, or withdraw the solicitation which amend or supplement the reply shall be considered. Unless otherwise provided by statute, the burden of proof shall rest with the party protesting the proposed agency action. In a competitive-procurement protest, other than a rejection of all bids, proposals, or replies, the administrative law judge shall conduct a de novo proceeding to determine whether the agency's proposed action is contrary to the agency's governing statutes, the agency's rules or policies, or the solicitation specifications. The standard of proof for such proceedings shall be whether the proposed agency action was clearly erroneous, contrary to competition, arbitrary, or capricious. In any bid-protest proceeding contesting an intended agency action to reject all bids, proposals, or replies, the standard of review by an administrative law judge shall be whether the agency's intended action is illegal, arbitrary, dishonest, or fraudulent.

(g)For purposes of this subsection, the definitions in s. 287.012 apply.

(4)INFORMAL DISPOSITION.—Unless precluded by law, informal disposition may be made of any proceeding by stipulation, agreed settlement, or consent order.

(5)APPLICABILITY.—This section does not apply to agency investigations preliminary to agency action.

History.—s. 1, ch. 74-310; s. 7, ch. 75-191; s. 8, ch. 76-131; s. 1, ch. 77-174; s. 5, ch. 77-453; ss. 6, 11, ch. 78-95; s. 6, ch. 78-425; s. 8, ch. 79-7; s. 7, ch. 80-95; s. 4, ch. 80-289; s. 57, ch. 81-259; s. 2, ch. 83-78; s. 9, ch. 83-216; s. 2, ch. 84-173; s. 4, ch. 84-203; ss. 1, 2, ch. 86-108; s. 44, ch. 87-6; ss. 1, 2, ch. 87-54; s. 5, ch. 87-385; s. 1, ch. 90-283; s. 4, ch. 91-30; s. 1, ch. 91-191; s. 22, ch. 92-315; s. 7, ch. 94-218; s. 1420, ch. 95-147; s. 1, ch. 95-328; s. 19, ch. 96-159; s. 1, ch. 96-423; s. 8, ch. 97-176; s. 5, ch. 98-200; s. 3, ch. 98-279; s. 47, ch. 99-2; s. 6, ch. 99-379; s. 2, ch. 2002-207; s. 5, ch. 2003-94; s. 7, ch. 2006-82; s. 12, ch. 2008-104; s. 12, ch. 2011-208.

120.573Mediation of disputes.—Each announcement of an agency action that affects substantial interests shall advise whether mediation of the administrative dispute for the type of agency action announced is available and that choosing mediation does not affect the right to an administrative hearing. If

the agency and all parties to the administrative action agree to mediation, in writing, within 10 days after the time period stated in the announcement for election of an administrative remedy under ss. 120.569 and 120.57, the time limitations imposed by ss. 120.569 and 120.57 shall be tolled to allow the agency and parties to mediate the administrative dispute. The mediation shall be concluded within 60 days of such agreement unless otherwise agreed by the parties. The mediation agreement shall include provisions for mediator selection, the allocation of costs and fees associated with mediation, and the mediating parties' understanding regarding the confidentiality of discussions and documents introduced during mediation. If mediation results in settlement of the administrative dispute, the agency shall enter a final order incorporating the agreement of the parties. If mediation terminates without settlement of the dispute, the agency shall notify the parties in writing that the administrative hearing processes under ss. 120.569 and 120.57 are resumed.

History.—s. 20, ch. 96-159; s. 9, ch. 97-176.

120.574Summary hearing.—

(1)(a)Within 5 business days following the division's receipt of a petition or request for hearing, the division shall issue and serve on all original parties an initial order that assigns the case to a specific administrative law judge and provides general information regarding practice and procedure before the division. The initial order shall also contain a statement advising the addressees that a summary hearing is available upon the agreement of all parties under subsection (2) and briefly describing the expedited time sequences, limited discovery, and final order provisions of the summary procedure.

(b)Within 15 days after service of the initial order, any party may file with the division a motion for summary hearing in accordance with subsection (2). If all original parties agree, in writing, to the summary proceeding, the proceeding shall be conducted within 30 days of the agreement, in accordance with the provisions of subsection (2).

(c)Intervenors in the proceeding shall be governed by the decision of the original parties regarding whether the case will proceed in accordance with the summary hearing process and shall not have standing to challenge that decision.

(d)If a motion for summary hearing is not filed within 15 days after service of the division's initial order, the matter shall proceed in accordance with ss. 120.569 and 120.57.

(2)In any case to which this subsection is applicable, the following procedures apply:

(a)Motions shall be limited to the following:

1.A motion in opposition to the petition.

2.A motion requesting discovery beyond the informal exchange of documents and witness lists described in paragraph (b). Upon a showing of necessity, additional discovery may be permitted in the discretion of the administrative law judge, but only if it can be completed not later than 5 days prior to the final hearing.

3.A motion for continuance of the final hearing date.

4.A motion requesting a prehearing conference, or the administrative law judge may require a prehearing conference, for the purpose of identifying: the legal and factual issues to be considered at the final hearing; the names and addresses of witnesses who may be called to testify at the final hearing; documentary evidence that will be offered at the final hearing; the range of penalties that may be imposed upon final hearing; and any other matter that the administrative law judge determines would expedite resolution of the proceeding. The prehearing conference may be held by telephone conference call.

5.During or after any preliminary hearing or conference, any party or the administrative law judge may suggest that the case is no longer appropriate for summary disposition. Following any argument requested by the parties, the administrative law judge may enter an order referring the case back to the formal adjudicatory process described in s. 120.57(1), in which event the parties shall proceed accordingly.

(b)Not later than 5 days prior to the final hearing, the parties shall furnish to each other copies of documentary evidence and lists of witnesses who may testify at the final hearing.

(c)All parties shall have an opportunity to respond, to present evidence and argument on all issues involved, to conduct cross-examination and submit rebuttal evidence, and to be represented by counsel or other qualified representative.

(d)The record in a case governed by this subsection shall consist only of:

1.All notices, pleadings, motions, and intermediate rulings.

2.Evidence received.

3.A statement of matters officially recognized.

4.Proffers of proof and objections and rulings thereon.

5.Matters placed on the record after an ex parte communication.

6.The written decision of the administrative law judge presiding at the final hearing.

7.The official transcript of the final hearing.

(e)The agency shall accurately and completely preserve all testimony in the proceeding and, upon request by any party, shall make a full or partial transcript available at no more than actual cost.

(f)The decision of the administrative law judge shall be rendered within 30 days after the conclusion of the final hearing or the filing of the transcript thereof, whichever is later. The administrative law judge's decision, which shall be final agency action subject to judicial review under s. 120.68, shall include the following:

1.Findings of fact based exclusively on the evidence of record and matters officially recognized.

2.Conclusions of law.

3.Imposition of a fine or penalty, if applicable.

4.Any other information required by law or rule to be contained in a final order.

History.—s. 21, ch. 96-159; s. 10, ch. 97-176; s. 11, ch. 2000-158; s. 10, ch. 2000-336.

120.595Attorney's fees.—

(1)CHALLENGES TO AGENCY ACTION PURSUANT TO SECTION 120.57(1).—

(a)The provisions of this subsection are supplemental to, and do not abrogate, other provisions allowing the award of fees or costs in administrative proceedings.

(b)The final order in a proceeding pursuant to s. 120.57(1) shall award reasonable costs and a reasonable attorney's fee to the prevailing party only where the nonprevailing adverse party has been determined by the administrative law judge to have participated in the proceeding for an improper purpose.

(c)In proceedings pursuant to s. 120.57(1), and upon motion, the administrative law judge shall determine whether any party participated in the proceeding for an improper purpose as defined by this subsection. In making such determination, the administrative law judge shall consider whether the nonprevailing adverse party has participated in two or more other such proceedings involving the same prevailing party and the same project as an adverse party and in which such two or more proceedings the nonprevailing adverse party did not establish either the factual or legal merits of its position, and shall consider whether the factual or legal position asserted in the instant proceeding would have been cognizable in the previous proceedings. In such event, it shall be rebuttably presumed that the nonprevailing adverse party participated in the pending proceeding for an improper purpose.

(d)In any proceeding in which the administrative law judge determines that a party participated in the proceeding for an improper purpose, the recommended order shall so designate and shall determine the award of costs and attorney's fees.

(e)For the purpose of this subsection:

1."Improper purpose" means participation in a proceeding pursuant to s. 120.57(1) primarily to harass or to cause unnecessary delay or for frivolous purpose or to needlessly increase the cost of litigation, licensing, or securing the approval of an activity.

2."Costs" has the same meaning as the costs allowed in civil actions in this state as provided in chapter 57.

3."Nonprevailing adverse party" means a party that has failed to have substantially changed the outcome of the proposed or final agency action which is the subject of a proceeding. In the event that a proceeding results in any substantial modification or condition intended to resolve the matters raised in a party's petition, it shall be determined that the party having raised the issue addressed is not a nonprevailing adverse party. The recommended order shall state whether the change is substantial for purposes of this subsection. In no event shall the term "nonprevailing party" or "prevailing party" be deemed to include any party that has intervened in a previously existing proceeding to support the position of an agency.

(2)CHALLENGES TO PROPOSED AGENCY RULES PURSUANT TO SECTION 120.56(2).—If the appellate court or

administrative law judge declares a proposed rule or portion of a proposed rule invalid pursuant to s. 120.56(2), a judgment or order shall be rendered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that its actions were substantially justified or special circumstances exist which would make the award unjust. An agency's actions are "substantially justified" if there was a reasonable basis in law and fact at the time the actions were taken by the agency. If the agency prevails in the proceedings, the appellate court or administrative law judge shall award reasonable costs and reasonable attorney's fees against a party if the appellate court or administrative law judge determines that a party participated in the proceedings for an improper purpose as defined by paragraph (1)(e). No award of attorney's fees as provided by this subsection shall exceed $50,000.

(3)CHALLENGES TO EXISTING AGENCY RULES PURSUANT TO SECTION 120.56(3) AND (5).—If the appellate court or administrative law judge declares a rule or portion of a rule invalid pursuant to s. 120.56(3) or (5), a judgment or order shall be rendered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that its actions were substantially justified or special circumstances exist which would make the award unjust. An agency's actions are "substantially justified" if there was a reasonable basis in law and fact at the time the actions were taken by the agency. If the agency prevails in the proceedings, the appellate court or administrative law judge shall award reasonable costs and reasonable attorney's fees against a party if the appellate court or administrative law judge determines that a party participated in the proceedings for an improper purpose as defined by paragraph (1)(e). No award of attorney's fees as provided by this subsection shall exceed $50,000.

(4)CHALLENGES TO AGENCY ACTION PURSUANT TO SECTION 120.56(4).—

(a)If the appellate court or administrative law judge determines that all or part of an agency statement violates s. 120.54(1)(a), or that the agency must immediately discontinue reliance on the statement and any substantially similar statement pursuant to s. 120.56(4)(e), a judgment or order shall be entered against the agency for reasonable costs and reasonable attorney's fees, unless the agency demonstrates that the statement is required by the Federal Government to implement or retain a delegated or approved program or to meet a condition to receipt of federal funds.

(b)Upon notification to the administrative law judge provided before the final hearing that the agency has published a notice of rulemaking under s. 120.54(3)(a), such notice shall automatically operate as a stay of proceedings pending rulemaking. The administrative law judge may vacate the stay for good cause shown. A stay of proceedings under this paragraph remains in effect so long as the agency is proceeding expeditiously and in good faith to adopt the statement as a rule. The administrative law judge shall award reasonable costs and reasonable attorney's fees accrued by the petitioner prior to the date the notice was published, unless the agency proves to the administrative law judge that it did not know and should not have known that the statement was an unadopted rule. Attorneys' fees and costs under this paragraph and paragraph (a) shall be

awarded only upon a finding that the agency received notice that the statement may constitute an unadopted rule at least 30 days before a petition under s. 120.56(4) was filed and that the agency failed to publish the required notice of rulemaking pursuant to s. 120.54(3) that addresses the statement within that 30-day period. Notice to the agency may be satisfied by its receipt of a copy of the s. 120.56(4) petition, a notice or other paper containing substantially the same information, or a petition filed pursuant to s. 120.54(7). An award of attorney's fees as provided by this paragraph may not exceed $50,000.

(c)Notwithstanding the provisions of chapter 284, an award shall be paid from the budget entity of the secretary, executive director, or equivalent administrative officer of the agency, and the agency shall not be entitled to payment of an award or reimbursement for payment of an award under any provision of law.

(d)If the agency prevails in the proceedings, the appellate court or administrative law judge shall award reasonable costs and attorney's fees against a party if the appellate court or administrative law judge determines that the party participated in the proceedings for an improper purpose as defined in paragraph (1)(e) or that the party or the party's attorney knew or should have known that a claim was not supported by the material facts necessary to establish the claim or would not be supported by the application of then-existing law to those material facts.

(5)APPEALS.—When there is an appeal, the court in its discretion may award reasonable attorney's fees and reasonable costs to the prevailing party if the court finds that the appeal was frivolous, meritless, or an abuse of the appellate process, or that the agency action which precipitated the appeal was a gross abuse of the agency's discretion. Upon review of agency action that precipitates an appeal, if the court finds that the agency improperly rejected or modified findings of fact in a recommended order, the court shall award reasonable attorney's fees and reasonable costs to a prevailing appellant for the administrative proceeding and the appellate proceeding.

(6)OTHER SECTIONS NOT AFFECTED.—Other provisions, including ss. 57.105 and 57.111, authorize the award of attorney's fees and costs in administrative proceedings. Nothing in this section shall affect the availability of attorney's fees and costs as provided in those sections.

History.—s. 25, ch. 96-159; s. 11, ch. 97-176; s. 48, ch. 99-2; s. 6, ch. 2003-94; s. 13, ch. 2008-104.

120.60Licensing.—

(1)Upon receipt of a license application, an agency shall examine the application and, within 30 days after such receipt, notify the applicant of any apparent errors or omissions and request any additional information the agency is permitted by law to require. An agency may not deny a license for failure to correct an error or omission or to supply additional information unless the agency timely notified the applicant within this 30-day period. The agency may establish by rule the time period for submitting any additional information requested by the agency. For good cause shown, the agency shall grant a request for an extension of time for submitting the additional information. If the applicant believes the agency's request for additional

information is not authorized by law or rule, the agency, at the applicant's request, shall proceed to process the application. An application is complete upon receipt of all requested information and correction of any error or omission for which the applicant was timely notified or when the time for such notification has expired. An application for a license must be approved or denied within 90 days after receipt of a completed application unless a shorter period of time for agency action is provided by law. The 90-day time period is tolled by the initiation of a proceeding under ss. 120.569 and 120.57. Any application for a license which is not approved or denied within the 90-day or shorter time period, within 15 days after conclusion of a public hearing held on the application, or within 45 days after a recommended order is submitted to the agency and the parties, whichever action and timeframe is latest and applicable, is considered approved unless the recommended order recommends that the agency deny the license. Subject to the satisfactory completion of an examination if required as a prerequisite to licensure, any license that is considered approved shall be issued and may include such reasonable conditions as are authorized by law. Any applicant for licensure seeking to claim licensure by default under this subsection shall notify the agency clerk of the licensing agency, in writing, of the intent to rely upon the default license provision of this subsection, and may not take any action based upon the default license until after receipt of such notice by the agency clerk.

(2)If an applicant seeks a license for an activity that is exempt from licensure, the agency shall notify the applicant and return any tendered application fee within 30 days after receipt of the original application.

(3)Each applicant shall be given written notice, personally or by mail, that the agency intends to grant or deny, or has granted or denied, the application for license. The notice must state with particularity the grounds or basis for the issuance or denial of the license, except when issuance is a ministerial act. Unless waived, a copy of the notice shall be delivered or mailed to each party's attorney of record and to each person who has made a written request for notice of agency action. Each notice must inform the recipient of the basis for the agency decision, inform the recipient of any administrative hearing pursuant to ss. 120.569 and 120.57 or judicial review pursuant to s. 120.68 which may be available, indicate the procedure that must be followed, and state the applicable time limits. The issuing agency shall certify the date the notice was mailed or delivered, and the notice and the certification must be filed with the agency clerk.

(4)When a licensee has made timely and sufficient application for the renewal of a license which does not automatically expire by statute, the existing license shall not expire until the application for renewal has been finally acted upon by the agency or, in case the application is denied or the terms of the license are limited, until the last day for seeking review of the agency order or a later date fixed by order of the reviewing court.

[1] (5)No revocation, suspension, annulment, or withdrawal of any license is lawful unless, prior to the entry of a final order, the agency has served, by personal service or certified mail, an administrative complaint which affords reasonable notice to the licensee of facts or conduct which warrant the intended action and

unless the licensee has been given an adequate opportunity to request a proceeding pursuant to ss. 120.569 and 120.57. When personal service cannot be made and the certified mail notice is returned undelivered, the agency shall cause a short, plain notice to the licensee to be published once each week for 4 consecutive weeks in a newspaper published in the county of the licensee's last known address as it appears on the records of the agency. If no newspaper is published in that county, the notice may be published in a newspaper of general circulation in that county.

(6)If the agency finds that immediate serious danger to the public health, safety, or welfare requires emergency suspension, restriction, or limitation of a license, the agency may take such action by any procedure that is fair under the circumstances if:

(a)The procedure provides at least the same procedural protection as is given by other statutes, the State Constitution, or the United States Constitution;

(b)The agency takes only that action necessary to protect the public interest under the emergency procedure; and

(c)The agency states in writing at the time of, or prior to, its action the specific facts and reasons for finding an immediate danger to the public health, safety, or welfare and its reasons for concluding that the procedure used is fair under the circumstances. The agency's findings of immediate danger, necessity, and procedural fairness are judicially reviewable. Summary suspension, restriction, or limitation may be ordered, but a suspension or revocation proceeding pursuant to ss. 120.569 and 120.57 shall also be promptly instituted and acted upon.

(7)No agency shall include as a condition of approval of any license any provision that is based upon a statement, policy, or guideline of another agency unless the statement, policy, or guideline is within the jurisdiction of the other agency. The other agency shall identify for the licensing agency the specific legal authority for each such statement, policy, or guideline. The licensing agency must provide the licensee with an opportunity to challenge the condition as invalid. If the licensing agency bases a condition of approval or denial of the license upon the statement, policy, or guideline of the other agency, any party to an administrative proceeding that arises from the approval with conditions or denial of the license may require the other agency to join as a party in determining the validity of the condition.

History.—s. 1, ch. 74-310; s. 10, ch. 76-131; s. 1, ch. 77-174; ss. 6, 9, ch. 77-453; s. 57, ch. 78-95; s. 8, ch. 78-425; s. 1, ch. 79-142; s. 6, ch. 79-299; s. 2, ch. 81-180; s. 6, ch. 84-203; s. 2, ch. 84-265; s. 1, ch. 85-82; s. 14, ch. 90-51; s. 762, ch. 95-147; s. 26, ch. 96-159; s. 326, ch. 96-410; s. 12, ch. 97-176; s. 7, ch. 2003-94; ss. 4, 5, ch. 2010-279; HJR 9-A, 2010 Special Session A; s. 10, ch. 2012-212.

[1]**Note.**—Section 21, ch. 2012-212, provides that "[e]xcept as otherwise expressly provided in this act, this act shall take effect July 1, 2012, and shall apply to legal notices that must be published on or after that date."

120.62Agency investigations.—

(1)Every person who responds to a request or demand by any agency or representative thereof for written data or an oral statement shall be entitled to a transcript or recording of his or her oral statement at no more than cost.

(2)Any person compelled to appear, or who appears voluntarily, before any presiding officer or agency in an investigation or in any agency proceeding has the right, at his or her own expense, to be accompanied, represented, and advised by counsel or by other qualified representatives.

History.—s. 1, ch. 74-310; s. 763, ch. 95-147; s. 28, ch. 96-159.

120.63Exemption from act.—

(1)Upon application of any agency, the Administration Commission may exempt any process or proceeding governed by this act from one or more requirements of this act:

(a)When the agency head has certified that the requirement would conflict with any provision of federal law or rules with which the agency must comply;

(b)In order to permit persons in the state to receive tax benefits or federal funds under any federal law; or

(c)When the commission has found that conformity with the requirements of the part or parts of this act for which exemption is sought would be so inconvenient or impractical as to defeat the purpose of the agency proceeding involved or the purpose of this act and would not be in the public interest in light of the nature of the intended action and the enabling act or other laws affecting the agency.

(2)The commission may not exempt an agency from any requirement of this act pursuant to this section until it establishes alternative procedures to achieve the agency's purpose which shall be consistent, insofar as possible, with the intent and purpose of the act.

(a)Prior to the granting of any exemption authorized by this section, the commission shall hold a public hearing after notice given as provided in s. 120.525. Upon the conclusion of the hearing, the commission, through the Executive Office of the Governor, shall issue an order specifically granting or denying the exemption and specifying any processes or proceedings exempted and the extent of the exemption; transmit to the committee and to the Department of State a copy of the petition, a certified copy of the order granting or denying the petition, and a copy of any alternative procedures prescribed; and give notice of the petition and the commission's response in the Florida Administrative Weekly.

(b)An exemption and any alternative procedure prescribed shall terminate 90 days following adjournment sine die of the then-current or next regular legislative session after issuance of the exemption order, or upon the effective date of any subsequent legislation incorporating the exemption or any partial exemption related thereto, whichever is earlier. The exemption granted by the commission shall be renewable upon the same or

similar facts not more than once. Such renewal shall terminate as would an original exemption.

History.—s. 1, ch. 74-310; s. 11, ch. 76-131; s. 1, ch. 77-53; s. 8, ch. 77-453; s. 87, ch. 79-190; s. 7, ch. 79-299; s. 70, ch. 79-400; s. 58, ch. 81-259; s. 29, ch. 96-159.

120.65Administrative law judges.—

(1)The Division of Administrative Hearings within the Department of Management Services shall be headed by a director who shall be appointed by the Administration Commission and confirmed by the Senate. The director, who shall also serve as the chief administrative law judge, and any deputy chief administrative law judge must possess the same minimum qualifications as the administrative law judges employed by the division. The Deputy Chief Judge of Compensation Claims must possess the minimum qualifications established in s. 440.45(2) and shall report to the director. The division shall be a separate budget entity, and the director shall be its agency head for all purposes. The Department of Management Services shall provide administrative support and service to the division to the extent requested by the director. The division shall not be subject to control, supervision, or direction by the Department of Management Services in any manner, including, but not limited to, personnel, purchasing, transactions involving real or personal property, and budgetary matters.

(2)The director has the right to appeal actions by the Executive Office of the Governor that affect amendments to the division's approved operating budget or any personnel actions pursuant to chapter 216 to the Administration Commission, which shall decide such issue by majority vote. The appropriations committees may advise the Administration Commission on the issue. If the President of the Senate and the Speaker of the House of Representatives object in writing to the effects of the appeal, the appeal may be affirmed by the affirmative vote of two-thirds of the commission members present.

(3)Each state agency as defined in chapter 216 and each political subdivision shall make its facilities available, at a time convenient to the provider, for use by the division in conducting proceedings pursuant to this chapter.

(4)The division shall employ administrative law judges to conduct hearings required by this chapter or other law. Any person employed by the division as an administrative law judge must have been a member of The Florida Bar in good standing for the preceding 5 years.

(5)If the division cannot furnish a division administrative law judge promptly in response to an agency request, the director shall designate in writing a qualified full-time employee of an agency other than the requesting agency to conduct the hearing. The director shall have the discretion to designate such a hearing officer who is located in that part of the state where the parties and witnesses reside.

(6)By rule, the division may establish:

(a)Further qualifications for administrative law judges and shall establish procedures by which candidates will be considered for employment or contract.

(b)The manner in which public notice will be given of vacancies in the staff of administrative law judges.

(c)Procedures for the assignment of administrative law judges.

(7)The division is authorized to provide administrative law judges on a contract basis to any governmental entity to conduct any hearing not covered by this section.

(8)The division shall have the authority to adopt reasonable rules to carry out the provisions of this act.

(9)Rules promulgated by the division may authorize any reasonable sanctions except contempt for violation of the rules of the division or failure to comply with a reasonable order issued by an administrative law judge, which is not under judicial review.

(10)Not later than February 1 of each year, the division shall issue a written report to the Administrative Procedures Committee and the Administration Commission, including at least the following information:

(a)A summary of the extent and effect of agencies' utilization of administrative law judges, court reporters, and other personnel in proceedings under this chapter.

(b)Recommendations for change or improvement in the Administrative Procedure Act or any agency's practice or policy with respect thereto.

(c)Recommendations as to those types of cases or disputes which should be conducted under the summary hearing process described in s. 120.574.

(d)A report regarding each agency's compliance with the filing requirement in s. 120.57(1)(m).

(11)The division shall be reimbursed for administrative law judge services and travel expenses by the following entities: water management districts, regional planning councils, school districts, community colleges, the Division of Florida Colleges, state universities, the Board of Governors of the State University System, the State Board of Education, the Florida School for the Deaf and the Blind, and the Commission for Independent Education. These entities shall contract with the division to establish a contract rate for services and provisions for reimbursement of administrative law judge travel expenses and video teleconferencing expenses attributable to hearings conducted on behalf of these entities. The contract rate must be based on a total-cost-recovery methodology.

History.—s. 1, ch. 74-310; s. 9, ch. 75-191; s. 14, ch. 76-131; s. 9, ch. 78-425; s. 46, ch. 79-190; s. 1, ch. 86-297; s. 46, ch. 87-6; s. 25, ch. 87-101; s. 54, ch. 88-1; s. 30, ch. 88-277; s. 51, ch. 92-279; s. 23, ch. 92-315; s. 55, ch. 92-326; s. 764, ch. 95-147; s. 31, ch. 96-159; s. 13, ch. 97-176; s. 38, ch. 2000-371; s. 4, ch. 2001-91; s. 1, ch. 2004-247; s. 8, ch. 2006-82; s. 14, ch. 2007-217; s. 8, ch. 2009-228.

120.651Designation of two administrative law judges to preside over actions involving department or boards.—The Division of Administrative Hearings shall designate at least two administrative law judges who shall specifically preside over actions involving the Department of Health or boards within the Department of Health. Each designated administrative law judge must be a member of The Florida Bar in good standing and must have legal, managerial, or clinical experience in issues related to health care or have attained board certification in health care law from The Florida Bar.

History.—s. 32, ch. 2003-416.

120.655Withholding funds to pay for administrative law judge services to school boards.—If a district school board fails to make a timely payment for the services provided by an administrative law judge of the Division of Administrative Hearings as provided annually in the General Appropriations Act, the Commissioner of Education shall withhold, from any general revenue funds the district is eligible to receive, an amount sufficient to pay for the administrative law judge's services. The commissioner shall transfer the amount withheld to the Division of Administrative Hearings in payment of such services.

History.—s. 1, ch. 92-121; s. 32, ch. 96-159.

120.66Ex parte communications.—

(1)In any proceeding under ss. 120.569 and 120.57, no ex parte communication relative to the merits, threat, or offer of reward shall be made to the agency head, after the agency head has received a recommended order, or to the presiding officer by:

(a)An agency head or member of the agency or any other public employee or official engaged in prosecution or advocacy in connection with the matter under consideration or a factually related matter.

(b)A party to the proceeding, the party's authorized representative or counsel, or any person who, directly or indirectly, would have a substantial interest in the proposed agency action.

Nothing in this subsection shall apply to advisory staff members who do not testify on behalf of the agency in the proceeding or to any rulemaking proceedings under s. 120.54.

(2)A presiding officer, including an agency head or designee, who is involved in the decisional process and who receives an ex parte communication in violation of subsection (1) shall place on the record of the pending matter all written communications received, all written responses to such communications, and a memorandum stating the substance of all oral communications received and all oral responses made, and shall also advise all parties that such matters have been placed on the record. Any party desiring to rebut the ex parte communication shall be allowed to do so, if such party requests the opportunity for rebuttal within 10 days after notice of such communication. The presiding officer may, if necessary to eliminate the effect of an ex parte communication, withdraw from the proceeding, in which case the entity that appointed the presiding officer shall assign a successor.

(3)Any person who makes an ex parte communication prohibited by subsection (1), and any presiding officer, including an agency head or designee, who fails to place in the record any such communication, is in violation of this act and may be assessed a civil penalty not to exceed $500 or be subjected to other disciplinary action.

History.—s. 1, ch. 74-310; s. 10, ch. 75-191; s. 12, ch. 76-131; s. 1, ch. 77-174; s. 10, ch. 78-425; s. 765, ch. 95-147; s. 33, ch. 96-159; s. 14, ch. 97-176.

120.665Disqualification of agency personnel.—

(1)Notwithstanding the provisions of s. 112.3143, any individual serving alone or with others as an agency head may be disqualified from serving in an agency proceeding for bias, prejudice, or interest when any party to the agency proceeding shows just cause by a suggestion filed within a reasonable period of time prior to the agency proceeding. If the disqualified individual was appointed, the appointing power may appoint a substitute to serve in the matter from which the individual is disqualified. If the individual is an elected official, the Governor may appoint a substitute to serve in the matter from which the individual is disqualified. However, if a quorum remains after the individual is disqualified, it shall not be necessary to appoint a substitute.

(2)Any agency action taken by a duly appointed substitute for a disqualified individual shall be as conclusive and effective as if agency action had been taken by the agency as it was constituted prior to any substitution.

History.—s. 1, ch. 74-310; s. 12, ch. 78-425; s. 2, ch. 83-329; s. 767, ch. 95-147; s. 34, ch. 96-159.

Note.—Former s. 120.71.

120.68Judicial review.—

(1)A party who is adversely affected by final agency action is entitled to judicial review. A preliminary, procedural, or intermediate order of the agency or of an administrative law judge of the Division of Administrative Hearings is immediately reviewable if review of the final agency decision would not provide an adequate remedy.

(2)(a)Judicial review shall be sought in the appellate district where the agency maintains its headquarters or where a party resides or as otherwise provided by law. All proceedings shall be instituted by filing a notice of appeal or petition for review in accordance with the Florida Rules of Appellate Procedure within 30 days after the rendition of the order being appealed. If the appeal is of an order rendered in a proceeding initiated under s. 120.56, the agency whose rule is being challenged shall transmit a copy of the notice of appeal to the committee.

(b)When proceedings under this chapter are consolidated for final hearing and the parties to the consolidated proceeding seek review of final or interlocutory orders in more than one district court of appeal, the courts of appeal are authorized to transfer and consolidate the review proceedings. The court may transfer such appellate proceedings on its own motion, upon motion of a party to one of the appellate proceedings, or by stipulation of the parties to the appellate proceedings. In determining whether to transfer a proceeding, the court may consider such factors as the interrelationship of the parties and the proceedings, the desirability of avoiding inconsistent results in related matters, judicial economy, and the burden on the parties of reproducing the record for use in multiple appellate courts.

(3)The filing of the petition does not itself stay enforcement of the agency decision, but if the agency decision has the effect of suspending or revoking a license, supersedeas shall be granted as a matter of right upon such conditions as are reasonable, unless the court, upon petition of the agency, determines that a supersedeas would constitute a probable danger to the health, safety, or welfare of the state. The agency also may grant a stay upon appropriate terms, but, whether or not the action has the effect of suspending or revoking a license, a petition to the agency for a stay is not a prerequisite to a petition to the court for supersedeas. In any event the court shall specify the conditions, if any, upon which the stay or supersedeas is granted.

(4)Judicial review of any agency action shall be confined to the record transmitted and any additions made thereto in accordance with paragraph (7)(a).

(5)The record for judicial review shall be compiled in accordance with the Florida Rules of Appellate Procedure.

(6)(a)The reviewing court's decision may be mandatory, prohibitory, or declaratory in form, and it shall provide whatever relief is appropriate irrespective of the original form of the petition. The court may:

1.Order agency action required by law; order agency exercise of discretion when required by law; set aside agency action; remand the case for further agency proceedings; or decide the rights, privileges, obligations, requirements, or procedures at issue between the parties; and

2.Order such ancillary relief as the court finds necessary to redress the effects of official action wrongfully taken or withheld.

(b)If the court sets aside agency action or remands the case to the agency for further proceedings, it may make such interlocutory order as the court finds necessary to preserve the interests of any party and the public pending further proceedings or agency action.

(7)The court shall remand a case to the agency for further proceedings consistent with the court's decision or set aside agency action, as appropriate, when it finds that:

(a)There has been no hearing prior to agency action and the reviewing court finds that the validity of the action depends upon disputed facts;

(b)The agency's action depends on any finding of fact that is not supported by competent, substantial evidence in the record of a hearing conducted pursuant to ss. 120.569 and 120.57; however, the court shall not substitute its judgment for that of the agency as to the weight of the evidence on any disputed finding of fact;

(c)The fairness of the proceedings or the correctness of the action may have been impaired by a material error in procedure or a failure to follow prescribed procedure;

(d)The agency has erroneously interpreted a provision of law and a correct interpretation compels a particular action; or

(e)The agency's exercise of discretion was:

1.Outside the range of discretion delegated to the agency by law;

2.Inconsistent with agency rule;

3.Inconsistent with officially stated agency policy or a prior agency practice, if deviation therefrom is not explained by the agency; or

4.Otherwise in violation of a constitutional or statutory provision;

but the court shall not substitute its judgment for that of the agency on an issue of discretion.

(8)Unless the court finds a ground for setting aside, modifying, remanding, or ordering agency action or ancillary relief under a specified provision of this section, it shall affirm the agency's action.

(9)No petition challenging an agency rule as an invalid exercise of delegated legislative authority shall be instituted pursuant to this section, except to review an order entered pursuant to a proceeding under s. 120.56 or an agency's findings of immediate danger, necessity, and procedural fairness prerequisite to the adoption of an emergency rule pursuant to s. 120.54(4), unless the sole issue presented by the petition is the constitutionality of a rule and there are no disputed issues of fact.

(10)If an administrative law judge's final order depends on any fact found by the administrative law judge, the court shall not substitute its judgment for that of the administrative law judge as to the weight of the evidence on any disputed finding of fact. The court shall, however, set aside the final order of the administrative law judge or remand the case to the administrative law judge, if it finds that the final order depends on any finding of fact that is not supported by competent substantial evidence in the record of the proceeding.

History.—s. 1, ch. 74-310; s. 13, ch. 76-131; s. 38, ch. 77-104; s. 1, ch. 77-174; s. 11, ch. 78-425; s. 4, ch. 84-173; s. 7, ch. 87-385; s. 36, ch. 90-302; s. 6, ch. 91-30; s. 1, ch. 91-191; s. 10, ch. 92-166; s. 35, ch. 96-159; s. 15, ch. 97-176; s. 8, ch. 2003-94.

120.69Enforcement of agency action.—

(1)Except as otherwise provided by statute:

(a)Any agency may seek enforcement of an action by filing a petition for enforcement, as provided in this section, in the circuit court where the subject matter of the enforcement is located.

(b)A petition for enforcement of any agency action may be filed by any substantially interested person who is a resident of the state. However, no such action may be commenced:

1.Prior to 60 days after the petitioner has given notice of the violation of the agency action to the head of the agency concerned, the Attorney General, and any alleged violator of the agency action.

2.If an agency has filed, and is diligently prosecuting, a petition for enforcement.

(c)A petition for enforcement filed by a nongovernmental person shall be in the name of the State of Florida on the relation of the petitioner, and the doctrines of res judicata and collateral estoppel shall apply.

(d)In an action brought under paragraph (b), the agency whose action is sought to be enforced, if not a

party, may intervene as a matter of right.

(2)A petition for enforcement may request declaratory relief; temporary or permanent equitable relief; any fine, forfeiture, penalty, or other remedy provided by statute; any combination of the foregoing; or, in the absence of any other specific statutory authority, a fine not to exceed $1,000.

(3)After the court has rendered judgment on a petition for enforcement, no other petition shall be filed or adjudicated against the same agency action, on the basis of the same transaction or occurrence, unless expressly authorized on remand. The doctrines of res judicata and collateral estoppel shall apply, and the court shall make such orders as are necessary to avoid multiplicity of actions.

(4)In all enforcement proceedings:

(a)If enforcement depends on any facts other than those appearing in the record, the court may ascertain such facts under procedures set forth in s. 120.68(7)(a).

(b)If one or more petitions for enforcement and a petition for review involving the same agency action are pending at the same time, the court considering the review petition may order all such actions transferred to and consolidated in one court. Each party shall be under an affirmative duty to notify the court when it becomes aware of multiple proceedings.

(c)Should any party willfully fail to comply with an order of the court, the court shall punish that party in accordance with the law applicable to contempt committed by a person in the trial of any other action.

(5)In any enforcement proceeding the respondent may assert as a defense the invalidity of any relevant statute, the inapplicability of the administrative determination to respondent, compliance by the respondent, the inappropriateness of the remedy sought by the agency, or any combination of the foregoing. In addition, if the petition for enforcement is filed during the time within which the respondent could petition for judicial review of the agency action, the respondent may assert the invalidity of the agency action.

(6)Notwithstanding any other provision of this section, upon receipt of evidence that an alleged violation of an agency's action presents an imminent and substantial threat to the public health, safety, or welfare, the agency may bring suit for immediate temporary relief in an appropriate circuit court, and the granting of such temporary relief shall not have res judicata or collateral estoppel effect as to further relief sought under a petition for enforcement relating to the same violation.

(7)In any final order on a petition for enforcement the court may award to the prevailing party all or part of the costs of litigation and reasonable attorney's fees and expert witness fees, whenever the court determines that such an award is appropriate.

History.—s. 1, ch. 74-310; s. 766, ch. 95-147; s. 36, ch. 96-159.

120.695Notice of noncompliance.—

(1)It is the policy of the state that the purpose of regulation is to protect the public by attaining compliance with the policies established by the Legislature. Fines and other penalties may be provided in

order to assure compliance; however, the collection of fines and the imposition of penalties are intended to be secondary to the primary goal of attaining compliance with an agency's rules. It is the intent of the Legislature that an agency charged with enforcing rules shall issue a notice of noncompliance as its first response to a minor violation of a rule in any instance in which it is reasonable to assume that the violator was unaware of the rule or unclear as to how to comply with it.

(2)(a)Each agency shall issue a notice of noncompliance as a first response to a minor violation of a rule. A "notice of noncompliance" is a notification by the agency charged with enforcing the rule issued to the person or business subject to the rule. A notice of noncompliance may not be accompanied with a fine or other disciplinary penalty. It must identify the specific rule that is being violated, provide information on how to comply with the rule, and specify a reasonable time for the violator to comply with the rule. A rule is agency action that regulates a business, occupation, or profession, or regulates a person operating a business, occupation, or profession, and that, if not complied with, may result in a disciplinary penalty.

(b)Each agency shall review all of its rules and designate those for which a violation would be a minor violation and for which a notice of noncompliance must be the first enforcement action taken against a person or business subject to regulation. A violation of a rule is a minor violation if it does not result in economic or physical harm to a person or adversely affect the public health, safety, or welfare or create a significant threat of such harm. If an agency under the direction of a cabinet officer mails to each licensee a notice of the designated rules at the time of licensure and at least annually thereafter, the provisions of paragraph (a) may be exercised at the discretion of the agency. Such notice shall include a subject-matter index of the rules and information on how the rules may be obtained.

(c)The agency's review and designation must be completed by December 1, 1995; each agency under the direction of the Governor shall make a report to the Governor, and each agency under the joint direction of the Governor and Cabinet shall report to the Governor and Cabinet by January 1, 1996, on which of its rules have been designated as rules the violation of which would be a minor violation.

(d)The Governor or the Governor and Cabinet, as appropriate pursuant to paragraph (c), may evaluate the review and designation effects of each agency and may apply a different designation than that applied by the agency.

(e)This section does not apply to the regulation of law enforcement personnel or teachers.

(f)Designation pursuant to this section is not subject to challenge under this chapter.

History.—s. 1, ch. 95-402.

120.72Legislative intent; references to chapter 120 or portions thereof.—Unless expressly provided otherwise, a reference in any section of the Florida Statutes to chapter 120 or to any section or sections or portion of a section of chapter 120 includes, and shall be understood as including, all subsequent amendments to chapter 120 or to the referenced section or sections or portions of a section.

History.—s. 3, ch. 74-310; s. 1, ch. 76-207; s. 1, ch. 77-174; s. 57, ch. 78-95; s. 13, ch. 78-425; s. 38, ch. 96-159.

120.73Circuit court proceedings; declaratory judgments.—Nothing in this chapter shall be construed to repeal any provision of the Florida Statutes which grants the right to a proceeding in the circuit court in lieu of an administrative hearing or to divest the circuit courts of jurisdiction to render declaratory judgments under the provisions of chapter 86.

History.—s. 11, ch. 75-191; s. 14, ch. 78-425.

120.74Agency review, revision, and report.—

(1)Each agency shall review and revise its rules as often as necessary to ensure that its rules are correct and comply with statutory requirements. Additionally, each agency shall perform a formal review of its rules every 2 years. In the review, each agency must:

(a)Identify and correct deficiencies in its rules;

(b)Clarify and simplify its rules;

(c)Delete obsolete or unnecessary rules;

(d)Delete rules that are redundant of statutes;

(e)Seek to improve efficiency, reduce paperwork, or decrease costs to government and the private sector;

(f)Contact agencies that have concurrent or overlapping jurisdiction to determine whether their rules can be coordinated to promote efficiency, reduce paperwork, or decrease costs to government and the private sector; and

(g)Determine whether the rules should be continued without change or should be amended or repealed to reduce the impact on small business while meeting the stated objectives of the proposed rule.

(2)Beginning October 1, 1997, and by October 1 of every other year thereafter, the head of each agency shall file a report with the President of the Senate, the Speaker of the House of Representatives, and the committee, with a copy to each appropriate standing committee of the Legislature, which certifies that the agency has complied with the requirements of this section. The report must specify any changes made to its rules as a result of the review and, when appropriate, recommend statutory changes that will promote efficiency, reduce paperwork, or decrease costs to government and the private sector. The report must specifically address the economic impact of the rules on small business. The report must identify the types of cases or disputes in which the agency is involved which should be conducted under the summary hearing process described in s. 120.574.

(3)Beginning in 2012, and no later than July 1 of each year, each agency shall file with the President of the Senate, the Speaker of the House of Representatives, and the committee a regulatory plan identifying and describing each rule the agency proposes to adopt for the 12-month period beginning on the July 1 reporting

date and ending on the subsequent June 30, excluding emergency rules.

(4)For the year 2011, the certification required in subsection (2) may omit any information included in the reports provided under s. 120.745. Reporting under subsections (1) and (2) shall be suspended for the year 2013, but required reporting under those subsections shall resume in 2015 and biennially thereafter.

History.—s. 46, ch. 96-399; s. 16, ch. 97-176; s. 9, ch. 2006-82; s. 15, ch. 2008-104; s. 8, ch. 2008-149; s. 4, ch. 2011-225.

120.745Legislative review of agency rules in effect on or before November 16, 2010.—

(1)DEFINITIONS.—The following definitions apply exclusively to this section:

(a)"Agency" has the same meaning and application as provided in s. 120.52(1), but for the purposes of this section excludes each officer and governmental entity in the state with jurisdiction in one county or less than one county.

(b)"Compliance economic review" means a good faith economic analysis that includes and presents the following information pertaining to a particular rule:

1.A justification for the rule summarizing the benefits of the rule; and

2.A statement of estimated regulatory costs as described in s. 120.541(2); however:

a.The applicable period for the economic analysis shall be 5 years beginning on July 1, 2011;

b.For the analysis required in s. 120.541(2)(a)3., the estimated regulatory costs over the 5-year period shall be used instead of the likely increase in regulatory costs after implementation; and

c.An explanation of the methodology used to conduct the analysis must be provided. A technical methodology need not be used to develop the statement of estimated regulatory costs, if the agency uses routine regulatory communications or its Internet website to reasonably survey regulated entities, political subdivisions, and local governments and makes good faith estimates of regulatory costs in conformity with recommendations from the Office of Fiscal Accountability and Regulatory Reform ("OFARR"), or from one or more legislative offices if requested by the agency and such request is approved by the President of the Senate and the Speaker of the House of Representatives.

(c)"Data collection rules" means those rules requiring the submission of data to the agency from external sources, including, but not limited to, local governments, service providers, clients, licensees, regulated entities, other constituents, and market participants.

(d)"Revenue rules" means those rules fixing amounts or providing for the collection of money.

(e)"Rule" has the same general meaning and application as provided in s. 120.52(16), but for purposes of this section may include only those rules for which publication in the Florida Administrative Code is required pursuant to s. 120.55(1). As used in this section, the term "rule" means each entire statement and all subparts published under a complete title, chapter, and decimal rule number in the Florida Administrative Code in compliance with Florida Administrative Code Rule 1B-30.001.

(2)ENHANCED BIENNIAL REVIEW.—By December 1, 2011, each agency shall complete an enhanced biennial

review of the agency's existing rules, which shall include, but is not limited to:

(a)Conduct of the review and submission of the report required by s. 120.74 and an explanation of how the agency has accomplished the requirements of s. 120.74(1). This paragraph extends the October 1 deadline provided in s. 120.74(2) for the year 2011.

(b)Review of each rule to determine whether the rule has been reviewed by OFARR pursuant to the Governor's Executive Order 2011-01.

(c)Review of each rule to determine whether the rule is a revenue rule, to identify the statute or statutes authorizing the collection of any revenue, to identify the fund or account into which revenue collections are deposited, and, for each revenue rule, to determine whether the rule authorizes, imposes, or implements:

1.Registration, license, or inspection fees.

2.Transportation service tolls for road, bridge, rail, air, waterway, or port access.

3.Fees for a specific service or purpose not included in subparagraph 1. or subparagraph 2.

4.Fines, penalties, costs, or attorney fees.

5.Any tax.

6.Any other amounts collected that are not covered under subparagraphs 1.-5.

(d)Review of each rule to determine whether the rule is a data collection rule, providing the following information for each rule determined to be a data collection rule:

1.The statute or statutes authorizing the collection of such data.

2.The purposes for which the agency uses the data and any purpose for which the data is used by others.

3.The policies supporting the reporting and retention of the data.

4.Whether and to what extent the data is exempt from public inspection under chapter 119.

(e)Identification of each entire rule the agency plans to repeal and, if so, the estimated timetable for repeal.

(f)Identification of each entire rule or subpart of a rule the agency plans to amend to substantially reduce the economic impact and the estimated timetable for amendment.

(g)Identification of each rule for which the agency will be required to prepare a compliance economic review, to include each entire rule that:

1.The agency does not plan to repeal on or before December 31, 2012;

2.Was effective on or before November 16, 2010; and

3.Probably will have any of the economic impacts described in s. 120.541(2)(a), for 5 years beginning on July 1, 2011, excluding in such estimation any part or subpart identified for amendment under paragraph (f).

(h)Listing of all rules identified for compliance economic review in paragraph (g), divided into two approximately equal groups, identified as "Group 1" and "Group 2." Such division shall be made at the

agency's discretion.

(i)Written certification of the agency head to the committee verifying the completion of the report for all rules of the agency, including each separate part or subsection. The duty to certify completion of the report is the responsibility solely of the agency head as defined in s. 120.52(3) and may not be delegated to any other person. If the defined agency head is a collegial body, the written certification must be prepared by the chair or equivalent presiding officer of that body.

(3)PUBLICATION OF REPORT.—No later than December 1, 2011, each agency shall publish, in the manner provided in subsection (7), a report of the entire enhanced biennial review pursuant to subsection (2), including the results of the review; a complete list of all rules the agency has placed in Group 1 or Group 2; the name, physical address, fax number, and e-mail address for the person the agency has designated to receive all inquiries, public comments, and objections pertaining to the report; and the certification of the agency head pursuant to paragraph (2)(i). The report of results shall summarize certain information required in subsection (2) in a table consisting of the following columns:

(a)Column 1: Agency name.

(b)Column 2: F.A.C. rule number, with subcolumns including:

1.Column 2a: F.A.C. title and any subtitle or chapter designation; and

2.Column 2b: F.A.C. number, excluding title and subtitle or chapter designation.

(c)Column 3: OFARR reviewed rule under Executive Order 2011-01. Entries should be "Y" or "N."

(d)Column 4: Revenue rule/fund or account with subcolumns including:

1.Column 4a: Licensure fees.

2.Column 4b: Transportation tolls.

3.Column 4c: Other fees.

4.Column 4d: Fines.

5.Column 4e: Tax.

6.Column 4f: Other revenue.

Entries should be "N" or the identification of the fund or account where receipts are deposited and provide notes indicating the statutory authority for revenue collection.

(e)Column 5: Data collection rule. Entries should be "Y" or "N." If "Y," provide notes supplying the information required in paragraph (2)(d).

(f)Column 6: Repeal. Entries should be "Y" or "N" for the entire rule. If "Y," provide notes estimating the timetable for repeal.

(g)Column 7: Amend. Entries should be "Y" or "N," based on the response required in paragraph (2)(f), and provide notes identifying each specific subpart that will be amended and estimating the timetable for amendment.

(h)Column 8: Effective on or before 11/16/2010. Entries should be "Y" or "N."

(i)Column 9: Section 120.541(2)(a) impacts. Entries should be "NA" if Column 8 is "N" or, if Column 6 is "Y," "NP" for not probable, based on the response required in subparagraph (2)(g)3., or "1" or "2," reflecting the group number assigned by the division required in paragraph (2)(h).

(4)PUBLIC COMMENT ON ENHANCED BIENNIAL REVIEW AND REPORT; OBJECTIONS.—Public input on reports required in subsection (3) may be provided by stating an objection to the information required in paragraphs (2)(b), (c), (d), and (g) and identifying the entire rule or any subpart to which the objection relates, and shall be submitted in writing or electronically to the person designated in the report.

(a)An objection under this subsection to a report that an entire rule or any subpart probably will not have, for 5 years beginning on July 1, 2011, any of the economic impacts described in s. 120.541(2)(a), must include allegations of fact upon which the objection is based, stating the precise information upon which a contrary evaluation of probable impact may be made. Allegations of fact related to other objections may be included.

(b)Objections may be submitted by any interested person no later than June 1, 2012.

(c)The agency shall determine whether to sustain an objection based upon the information provided with the objection and whether any further review of information available to the agency is necessary to correct its report.

(d)No later than 20 days after the date an objection is submitted, the agency shall publish its determination of the objection in the manner provided in subsection (7).

(e)The agency's determination with respect to an objection is final but not a final agency action subject to further proceedings, hearing, or judicial review.

(f)If the agency sustains an objection, it shall amend its report within 10 days after the determination. The amended report shall indicate that a change has been made, the date of the last change, and identify the amended portions. The agency shall publish notice of the amendment in the manner provided in subsection (7).

(g)On or before July 1, 2012, the agency shall deliver a written certification of the agency head or designee to the committee verifying the completion of determinations of all objections under this subsection and of any report amendments required under paragraph (f). The certification shall be published as an addendum to the report required in subsection (3). Notice of the certification shall be published in the manner provided in subsection (7).

(5)COMPLIANCE ECONOMIC REVIEW OF RULES AND REQUIRED REPORT.—Each agency shall perform a compliance economic review and report for all rules, including separate reviews of subparts, listed under Group 1 "Group 1 rules" or Group 2 "Group 2 rules" pursuant to subparagraph (2)(g)3. Group 1 rules shall be reviewed and reported on in 2012, and Group 2 rules shall be reviewed and reported on in 2013.

(a)No later than May 1, each agency shall:

1.Complete a compliance economic review for each entire rule or subpart in the appropriate group.

2.File the written certification of the agency head with the committee verifying the completion of each compliance economic review required for the respective year. The certification shall be dated and published as an addendum to the report required in subsection (3). The duty to certify completion of the required compliance economic reviews is the responsibility solely of the agency head as defined in s. 120.52(3) and may not be delegated to any other person. If the defined agency head is a collegial body, the written certification must be prepared by the chair or equivalent presiding officer of that body.

3.Publish a copy of the compliance economic review, directions on how and when interested parties may submit lower cost regulatory alternatives to the agency, and the date the notice is published in the manner provided in subsection (7).

4.Publish notice of the publications required in subparagraphs 2. and 3. in the manner provided in subsection (7).

5.Submit each compliance economic review to the rules ombudsman in the Executive Office of the Governor for [1]the ombudsman's review.

(b)Any agency rule, including subparts, reviewed pursuant to Executive Order 2011-01 are exempt from the compliance economic review if the review found that the rule:

1.Does not unnecessarily restrict entry into a profession or occupation;

2.Does not adversely affect the availability of professional or occupational services to the public;

3.Does not unreasonably affect job creation or job retention;

4.Does not place unreasonable restrictions on individuals attempting to find employment;

5.Does not impose burdensome costs on businesses; or

6.Is justifiable when the overall cost-effectiveness and economic impact of the regulation, including indirect costs to consumers, is considered.

(c)No later than August 1, the rules ombudsman in the Executive Office of the Governor may submit lower cost regulatory alternatives to any rule to the agency that adopted the rule. No later than June 15, other interested parties may submit lower cost regulatory alternatives to any rule.

(d)No later than December 1, each agency shall publish a final report of the agency's review under this subsection in the manner provided in subsection (7). For each rule the report shall include:

1.The text of the rule.

2.The compliance economic review for the rule.

3.All lower regulatory cost alternatives received by the agency.

4.The agency's written explanation for rejecting submitted lower regulatory cost alternatives.

5.The agency's justification to repeal or amend the rule or to retain the rule without amendment.

6.The written certification of the agency head to the committee verifying the completion of the reviews and reporting required under this subsection for that year. The certification shall be dated and published as an addendum to the report required in subsection (3). The duty to certify completion of the report is the responsibility solely of the agency head as defined in s. 120.52(3) and may not be delegated to any other person. If the defined agency head is a collegial body, the written certification must be prepared by the chair or equivalent presiding officer of that body.

(e)Notice of publication of the final report and certification shall be published in the manner provided in subsection (7).

(f)By December 1, each agency shall begin proceedings under s. 120.54(3) to amend or repeal those rules so designated in the report under this subsection. Proceedings to repeal rules are exempt from the requirements for the preparation, consideration, or use of a statement of estimated regulatory costs under s. 120.54 and the provisions of s. 120.541.

(6)LEGISLATIVE CONSIDERATION.—With respect to a rule identified for retention without amendment in the report required in subsection (5), the Legislature may consider specific legislation nullifying the rule or altering the statutory authority for the rule.

(7)MANNER OF PUBLICATION OF NOTICES, DETERMINATIONS, AND REPORTS.—Agencies shall publish notices, determinations, and reports required under this section exclusively in the following manner:

(a)The agency shall publish each notice, determination, and complete report on its Internet website. If the agency does not have an Internet website, the information shall be published on the committee's Internet website using www.japc.state.fl.us/[agency name]/ in place of the address of the agency's Internet website. The following URL formats shall be used:

1.Reports required under subsection (3), including any reports amended as a result of a determination under subsection (4):

[Address of agency's Internet website]/2011_Rule_review/
[Florida Administrative Code (F.A.C.) title and subtitle (if applicable) designation for the rules included].

(Example: http://www.dos.state.fl.us/2011_Rule_review/1S).

2.The lists of Group 1 rules and Group 2 rules, required under subsection (3):

[Address of agency's Internet website]/2011_Rule_review/
Economic_Review/Schedule.

(Example: http://www.dos.state.fl.us/2011_Rule_review/
Economic_Review/Schedule).

3.Determinations under subsection (4):

[Address of agency's Internet website]/2011_Rule_review/
Objection_Determination/[F.A.C. Rule number].

(Example: http://www.dos.state.fl.us/2011_Rule_review/Objection_Determination/1S-1.001).

4.Completed compliance economic reviews reported under subsection (5):

[Address of agency's Internet website]/2011_Rule_review/Economic_Review/[F.A.C. Rule number].

(Example: http://www.dos.state.fl.us/2011_Rule_review/Economic_Review/1S-1.001).

5.Final reports under paragraph (5)(d), with the appropriate year:

[Address of agency's Internet website]/2011_Rule_review/Economic_Review/[YYYY_Final_Report].

(Example: http://www.dos.state.fl.us/2011_Rule_review/Economic_Review/2012_Final_Report).

(b)1.Each notice shall be published using the following URL format:

[Address of agency's Internet website]/2011_Rule_review/Notices.

(Example: http://www.dos.state.fl.us/2011_Rule_review/Notices).

2.Once each week a copy of all notices published in the previous week on the Internet under this paragraph shall be delivered to the Department of State, for publication in the next available issue of the Florida Administrative Weekly, and a copy shall be delivered by electronic mail to the committee.

3.Each notice shall identify the publication for which notice is being given and include:

a.The name of the agency.

b.The name, physical address, fax number, and e-mail address for the person designated to receive all inquiries, public comments, and objections pertaining to the publication identified in the notice.

c.The particular Internet address through which the publication may be accessed.

d.The date the notice and publication is first published on the agency's Internet website.

(c)Publication pursuant to this section is deemed to be complete as of the date the notice, determination, or report is posted on the agency's Internet website.

(8)FAILURE TO FILE CERTIFICATION OF COMPLETION.—If an agency fails to timely file any written certification required in paragraph (2)(i), paragraph (4)(g), subparagraph (5)(a)2., or subparagraph (5)(d)6., the entire rulemaking authority delegated to the agency by the Legislature under any statute or law shall be suspended automatically as of the due date of the required certification and shall remain suspended until the date that the agency files the required certification with the committee.

(a)During the period of any suspension under this subsection, the agency has no authority to engage in rulemaking under s. 120.54.

(b)A suspension under this subsection does not authorize an agency to promulgate any statement defined as a rule under s. 120.52(16).

(c)A suspension under this subsection shall toll the time requirements under s. 120.54 for any rulemaking proceeding the agency initiated before the date of suspension, which time requirements shall resume on the date the agency files the written certification with the committee and publishes notice of the required certification in the manner provided in subsection (7).

(d)Failure to timely file a written certification required under paragraph (2)(i) tolls the time for public response, which period shall not begin until the date the agency files the written certification with the committee and publishes notice of the required certification in the manner provided in subsection (7). The period for public response shall be extended by the number of days equivalent to the period of suspension under this subsection.

(e)Failure to timely file a written certification required under subparagraph (5)(a)2. shall toll the deadline for submission of lower cost regulatory alternatives for any rule or subpart for which a compliance economic review has not been timely published. The period of tolling shall be the number of days after May 1 until the date of the certification as published.

(9)EXEMPTION FROM ENHANCED BIENNIAL REVIEW AND COMPLIANCE ECONOMIC REVIEW.—

(a)An agency is exempt from subsections (1)-(8) if it has cooperated or cooperates with OFARR in a review of the agency's rules in a manner consistent with Executive Order 2011-01, or any alternative review directed by OFARR; if the agency or OFARR identifies each data collection rule and each revenue rule; and if the information developed thereby becomes publicly available on the Internet by December 1, 2011. Each such agency is exempt from the biennial review required in s. 120.74(2) for the year 2011.

(b)For each rule reviewed under this subsection, OFARR may identify whether the rule imposes a significant regulatory cost or economic impact and shall schedule and obtain or direct a reasonable economic estimate of such cost and impact for each rule so identified. A report on each such estimate shall be published on the Internet by December 31, 2013. On or before October 1, 2013, the agency head shall certify in writing to the committee that the agency has completed each economic estimate required under this paragraph, and thereupon the agency is exempt from the biennial review required in s. 120.74(2) for the year 2013.

(c)The exemption under this paragraph does not apply unless the agency head certifies in writing to the committee, on or before October 1, 2011, that the agency has chosen such exemption and has cooperated with OFARR in undertaking the review required in paragraph (a).

(10)REPEAL.—This section is repealed July 1, 2014.

History.—s. 5, ch. 2011-225; s. 10, ch. 2012-5; s. 3, ch. 2012-27.

[1]**Note.**—The words "the ombudsman's" were substituted by the editors for the word "its."

120.7455Legislative survey of regulatory impacts.—

(1)From July 1, 2011, until July 1, 2014, the Legislature may establish and maintain an Internet-based public survey of regulatory impact soliciting information from the public regarding the kind and degree of regulation affecting private activities in the state. The input may include, but need not be limited to:

(a)The registered business name or other name of each reporting person.

(b)The number and identity of agencies licensing, inspecting, registering, permitting, or otherwise regulating lawful activities of the reporting person.

(c)The types, numbers, and nature of licenses, permits, and registrations required for various lawful activities of the reporting person.

(d)The identity of local, state, and federal agencies, and other entities acting under color of law which regulate the lawful activities of the reporting person or otherwise exercise power to enforce laws applicable to such activities.

(e)The identification and nature of each ordinance, law, or administrative rule or regulation deemed unreasonably burdensome by the reporting person.

(2)The President of the Senate and the Speaker of the House of Representatives may certify in writing to the chair of the committee and to the Attorney General the establishment and identity of any Internet-based public survey established under this section.

(3)Any person reporting or otherwise providing information solicited by the Legislature in conformity with this section is immune from any enforcement action or prosecution that:

(a)Is instituted on account of, or in reliance upon, the fact of reporting or nonreporting of information in response to the Legislature's solicitation of information pursuant to this section; or

(b)Uses information provided in response to the Legislature's solicitation of information pursuant to this section.

(4)Any alleged violator against whom an enforcement action is brought may object to any proposed penalty in excess of the minimum provided by law or rule on the basis that the action is in retaliation for the violator providing or withholding any information in response to the Legislature's solicitation of information pursuant to this section. If the presiding judge determines that the enforcement action was motivated in whole or in part by retaliation, any penalty imposed is limited to the minimum penalties provided by law for each separate violation adjudicated.

History.—s. 6, ch. 2011-225.

120.80Exceptions and special requirements; agencies.—

(1)DIVISION OF ADMINISTRATIVE HEARINGS.—

(a)*Division as a party.*—Notwithstanding s. 120.57(1)(a), a hearing in which the division is a party may not be conducted by an administrative law judge assigned by the division. An attorney assigned by the Administration Commission shall be the hearing officer.

(b)*Workers' compensation.*—Notwithstanding s. 120.52(1), a judge of compensation claims, in adjudicating matters under chapter 440, is not an agency or part of an agency for purposes of this chapter.

(2)DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES.—

(a)Marketing orders under chapter 527, chapter 573, or chapter 601 are not rules.

(b)Notwithstanding s. 120.57(1)(a), hearings held by the Department of Agriculture and Consumer Services pursuant to chapter 601 need not be conducted by an administrative law judge assigned by the division.

(3)OFFICE OF FINANCIAL REGULATION.—

(a)Notwithstanding s. 120.60(1), in proceedings for the issuance, denial, renewal, or amendment of a license or approval of a merger pursuant to title XXXVIII:

1.a.The Office of Financial Regulation of the Financial Services Commission shall have published in the Florida Administrative Weekly notice of the application within 21 days after receipt.

b.Within 21 days after publication of notice, any person may request a hearing. Failure to request a hearing within 21 days after notice constitutes a waiver of any right to a hearing. The Office of Financial Regulation or an applicant may request a hearing at any time prior to the issuance of a final order. Hearings shall be conducted pursuant to ss. 120.569 and 120.57, except that the Financial Services Commission shall by rule provide for participation by the general public.

2.Should a hearing be requested as provided by sub-subparagraph 1.b., the applicant or licensee shall publish at its own cost a notice of the hearing in a newspaper of general circulation in the area affected by the application. The Financial Services Commission may by rule specify the format and size of the notice.

3.Notwithstanding s. 120.60(1), and except as provided in subparagraph 4., every application for license for a new bank, new trust company, new credit union, or new savings and loan association shall be approved or denied within 180 days after receipt of the original application or receipt of the timely requested additional information or correction of errors or omissions. Any application for such a license or for acquisition of such control which is not approved or denied within the 180-day period or within 30 days after conclusion of a public hearing on the application, whichever is later, shall be deemed approved subject to the satisfactory completion of conditions required by statute as a prerequisite to license and approval of insurance of accounts for a new bank, a new savings and loan association, or a new credit union by the appropriate insurer.

4.In the case of every application for license to establish a new bank, trust company, or capital stock savings association in which a foreign national proposes to own or control 10 percent or more of any class of voting securities, and in the case of every application by a foreign national for approval to acquire control of a bank, trust company, or capital stock savings association, the Office of Financial Regulation shall request that a public hearing be conducted pursuant to ss. 120.569 and 120.57. Notice of such hearing shall be published by

the applicant as provided in subparagraph 2. The failure of any such foreign national to appear personally at the hearing shall be grounds for denial of the application. Notwithstanding the provisions of s. 120.60(1) and subparagraph 3., every application involving a foreign national shall be approved or denied within 1 year after receipt of the original application or any timely requested additional information or the correction of any errors or omissions, or within 30 days after the conclusion of the public hearing on the application, whichever is later.

(b)In any application for a license or merger pursuant to title XXXVIII which is referred by the agency to the division for hearing, the administrative law judge shall complete and submit to the agency and to all parties a written report consisting of findings of fact and rulings on evidentiary matters. The agency shall allow each party at least 10 days in which to submit written exceptions to the report.

(4)DEPARTMENT OF BUSINESS AND PROFESSIONAL REGULATION.—

(a)*Business regulation.*—The Division of Pari-mutuel Wagering is exempt from the hearing and notice requirements of ss. 120.569 and 120.57(1)(a), but only for stewards, judges, and boards of judges when the hearing is to be held for the purpose of the imposition of fines or suspensions as provided by rules of the Division of Pari-mutuel Wagering, but not for revocations, and only upon violations of subparagraphs 1.-6. The Division of Pari-mutuel Wagering shall adopt rules establishing alternative procedures, including a hearing upon reasonable notice, for the following violations:

1.Horse riding, harness riding, greyhound interference, and jai alai game actions in violation of chapter 550.

2.Application and usage of drugs and medication to horses, greyhounds, and jai alai players in violation of chapter 550.

3.Maintaining or possessing any device which could be used for the injection or other infusion of a prohibited drug to horses, greyhounds, and jai alai players in violation of chapter 550.

4.Suspensions under reciprocity agreements between the Division of Pari-mutuel Wagering and regulatory agencies of other states.

5.Assault or other crimes of violence on premises licensed for pari-mutuel wagering.

6.Prearranging the outcome of any race or game.

(b)*Professional regulation.*—Notwithstanding s. 120.57(1)(a), formal hearings may not be conducted by the Secretary of Business and Professional Regulation or a board or member of a board within the Department of Business and Professional Regulation for matters relating to the regulation of professions, as defined by chapter 455.

(5)FLORIDA LAND AND WATER ADJUDICATORY COMMISSION.—Notwithstanding the provisions of s. 120.57(1)(a), when the Florida Land and Water Adjudicatory Commission receives a notice of appeal pursuant to s. 380.07, the commission shall notify the division within 60 days after receipt of the notice of appeal if the

commission elects to request the assignment of an administrative law judge.

(6)DEPARTMENT OF LAW ENFORCEMENT.—Law enforcement policies and procedures of the Department of Law Enforcement which relate to the following are not rules as defined by this chapter:

(a)The collection, management, and dissemination of active criminal intelligence information and active criminal investigative information; management of criminal investigations; and management of undercover investigations and the selection, assignment, and fictitious identity of undercover personnel.

(b)The recruitment, management, identity, and remuneration of confidential informants or sources.

(c)Surveillance techniques, the selection of surveillance personnel, and electronic surveillance, including court-ordered and consensual interceptions of communication conducted pursuant to chapter 934.

(d)The safety and release of hostages.

(e)The provision of security and protection to public figures.

(f)The protection of witnesses.

(7)DEPARTMENT OF CHILDREN AND FAMILY SERVICES.—Notwithstanding s. 120.57(1)(a), hearings conducted within the Department of Children and Family Services in the execution of those social and economic programs administered by the former Division of Family Services of the former Department of Health and Rehabilitative Services prior to the reorganization effected by chapter 75-48, Laws of Florida, need not be conducted by an administrative law judge assigned by the division.

(8)DEPARTMENT OF HIGHWAY SAFETY AND MOTOR VEHICLES.—

(a)*Drivers' licenses.*—

1.Notwithstanding s. 120.57(1)(a), hearings regarding drivers' licensing pursuant to chapter 322 need not be conducted by an administrative law judge assigned by the division.

2.Notwithstanding s. 120.60(5), cancellation, suspension, or revocation of a driver's license shall be by personal delivery to the licensee or by first-class mail as provided in s. 322.251.

(b)*Wrecker operators.*—Notwithstanding s. 120.57(1)(a), hearings held by the Division of the Florida Highway Patrol of the Department of Highway Safety and Motor Vehicles to deny, suspend, or remove a wrecker operator from participating in the wrecker rotation system established by s. 321.051 need not be conducted by an administrative law judge assigned by the division. These hearings shall be held by a hearing officer appointed by the director of the Division of the Florida Highway Patrol.

(9)OFFICE OF INSURANCE REGULATION.—Notwithstanding s. 120.60(1), every application for a certificate of authority as required by s. 624.401 shall be approved or denied within 180 days after receipt of the original application. Any application for a certificate of authority which is not approved or denied within the 180-day period, or within 30 days after conclusion of a public hearing held on the application, shall be deemed approved, subject to the satisfactory completion of conditions required by statute as a prerequisite to licensure.

(10)DEPARTMENT OF ECONOMIC OPPORTUNITY.—

(a)Notwithstanding s. 120.54, the rulemaking provisions of this chapter do not apply to reemployment assistance appeals referees.

(b)Notwithstanding s. 120.54(5), the uniform rules of procedure do not apply to appeal proceedings conducted under chapter 443 by the Reemployment Assistance Appeals Commission, special deputies, or reemployment assistance appeals referees.

(c)Notwithstanding s. 120.57(1)(a), hearings under chapter 443 may not be conducted by an administrative law judge assigned by the division, but instead shall be conducted by the Reemployment Assistance Appeals Commission in reemployment assistance appeals, reemployment assistance appeals referees, and the Department of Economic Opportunity or its special deputies under s. 443.141.

(11)NATIONAL GUARD.—Notwithstanding s. 120.52(16), the enlistment, organization, administration, equipment, maintenance, training, and discipline of the militia, National Guard, organized militia, and unorganized militia, as provided by s. 2, Art. X of the State Constitution, are not rules as defined by this chapter.

(12)PUBLIC EMPLOYEES RELATIONS COMMISSION.—

(a)Notwithstanding s. 120.57(1)(a), hearings within the jurisdiction of the Public Employees Relations Commission need not be conducted by an administrative law judge assigned by the division.

(b)Section 120.60 does not apply to certification of employee organizations pursuant to s. 447.307.

(13)FLORIDA PUBLIC SERVICE COMMISSION.—

(a)Agency statements that relate to cost-recovery clauses, factors, or mechanisms implemented pursuant to chapter 366, relating to public utilities, are exempt from the provisions of s. 120.54(1)(a).

(b)Notwithstanding ss. 120.569 and 120.57, a hearing on an objection to proposed action of the Florida Public Service Commission may only address the issues in dispute. Issues in the proposed action which are not in dispute are deemed stipulated.

(c)The Florida Public Service Commission is exempt from the time limitations in s. 120.60(1) when issuing a license.

(d)Notwithstanding the provisions of this chapter, in implementing the Telecommunications Act of 1996, Pub. L. No. 104-104, the Public Service Commission is authorized to employ procedures consistent with that act.

(e)Notwithstanding the provisions of this chapter, s. 350.128, or s. 364.381, appellate jurisdiction for Public Service Commission decisions that implement the Telecommunications Act of 1996, Pub. L. No. 104-104, shall be consistent with the provisions of that act.

(f)Notwithstanding any provision of this chapter, all public utilities and companies regulated by the Public Service Commission shall be entitled to proceed under the interim rate provisions of chapter 364 or the

procedures for interim rates contained in chapter 74-195, Laws of Florida, or as otherwise provided by law.

(14)DEPARTMENT OF REVENUE.—

(a)*Assessments.*—An assessment of tax, penalty, or interest by the Department of Revenue is not a final order as defined by this chapter. Assessments by the Department of Revenue shall be deemed final as provided in the statutes and rules governing the assessment and collection of taxes.

(b)*Taxpayer contest proceedings.*—

1.In any administrative proceeding brought pursuant to this chapter as authorized by s. 72.011(1), the taxpayer shall be designated the "petitioner" and the Department of Revenue shall be designated the "respondent," except that for actions contesting an assessment or denial of refund under chapter 207, the Department of Highway Safety and Motor Vehicles shall be designated the "respondent," and for actions contesting an assessment or denial of refund under chapters 210, 550, 561, 562, 563, 564, and 565, the Department of Business and Professional Regulation shall be designated the "respondent."

2.In any such administrative proceeding, the applicable department's burden of proof, except as otherwise specifically provided by general law, shall be limited to a showing that an assessment has been made against the taxpayer and the factual and legal grounds upon which the applicable department made the assessment.

3.a.Prior to filing a petition under this chapter, the taxpayer shall pay to the applicable department the amount of taxes, penalties, and accrued interest assessed by that department which are not being contested by the taxpayer. Failure to pay the uncontested amount shall result in the dismissal of the action and imposition of an additional penalty of 25 percent of the amount taxed.

b.The requirements of s. 72.011(2) and (3)(a) are jurisdictional for any action under this chapter to contest an assessment or denial of refund by the Department of Revenue, the Department of Highway Safety and Motor Vehicles, or the Department of Business and Professional Regulation.

4.Except as provided in s. 220.719, further collection and enforcement of the contested amount of an assessment for nonpayment or underpayment of any tax, interest, or penalty shall be stayed beginning on the date a petition is filed. Upon entry of a final order, an agency may resume collection and enforcement action.

5.The prevailing party, in a proceeding under ss. 120.569 and 120.57 authorized by s. 72.011(1), may recover all legal costs incurred in such proceeding, including reasonable attorney's fees, if the losing party fails to raise a justiciable issue of law or fact in its petition or response.

6.Upon review pursuant to s. 120.68 of final agency action concerning an assessment of tax, penalty, or interest with respect to a tax imposed under chapter 212, or the denial of a refund of any tax imposed under chapter 212, if the court finds that the Department of Revenue improperly rejected or modified a conclusion of law, the court may award reasonable attorney's fees and reasonable costs of the appeal to the prevailing appellant.

(c)*Proceedings to establish paternity or paternity and child support; orders to appear for genetic testing; proceedings for administrative support orders.*—In proceedings to establish paternity or paternity and child support pursuant to s. 409.256 and proceedings for the establishment of administrative support orders pursuant to s. 409.2563, final orders in cases referred by the Department of Revenue to the Division of Administrative Hearings shall be entered by the division's administrative law judge and transmitted to the Department of Revenue for filing and rendering. The Department of Revenue has the right to seek judicial review under s. 120.68 of a final order entered by an administrative law judge. The Department of Revenue or the person ordered to appear for genetic testing may seek immediate judicial review under s. 120.68 of an order issued by an administrative law judge pursuant to s. 409.256(5)(b). Final orders that adjudicate paternity or paternity and child support pursuant to s. 409.256 and administrative support orders rendered pursuant to s. 409.2563 may be enforced pursuant to s. 120.69 or, alternatively, by any method prescribed by law for the enforcement of judicial support orders, except contempt. Hearings held by the Division of Administrative Hearings pursuant to ss. 409.256, 409.2563, and 409.25635 shall be held in the judicial circuit where the person receiving services under Title IV-D resides or, if the person receiving services under Title IV-D does not reside in this state, in the judicial circuit where the respondent resides. If the department and the respondent agree, the hearing may be held in another location. If ordered by the administrative law judge, the hearing may be conducted telephonically or by videoconference.

(15)DEPARTMENT OF HEALTH.—Notwithstanding s. 120.57(1)(a), formal hearings may not be conducted by the State Surgeon General, the Secretary of Health Care Administration, or a board or member of a board within the Department of Health or the Agency for Health Care Administration for matters relating to the regulation of professions, as defined by chapter 456. Notwithstanding s. 120.57(1)(a), hearings conducted within the Department of Health in execution of the Special Supplemental Nutrition Program for Women, Infants, and Children; Child Care Food Program; Children's Medical Services Program; the Brain and Spinal Cord Injury Program; and the exemption from disqualification reviews for certified nurse assistants program need not be conducted by an administrative law judge assigned by the division. The Department of Health may contract with the Department of Children and Family Services for a hearing officer in these matters.

(16)FLORIDA BUILDING COMMISSION.—

(a)Notwithstanding the provisions of s. 120.542, the Florida Building Commission may not accept a petition for waiver or variance and may not grant any waiver or variance from the requirements of the Florida Building Code.

(b)The Florida Building Commission shall adopt within the Florida Building Code criteria and procedures for alternative means of compliance with the code or local amendments thereto, for enforcement by local governments, local enforcement districts, or other entities authorized by law to enforce the Florida Building Code. Appeals from the denial of the use of alternative means shall be heard by the local board, if one exists,

and may be appealed to the Florida Building Commission.

(c)Notwithstanding ss. 120.565, 120.569, and 120.57, the Florida Building Commission and hearing officer panels appointed by the commission in accordance with s. 553.775(3)(c)1. may conduct proceedings to review decisions of local building code officials in accordance with s. 553.775(3)(c).

(d)Section 120.541(3) does not apply to the adoption of amendments and the triennial update to the Florida Building Code expressly authorized by s. 553.73.

(17)STATE FIRE MARSHAL.—Section 120.541(3) does not apply to the adoption of amendments and the triennial update to the Florida Fire Prevention Code expressly authorized by s. 633.0215.

(18)DEPARTMENT OF TRANSPORTATION.—Sections 120.54(3)(b) and 120.541 do not apply to the adjustment of tolls pursuant to s. 338.165(3).

History.—s. 41, ch. 96-159; s. 13, ch. 98-166; s. 10, ch. 99-8; s. 4, ch. 99-397; s. 1, ch. 2000-141; s. 17, ch. 2000-151; s. 2, ch. 2000-160; s. 11, ch. 2000-304; s. 4, ch. 2000-305; ss. 2, 11, ch. 2000-312; s. 4, ch. 2000-355; s. 3, ch. 2000-367; s. 18, ch. 2001-158; s. 2, ch. 2001-279; s. 8, ch. 2002-173; s. 1, ch. 2002-239; s. 3, ch. 2003-36; s. 139, ch. 2003-261; s. 1, ch. 2004-52; s. 7, ch. 2004-334; ss. 12, 13, ch. 2005-39; s. 1, ch. 2005-96; s. 13, ch. 2005-147; s. 1, ch. 2005-209; s. 5, ch. 2006-45; s. 9, ch. 2008-6; s. 16, ch. 2008-104; s. 5, ch. 2009-187; s. 1, ch. 2011-64; s. 50, ch. 2011-142; s. 8, ch. 2011-225; s. 43, ch. 2012-30.

120.81Exceptions and special requirements; general areas.—

(1)EDUCATIONAL UNITS.—

(a)Notwithstanding s. 120.536(1) and the flush left provisions of s. 120.52(8), district school boards may adopt rules to implement their general powers under s. 1001.41.

(b)The preparation or modification of curricula by an educational unit is not a rule as defined by this chapter.

(c)Notwithstanding s. 120.52(16), any tests, test scoring criteria, or testing procedures relating to student assessment which are developed or administered by the Department of Education pursuant to s. 1003.43, s. 1003.438, s. 1008.22, or s. 1008.25, or any other statewide educational tests required by law, are not rules.

(d)Notwithstanding any other provision of this chapter, educational units shall not be required to include the full text of the rule or rule amendment in notices relating to rules and need not publish these or other notices in the Florida Administrative Weekly, but notice shall be made:

1.By publication in a newspaper of general circulation in the affected area;

2.By mail to all persons who have made requests of the educational unit for advance notice of its proceedings and to organizations representing persons affected by the proposed rule; and

3.By posting in appropriate places so that those particular classes of persons to whom the intended action is directed may be duly notified.

(e)Educational units, other than the Florida School for the Deaf and the Blind, shall not be required to

make filings with the committee of the documents required to be filed by s. 120.54 or s. 120.55(1)(a)4.

(f)Notwithstanding s. 120.57(1)(a), hearings which involve student disciplinary suspensions or expulsions may be conducted by educational units.

(g)Sections 120.569 and 120.57 do not apply to any proceeding in which the substantial interests of a student are determined by a state university or a community college.

(h)Notwithstanding ss. 120.569 and 120.57, in a hearing involving a student disciplinary suspension or expulsion conducted by an educational unit, the 14-day notice of hearing requirement may be waived by the agency head or the hearing officer without the consent of parties.

(i)For purposes of s. 120.68, a district school board whose decision is reviewed under the provisions of s. 1012.33 and whose final action is modified by a superior administrative decision shall be a party entitled to judicial review of the final action.

(j)Notwithstanding s. 120.525(2), the agenda for a special meeting of a district school board under authority of s. 1001.372(1) shall be prepared upon the calling of the meeting, but not less than 48 hours prior to the meeting.

(k)Students are not persons subject to regulation for the purposes of petitioning for a variance or waiver to rules of educational units under s. 120.542.

(l)Sections 120.54(3)(b) and 120.541 do not apply to the adoption of rules pursuant to s. 1012.22, s. 1012.27, s. 1012.335, s. 1012.34, or s. 1012.795.

(2)LOCAL UNITS OF GOVERNMENT.—

(a)Local units of government with jurisdiction in only one county or part thereof shall not be required to make filings with the committee of the documents required to be filed by s. 120.54.

(b)Notwithstanding any other provision of this chapter, units of government with jurisdiction in only one county or part thereof need not publish required notices in the Florida Administrative Weekly, but shall publish these notices in the manner required by their enabling acts for notice of rulemaking or notice of meeting. Notices relating to rules are not required to include the full text of the rule or rule amendment.

(3)PRISONERS AND PAROLEES.—

(a)Notwithstanding s. 120.52(13), prisoners, as defined by s. 944.02, shall not be considered parties in any proceedings other than those under s. 120.54(3)(c) or (7), and may not seek judicial review under s. 120.68 of any other agency action. Prisoners are not eligible to seek an administrative determination of an agency statement under s. 120.56(4). Parolees shall not be considered parties for purposes of agency action or judicial review when the proceedings relate to the rescission or revocation of parole.

(b)Notwithstanding s. 120.54(3)(c), prisoners, as defined by s. 944.02, may be limited by the Department of Corrections to an opportunity to present evidence and argument on issues under consideration by submission of written statements concerning intended action on any department rule.

(c)Notwithstanding ss. 120.569 and 120.57, in a preliminary hearing for revocation of parole, no less than 7 days' notice of hearing shall be given.

(4)REGULATION OF PROFESSIONS.—Notwithstanding s. 120.569(2)(g), in a proceeding against a licensed professional or in a proceeding for licensure of an applicant for professional licensure which involves allegations of sexual misconduct:

(a)The testimony of the victim of the sexual misconduct need not be corroborated.

(b)Specific instances of prior consensual sexual activity between the victim of the sexual misconduct and any person other than the offender is inadmissible, unless:

1.It is first established to the administrative law judge in a proceeding in camera that the victim of the sexual misconduct is mistaken as to the identity of the perpetrator of the sexual misconduct; or

2.If consent by the victim of the sexual misconduct is at issue and it is first established to the administrative law judge in a proceeding in camera that such evidence tends to establish a pattern of conduct or behavior on the part of such victim which is so similar to the conduct or behavior in the case that it is relevant to the issue of consent.

(c)Reputation evidence relating to the prior sexual conduct of a victim of sexual misconduct is inadmissible.

(5)HUNTING AND FISHING REGULATION.—Agency action which has the effect of altering established hunting or fishing seasons, or altering established annual harvest limits for saltwater fishing if the procedure for altering such harvest limits is set out by rule of the Fish and Wildlife Conservation Commission, is not a rule as defined by this chapter, provided such action is adequately noticed in the area affected through publishing in a newspaper of general circulation or through notice by broadcasting by electronic media.

(6)RISK IMPACT STATEMENT.—The Department of Environmental Protection shall prepare a risk impact statement for any rule that is proposed for approval by the Environmental Regulation Commission and that establishes or changes standards or criteria based on impacts to or effects upon human health. The Department of Agriculture and Consumer Services shall prepare a risk impact statement for any rule that is proposed for adoption that establishes standards or criteria based on impacts to or effects upon human health.

(a)This subsection does not apply to rules adopted pursuant to federally delegated or mandated programs where such rules are identical or substantially identical to the federal regulations or laws being adopted or implemented by the Department of Environmental Protection or Department of Agriculture and Consumer Services, as applicable. However, the Department of Environmental Protection and the Department of Agriculture and Consumer Services shall identify any risk analysis information available to them from the Federal Government that has formed the basis of such a rule.

(b)This subsection does not apply to emergency rules adopted pursuant to this chapter.

(c)The Department of Environmental Protection and the Department of Agriculture and Consumer Services shall prepare and publish notice of the availability of a clear and concise risk impact statement for all applicable rules. The risk impact statement must explain the risk to the public health addressed by the rule and shall identify and summarize the source of the scientific information used in evaluating that risk.

(d)Nothing in this subsection shall be construed to create a new cause of action or basis for challenging a rule nor diminish any existing cause of action or basis for challenging a rule.

History.—s. 42, ch. 96-159; s. 17, ch. 97-176; s. 49, ch. 99-2; s. 65, ch. 99-245; s. 7, ch. 99-379; s. 28, ch. 99-398; s. 4, ch. 2000-214; s. 897, ch. 2002-387; s. 17, ch. 2008-104; s. 4, ch. 2010-78; s. 9, ch. 2011-225.

CHAPTER 64B16-25
ORGANIZATION AND PURPOSE

64B16-25.130 Executive Director (Repealed)
64B16-25.170 Probable Cause Panel
64B16-25.340 Meetings and Workshops

64B16-25.130 Executive Director.

Rulemaking Authority 465.005 FS. Law Implemented 48.111(2), 456.004, 456.009 FS. History–New 10-17-79, Formerly 21S-8.04, 21S-8.004, Amended 7-30-91, Formerly 21S-25.130, 61F10-25.130, 59X-25.130, Amended 10-29-97, 11-2-03, Repealed 3-28-12.

64B16-25.170 Probable Cause Panel.

(1) The determination as to whether probable cause exists to believe that a violation of Chapter 456, Part II, 465, 499, or 893, F.S., or of the rules promulgated thereunder, has occurred shall be made by the probable cause panel. The panel shall meet as necessary.

(2) The probable cause panel shall be composed of two (2) persons, either current or former board members appointed by the chairman of the Board. One appointee must be a current board member. The panel must include a former or current board member who is a licensed pharmacist. An appointee may be a former board member.

Rulemaking Authority 465.005 FS. Law Implemented 456.073 FS. History–New 10-17-79, Formerly 21S-8.08, 21S-8.008, 21S-25.170, 61F10-25.170, 59X-25.170, Amended 11-24-09.

64B16-25.340 Meetings and Workshops.

The following are considered to be official meetings of the Board:

(1) Board Meetings.

(2) Examination Committee Meetings.

(3) Tripartite Continuing Education Committee Meeting.

(4) Meetings of committees set out in the official minutes of the Board where statutory authority is given by the practice act.

(5) Meetings of a Board member with Department staff or contractors of the Department at the Department's or Board's request. Any participation or meeting of members noticed or unnoticed will be on file in the Board office.

(6) Where a Board member has been requested by the State Surgeon General to participate in a meeting.

(7) Probable Cause Panel meetings.

(8) All activity of Board members, if authorized by the Board, when grading, proctoring or reviewing examinations given by the Department.

(9) All participation in Board authorized meetings with professional associations of which the Board is a member or invitee. This would include all meetings of the National Association of Boards of Pharmacy of which the Board is a member as well as Board authorized participation in meetings of national or professional associations or organizations involved in educating, regulating and reviewing the profession over which the Board has statutory authority.

(10) Any and all other activities which are Board approved and which are necessary for Board members to attend in order to further protect the public health, safety and welfare, through the regulation of which the Board has statutory authority.

Rulemaking Authority 456.011(4) FS. Law Implemented 456.011(4) FS. History–New 9-30-81, Amended 11-13-81, 12-31-81, Formerly 21S-10.05, 21S-10.005, Amended 7-30-91, Formerly 21S-25.340, 61F10-25.340, 59X-25.340, Amended 2-18-08.

CHAPTER 64B16-26
PHARMACISTS LICENSURE

64B16-26.100 Pharmacists Newly Licensed (Repealed)
64B16-26.101 Fees and License Renewal Application
64B16-26.1001 Examination and Application Fees
64B16-26.1002 Initial License Fees
64B16-26.1003 Active License Renewal Fees
64B16-26.1004 Inactive License Election; Renewal; Fees
64B16-26.1005 Retired License Election; Renewal; Fees.
64B16-26.1012 Approved Continuing Education Provider Renewal Fee
64B16-26.102 Inactive License Renewal (Repealed)
64B16-26.1021 Delinquent License Reversion; Reinstatement; Fees
64B16-26.1022 Permit Fees
64B16-26.103 Continuing Education Credits; Renewal
64B16-26.1031 Influenza Immunization Certification Program
64B16-26.1032 Influenza Immunization Administration Certification Application
64B16-26.104 Exemptions for Members of the Armed Forces; Spouses
64B16-26.105 Consultant Pharmacists Initial Registration Fee and Renewal Fee (Repealed)
64B16-26.106 Nuclear Pharmacists Initial Registration Fee and Renewal Fee (Repealed)
64B16-26.107 Inactive Nuclear Pharmacist License Renewal (Repealed)
64B16-26.200 Examination Requirements
64B16-26.201 Reexamination (Repealed)
64B16-26.202 Examination Review Procedure (Repealed)
64B16-26.203 Licensure by Examination; Application
64B16-26.2031 Licensure by Examination; Foreign Pharmacy Graduates
64B16-26.2032 Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates)
64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates)
64B16-26.2035 Examination Fees (Repealed)
64B16-26.204 Licensure by Endorsement
64B16-26.205 Requirements for Foreign Pharmacy Graduates to Be Admitted to the Pharmacist Licensure Examination (Repealed)
64B16-26.300 Consultant Pharmacist Licensure
64B16-26.301 Subject Matter for Consultant Pharmacist Training Program
64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education
64B16-26.303 Nuclear Pharmacist Licensure
64B16-26.304 Subject Matter for Nuclear Pharmacist License Renewal Continuing Education Programs
64B16-26.320 Subject Matter for Continuing Education to Order and Evaluate Laboratory Tests
64B16-26.350 Requirements for Pharmacy Technician Registration
64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs
64B16-26.355 Subject Matter for Registered Pharmacy Technician Continuing Education
64B16-26.400 Pharmacy Interns; Registration; Employment
64B16-26.401 Requirements for an Internship Program Sufficient to Qualify an Applicant for Licensure by Examination (Repealed)
64B16-26.600 Tripartite Continuing Education Committee
64B16-26.601 Standards for Approval of Courses and Providers
64B16-26.6012 Guidelines for Board Ordered Disciplinary Continuing Education Courses
64B16-26.603 Continuing Education Records Requirements
64B16-26.602 Recommendation by the Tripartite Continuing Education Committee (Repealed)
64B16-26.606 Number of Required Hours (Repealed)

64B16-26.100 Pharmacists Newly Licensed.

Rulemaking Authority 456.013(2), 465.005 FS. Law Implemented 456.013(2), 465.008 FS. History–New 3-19-79, Formerly 21S-6.04, Amended 1-7-87, 12-29-88, 10-16-90, Formerly 21S-6.004, Amended 1-10-93, Formerly 21S-26.100, 61F10-26.100, 59X-26.100, Amended 4-17-01, Repealed 3-10-05.

64B16-26.101 Fees and License Renewal Application.

Rulemaking Authority 465.005 FS. Law Implemented 456.036, 456.064, 465.008 FS. History–New 3-19-79, Formerly 21S-6.05, Amended 1-7-87, 4-21-87, 12-29-88, Formerly 21S-6.005, Amended 7-31-91, 1-10-93, Formerly 21S-26.101, 61F10-26.101, Amended 3-10-96, Formerly 59X-26.101, Amended 12-31-97, 12-3-00, 3-18-01, 10-15-01, Repealed 3-10-05.

64B16-26.1001 Examination and Application Fees.

(1) The non-refundable examination fee for licensure by examination shall be $100, payable to the Board. Examination fees for the National Practice Examination and jurisprudence examination are payable to the examination vendor.

(2) The non-refundable application fee licensure by endorsement shall be $100, payable to the Board.

(3) The non-refundable application fee for a continuing education provider seeking approved provider status shall be $150, payable to the Board.

(4) The non-refundable application fee for the Influenza Immunization Certification shall be $55, payable to the Board.

(5) The non-refundable application fee for registered pharmacy technicians shall be $50, payable to the Board.

Rulemaking Authority 465.005, 465.009 FS. Law Implemented 456.025(7), 465.007, 465.0075, 465.009, 465.014 FS. History–New 1-11-05, Amended 10-30-07, 11-15-09, 7-7-10.

64B16-26.1002 Initial License Fees.

(1) The initial license fee for a pharmacist license shall be $190 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(2) The initial license fee for a consultant pharmacist license shall be $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(3) The initial license fee for a nuclear pharmacist license shall be $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(4) The initial registration fee for a registered pharmacy technician shall be $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

Rulemaking Authority 465.005, 465.0125, 465.0126 FS. Law Implemented 456.013(2), 456.065(3), 465.0125, 465.0126, 465.014 FS. History–New 1-11-05, Amended 11-24-09.

64B16-26.1003 Active License Renewal Fees.

(1) The biennial license renewal fee for an active pharmacist license shall be $200 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(2) The biennial license renewal fee for a consultant pharmacist active license shall be $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(3) The biennial license renewal fee for a nuclear pharmacist active license shall be $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(4) The biennial registration renewal fee for a registered pharmacy technician shall be $50 plus $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

Rulemaking Authority 456.036, 465.005, 465.008, 465.0125, 465.0126 FS. Law Implemented 456.036, 456.065(3), 465.008, 465.0125, 465.0126, 465.014 FS. History–New 1-11-05, Amended 2-24-10, 2-1-12.

64B16-26.1004 Inactive License Election; Renewal; Fees.

(1) A pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $245 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $245 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, submits the reactivation fee of $70, and the current active renewal fee set forth in Rule 64B16-26.1001, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status and submits the reactivation fee of $70, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(2) A consultant pharmacist licensee may elect:

(a) At the time of license renewal to place the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the consultant pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status consultant pharmacist license to active status, provided the consultant pharmacist licensee meets the continuing education requirements of subsection 64B16-26.103(2), F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of $25, and the active consultant pharmacist renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, and submits the reactivation fee of $25, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(3) A nuclear pharmacist licensee may elect:

(a) At the time of license renewal to place the nuclear pharmacist license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of license renewal, if the nuclear pharmacist license is inactive, to continue the license on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $100 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of license renewal to change the inactive status license to active status, provided the nuclear pharmacist meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status, and by submitting a reactivation fee of $50, and the active nuclear license renewal fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than license renewal to change the inactive status license to active status, provided the nuclear pharmacist licensee meets the continuing education requirements of Rule 64B16-26.304, F.A.C., for each biennium the license was on inactive status and by submitting a reactivation fee of $50, a change of status fee of $25 and the difference between the inactive status renewal fee and the active status renewal fee, if any exists.

(4) A registered pharmacy technician may elect:

(a) At the time of renewal to place the registered pharmacy technician registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(b) At the time of renewal, if the registered pharmacy technician registration is inactive, to continue the registration on inactive status by submitting a written request with the board for inactive status and submitting the inactive status renewal fee of $50 plus a $5 unlicensed activity fee pursuant to Section 456.065(3), F.S.

(c) At the time of renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status, and by submitting a reactivation fee of $50, and the active registration fee set forth in Rule 64B16-26.1003, F.A.C.

(d) At a time other than renewal to change the inactive status registration to active status, provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status and by submitting a reactivation fee of $50, a change of status fee of $25 and the difference between the inactive

status renewal fee and the active status renewal fee, if any exists.

Rulemaking Authority 456.036, 465.005, 465.012, 465.0125, 465.0126 FS. Law Implemented 456.036, 456.065(3), 465.012, 465.0125, 465.0126 FS. History–New 1-11-05, Amended 10-30-07, 10-27-09.

64B16-26.1005 Retired License Election; Renewal; Fees.

(1) A licensee may elect to place his or her license on retired status.

(a) At the time of license renewal, to place the license on retired status, the licensee must submit a written request with the board for retired status and submit the retired status fee of $50.00 pursuant to Section 456.036(4)(b), F.S., and the current unlicensed activity fee.

(b) At a time other than license renewal, to place the license on retired status, the licensee must submit a written request to the Board for the retired status plus submit the retired status fee of $50.00 pursuant to Section 456.036(4)(b), F.S., plus a change of status fee of $25.00, plus the current unlicensed activity fee.

(c) Before the license of a retired status licensee is reactivated, the licensee must meet the continuing education requirements in Rule 64B16-26.103, F.A.C., and pay any renewal fees imposed on an active status licensee for all biennial licensure periods, plus the current unlicensed activity fee during which the licensee was on retired status.

(2) Any pharmacist applying for an active status license who has been on retired status for 5 years or more, or if licensed elsewhere, has not been active during the past 5 years, shall as a condition of licensure, demonstrate that he or she is able to practice with the care and skill sufficient to protect the health, safety, and welfare of the public by:

(a) If inactive for less than 5 years, the licensee must pass a jurisprudence examination;

(b) If inactive for 5 or more years, in addition to paragraph (a), the licensee must pass the NAPLEX.

Rulemaking Authority 456.036(15) FS. Law Implemented 456.013, 456.036(4)(b) FS. History–New 11-29-06, Amended 12-22-09.

64B16-26.1012 Approved Continuing Education Provider Renewal Fee.

The biennial fee to renew as an approved continuing education provider shall be $150.

Rulemaking Authority 456.013(9), 465.005 FS. Law Implemented 456.013(9), 465.009, 465.012 FS. History–New 1-11-05.

64B16-26.1021 Delinquent License Reversion; Reinstatement; Fees.

(1) An active or inactive license that is not renewed by midnight of the expiration date of the license shall automatically revert to delinquent status.

(2) A pharmacist may request that a delinquent license be reinstated to active or inactive status, provided the licensee meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the license was on inactive status, and by submitting a reactivation fee of $100 plus the current fee for an active status or inactive status license set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(3) A consultant pharmacist may request that a delinquent consultant pharmacist license be reinstated to an active or inactive status by submitting a delinquent fee of $100 plus the current fee for an active or inactive status consultant pharmacist license set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(4) A nuclear pharmacist may request that a delinquent nuclear pharmacist license be reinstated to an active or inactive license status by submitting a delinquent fee of $100 plus the current fee for an active or inactive nuclear pharmacist license set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(5) A registered pharmacy technician may request that a delinquent registered pharmacy technician registration be reinstated to an active or inactive status provided the registered pharmacy technician meets the continuing education requirements of Rule 64B16-26.103, F.A.C., for each biennium the registration was on inactive status, and by submitting a reactivation fee of $25 plus the current fee for an active or inactive status registered pharmacy technician registration set forth in Rule 64B16-26.1003 or 64B16-26.1004, F.A.C.

(6) A license in delinquent status that is not renewed prior to midnight of the expiration date of the current licensure cycle shall be rendered null without any further action by the Department. Any subsequent license shall be the result of applying for and meeting all requirements imposed on an applicant for new licensure.

Rulemaking Authority 456.036, 465.005, 465.012 FS. Law Implemented 456.036, 465.012 FS. History–New 1-11-05, Amended 10-27-09.

64B16-26.102 Inactive License Renewal.

Rulemaking Authority 465.005 FS. Law Implemented 465.008, 465.012 FS. History–New 3-19-79, Formerly 21S-6.06, Amended 1-7-87, 12-29-88, Formerly 21S-6.006, Amended 7-31-91, 1-10-93, Formerly 21S-26.102, 61F10-26.102, Amended 3-10-96, Formerly 59X-26.102, Amended 3-18-01, Repealed 3-10-05.

64B16-26.1022 Permit Fees.

(1) The initial permit fee for a pharmacy, as provided by Section 465.022(8)(a), F.S., shall be $250.

(2) The biennial permit renewal fee for a pharmacy, as provided by Section 465.022(8)(b), F.S., shall be $250.

(3) The change of location fee for a pharmacy, as provided by Section 465.022(8)(d), F.S., shall be $100.

(4) The delinquent fee for a pharmacy permit, as provided by Section 465.022(8)(c), F.S., shall be $100.

Rulemaking Authority 465.005, 465.022(8) FS. Law Implemented 465.022(8) FS. History–New 1-11-05.

64B16-26.103 Continuing Education Credits; Renewal.

(1) Prior to biennal renewal of pharmacist licensure, a licensee shall complete no less than 30 hours of approved courses of continued professional pharmaceutical education within the 24 month period prior to the expiration date of the license. The following conditions shall apply.

(a) Upon a licensee's first renewal of licensure, the licensee must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of licensure may be applied to satisfy the general continuing education hours requirement.

(b) The initial renewal of a pharmacist license will not require completion of courses of continued professional pharmaceutical education hours if the license was issued less than 12 months prior to the expiration date of the license. If the initial renewal occurs 12 months or more after the initial licensure, then 15 hours of continued professional pharmaceutical education hours shall be completed prior to the renewal of the license but no earlier than the date of initial licensure

(c) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(d) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The licensee must sign in with the Executive Director or designee of the Board before the meeting day begins;

2. The licensee must remain in continuous attendance;

3. The licensee cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(e) A member of the Board of Pharmacy may obtain five (5) hours of continuing education in the subject area of risk management for attendance at one Board meeting at which disciplinary hearings are conducted. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(f) Up to five hours per biennium of continuing education credit may be fulfilled by the performance of volunteer services to the indigent as provided in Section 456.013(9), F.S., or to underserved populations, or in areas of critical need within the state where the licensee practices. In order to receive credit, the licensee must make application to and receive approval in advance from the Board. Application shall be made on form DH-MQA 1170 (Rev. 02/09), Individual Request for Continuing Education for Volunteers, which is hereby incorporated by reference. The form can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin

#C04, Tallahassee, Florida 32399-3254. One hour credit shall be given for each two hours volunteered in the 24 months prior to the expiration date of the license. In the application for approval, the licensee shall disclose the type, nature and extent of services to be rendered, the facility where the services will be rendered, the number of patients expected to be serviced, and a statement indicating that the patients to be served are indigent. If the licensee intends to provide services in underserved or critical need areas, the application shall provide a brief explanation as to those facts. A licensee who is completing community service as a condition of discipline imposed by the board cannot use such service to complete continuing education requirements.

(g) Continuing education credit shall be granted for completion of post professional degree programs provided by accredited colleges or schools of pharmacy. Credit shall be awarded at the rate of 5 hours of continuing education credit per semester hour completed within the 24 months prior to the expiration date of the license.

(h) Continuing education may consist of post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other educational opportunities which advance the practice of the profession of pharmacy if approved by the Board. A course shall be approved prior to completion and will be evaluated by the Tripartite Committee using the standards found in Rule 64B16-26.601, F.A.C. Individuals must submit requests for course approval at least 45 days in advance of the program or course by completing the approved application form DOH/MQA/PH 112, (Rev. 6/12), entitled Individual Requests for Continuing Education Credit, which is incorporated by reference, and which can be obtained from http://www.flrules.org/Gateway/reference.asp?No=Ref-01636 and the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or from the website located at http://www.doh.state.fl.us/mqa/pharmacy. Individuals seeking course approval must attach to the application a detailed program outline, overview or syllabus which describes the educational content, objectives and faculty qualifications.

(i) Any volunteer expert witness who is providing expert witness opinions for cases being reviewed by the Department of Health pursuant to Chapter 465, F.S., shall receive five (5) hours of credit in the area of risk management for each case reviewed in the 24 months prior to the expiration date of the license, up to a maximum of ten (10) hours per biennium.

(j) The presenter of a live seminar, a live video teleconference or through an interactive computer-based application shall receive 1 credit for each course credit hour presented, however presenter will not receive additional credit for multiple same course presentations.

(k) All programs approved by the ACPE for continuing education for pharmacists are deemed approved by the Board for general continuing education hours for pharmacists. Any course necessary to meet the continuing education requirement for HIV/AIDS, medication errors, or consultant pharmacist license renewal shall be Board approved.

(l) General continuing education earned by a non-resident pharmacist in another state that is not ACPE approved, but is approved by the board of pharmacy in the state of residence can be applied to meet the requirements of license renewal in subsection (1) above.

(m) At least ten (10) of the required 30 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

(2) Prior to renewal a consultant pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.302, F.A.C., within the 24 month period prior to the expiration date of the consultant license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1) above. However, if consultant recertification hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a consultant pharmacist license occurs less than 12 months after the initial licensure, then completion of consultant courses of continuing education hours will not be required.

(b) If the initial renewal of a consultant pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of consultant continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(3) Prior to renewal a nuclear pharmacist shall complete no less than 24 hours of Board approved continuing education in the course work specified in Rule 64B16-26.304, F.A.C., within the 24 month period prior to the expiration date of the nuclear pharmacist license. The hours earned to satisfy this requirement cannot be used to apply toward the 30 hours required in subsection (1) above. However, if nuclear pharmacist license renewal hours are earned and not used to meet the requirements of this paragraph, they may be applied by the licensee to the 30 hours required in subsection (1).

(a) If the initial renewal of a nuclear pharmacist license occurs less than 12 months after the initial licensure, then completion of

courses of nuclear pharmacy continuing education hours will not be required.

(b) If the initial renewal of a nuclear pharmacist license occurs 12 months or more after the initial licensure, then 12 hours of nuclear pharmacy continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(c) All programs approved by the ACPE for continuing education for nuclear pharmacists are deemed approved by the Board for general continuing education hours for nuclear pharmacists.

(4) Prior to renewal a registered phamacy technician shall complete no less than twenty (20) hours of Board approved continuing education in the course work specified in Rule 64B16-26.355, F.A.C., within the 24 month period prior to the expiration date of the phamacy technician registration.

(a) Upon a pharmacy technician's first renewal, registrtant must document the completion of one (1) hour of board approved continuing education which includes the topics of Human Immunodeficiency Virus and Acquired Immune Deficiency Syndrome; the modes of transmission, including transmission from a healthcare worker to a patient and the patient to the healthcare worker; infection control procedures, including universal precautions; epidemiology of the disease; related infections including tuberculosis (TB); clinical management; prevention; and current Florida law on AIDS and its impact on testing, confidentiality of test results, and treatment of patients. In order to meet this requirement, licensees must demonstrate that the course includes information on the State of Florida law on HIV/AIDS and its impact on testing, reporting, the offering of HIV testing to pregnant women, and partner notification issues pursuant to Sections 381.004 and 384.25, F.S. Any HIV/AIDS continuing education course taken during the second or subsequent renewal of registration may be applied to satisfy the general continuing education hours requirement.

(b) If the initial renewal of a pharmacy technician registration occurs less than 12 months after the initial licensure, then completion of courses of a pharmacy technician registration education hours will not be required.

(c) If the initial renewal of a pharmacy techician registration occurs 12 months or more after the initial licensure, then 12 hours of registered phamacy technician continuing education hours must be completed prior to the renewal date of the license but no earlier than the date of initial licensure.

(d) All programs approved by the ACPE for continuing education for pharmacy technicians are deemed approved by the Board for general continuing education hours for registered pharmacy technicians. Any course necessary to meet the continuing education requirement for HIV/AIDS license renewal shall be Board approved.

(e) Prior to renewal a licensee must complete, within the 24 month period prior to the expiration date of the license, a two-hour continuing education course approved in advance by the Board on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. Hours obtained pursuant to this section may be applied by the licensee to the requirements of subsection (1).

(f) Five hours of continuing education in the subject area of risk management may be obtained by attending one full day or eight (8) hours of a board meeting at which disciplinary hearings are conducted by the Board of Pharmacy in compliance with the following:

1. The registratrant must sign in with the Executive Director or designee of the Board before the meeting day begins;

2. The registrant must remain in continuous attendance;

3. The registrant cannot receive continuing education credit for attendance at a board meeting if required to appear before the board; and

4. The maximum continuing education hours allowable per biennium under this paragraph shall be ten (10).

(g) At least four (4) of the required 20 hours must be obtained either at a live seminar, a live video teleconference, or through an interactive computer-based application.

Rulemaking Authority 456.033, 465.009 FS. Law Implemented 456.013(7), (9), 456.033, 465.009 FS. History–New 3-19-79, Formerly 21S-6.07, Amended 1-7-87, Formerly 21S-6.007, Amended 7-31-91, 10-14-91, Formerly 21S-26.103, 61F10-26.103, Amended 7-1-97, Formerly 59X-26.103, Amended 7-11-00, 10-15-01, 1-2-02, 1-12-03, 4-12-05, 5-26-09, 5-27-10, 9-20-12.

64B16-26.1031 Influenza Immunization Certification Program.

(1) All applications for immunization certification programs shall be made on board approved form DH-MQA 1234, "Immunization Certification Program Application", effective 04/10, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850) 488-0595, or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) The Board shall approve for initial certification of pharmacist administration of influenza immunizations, programs of study not less than 20 hours that include coursework covering all of the following;

(a) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) Immunization Schedules;

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry through enrollment application DH Form 1997 (effective 10/07) herein incorporated by reference and may be obtained from the Board office by writing to the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or by telephoning 1(877)888-7468;

(d) Vaccine storage and handling;

(e) Bio-Hazardous waste disposal and sterile techniques;

(f) Entering, negotiating and performing pursuant to physician oversight protocols;

(g) Community immunization resources and programs;

(h) Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;

(i) Procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);

(j) Reimbursement procedures and vaccine coverage by federal, state and local governmental jurisdictions and private third party payors;

(k) Administration techniques;

(l) The current influenza immunization guidelines and recommendations of the United States Department of Health Centers for Disease Control and Prevention published in the Morbidity Weekly Report (MMWR) December 1, 2006, Vol. 55 No. RR-15 and updated MMWR July 13, 2007, Vol. 56, No. RR-6;

(m) Review of Section 465.189, F.S.; and

(n) Cardiopulmonary Resuscitation (CPR) training.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 3-20-08, Amended 8-30-10.

64B16-26.1032 Influenza Immunization Administration Certification Application.

All applications for immunization certification shall be made on board approved form DH-MQA 1125, "Immunization Administration Certification Application," effective February 2010, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable application fee as set forth in Rule 64B16-26.1001, F.A.C.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 9-21-10.

64B16-26.104 Exemptions for Members of the Armed Forces; Spouses.

(1) Any pharmacist or registered pharmacy technician on active duty with the Armed Forces of the United States who at the time of becoming a member of the Armed Forces of the United States was in good standing with the Board and was entitled to practice the profession of pharmacy or registered as a pharmacy technician in Florida shall be exempt from all license renewal provisions so long as the licensee is on active duty with the Armed Forces and for a period of six months after discharge so long as the licensee is not engaged in the practice of pharmacy in the private sector for profit.

(2) A pharmacist or registered pharmacy technician who is a spouse of a member of the Armed Forces of the United States and who was caused to be absent from the State of Florida because of the spouse's duties with the Armed Forces shall be exempt from all license renewal provisions.

Rulemaking Authority 465.005 FS. Law Implemented 456.024 FS. History–New 3-19-79, Amended 4-30-85, Formerly 21S-6.09, 21S-6.009, Amended 7-31-91, Formerly 21S-26.104, 61F10-26.104, 59X-26.104, Amended 1-11-05, 10-27-09.

64B16-26.105 Consultant Pharmacists Initial Registration Fee and Renewal Fee.

Rulemaking Authority 465.005, 465.008, 465.0125 FS. Law Implemented 456.036, 465.0125 FS. History–New 10-26-83, Amended 2-21-84, Formerly 21S-6.10, 21S-6.010, 21S-26.105, 61F10-26.105, Amended 3-28-95, Formerly 59X-26.105, Repealed 3-10-05.

64B16-26.106 Nuclear Pharmacists Initial Registration Fee and Renewal Fee

Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 456.036, 465.0126 FS. History–New 12-29-88, Formerly 21S-6.011, 21S-26.106, 61F10-26.106, Amended 6-26-95, 3-11-96, Formerly 59X-26.106, Repealed 3-10-05.

64B16-26.107 Inactive Nuclear Pharmacist License Renewal.

Rulemaking Authority 465.005, 465.008, 465.012, 465.022(8) FS. Law Implemented 465.008, 465.012, 465.022(8) FS. History–New 6-26-95, Formerly 59X-26.107, Repealed 3-10-05.

64B16-26.200 Examination Requirements.

The examination provided in Section 465.007, F.S., shall be as follows:

(1) Part A – North American Pharmacist Licensure Examination (NAPLEX).

(2) Part B – Multistate Pharmacy Jurisprudence Examination – Florida Version.

Rulemaking Authority 456.017, 465.005 FS. Law Implemented 456.017 FS. History–New 10-17-79, Amended 2-8-81, 6-22-82, 8-16-84, 4-30-85, Formerly 21S-12.01, Amended 5-6-86, Formerly 21S-12.001, Amended 1-10-93, Formerly 21S-26.200, 61F10-26.200, Amended 7-1-97, Formerly 59X-26.200, Amended 3-22-99, 1-11-05.

64B16-26.201 Reexamination.

Rulemaking Authority 456.017, 465.005 FS. Law Implemented 456.017 FS. History–New 10-17-79, Amended 2-8-81, 11-27-84, 4-30-85, Formerly 21S-12.02, Amended 5-6-86, Formerly 21S-12.002, 21S-26.201, 61F10-26.201, 59X-26.201, Repealed 3-10-05.

64B16-26.202 Examination Review Procedure.

Rulemaking Authority 456.017(2) FS. Law Implemented 456.017(2) FS. History–New 10-17-79, Amended 12-27-82, Formerly 21S-12.03, Amended 12-24-89, Formerly 21S-12.003, 21S-26.202, 61F10-26.202, 59X-26.202, Repealed 3-10-05.

64B16-26.203 Licensure by Examination; Application.

Applicants who are at least 18 years of age and a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education may apply to take the licensure examination.

(1) All applications for licensure by examination must be made on board approved form DOH/MQA/101, Pharmacist Examination Application for U.S. and Puerto Rico Graduates and Instructions, (Rev 9/09), which is hereby incorporated by reference, and which can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850)488-0595 to request an application or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable examination fee and an initial license fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) The applicant must submit proof of having met the following requirements:

(a) Completion of an internship program provided by either an accredited school or college of pharmacy or a state board of pharmacy or jointly by both provided that the program meets requirements of Rule 64B16-26.2032, F.A.C.

(b) Completion of a board approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For those applicants who apply within one year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety, as evidenced by a letter attesting to subject matter covered from the Dean of the University.

(3) An applicant must reapply if all requirements for licensure are not met within one year of the receipt of the application.

(4) Passing examination scores may be used upon reapplication only if the examination was completed within 3 years of the reapplication.

Rulemaking Authority 456.033, 465.005 FS. Law Implemented 456.013(1), (7), 456.025(3), 456.033, 465.007, 465.022 FS. History–New 10-17-79, Formerly 21S-12.04, 21S-12.004, Amended 7-31-91, 10-14-91, Formerly 21S-26.203, 61F10-26.203, Amended 7-1-97, Formerly 59X-26.203, Amended 8-17-99, 10-15-01, 1-2-02, 1-12-03, 1-11-05, 2-18-08, 5-26-09, 5-11-10.

64B16-26.2031 Licensure by Examination; Foreign Pharmacy Graduates.

In order for a foreign pharmacy graduate to be admitted to the professional licensure examination, the applicant must be a graduate of a four year undergraduate pharmacy program at a school or college outside the United States and have completed an internship program approved by the Board.

(1) All applications for licensure by examination must be made on form DH-MQA 103 (Rev. 09/09), Pharmacist Examination Application For Foreign Graduates and Instructions, which is hereby incorporated by reference. Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the Board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable examination fee and an initial license fee set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(a) For applications received at the Board of Pharmacy on or before June 30, 2009, the applicant must:

1. Successfully pass the foreign pharmacy graduate equivalency examination which is given by the Foreign Pharmacy Graduate Equivalency Commission with a minimum score of 75%.

2. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is administered by the Educational Testing Service, Inc., with a score of at least 500 for the pencil and paper test or 173 for the computer version and by passing the Test of Spoken English (TSE) with a score of 45 on the recalibrated TSE; or

3. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language Internet-based test (TOEFL ibt) with scores of: Listening – 18; Reading – 21; Speaking – 26; and Writing – 24.

(b) For applications received at the Board of Pharmacy on or after July 1, 2009, the applicant must:

1. Successfully pass the foreign pharmacy graduate equivalency examination which is given by the Foreign Pharmacy Graduate Equivalency Commission with a minimum score of 75%;

2. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language (TOEFL), which is administered by the Educational Testing Service, Inc., with a score of at least 550 for the pencil and paper test or 213 for the computer version and by passing the Test of Spoken English (TSE) with a score of 50 on the recalibrated TSE; or

3. Demonstrate proficiency in the use of English by passing the Test of English as a Foreign Language Internet-based test (TOEFL ibt) with scores of: Listening – 18; Reading – 21; Speaking – 26; and Writing – 24.

(2) Complete 2080 hours of supervised work activity, of which a minimum of 500 hours must be completed within the State of Florida. Such experience must be equivalent to that required in the internship program as set forth in Rule 64B16-26.2032, F.A.C. The work experience program including both the preceptor and the permittee must be approved by the Board of Pharmacy. The work experience shall be documented on form DH-MQA 1153 (Rev. 01/10), Foreign Graduate Intern Work Activity Manual, which is hereby incorporated by reference. Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a manual or download the manual from the Board's website at http://www.doh.state.fl.us/mqa/pharmacy. Further, no program of supervised work activity shall be approved for any applicant until said applicant has obtained the specified passing scores on the Foreign Pharmacy Graduate Equivalency Examination.

(3) Completion of a Board approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For applicants who apply within one year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety as evidence by a letter attesting to subject matter covered from the Dean of the University.

Rulemaking Authority 465.005, 465.007 FS. Law Implemented 465.007 FS. History–New 1-11-05, Amended 8-8-07, 6-10-09, 5-27-10.

64B16-26.2032 Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates).

A U.S. pharmacy student or graduate is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(1) All applications for registration must be made on form DH-MQA 104, Pharmacy Intern Application for U.S. Pharmacy Students/Graduates and Instructions, (Rev. 09/09), which is hereby incorporated by reference. Contact the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) An applicant for pharmacy intern registration must submit proof of:

(a) Enrollment in an intern program at a college or school of pharmacy accredited by the Accreditation Council of Pharmaceutical Education (ACPE); or

(b) Graduation from a college or school of pharmacy accredited by the ACPE.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirement of either paragraph (2)(a) or (2)(b), unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filing, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

(5) All internship experience for the purpose of qualifying for the examination pursuant to Section 465.007(1)(c), F.S., shall be obtained in a community pharmacy, institutional pharmacy or any Florida Board of Pharmacy approved pharmacy practice, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at college or school of pharmacy accredited by the ACPE shall assure that community or institutional pharmacies utilized for the obtaining of internship experience meet the following minimum requirements:

(a) The pharmacy shall hold a current license or permit issued by the state in which they are operating and shall have available all necessary equipment for professional services, necessary reference works, in addition to the official standards and current professional journals.

(b) The pharmacy shall be operated at all times under the supervision of a pharmacist and shall be willing to train persons desiring to obtain professional experience.

(c) The pharmacy shall establish to the program's satisfaction that the pharmacy fills, compounds and dispenses a sufficient number, kind and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding and dispensing of prescription drugs.

(d) The pharmacy shall have a clear record as to observance of federal, state and municipal laws and ordinances covering any phase of activity in which it is engaged.

(7) The program shall assure that all preceptors meet the following requirements:

(a) The pharmacist shall willingly accept the responsibility for professional guidance and training of the intern and be able to devote time to preceptor training sessions and to instruction of the intern.

(b) The pharmacist shall hold current licensure in the state in which pharmacy is practiced.

(c) The pharmacist shall be ineligible to serve as a preceptor during any period in which the pharmacist's license to practice pharmacy is revoked, suspended, on probation, or subject to payment of an unpaid fine levied by lawful Board order, or during any period in which the pharmacist's license is the subject of ongoing disciplinary proceedings.

(d) The pharmacist shall agree to assist the school or college of pharmacy in the achievement of the educational objectives set forth and to provide a professional environment for the training of the intern.

(e) Evidence shall be provided of the pharmacist's desire to continue broadening professional education and of an active involvement in a patient-oriented practice.

(8) In the event a program meets all the requirements set forth in subsection (6) of this rule, except for prior approval by the Florida Board of Pharmacy, any applicant submitting it for the purpose of qualifying for licensure by examination must show in addition to successful completion of the internship:

(a) Approval of the program by a state board of pharmacy; and

(b) Sufficient hours to total 2080 hours; or

(c) Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total 2080 hours when combined with the internship hours.

(9) All internship hours may be obtained prior to the applicant's graduation.

(10) Proof of completion of an internship program shall consist of a certification that the applicant has completed the program. If additional hours are required to total 2080 hours, satisfactory proof of the additional hours shall be constituted by the program's certification of completion of the additional hours.

(11) Hours worked in excess of 50 hours per week prior to the applicant's graduation or in excess of 60 hours per week after an applicant's graduation, will not be credited toward meeting the required internship hours.

(12) The Board approves all internships that are required to obtain the doctor of pharmacy degree from institutions which are accredited as provided by Section 465.007(1)(b)1., F.S. Applicants graduating after January 1, 2001 with the doctor of pharmacy degree from such institutions shall be deemed to have met the requirements of this section with documentation of graduation.

(13) The Board may conduct periodic review of programs to assure compliance with these rules.

(14) Proof of current licensure in another state and work as a pharmacist for up to 2080 hours may substitute for all or part of the internship requirement.

(15) Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under subsection (5) of this rule.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.007, 465.0075, 465.013 FS. History–New 4-1-07, Amended 7-7-10, 10-7-12.

64B16-26.2033 Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates).

A foreign pharmacy graduate is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(1) All applicants for intern registration must be made on form DH-MQA 102, "Pharmacy Intern Application for Foreign Graduates and Instructions," effective September 2009, which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850) 488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) An applicant for foreign pharmacy graduate intern registration in Florida must submit proof of:

(a) Eligibility by the Foreign Pharmacy Graduate Equivalency Committee to sit for the Foreign Pharmacy Graduate Equivalency Examination, or

(b) A passing score on the Foreign Pharmacy Graduate Equivalency Examination to be considered a graduate of an accredited college or school of pharmacy.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b) of subsection (1), and submitted a completed application as required in subsection (2) unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

(5) All internship experience for the purpose of qualifying for the examination pursuant to Section 465.007(1)(c), F.S., shall be obtained in a community pharmacy, institutional pharmacy or any Florida Board of Pharmacy approved pharmacy practice, which includes significant aspects of the practice of pharmacy as defined in Section 465.003(13), F.S.

(6) An internship program at an accredited college or school of pharmacy shall assure that community or institutional pharmacies utilized for the obtaining of internship experience meet the following minimum requirements:

(a) The pharmacy shall hold a current license or permit issued by the state in which they are operating and shall have available all necessary equipment for professional services, necessary reference works, in addition to the official standards and current professional journals.

(b) The pharmacy shall be operated at all times under the supervision of a pharmacist and shall be willing to train persons desiring to obtain professional experience.

(c) The pharmacy shall establish to the program's satisfaction that the pharmacy fills, compounds and dispenses a sufficient number, kind and variety of prescriptions during the course of a year so as to afford to an intern a broad experience in the filling, compounding and dispensing of prescription drugs.

(d) The pharmacy shall have a clear record as to observance of federal, state and municipal laws and ordinances covering any phase of activity in which it is engaged.

(e) No pharmacist may be responsible for the supervision of more than one intern at any one time.

(7) The program shall assure that all preceptors meet the following requirements:

(a) The pharmacist shall willingly accept the responsibility for professional guidance and training of the intern and be able to devote time to preceptor training sessions and to instruction of the intern.

(b) The pharmacist shall hold current licensure in the state in which pharmacy is practiced.

(c) The pharmacist shall be ineligible to serve as a preceptor during any period in which the pharmacist's license to practice pharmacy is revoked, suspended, on probation, or subject to payment of an unpaid fine levied by lawful Board order, or during any period in which the pharmacist's license is the subject of ongoing disciplinary proceedings.

(d) The pharmacist shall agree to assist the school or college of pharmacy in the achievement of the educational objectives set forth and to provide a professional environment for the training of the intern.

(e) Evidence shall be provided of the pharmacist's desire to continue broadening professional education and of an active involvement in a patient-oriented practice.

(8) In the event a program meets all the requirements set forth in subsection (2) of this rule, except for prior approval by the Florida Board of Pharmacy, any applicant submitting it for the purpose of qualifying for licensure by examination must show in addition to successful completion of the internship:

(a) Approval of the program by a state board of pharmacy; and

(b) Sufficient hours to total 1580 hours; or

(c) Licensure in another state and work performed as a pharmacist for a sufficient number of hours to total 1580 hours when combined with the internship hours.

(9) All internship hours may be obtained prior to the applicant's graduation.

(10) Proof of completion of an internship program shall consist of a certification that the applicant has completed the program. If additional hours are required to total 2080 hours, satisfactory proof of the additional hours shall be constituted by the program's certification of completion of the additional hours.

(11) Hours worked in excess of 50 hours per week prior to the applicant's graduation or in excess of 60 hours per week after an applicant's graduation, will not be credited toward meeting the required internship hours.

(12) The Board approves all internships that are required to obtain the doctor of pharmacy degree from institutions which are accredited as provided by Section 465.007(1)(b)1., F.S. Applicants graduating after January 1, 2001 with the doctor of pharmacy degree from such institutions shall be deemed to have met the requirements of this section with documentation of graduation.

(13) The Board may conduct periodic review of programs to assure compliance with these rules.

(14) Proof of current licensure in another state and work as a pharmacist for up to 1580 hours may substitute for all or part of the internship hours requirement.

(15) Governmental and private radiopharmacy internship programs shall not apply to the pharmacy internship required under subsection (1) of this rule.

(16) All foreign pharmacy graduates must complete 500 hours of supervised work activity within the state of Florida as provided by Section 465.007(1)(b)2., F.S. The supervised work activity program experience shall be documented on form DH-MQA 1153, "Foreign Graduate Registered Intern Work Activity Manual," effective 01/10. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or (850)488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. Further, this 500 hours of work activity program shall not be recognized for any applicant until said applicant has obtained the passing score on the Foreign Pharmacy Graduate Equivalency Exam as provided in Section 465.007, F.S.

Rulemaking Authority 465.005 FS. Law Implemented 456.013(1), 465.002, 465.007, 465.0075, 465.013 FS. History–New 5-27-10.

64B16-26.2035 Examination Fees.

Rulemaking Authority 465.005 FS. Law Implemented 465.007 FS. History–New 9-19-94, Amended 3-10-96, Formerly 59X-26.2035, Amended 3-22-99, 10-30-00, Repealed 3-10-05

64B16-26.204 Licensure by Endorsement.

An applicant for licensure by endorsement must be at least 18 years of age and a recipient of a degree from a school or college of pharmacy accredited by an accrediting agency recognized and approved by the United States Office of Education.

(1) All applications for licensure by endorsement shall be made on board approved form DOH/MQA100 effective June 2010. Pharmacist Licensure by Endorsement Application and Instructions (U.S. and territories), which is hereby incorporated by reference, can be obtained from the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request a form or download the form from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable application fee and initial licensure fee as set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) The applicant must submit satisfactory proof that one of the following requirements has been met:

(a) Two (2) years of active practice, as defined in Section 465.0075(1)(c), F.S., within the immediately preceding five (5) years. If the applicant meets the requirements of this section, proof of completion of 30 hours of Florida Board of Pharmacy, ACPE, or other state board of pharmacy approved continuing education obtained in the two calendar years immediately preceding application, must also be submitted.

(b) Successful completion of an internship meeting the requirements of Section 465.007(1)(c), F.S., within the immediately preceding two (2) years.

(3) Completion of a Board approved course not less than 2 hours on medication errors that covers the study of root-cause analysis, error reduction and prevention, and patient safety. For applicants who apply within one year following receipt of their pharmacy degree, completed academic course work on medication errors will be accepted by the Board as an educational course under this section, provided such course work is no less than 2 contact hours and that it covers the study of root-cause analysis, error reduction and prevention, and patient safety as evidenced by a letter attesting to subject matter covered from an official of the university where the course was taken.

(4) Applicants qualifying under the education requirements of Section 465.007(1)(b)2., F.S., (foreign graduates), must complete the requirements of Rule 64B16-26.2031, F.A.C., prior to certification for the examination required in subsection (6) of this rule.

(5) All requirements for licensure by endorsement must be met within one (1) year of the receipt of the application. Applicants failing to meet this requirement must reapply.

(6) Applicants applying under the provisions of Section 465.0075, F.S., must have obtained a passing score on the licensure examination as described in subsection 64B16-26.200(1), F.A.C.

(7) Applicants applying under the provisions of Section 465.0075, F.S., shall cause the National Association of Boards of Pharmacy, or other similar organization to issue a Transfer of Pharmaceutical Licensure certificate showing examination date, examination results, states of licensure, disciplinary actions, and licensure status.

(8) Applicants deemed qualified for licensure by endorsement shall be required to complete the Multistate Pharmacy Jurisprudence Examination – Florida Version. Passing scores on this examination may be used upon reapplication only if the examination was completed within three (3) years of the reapplication.

Rulemaking Authority 465.005, 465.0075 FS. Law Implemented 456.013(1), 465.007, 465.0075, 465.022 FS. History–New 11-8-01, Amended 1-11-05, 2-18-08, 5-26-09, 10-10-10.

64B16-26.205 Requirements for Foreign Pharmacy Graduates to Be Admitted to the Pharmacist Licensure Examination.

Rulemaking Authority 465.005, 465.007 FS. Law Implemented 465.007 FS. History–New 4-18-84, Formerly 21S-12.06, Amended 9-17-87, Formerly 21S-12.006, Amended 7-31-91, 1-10-93, 4-8-93, Formerly 21S-26.205, 61F10-26.205, Amended 3-10-96, Formerly 59X-26.205, Amended 8-17-99, Repealed 3-10-05.

64B16-26.300 Consultant Pharmacist Licensure.

(1) No person shall serve as consultant pharmacist as defined in Section 465.003(3), F.S., unless that person holds a license as a consultant pharmacist.

(2) Application for consultant pharmacist licensure shall be made on form DOH-MQA 1109, 02/09, Consultant Pharmacist Application and Information, which is hereby incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at www.doh.state.fl.us/mqa/pharmacy. The application shall be accompanied by a non-refundable application fee.

(3) In order to be licensed as a consultant pharmacist, a person must meet the following requirements:

(a) Hold a license as a pharmacist which is active and in good standing,

(b) Successfully complete a consultant pharmacist course of no fewer than twelve (12) hours, sponsored by an accredited college of pharmacy located within the State of Florida, and approved by the Florida Board of Pharmacy Tripartite Continuing Education Committee which is based on the Statement of the Competencies Required in Institutional Pharmacy Practice and subject matter set forth in Rule 64B16-26.301, F.A.C. The course shall be instructionally designed to include a cognitive test on which the applicant must score a passing grade for certification of successful completion of the course.

(c) Successfully complete a period of assessment and evaluation under the supervision of a preceptor within one (1) year of completion of the course set forth in paragraph (b) above. This period of assessment and evaluation shall be completed over no more than three (3) consecutive months and shall include at least 40 hours of training in the following practice areas, 60% of which shall occur on-site at an institution that holds a pharmacy permit. The training shall include:

Minimum Skills Required	Percent of Time	Hours
Minimum of 40 Hours in Maximum of Three Months		
1. Regimen review, documentation and communication. a. Demonstrate ability to carry out process and understand documentation functions. b. Understand and perform drug regimen review. Communicate findings to appropriate individuals or groups. c. The applicant is responsible for learning other skills needed to perform in his/her type of facility where he/she is or will be the consultant Pharmacist of Record.	60%	24
2. Facility review. Demonstrate areas that should be evaluated, documentation, and reporting procedures.	20%	8
3. Committee and Reports. Review quarterly Quality of Care Committee minutes and preparation and delivery of pharmacist quarterly report.	5%	2
4. Policy and Procedures. Preparation, review, updating Policy and Methods.	5%	2
5. Principles of formulary management. Demonstrate ability to manage formulary.	5%	2
6. Professional Relationships. Knowledge and interaction of facility administration and professional staff.	5%	2

(4) In order to act as a preceptor, a person shall:

(a) Be a consultant pharmacist of record at an institutional pharmacy which is required to have a consultant pharmacist under

the provisions of Chapter 465, F.S., and these rules.

(b) Have a minimum of one (1) year of experience as a consultant pharmacist of record.

(c) Maintain all pharmacist licenses in good standing with the Board.

(d) Not act as a preceptor to more than two (2) applicants at the same time.

(5) Upon completion of the requirements set forth above, the applicant's preceptor shall confirm that the applicant's assessment and evaluation have met the requirements and that the applicant has successfully completed all required assignments under the preceptor's guidance and supervision.

(6) After licensure a consultant pharmacist's license shall be renewed biennially upon payment of the fee set forth in Rule 64B16-26.1003, F.A.C., and upon completing twenty-four (24) hours of board approved continuing education based upon the provisions of Rule 64B16-26.302, F.A.C.

(7) The number of hours earned in recertification programs by a consultant pharmacist, if applied to the twenty-four (24) hours required for consultant pharmacist license renewal, may not be used toward the thirty (30) hours of continued professional pharmaceutical education credits as set forth in Rule 64B16-26.103, F.A.C.

(8) An applicant who applies for a consultant pharmacist license after the effective date of this rule shall be required to complete the assessment and evaluation required in paragraph (3)(c) prior to being licensed as a consultant pharmacist.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 5-19-72, Revised 4-19-74, Repromulgated 12-18-74, Amended 10-17-79, 4-8-80, 7-29-81, 7-1-83, 4-10-84, 4-30-85, Formerly 21S-1.26, 21S-1.026, Amended 7-31-91, 10-14-91, Formerly 21S-26.300, 61F10-26.300, Amended 9-19-94, 3-28-95, 3-10-96, Formerly 59X-26.300, Amended 5-22-01, 5-5-05, 11-29-06, 3-29-10.

64B16-26.301 Subject Matter for Consultant Pharmacist Training Program.

(1) Jurisprudence.

(a) Laws and regulations, state and federal, pertaining to institutional pharmacy and health care facilities.

(b) Laws and regulations, state and federal, pertaining to the safe and controlled storage of alcohol and other related substances, and relating to fire and health-hazard control.

(2) Policy and Procedures.

(a) Written procedures for outlining the medication system in effect.

1. Traditional systems.

2. Unit-dose systems.

a. Centralized.

b. Decentralized.

c. Automated medication systems.

3. Routine and emergency use of drugs.

4. After hours procedure for medication dispensing.

5. Managing drug shortages.

(b) Record keeping and reports.

1. Controlled substance control and record-of-usage.

2. Alcohol inventory and record-of-usage.

3. Patient drug use control and records.

a. Recalls.

b. Medication use evaluation.

c. Medication errors.

4. Drug charges, methods, accountability, and reports.

5. Statistical reports of usage, volume, etc.

(3) Administrative Responsibilities.

(a) Fiscal Control.

1. Perpetual and traditional inventory systems.

2. Application of EDP techniques.

(b) Personnel Management, orientation and training.

(c) Intra-professional relations pertaining to medication use.

(d) Inter-professional relations with other members of the institutional health care team.

1. Pharmacy & Therapeutic Committee.

a. Rational drug therapy; review of medication use and prescribing.

b. Formulary development – evaluation, appraisal, selection, procurement, storage, distribution, medication safety, criteria for use development and safety.

c. Automatic stop orders on potent and dangerous drugs.

d. Controls on storage and use of investigational drugs.

2. In-service education of nurses and other health-related personnel.

3. Infectious Disease Committee.

(4) Professional Responsibilities.

(a) Drug information retrieval and methods of dispersal.

(b) Development of pharmacy practice.

(c) Development of an IV Admixture service.

(d) Procedures to enhance medication safety.

1. Availability of equipment, technique, etc., to prepare special dosage forms for pediatric and geriatric patients.

2. Preparation of sterile dosage forms.

3. Proper writing, transcribing and initiating and/or transferring patient medication orders; development of physician's chart order copy system.

4. Safety of patient self-medication and control of drugs at bedside.

5. Reporting and trending adverse drug reactions.

6. Screening for potential drug interactions.

7. Development and maintenance of up-to-date emergency kits.

(e) Maintain drug quality and safe storage.

1. Procedures for eliminating out-dated drugs.

2. Requirements for safe and appropriate storage conditions.

(f) Maintain drug identity.

1. Procedures for labeling, transferring of bulk medications, etc.

2. Manufacturing and packaging procedures.

3. Pre-packaging control and supervision.

(5) The Institutional Environment.

(a) The institution's pharmacy function and purpose.

(b) Interdepartmental relationships important to the institutional pharmacy.

(c) Understanding of scope of service and in-patient care mission of the institution.

(d) Special training with respect to the operation of nursing homes and Extended Care Facilities (ECF)/pharmacy relationship and special procurement procedures.

(6) Nuclear pharmacy.

(a) Procurement.

(b) Compounding.

(c) Quality control procedures.

(d) Dispensing.

(e) Distribution.

(f) Basic radiation protection and practices.

(g) Consultation and education to the nuclear medicine community; including patients, pharmacists, other health professionals, and the general public.

(h) Research and development of new formulations.

(i) Record keeping.

(j) Reporting adverse drug reactions and medication errors.

(k) Screening for potential drug interaction.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 5-19-72, Amended 12-18-74, 10-17-79, Formerly 21S-

1.27, 21S-1.027, Amended 7-31-91, Formerly 21S-26.301, 61F10-26.301, 59X-26.301, Amended 5-5-05.

64B16-26.302 Subject Matter for Consultant Pharmacist Licensure Renewal Continuing Education.

A Consultant Pharmacist License Renewal Continuing Education Program must contain at least three (3) hours of training in any of the subjects specified below. Duplicate courses are not acceptable.

(1) Drug Therapy – Disease State. Patient Drug Therapy – management and monitoring.

(a) Drug, Disease State Information – In-depth disclosure of the drug or therapeutic class of drugs or disease state including pharmacology, side effects and interaction.

(b) New Therapeutic Modalities: Expansion of current drug therapy or treatment.

(c) Patient Assessment: Assessment techniques by consultant pharmacist to determine the need and effectiveness of indicated drug therapy along with identification and assessment of side effects on patient's well-being.

(d) Pertinent Laboratory Tests.

(e) Therapeutic Dosing.

(2) Administrative Responsibilities.

(a) Update on Administrative Responsibilities.

1. Legal requirements including statutes, rules and regulation (Federal and State).

2. The Joint Commission on the Accreditation of Healthcare Organizations.

3. Personnel requirements.

4. Health Insurance Portability and Accountability.

(b) Focus on Consultant Pharmacist Practice Issues/Concerns.

1. How to get things accomplished in complex organizations.

2. Key contacts to be effective as a consultant pharmacist.

3. Considerations and preparation for site inspections.

(3) Consultant Pharmacist Facility Responsibilities. This segment details the requirements in one of the facility types for which a consultant pharmacist is required. Only one practice setting may be included in each program.

(a) Pharmacist-Medication Responsibilities – Assessment mechanism for delivery system, review procedures and monitoring processes.

(b) Pharmacist-Patient Responsibilities – Patient assessment, laboratory test monitoring and therapeutic dosing.

(c) Committee Responsibilities – Make-up and responsibilities for various facility committees.

(d) Reporting requirements.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0125 FS. History–New 10-14-91, Formerly 21S-26.302, 61F10-26.302, 59X-26.302, Amended 5-5-05, 7-21-09.

64B16-26.303 Nuclear Pharmacist Licensure.

(1) A pharmacist licensed to practice pharmacy in this state who performs a radiopharmaceutical service shall, prior to engaging in such specialized practice, be actively licensed as a nuclear pharmacist.

(2) A pharmacist seeking licensure as a nuclear pharmacist in this state shall submit to the Board of Pharmacy a course outline from an accredited college of pharmacy or other program recognized by the Florida Department of Health and the Florida Board of Pharmacy (a program comparable to those offered by accredited colleges of pharmacy for the training of nuclear pharmacists), and a certificate of training which provides a minimum of 200 clock hours of formal didactic training, which includes:

(a) Radiation physics and instrumentation (85 hours).

(b) Radiation protection (45 hours).

(c) Mathematics pertaining to the use and measurement of radioactivity (20 hours).

(d) Radiation biology (20 hours).

(e) Radiopharmaceutical chemistry (30 hours).

(3) Such academic training programs will be submitted to the Board of Pharmacy for approval by an accredited educational institution which operates under the auspices of or in conjunction with an accredited college of pharmacy.

(4) The minimum on-the-job training which shall be included in a radiopharmacy internship is 500 hours of training and experience in the handling of unsealed radioactive material under the supervision of a licensed nuclear pharmacist. The training and

experience shall include but shall not be limited to the following:

(a) Ordering, receiving and unpackaging in a safe manner, radioactive material, including the performance of related radiation surveys.

(b) Calibrating dose calibrators, scintillation detectors, and radiation monitoring equipment.

(c) Calculating, preparing and verifying patient doses, including the proper use of radiation shields.

(d) Following appropriate internal control procedures to prevent mislabeling.

(e) Learning emergency procedures to safely handle and contain spilled materials, including related decontamination procedures and surveys.

(f) Eluting technetium-99m from generator systems, assaying the eluate for technetium-99m and for molybdenum-99 contamination, and processing the eluate with reagent kits to prepare technetium-99m labeled radiopharmaceuticals.

(g) Clinical practice concepts.

(5) If the didactic and experiential training required in this section have not been completed within the last seven (7) years, the applicant must have been engaged in the lawful practice of nuclear pharmacy in another jurisdiction at least 1080 hours during the last seven (7) years.

Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 465.0126 FS. History–New 1-18-05.

64B16-26.304 Subject Matter for Nuclear Pharmacist License Renewal Continuing Education Programs.

(1) A licensee completing the continuing education requirement for nuclear pharmacist license renewal pursuant to Rule 64B16-26.103, F.A.C., shall complete twenty-four (24) additional hours per biennium of coursework each two year period by or through a Committee approved provider, instructionally designed to provide in-depth treatment of nuclear pharmacy practice with suggested subject matter set out in subsection (2) of this rule.

(2) Content of nuclear pharmacist continuing education program.

(a) Application of radiopharmaceutical theory in a practice or a research setting with respect to the drug products and their clinical application. Provision of drug and radiopharmaceutical information as it pertains to optimal handling and use of these products in a clinical setting.

(b) Effective communication skills in a multi-disciplinary environment with patients, nuclear medicine physicians, nuclear medicine technologists, radiation safety personnel and other nuclear pharmacists. The multi-faceted regulatory environment requires such skills in the preparation and maintenance of a radioactive by-product materials license, the identification and reporting of adverse reactions and misadministration, instances of poor product performance, environmental and personnel radiation safety.

(c) Application of the most rigorous and up-to-date principles of radiation safety and quality assurance in order to assure regulatory compendia, and operational standards for drug and radiopharmaceutical products and equipment. Record-keeping and other documentation activities essential to procurement, storage, compounding, handling and use, distribution and disposal should be emphasized.

(d) Management of a nuclear pharmacy unit in accordance with regulatory and administrative agencies' requirements.

(e) Advances in drug, radiopharmaceutical or related technology (including, but not limited to: monoclonal antibodies, magnetic resonance imaging, computed tomography, positron-emission tomography, radioplaque and other contact enhancement agents, radioimmunoassay) with emphasis on paragraphs (a)-(d) above for such new agents.

Rulemaking Authority 465.005, 465.0126 FS. Law Implemented 465.0126 FS. History–New 1-18-05.

64B16-26.320 Subject Matter for Continuing Education to Order and Evaluate Laboratory Tests.

(1) Consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree that wish to order and evaluate laboratory tests under the provisions of Section 465.0125, F.S., shall successfully complete the requirements of a continuing education course set forth herein prior to such practice. Successful completion of the course will certify the pharmacist for this practice for two (2) years from date of completion.

(2) Providers of courses seeking approval under this section shall meet the procedures and standards provided for in Rule 64B16-26.601, F.A.C. Courses approved under this section shall be at least three (3) hours in duration for initial certification and at least one (1) hour for recertification, and shall cover the following subjects:

(a) Requirements for monitoring laboratory values,

(b) Interpretation of laboratory values,

(c) Use of laboratory data to monitor and improve drug therapy,

(d) Legal aspects, restrictions, and requirements for obtaining laboratory studies,

(e) Use of laboratory data and therapeutic outcomes,

(f) Documentation of interventions, and

(g) Laboratory studies as an element of complete patient care.

(3) A consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a consultant pharmacist license under Rule 64B16-26.300, F.A.C., or may apply such continuing education hours toward the continuing education requirement for renewal of a pharmacist license under Rule 64B16-26.103, F.A.C., but may not use the same continuing education hours to satisfy both requirements. A Doctor of Pharmacy who is not a consultant pharmacist may apply the three (3) hour initial certification course and the one (1) hour recertification course toward the continuing education requirement for renewal of a pharmacist license under Rule 64B16-26.103, F.A.C.

Rulemaking Authority 465.009, 465.0125(3) FS. Law Implemented 465.009, 465.0125(2) FS. History–New 2-23-98, Amended 6-15-98, 1-12-03, 3-10-05.

64B16-26.350 Requirements for Pharmacy Technician Registration.

Applicants who are at least 17 years of age may apply to become a registered pharmacy technician.

(1) All applicants for registration must be made on form DH-MQA PH1183, "Pharmacy Technician Registration Application and Instructions" effective September 2009, which is incorporated by reference. Contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595 to request an application or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy. The application must be accompanied with a non-refundable application fee and an initial registration fee set forth in Rules 64B16-26.1001 and 64B16-26.1002, F.A.C.

(2) Prior to January 1, 2011, a registered pharmacy technician must submit proof of having met one of the following requirements:

(a) Completed a Board approved training course as outlined in Rule 64B16-26.351, F.A.C; or

(b) Worked as a registered pharmacy technician for a minimum of 1500 hours under the supervision of a pharmacist; or

(c) Received certification as a pharmacy technician by a certification program accredited by the National Commission for Certifying Agencies.

(3) Applicants applying for registration after January 1, 2011 must submit proof of completion of a Board approved training course as outlined in Rule 64B16-26.351, F.A.C.

Rulemaking Authority 465.014 FS. Law Implemented 465.014 FS. History–New 8-5-10.

64B16-26.351 Standards for Approval of Registered Pharmacy Technician Training Programs.

(1) The following programs are approved Registered Pharmacy Technician Training programs:

(a) Pharmacy technician training programs accredited, on or before January 1, 2011 by the American Society of Health-System Pharmacists,

(b) Pharmacy technician training programs at institutions accredited, on or before January 1, 2011 by the Southern Association of Colleges and Schools,

(c) Pharmacy technician training programs approved on or before January 1, 2011 by the Florida Commission for Independent Education,

(d) Pharmacy technician training programs provided by a branch of the federal armed services on or before January 1, 2011.

(e) Pharmacy technician training programs at institutions accredited on or before January 1, 2011 by the Council on Occupational Education.

(2) All programs not listed in paragraphs (1)(a) through (e) and which are not employer based programs, must:

(a) Meet the requirements of and be licensed by the Commission for Independent Education pursuant to Chapter 1005, F.S., or the equivalent licensing authority of another state or be within the public school system of the State of Florida; and:

(b) Offer a course of study that includes classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA),

2. Pharmacy law:

a. Federal law,

b. Florida State law,

c. Florida State rules,

d. Pharmacy technician Florida rules and law,

3. Pharmaceutical – medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention,

b. Prescriptions and medication orders,

4. Records management and inventory control:

a. Pharmaceutical supplies,

b. Medication labeling,

c. Medication packaging and storage,

d. Controlled substances,

e. Adjudication and billing,

5. Interpersonal relations, communications, and ethics:

a. Diversity of communications,

b. Empathetic communications,

c. Ethics governing pharmacy practice,

d. Patient and caregiver communication,

6. Pharmaceutical calculations.

(c) Apply directly to the Board of Pharmacy on approved form DH-MQA 1239 "Board of Pharmacy Application for Registered Pharmacy Technician Training Programs," effective December 2010, https://www.flrules.org/gateway/reference.asp?NO=Ref-00717, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board's website at http//:www.doh.state.fl.us/mqa/pharmacy and provide the following information:

1. Sample transcript and diploma;

2. Copy of curriculum, catalog or other course descriptions; and

3. Faculty credentials.

(d) Use materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.

2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.

3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(e) Demonstrate that the faculty is qualified to teach the subject-matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

(3) All other training programs must be employer based. Any pharmacy technician training program sponsored by a Florida permitted pharmacy or affiliated group of pharmacies under common ownership, must contain a minimum of 160 hours of training, that extends over a period not to exceed 6 months; is provided solely to employees of said pharmacy or affiliated group; and has been approved by the Board. An application for approval of a Registered Pharmacy Technician Training Program shall be made on Board of Pharmacy approved form DH-MQA 1239 "Board of Pharmacy Application for Registered Pharmacy Technician Training Programs," effective December 2010. The applicant must attach to the application copy of curriculum, catalog or other course description. All employer based programs must:

(a) Offer a course of study that includes a classroom study and clinical instruction that includes the following:

1. Introduction to pharmacy and health care systems:

a. Confidentiality,

b. Patient rights and Health Insurance Portability and Accountability Act (HIPAA).

2. Pharmacy law:

a. Federal law,

b. Florida State law,

c. Florida State rules,

d. Pharmacy technician Florida rules and law.

3. Pharmaceutical-medical terminology, abbreviations, and symbols:

a. Medication safety and error prevention,

b. Prescriptions and medication orders.

4. Records management and inventory control:

a. Pharmaceutical supplies,

b. Medication labeling,

c. Medication packaging and storage,

d. Controlled substances,

e. Adjudication and billing.

5. Interpersonal relations, communications, and ethics:

a. Diversity of communications,

b. Empathetic communications,

c. Ethics governing pharmacy practice,

d. Patient and caregiver communication.

6. Pharmaceutical calculations.

(b) Use materials and methods that demonstrate that:

1. Learning experiences and teaching methods convey the content stated above.

2. Time allocated for each participant shall be sufficient to meet the objectives of each activity.

3. Principles of adult education are utilized in determining teaching strategies and learning activities.

(c) Demonstrate that the faculty is qualified to teach the subject matter by complying with the following:

1. The program shall provide evidence of academic preparation or experience in the subject matter by submitting a job description, resume or curriculum vitae which describes the faculty member's work experience and level of academic preparation.

2. When the subject matter of an offering includes pharmacy technician practice, a licensed pharmacist or registered pharmacy technician with expertise in the content area must be involved in the planning and instruction.

3. Pharmacy technician faculty supervising learning experiences in a clinical area in this State shall be licensed or registered.

4. When an offering includes clinical practice training in Florida, a Florida licensed pharmacist competent in the practice area shall provide supervision.

(d) Give participants an opportunity to evaluate learning experiences, instructional methods, facilities and resources used for the offering. To ensure participants will be given an opportunity to evaluate the program, the applicant must submit a sample evaluation to be reviewed by the Board.

(e) Ensure that self-directed learning experiences, including but not limited to home study, computer programs, internet or web-based courses evaluate participant knowledge at the completion of the learning experience. The evaluation must include a minimum of 100 questions. The participant must achieve a minimum score of 70% on the evaluation to receive the certificate of completion. The evaluation must be graded by the provider.

(f) Designate a person to assume responsibility for registered pharmacy technician training program. If the contact person is not a licensed pharmacist or registered pharmacy technician, provision should be made for insuring licensed pharmacist or registered pharmacy technician input in overall program planning and evaluation.

(g) Establish written policies and procedures for implementation of the registered pharmacy technician training program.

(h) Maintain a system of record-keeping which provides for storage of program information.

(i) Maintain program records for a period not less than three years during which time the records must be available for inspection by the board or department.

(j) Furnish each participant with an authenticated individual Certificate of Completion.

Rulemaking Authority 465.014 FS. Law Implemented 465.014 FS. History–New 6-23-10, Amended 11-17-11.

64B16-26.355 Subject Matter for Registered Pharmacy Technician Continuing Education.

A Registered Pharmacy Technician Continuing Education Program must contain subject matter specifically designed to meet the objectives and the stated level and learning needs of the participants. The content shall be planned in logical order and reflect input from experts in the subject matter. Appropriate subject matter for continuing education offering shall reflect the professional educational needs for the learner in order to meet the health care needs of the consumer and consist of content from one or more of the following:

(1) Pharmacy technician practice areas and special health care problems.

(2) Biological, physical, behavioral and social sciences.

(3) Legal aspects of health care.

(4) Management/administration of health care personnel and patient care.

(5) Teaching/learning process of health care personnel and patients.

(6) Subjects which are taken at an accredited educational institution as verified by an official transcript, that meet any one of the criteria in Rule 64B16-26.351, F.A.C., and are advanced beyond that completed for original registration shall be approved for continuing education under this rule.

Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History–New 10-10-10.

64B16-26.400 Pharmacy Interns; Registration; Employment.

(1) A pharmacy intern is required to be registered with the Department of Health as an intern before being employed as an intern in a pharmacy in Florida.

(2) An applicant for pharmacy intern registration must submit proof of:

(a) Enrollment in an intern program at an accredited college or school of pharmacy or;

(b) Graduation from an accredited college or school of pharmacy and not yet licensed in the state. For purposes of this rule only, any individual who has been accepted by the Foreign Pharmacy Graduate Examination Commission to sit for the Foreign Pharmacy Graduate Equivalency Examination shall be considered a graduate of an accredited college or school of pharmacy. The internship experience allowed under this provision shall not count toward the 500-hours internship required subsequent to passage of the Foreign Pharmacy Graduate Equivalency Examination as mandated in Section 465.007(1)(b)2., F.S., and as defined in Rule 64B16-26.203, F.A.C.

(3) Upon the receipt of proof satisfactory to the Board that the intern applicant meets the requirements of either paragraph (a) or (b) of subsection (2), and unless there exists good cause for the Board's refusal to certify an applicant as set forth in Section 465.013, F.S., the Board shall certify the applicant to the Department for registration as an intern.

(4) No intern shall perform any acts relating to the filling, compounding, or dispensing of medicinal drugs unless it is done under the direct and immediate personal supervision of a person actively licensed to practice pharmacy in this state.

Rulemaking Authority 465.005 FS. Law Implemented 465.013 FS. History–Amended 8-20-63, 5-19-72, 8-18-73, Repromulgated 12-18-74, Amended 11-10-80, 4-30-85, Formerly 21S-1.21, Amended 10-20-88, Formerly 21S-1.021, Amended 7-31-91, 1-10-93, Formerly 21S-26.400, 61F10-26.400, 59X-26.400, Amended 3-10-05.

64B16-26.401 Requirements for an Internship Program Sufficient to Qualify an Applicant for Licensure by Examination.

Rulemaking Authority 465.005 FS. Law Implemented 465.007 FS. History–New 8-20-83, Amended 5-19-72, 8-18-73, 12-18-74, 11-10-80, 10-25-84, Formerly 21S-1.22, 21S-1.022, Amended 7-31-91, Formerly 21S-26.401, Amended 12-27-93, Formerly 61F10-26.401, 59X-26.401, Amended 4-19-01, Repealed 3-10-05.

64B16-26.600 Tripartite Continuing Education Committee.

(1) The Tripartite Continuing Education Committee will be composed of equal representation from the Board of Pharmacy, each College or School of Pharmacy in the State, and practicing pharmacists within the State. The members of the Committee shall be selected by the Board of Pharmacy and shall serve for a period of two years. The chairman of the committee shall be selected by the Chair of the Board.

(2) The Tripartite Continuing Education Committee shall perform the following duties pursuant to Rule 64B16-26.601, F.A.C.:

(a) Review continuing education providers and make recommendations to the Board;

(b) Approve continuing education course or program for approved providers or individuals that are non-approved providers for the following:

1. General;
2. Initial Consultant Pharmacist Certification;
3. Consultant Recertification;
4. Nuclear Recertification;
5. Medication Errors;
6. HIV/AIDS;
7. Laboratory Tests;
8. Laws and Rules;
9. Quality Related Events.

(3) The Tripartite Continuing Education Committee shall perform auditing and monitoring activities pursuant to Rule 64B16-26.601, F.A.C. The Tripartite Committee shall perform an audit on each approved continuing education provider 90 days prior to the end of the biennium. The approved provider shall submit the following information for one program of the provider's choosing and one program selected by the Board:

(a) Title, date and location of the program;

(b) Program Number;

(c) Any Co-sponsors;

(d) Total number of pharmacists attending;

(e) Rosters of attendees with appropriate license numbers;

(f) Brochures of program announcement;

(g) CV's of each speaker;

(h) Handouts, Copy of CE Credit statement, educational materials distributed as part of the program; and

(i) Summary report of program evaluations.

(4) The Committee shall hold meetings as may be convened at the call of the Chairman of the Committee.

Rulemaking Authority 465.005, 465.009(5) FS. Law Implemented 465.009 FS. History–New 10-18-79, Amended 7-29-81, Formerly 21S-13.01, 21S-13.001, 21S-26.600, 61F10-26.600, 59X-26.600, Amended 10-15-01, 3-10-05, 6-11-09.

64B16-26.601 Standards for Approval of Courses and Providers.

(1) Each proposal for program or course approval submitted by a qualified provider must contain a detailed outline of the content of said program or course on forms which will be provided by the Board of Pharmacy upon request, and must build upon Standards of Practice and a basic course or courses offered in the curricula of accredited colleges or schools of pharmacy. Continuing education may consist of post-baccalaureate degree programs offered by accredited colleges or schools of pharmacy, post-graduate studies, institutes, seminars, lectures, conferences, workshops, correspondence courses, or other such committee-approved educational methods.

(2) All offerings must meet the following standards:

(a) Education Content Development.

1. Continuing education offerings shall involve advance planning that includes a statement of measurable educational goals and behavioral objectives.

2. Continuing education offerings shall be designed to reflect the educational needs of the pharmacist and build on the standards for practice and courses in the curricula of accredited colleges or schools of pharmacy.

3. Each continuing education offering shall be designed to explore one subject or a group of closely related subjects or

standards.

(b) Methods of Delivery.

1. The method of delivery of a course shall be determined by giving appropriate consideration to such factors as educational content, objectives, and composition of the audience.

2. The method of delivery must encourage active participation and involvement on the part of the pharmacist.

(c) Program Faculty Qualifications.

1. The program faculty for a particular continuing education offering shall be competent in the subject matter and qualified by experience.

2. An appropriate number of program faculty for each activity shall be utilized.

3. There shall be adequate personnel to assist with administrative matters and personnel with competencies outside content areas in cases where the method of delivery requires technical or other special expertise.

(d) Facilities.

1. The facilities to be utilized shall be appropriate and adequate to the content, method of delivery, size of the audience and promote the attainment of the objectives of the offering.

(e) Evaluation. The provider must make provision for evaluation of the participants' attainment of the stated learner objectives through in-process activities that provide a measurable demonstration of the learner's achievement(s).

2. The provider must develop and employ an evaluation mechanism for the purpose of allowing the participant to assess his/her achievement of personal objectives.

3. The provider shall develop and employ an evaluation mechanism that will assess the effectiveness of the learning experiences, instructional methods, facilities, and resources used for the offering.

(f) Contact Hour Criteria. The number of contact hours or Continuing Education Units shall be determined by the provider in advance of the offering subject to approval by the committee and awarded upon the successful completion of the entire planned education experience.

(g) Record Keeping.

1. Records of individual offerings shall be maintained by the provider for inspection by the Board. The records shall be adequate to serve the needs of the participants and to permit the Board to monitor for adherence to the standards for continuing education offerings as outlined in the rules.

2. An individual certificate of attendance specifying title of offering, provider number, date of offering, and number of contact hours earned shall be furnished to each participant by the provider.

3. Records shall be maintained by the provider for a minimum of three (3) years.

(3) Providers seeking board approval shall meet each of the standards outlined herein:

(a) All continuing education offerings conducted by the provider shall meet the standards for continuing education offerings as outlined in these rules.

(b) There shall be a visible, continuous, and identifiable authority charged with administration of continuing education programs. The person or persons in whom the administrative function is vested shall be qualified by virtue of background and experience and approval by the committee.

(4) All programs approved by the Accreditation Council on Pharmacy Education (ACPE) for continuing education for pharmacists may be deemed approved by this Board for general continuing education hours for pharmacists.

(5) Entities or individuals who wish to become approved providers of continuing education must submit an initial approval fee of $150 and provide information to demonstrate compliance with the requirements of this rule. A provider seeking to renew approved provider status shall pay a renewal fee of $150.

(6) Entities or individuals applying for approval of an individual program shall submit a fee of $50 and provide information to demonstrate compliance with this rule.

Rulemaking Authority 465.005, 465.009 FS. Law Implemented 456.025(7), 465.009 FS. History–New 10-17-79, Amended 7-29-81, Formerly 21S-13.02, 21S-13.002, Amended 1-10-93, Formerly 21S-26.601, 61F10-26.601, 59X-26.601, Amended 1-29-03.

64B16-26.6012 Guidelines for Board Ordered Disciplinary Continuing Education Courses.

Any continuing education course being taken as part of a disciplinary order, unless otherwise ordered by the Board, may be conducted by any method, including live, correspondence, or distant education.

(1) Laws and Rules courses shall be at least twelve (12) hours in length. The program shall include review and analysis of the laws regulating the profession of pharmacy in the State of Florida with discussion of recent changes to Florida Statutes and Board of Pharmacy rules. The remainder of the continuing education program shall be derived from the following areas:

(a) Federal laws related to:

1. Handling, management, and dispensing of controlled substances;
2. Protected patient information; and
3. Medicare.

(b) Chapters 456, 499 and 893, F.S;

(c) Florida Medicaid program;

(d) Nursing home and Assisted Living Facility regulations;

(e) Prescriber laws and regulations;

(f) Pharmacy ethics;

(g) The Joint Commission (TJC) standards;

(h) Food and Drug Administration policies and procedures;

(i) Implementation of disaster and emergency preparedness plans by Florida pharmacists and pharmacy services providers; and

(j) Occupational Safety and Health Administration (OSHA) and National Institute for Occupational Safety and Health (NIOSH) guidelines and requirements for pharmacy employers.

(2) Quality Related Event (QRE) courses shall be at least eight (8) hours in length.

(a) Course material shall include:

1. Pharmacy error detection;
2. Pharmacy error prevention; and
3. Case studies of pharmacists who have made dosing calculation, checking/interpreting prescriptions, or dispensing errors.

(b) Course material shall include the following specific subject areas:

1. Common error types and causes;
2. Root cause analysis;
3. Process mapping and management;
4. System analysis;
5. Failure mode and effects analysis;
6. Human factors, cognitive and personality impacts;
7. Practice management and effective delegation tools;
8. Stress management;
9. Effective communication;
10. Continuous Quality Improvement (CQI) rules;
11. CQI implementation tools;
12. Individual self assessment, planning, and goal setting. The individual self assessment shall include a requirement that the pharmacist prepare a written report, in essay form, summarizing the impact of the course, what the pharmacist learned, and the changes that the pharmacist will implement in practice as a result of the course.

Rulemaking Authority 456.072(2) 465.005, 465.016(4) FS. Law Implemented 456.072(2), 465.016(4) FS. History–New 7-21-09.

64B16-26.602 Recommendation by the Tripartite Continuing Education Committee.

Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Amended 7-29-81, Formerly 21S-13.03, 21S-13.003, 21S-26.602, Amended 7-18-94, Formerly 61F10-26.602, 59X-26.602, Repealed 8-16-01

64B16-26.603 Continuing Education Records Requirements.

Each pharmacist shall retain documentation of participation in continuing education programs required for license renewal for not less than two years after the license is renewed for audit purposes if and when such audit is undertaken by the Department of Health and the Board of Pharmacy. Such documentation shall consist of statements of credit for lecture attendance, certification forms from instructors, or course completion slips from correspondence courses.

Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Formerly 21S-13.04, Amended 5-10-89, Formerly 21S-13.004, 21S-26.603, 61F10-26.603, 59X-26.603, Amended 1-11-05.

64B16-26.606 Number of Required Hours.

Rulemaking Authority 465.005 FS. Law Implemented 465.009 FS. History–New 10-17-79, Formerly 21S-13.07, 21S-13.007, Amended 7-31-91, Formerly 21S-26.606, 61F10-26.606, 59X-26.606, Amended 2-23-98, 1-12-03, Repealed 3-10-05.

CHAPTER 64B16-27
PHARMACY PRACTICE

64B16-27.100 Display of Current License; Pharmacist, Registered Pharmacy Technician Intern Identification
64B16-27.1001 Practice of Pharmacy
64B16-27.1003 Transmission of Prescription Orders
64B16-27.101 Counterfeit Drugs
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64B16-27.100 Display of Current License; Pharmacist, Registered, Intern, and Registered Pharmacy Technician Identification.

(1) The current license of each pharmacist engaged in the practice of the profession of pharmacy as defined by Section 465.003(13), F.S., in any pharmacy shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such manner that said license can be easily read by patrons of said establishment. Pharmacists employed in secondary practice sites shall present a valid wallet license as evidence of licensure upon request.

(2) No pharmacist shall display, cause to be displayed or allow to be displayed, their license in any pharmacy where said pharmacist is not engaged in the practice of the profession as defined in Section 465.003(13), F.S.

(3) A pharmacist and registered pharmacy intern must be clearly identified by a means such as an identification badge or monogrammed smock showing their name and if they are a pharmacist or a registered pharmacy intern.

(4) The current registration of each registered pharmacy technician shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such a manner that can be easily read by patrons of said establishment. Registered

pharmacy technicians employed in a secondary practice site shall present a valid wallet registration as evidence of registration upon request.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.06, 21S-1.006, Amended 7-30-91, Formerly 21S-27.100, 61F10-27.100, Amended 1-30-96, Formerly 59X-27.100, Amended 11-18-07, 1-1-10.

64B16-27.1001 Practice of Pharmacy.

Those functions within the definition of the practice of the profession of pharmacy, as defined by Section 465.003(13), F.S., are specifically reserved to a pharmacist or a duly registered pharmacy intern in this state acting under the direct and immediate personal supervision of a pharmacist. The following subjects come solely within the purview of the pharmacist.

(1) A pharmacist or registered pharmacy intern must:

(a) Supervise and be responsible for the controlled substance inventory.

(b) Receive verbal prescriptions from a practitioner.

(c) Interpret and identify prescription contents.

(d) Engage in consultation with a practitioner regarding interpretation of the prescription and date in patient profile.

(e) Engage in professional communication with practitioners, nurses or other health professionals.

(f) Advise or consult with a patient, both as to the prescription and the patient profile record.

(2) When parenteral and bulk solutions of all sizes are prepared, regardless of the route of administration, the pharmacist must:

(a) Interpret and identify all incoming orders.

(b) Mix all extemporaneous compounding or be physically present and give direction to the registered pharmacy technician for reconstitution, for addition of additives, or for bulk compounding of the parenteral solution.

(c) Physically examine, certify to the accuracy of the final preparation, thereby assuming responsibility for the final preparation.

(d) Systemize all records and documentation of processing in such a manner that professional responsibility can be easily traced to a pharmacist.

(3) Only a pharmacist may make the final check of the completed prescription thereby assuming the complete responsibility for its preparation and accuracy.

(4) The pharmacist, as an integral aspect of dispensing, shall be directly and immediately available to the patient or the patient's agent for consultation and shall not dispense to a third party. No prescription shall be deemed to be properly dispensed unless the pharmacist is personally available.

(5) The pharmacist performing in this state any of the acts defined as "the practice of the profession of pharmacy" in Section 465.003(13), F.S., shall be actively licensed as a pharmacist in this state, regardless of whether the practice occurs in a permitted location (facility) or other location.

(6) The pharmacist may take a meal break, not to exceed 30 minutes in length, during which the pharmacy department of a permittee shall not be considered closed, under the following conditions:

(a) The pharmacist shall be considered present and on duty during any such meal break if a sign has been prominently posted in the pharmacy indicating the specific hours of the day during which meal breaks may be taken by the pharmacist and assuring patients that a pharmacist is available on the premises for consultation upon request during a meal break.

(b) The pharmacist shall be considered directly and immediately available to patients during such meal breaks if patients to whom medications are delivered during meal breaks are verbally informed that they may request that a pharmacist contact them at the pharmacist's earliest convenience after the meal break, and if a pharmacist is available on the premises during the meal break for consultation regarding emergency matters. Only prescriptions with the final certification by the pharmacist may be delivered.

(c) The activities of registered pharmacy technicians during such a meal break shall be considered to be under the direct and immediate personal supervision of a pharmacist if the pharmacist is available on the premises during the meal break to respond to questions by the technicians, and if at the end of the meal break the pharmacist certifies all prescriptions prepared by the registered pharmacy technicians during the meal break.

(7) The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one pharmacist and one registered pharmacy technician. In every pharmacy, the

pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in the licensee's employ or under the licensee's supervision.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 11-18-07, Amended 1-1-10.

64B16-27.1003 Transmission of Prescription Orders.

Prescriptions may be transmitted from prescriber to dispenser in written form or by any means of communication. Prescriptions may be transmitted by facsimile systems as provided in Section 465.035, F.S., and federal law. Any direct transmission of prescriptions, including verbal, facsimile, telephonic or electronic data transmission, shall only be with the approval of the patient or patient's agent. The pharmacist receiving any such transmitted prescription shall not participate in any system that the pharmacist knows or should have reason to know restricts the patient's choice of pharmacy. The pharmacist shall take such measures necessary to ensure the validity of all prescriptions received.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 11-18-07.

64B16-27.101 Counterfeit Drugs.

No pharmacist or pharmacy employee or proprietor shall knowingly purchase, sell, possess or distribute drugs which are commonly called counterfeit, or which are misbranded, or improperly labeled as described by the Florida Drug and Cosmetic Law.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.15, 21S-1.015, Amended 7-30-91, Formerly 21S-27.101, 61F10-27.101, 59X-27.101.

64B16-27.103 Oral Prescriptions and Copies.

(1) Only a pharmacist or registered pharmacy intern acting under the supervision of a pharmacist may, in the State of Florida, accept an oral prescription of any nature.

(2) Only a pharmacist or registered pharmacy intern acting under the supervision of a pharmacist may, in the State of Florida, prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written, and when said copy is given a notation shall be made upon the prescription that a copy has been given, the date given, and to whom given.

Rulemaking Authority 465.005, 465.0155, 465.014, 465.022 FS. Law Implemented 465.003(13), 465.014, 465.022, 893.07(1)(b) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.18, 21S-1.018, 21S-27.103, 61F10-27.103, Amended 9-19-94, Formerly 59X-27.103, Amended 10-15-01, 11-18-07.

64B16-27.104 Conduct Governing Pharmacists and Pharmacy Permittees.

(1) A pharmacist or pharmacy shall be permitted to advertise medicinal drugs other than those controlled substances specified in Chapter 893, F.S., and patent and proprietary preparations so long as such advertising is not false, misleading or deceptive.

(2) No pharmacist, employer or employee of a pharmacy shall maintain a location, other than a pharmacy for which a permit has been issued by the Florida Board of Pharmacy, from which to solicit, accept or dispense prescriptions.

(3) No pharmacist or pharmacy, or employee or agent thereof, shall enter into or engage in any agreement or arrangement with any physician or other practitioner or nursing home or extended care facility for the payment or acceptance of compensation in any form or type for the recommending of the professional services of either; or enter into a rebate or percentage rental agreement of any kind, whereby in any way a patient's free choice of a pharmacist or pharmacy is or may be limited.

(4) No pharmacist, employer or employee of a pharmacy may knowingly place in stock of any pharmacy any part of any prescription compounded for, or dispensed to, any customer of any pharmacy and returned by said customer, unless otherwise permitted by Rule 64B16-28.118, F.A.C.

(5) Pursuant to Section 465.018, F.S., a permit for a community pharmacy may not be issued unless a licensed pharmacist is designated as the prescription department manager responsible for maintaining all drug records, providing for the security of the prescription department and following such other rules as relate to the practice of the profession of pharmacy. The Board shall not register a prescription department manager as the manager of more than one pharmacy. The Board shall grant an exception to this requirement upon application by the permittee and the prescription department manager showing circumstances such as proximity of

permits and limited pharmacist workload that would allow the manager to carry out all duties and responsibilities required of a prescription department manager.

Rulemaking Authority 465.005, 465.0155, 465.018, 465.022 FS. Law Implemented 465.018, 465.022, 465.024 FS. History–New 10-20-81, Formerly 21S-1.20, 21S-1.020, Amended 7-30-91, Formerly 21S-27.104, 61F10-27.104, 59X-27.104, Amended 11-18-07.

64B16-27.1042 Rebates Prohibited; Violations Defined.

As provided in Section 465.185(1), F.S., acts which will be considered as falling within the range of activities which would justify discipline against a pharmacist or permittee as provided in Section 465.016(1)(e) or Section 465.023(1)(c), F.S., shall include:

(1) Offering or providing cash, or goods, or entertainment (including, money, food or decorations) to a health care facility (as defined in Section 408.032(7), F.S.) or its representative in exchange for favorable consideration in obtaining or maintaining the business of the facility;

(2) Offering or providing supplies or equipment to a health care facility (as defined in Section 408.032(7), F.S.) at no charge or below market value when these items are not integral elements of the medication distribution system;

(3) Paying rent to a health care facility (as defined in Section 408.032(7), F.S.) for space that is not used or is unusable or paying a rental rate for space that is significantly greater than the usual and customary rental rate for similar space;

(4) Offering or providing computers, FAX machines, or other electronic devices to a health care facility (as defined in Section 408.032(7), F.S.) when that equipment is not an integral element in providing pharmacy or consultant services;

(5) Offering or providing a health care facility (as defined in Section 408.032(7), F.S.) consultant pharmacist services, or providing patient medical record systems, or any personnel services outside the practice of pharmacy, at no charge, below market value, or below cost in exchange for obtaining or maintaining the business of the facility.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.185, 465.0155 FS. History–New 3-9-94, Formerly 61F10-27.1042, 59X-27.1042.

64B16-27.105 Transfer of Prescriptions.

(1) A pharmacist or registered pharmacy intern acting under the direct personal supervision of a Florida registered pharmacist may transfer a valid prescription which is on file in another pharmacy in this state or any other state if such transfer is consistent with the conditions set forth in Section 465.026, F.S. Prior to dispensing, the pharmacist or pharmacy where the prescription is on file shall be notified verbally, or by any electronic means that the former prescription must be voided.

(2) In processing a transferred prescription pursuant to Section 465.026, F.S., the pharmacist has the option of substituting a generically equivalent product if such substitution is consistent with the provisions of Section 465.025, F.S.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.026 FS. History–New 1-3-79, Formerly 21S-1.33, 21S-1.033, Amended 7-30-91, Formerly 21S-27.105, 61F10-27.105, Amended 9-19-94, Formerly 59X-27.105, Amended 6-15-98.

64B16-27.120 Ordering and Evaluation of Laboratory Tests.

Those consultant pharmacists and pharmacists holding the Doctor of Pharmacy degree that meet the continuing education requirements of Rule 64B16-26.320, F.A.C., may order and evaluate laboratory tests to the extent allowed by the provisions of Section 465.0125, F.S. Evidence of such training and authorization to perform these tasks shall be furnished to the board, the patient, or the patient's physician upon request.

Rulemaking Authority 465.0125(3) FS. Law Implemented 465.0125(2) FS. History–New 2-23-98.

64B16-27.200 Purpose and Effect.

The purpose of this rule chapter is to set forth pursuant to the requirements of Section 465.186, F.S., the medicinal drug products which may be ordered and dispensed by pharmacists to the public and to set forth the terms and conditions under which such ordering and dispensing by the pharmacist may take place. The list of drugs set forth below and the conditions under which said drugs may be ordered and dispensed have been determined pursuant to a joint committee of medical, osteopathic and pharmacy professionals as created by Section 465.186, F.S.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.001, 21S-27.200, 61F10-27.200, 59X-

27.200.

64B16-27.210 General Terms and Conditions to Be Followed by a Pharmacist When Ordering and Dispensing Approved Medicinal Drug Products.

Pursuant to the authority of the Formulary Committee in Section 465.186, F.S., a pharmacist may order the medicinal drug products listed in Rule 64B16-27.220, F.A.C., subject to the following terms and limitations:

(1) Injectable products shall not be ordered by the pharmacist.

(2) No oral medicinal drugs shall be ordered by a pharmacist for a pregnant patient or nursing mother.

(3) In any case of dispensing hereunder, the amount or quantity of drug dispensed shall not exceed a 34-day supply or standard course of treatment unless subject to the specific limitations in this rule. Patients shall be advised that they should seek the advice of an appropriate health care provider if their present condition, symptom, or complaint does not improve upon the completion of the drug regimen.

(4) The directions for use of all prescribed medicinal drugs shall not exceed the manufacturer's recommended dosage.

(5) The pharmacist may only perform the acts of ordering and dispensing in a pharmacy which has been issued a permit by the Board of Pharmacy.

(6) The pharmacist shall create a prescription when ordering and dispensing medicinal drug products which shall be maintained in the prescription files of the pharmacy. The pharmacist shall place the trade or generic name and the quantity dispensed on the prescription label, in addition to all other label requirements.

(7) The pharmacist shall maintain patient profiles, separate from the prescription order, for all patients for whom the pharmacist orders and dispenses medicinal drug products and shall initial and date each profile entry. Such profiles shall be maintained at the pharmacy wherein the ordering and dispensing originated for a period of two (2) years.

(8) In the patient profiles, the pharmacist shall record as a minimum the following information if a medicinal drug product is ordered and dispensed.

(a) Patient's chief complaint or condition in the patient's own words.

(b) A statement regarding the patient's medical history.

(c) A statement regarding the patient's current complaint which may include, onset, duration and frequency of the problem.

(d) The medicinal drug product ordered and dispensed.

(e) The pharmacist ordering and dispensing the medicinal drug product shall initial the profile.

(f) The prescription number shall be recorded in the patient's profile.

(9) A medicinal drug product may be ordered, and dispensed only by the pharmacist so ordering.

(10) Only legend medicinal drugs may be prescribed by a pharmacist. Over-the-counter drugs are exempt from the requirements of this rule and shall be recommended as over-the-counter products.

(11) Pharmacy interns and technicians may not be involved in the ordering of the medicinal drugs permitted in this rule.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.002, 21S-27.210, 61F10-27.210, 59X-27.210, Amended 11-18-07.

64B16-27.211 Prescription Refills.

No prescription may be filled or refilled in excess of one (1) year from the date of the original prescription was written. No prescription for a controlled substance listed in Schedule II may be refilled. No prescription for a controlled substance listed in Schedules III, IV, or V may be filled or refilled more than five (5) times within a period of six (6) months after the date on which the prescription was written.

Rulemaking Authority 465.005, 465.016(1), 465.022(1)(a), 893.04 FS. Law Implemented 465.022 FS. History–New 11-18-07.

64B16-27.220 Medicinal Drugs Which May Be Ordered by Pharmacists.

A Pharmacist may order and dispense from the following formulary, within their professional judgment, subject to the stated conditions.

(1) Oral analgesics for mild to moderate pain. The pharmacist may order these drugs for minor pain and menstrual cramps for patients with no history of peptic ulcer disease. The prescription shall be limited to a six (6) day supply for one treatment. If appropriate, the prescription shall be labeled to be taken with food or milk.

(a) Magnesium salicylate/phenyltoloxamine citrate.

(b) Acetylsalicylic acid (Zero order release, long acting tablets).

(c) Choline salicylate and magnesium salicylate.

(d) Naproxen sodium.

(e) Naproxen.

(f) Ibuprofen.

(2) Urinary analgesics. Phenazopyridine, not exceeding a two (2) day supply. The prescriptions shall be labeled about the tendency to discolor urine. If appropriate, the prescription shall be labeled to be taken after meals.

(3) Otic analgesics. Antipyrine 5.4%, benzocaine 1.4%, glycerin, if clinical signs or symptions of tympanic membrane perforation do not exist. The product shall be labeled for use in the ear only.

(4) Anti-nausea preparations.

(a) Meclizine up to 25 mg., except for a patient currently using a central nervous system (CNS) depressant. The prescription shall be labeled to advise the patient of drowsiness and to caution against concomitant use with alcohol or other depressants.

(b) Scopolamine not exceeding 1.5 mg. per dermal patch. Patient shall be warned to seek appropriate medical attention if eye pain, redness or decreased vision develops.

(5) Antihistamines and decongestants. The following, including their salts, either as a single ingredient product or in combination, including nasal decongestants, may be ordered for a patient above 6 years of age.

(a) Antihistamines. The pharmacist shall warn the patient that an antihistamine should not be used by patients with bronchial asthma or other lower respiratory symptoms, glaucoma, cardiovascular disorders, hypertension, prostate conditions and urinary retention. An antihistamine shall be labeled to advise the patient of drowsiness and caution against the concomitant use with alcohol or other depressants.

1. Diphenhydramine.

2. Carbinoxamine.

3. Pyrilamine.

4. Dexchlorpheniramine.

5. Brompheniramine.

(b) Decongestants. The pharmacist shall not order an oral decongestant for use by a patient with coronary artery disease, angina, hyperthyroidism, diabetes, glaucoma, prostate conditions, hypertension, or a patient currently using a monoamine oxidase inhibitor.

1. Phenylephrine.

2. Azatadine.

(6) Topical antifungal/antibacterials. The pharmacist shall warn the patient that any of the products should not be used near deep or puncture wounds and contact with eyes or mucous membranes should be avoided. Iodochlorhydroxyquin preparations shall be labeled with staining potential.

(a) Iodochlorhydroxyquin with 0.5% Hydrocortisone (not exceeding 20 grams).

(b) Haloprogin 1%.

(c) Clotrimazole topical cream and lotion.

(d) Erythromycin topical.

(7) Topical anti-inflammatory. The pharmacist shall warn the patient that hydrocortisone should not be used on bacterial infections, viral infections, fungal infections, or by patients with impaired circulation. The prescription shall be labeled to advise the patient to avoid contact with eyes, mucous membranes or broken skin. Preparations containing hydrocortisone not exceeding 2.5%.

(8) Otic antifungal/antibacterial. Acetic acid 2% in aluminum acetate solution which shall be labeled for use in ears only.

(9) Keratolytics. Salicylic acid 16.7% and lactic acid 16.7% in flexible collodion, to be applied to warts, except for patients under two (2) years of age, and those with diabetes or impaired circulation. Prescriptions shall be labeled to avoid contact with normal skin, eyes and mucous membranes.

(10) Vitamins with fluoride. (This does not include vitamins with folic acid in excess of 0.9 mg.)

(11) Medicinal drug shampoos containing Lindane. The pharmacist shall:

(a) Limit the order to the treatment of head lice only;

(b) Order no more than four (4) ounces per person; and

(c) Provide the patient with the appropriate instructions and precautions for use.

(12) Ophthalmics. Naphazoline 0.1% ophthalmic solution.

(13) Histamine H2 antagonists. The pharrmacist shall advise the patient to seek medical attention if symptom persist longer than 14 days while using the medication or if stools darken or contain blood.

(a) Cimetidine.

(b) Famotidine.

(c) Ranitidine HCl.

(14) Acne products. Benzoyl Peroxide. The prescription shall be labeled to advise the patient to avoid use on the eye, eyelid, or mucous membranes.

(15) Topical Antiviral.

(a) Acyclovir ointment may be ordered for the treatment of herpes simplex infections of the lips.

(b) Penciclovir.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Amended 10-7-90, Formerly 21S-18.003, Amended 7-30-91, Formerly 21S-27.220, 61F10-27.220, Amended 3-12-97, Formerly 59X-27.220, Amended 6-15-98, 11-30-99, 11-18-07.

64B16-27.230 Fluoride Containing Products That May Be Ordered by Pharmacists.

Oral medicinal drug products containing fluoride may be ordered by pharmacists for their patients who do not have fluoride supplement in their drinking water, pursuant to the following limitations:

(1) The fluoride content of drinking water does not exceed 0.5 ppm.

(2) Once a fluoride treatment has been initiated with one specific fluoride medicinal drug product it should not be interchanged with a product of a different manufacturer for the course of the treatment.

(3) If the fluoride content is less than 0.5 ppm then the following dosage schedule for oral usage shall be followed.

(a)1. For ages 0-6 months.

a. Less than 0.3 ppm in water – no supplementation,

b. 0.3-0.6 ppm in water – no supplementation,

c. 0.6 ppm in water – no supplementation,

2. For ages 6 months – 3 years,

a. Less than 0.3 ppm in water – supplement with 0.25 mg. F/day,

b. 0.3-0.6 ppm in water – no supplementation,

c. 0.6 ppm in water – no supplementation.

3. For ages 3-6 years.

a. Less than 0.3 ppm in water – supplement with 0.5 mg. F/day,

b. 0.3-0.6 ppm in water – supplement with 0.25 mg. F/day,

c. 0.6 ppm in water – no supplementation.

4. For ages 6-16 years.

a. Less than 0.3 ppm in water – supplement with 1.00 mg. F/day,

b. 0.3-0.6 ppm in water – supplement with 0.5 mg. F/day,

c. 0.6 ppm in water – no supplementation.

(b) No more than 264 mg. of sodium fluoride may be dispensed at any one time to a patient.

(c) Notwithstanding the provisions of subsection 64B16-27.210(3), F.A.C., a pharmacist may continue a course of therapy with fluoride products until appropriate referral to another health care practitioner is indicated or in no event shall the course of therapy be more than one (1) year.

Rulemaking Authority 465.186(2) FS. Law Implemented 465.186 FS. History–New 5-1-86, Formerly 21S-18.004, 21S-27.230, 61F10-27.230, 59X-27.230, Amended 6-15-98.

64B16-27.300 Standards of Practice - Continuous Quality Improvement Program.

(1) "Continuous Quality Improvement Program" means a system of standards and procedures to identify and evaluate quality-related events and improve patient care.

(2) "Quality-Related Event" means the inappropriate dispensing or administration of a prescribed medication including:

(a) A variation from the prescriber's prescription order, including, but not limited to:

1. Incorrect drug;
2. Incorrect drug strength;
3. Incorrect dosage form;
4. Incorrect patient; or
5. Inadequate or incorrect packaging, labeling, or directions.

(b) A failure to identify and manage:

1. Over-utilization or under-utilization;
2. Therapeutic duplication;
3. Drug-disease contraindications;
4. Drug-drug interactions;
5. Incorrect drug dosage or duration of drug treatment;
6. Drug-allergy interactions; or
7. Clinical abuse/misuse.

(3)(a) Each pharmacy shall establish a Continuous Quality Improvement Program which program shall be described in the pharmacy's policy and procedure manual and, at a minimum shall contain:

1. Provisions for a Continuous Quality Improvement Committee that may be comprised of staff members of the pharmacy, including pharmacists, registered pharmacy interns, registered pharmacy technicians, clerical staff, and other personnel deemed necessary by the prescription department manager or the consultant pharmacist of record;

2. Provisions for the prescription department manager or the consultant pharmacist of record to ensure that the committee conducts a review of Quality Related Events at least every three months.

3. A planned process to record, measure, assess, and improve the quality of patient care; and

4. The procedure for reviewing Quality Related Events.

(b) As a component of its Continuous Quality Improvement Program, each pharmacy shall assure that, following a Quality-Related Event, all reasonably necessary steps have been taken to remedy any problem for the patient.

(c) At a minimum, the review shall consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.

(4) Each Quality-Related Event that occurs, or is alleged to have occurred, as the result of activities in a pharmacy, shall be documented in a written record or computer database created solely for that purpose. The Quality-Related Event shall be initially documented by the pharmacist to whom it is described, and it shall be recorded on the same day of its having been described to the pharmacist. Documentation of a Quality-Related Event shall include a description of the event that is sufficient to permit categorization and analysis of the event. Pharmacists shall maintain such records at least until the event has been considered by the committee and incorporated in the summary required in subsection (5) below.

(5) Records maintained as a component of a pharmacy Continuous Quality Improvement Program are confidential under the provisions of Section 766.101, F.S. In order to determine compliance the Department may review the policy and procedures and a Summarization of Quality-Related Events. The summarization document shall analyze remedial measures undertaken following a Quality-Related Event. No patient name or employee name shall be included in this summarization. The summarization shall be maintained for two years. Records are considered peer-review documents and are not subject to discovery in civil litigation or administrative actions.

Rulemaking Authority 465.0155 FS. Law Implemented 465.0155 FS. History–New 7-15-99, Amended 1-2-02, 6-16-03, 11-18-07, 1-1-10.

64B16-27.400 Practice of Pharmacy.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(11)(b), (13), 465.014, 465.026 FS. History–New 2-14-77, Formerly 21S-4.01, 21S-4.001, Amended 7-30-91, Formerly 21S-27.400, 61F10-27.400, Amended 1-30-96, 10-1-96, Formerly 59X-27.400, Amended 4-13-00, Repealed 10-5-09.

64B16-27.410 Registered Pharmacy Technician, to Pharmacist Ratio.

(1) Registered pharmacy technicians may assist a pharmacist in performing professional services within a pharmacy environment provided that no pharmacist shall supervise more than one registered pharmacy technician unless otherwise permitted by the Florida Board of Pharmacy. A pharmacist's supervision of a registered pharmacy technician in a working environment

requires that a registered pharmacy technician be under the direct personal supervision of a pharmacist.

(2) The prescription department manager or consultant pharmacist of record is required to submit a written request and receive approval prior to the pharmacy's allowing a pharmacist to supervise more than one registered pharmacy technician as permitted by law. Such requests shall be reviewed and pre-approved by Board staff according to the guidelines adopted herein, and submitted to the Board for ratification.

(3) The request to practice with a ratio greater than 1:1 shall include a brief description of the workflow needs that justify the ratio request. The brief description of workflow needs shall include the operating hours of the pharmacy, number of pharmacists, registered interns, and registered pharmacy technicians employed.

(4) A pharmacy that employs pharmacy technicians shall meet the following conditions:

(a) Establish written job descriptions, task protocols, and policies and procedures that pertain to duties performed by the registered pharmacy technician and provide this information to the Board upon request;

(b) Establish that each registered pharmacy technician is knowledgeable in the established job descriptions, task protocols, and policy and procedures in the pharmacy setting in which the technician is to perform his or her duties;

(c) Ensure that the duties assigned to any registered pharmacy technician do not exceed the established job descriptions, task protocols, and policy and procedures, nor involve any of the prohibited tasks in Rule 64B16-27.420, F.A.C.; or

(d) Ensure that each registered pharmacy technician receives employer-based or on-the-job training in order for the registered pharmacy technician to assume his or her responsibilities and maintain documentation of the training.

(5) The pharmacy shall maintain a policy and procedure manual with regard to registered pharmacy technicians which shall include the following:

(a) Supervision by a pharmacist;

(b) Minimum qualifications as established by law;

(c) Documentation of in-service education and/or on-going training and demonstration of competency, specific to practice site and job function;

(d) General duties and responsibilities of registered pharmacy technicians;

(e) Retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;

(f) All functions related to prescription processing;

(g) All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;

(h) rescription refill and renewal authorization;

(i) Registered pharmacy technician functions related to automated pharmacy systems; and

(j) Continuous quality improvement program.

Rulemaking Authority 465.005 FS. Law Implemented 465.014, 893.07(1)(b) FS. History–New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10.

64B16-27.420 Registered Pharmacy Technician Responsibilities.

(1) Registered pharmacy technicians may assist the pharmacist in performing the following tasks:

(a) Retrieval of prescription files, patient files and profiles and other such records pertaining to the practice of pharmacy;

(b) Data Entry;

(c) Label preparation;

(d) The counting, weighing, measuring, pouring and mixing of prescription medication or stock legend drugs and controlled substances, including the filling of an automated medication system;

(e) Initiate communication to a prescribing practitioner or their medical staffs (or agents) regarding patient prescription refill authorization requests. For the purposes of this section "prescription refill" means the dispensing of medications pursuant to a prescriber's authorization provided on the original prescription;

(f) Initiate communication to confirm the patient's name, medication, strength, quantity, directions and date of last refill;

(g) Initiate communication to a prescribing practitioner or their medical staff (or agents) to obtain clarification on missing or illegible dates, prescriber name, brand/generic preference, quantity, DEA registration number or license numbers; and

(h) May accept authorization for a prescription renewal. For the purposes of this section, "prescription renewal" means the dispensing of medications pursuant to a practitioner's authorization to fill an existing prescription that has no refill remaining.

(2) Registered Pharmacy technicians shall not:

(a) Receive new verbal prescriptions or any change in the medication, strength or directions;

(b) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(c) Conduct a final verification of dosage and directions;

(d) Engage in prospective drug review;

(e) Provide patient counseling;

(f) Monitor prescription usage; and

(g) Override clinical alerts without first notifying the pharmacist.

(3) Nuclear pharmacy permits allow the registered pharmacy technician to receive diagnostic orders only. The pharmacist must receive therapy or blood product procedure orders.

(4)(a) All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as a "registered pharmacy technician"; and

(b) All registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

Rulemaking Authority 465.005, 465.014 FS. Law Implemented 465.014 FS. History–New 8-31-87, Formerly 21S-4.0025, Amended 7-30-91, Formerly 21S-27.420, 61F10-27.420, 59X-27.420, Amended 2-23-98, 1-1-10, 8-26-12.

64B16-27.430 Responsibilities of the Pharmacist.

The delegation of any duties, tasks or functions to registered pharmacy interns and registered pharmacy technicians must be performed subject to a continuing review and ultimate supervision of the pharmacist who instigated the specific task, so that a continuity of supervised activity is present between one (1) pharmacist and one (1) registered pharmacy technician. In every pharmacy, the licensed pharmacist shall retain the professional and personal responsibility for any delegated act performed by registered pharmacy interns and registered pharmacy technicians in his employ and under his supervision.

Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History–New 2-14-77, Formerly 21S-4.03, Amended 9-1-87, Formerly 21S-4.003, 21S-27.430, 61F10-27.430, 59X-27.430, Amended 1-1-10.

64B16-27.440 Policies and Procedures.

Any pharmacy utilizing registered pharmacy technicians shall be required to have written policies and procedures regarding the number of positions and their utilization, including the specific scope of responsibilities of technicians, available for inspection by the Florida Board of Pharmacy or its authorized agents and representatives.

Rulemaking Authority 465.005 FS. Law Implemented 465.014 FS. History–New 2-14-77, Formerly 21S-4.04, 21S-4.004, Amended 9-9-92, Formerly 21S-27.440, 61F10-27.440, 59X-27.440, Amended 1-1-10.

64B16-27.500 Negative Drug Formulary.

The negative drug formulary is composed of medicinal drugs which have been specifically determined by the Board of Pharmacy and the Board of Medicine to demonstrate clinically significant biological or therapeutic inequivalence and which, if substituted, could produce adverse clinical effects, or could otherwise pose a threat to the health and safety of patients receiving such prescription medications. Except where certain dosage forms are included on the negative drug formulary as a class, all medicinal drugs are listed by their official United States Pharmacopoeia Non-Proprietary (generic) name. The generic name of a drug shall be applicable to and include all brand-name equivalents of such drug for which a prescriber may write a prescription. Substitution by a dispensing pharmacist on a prescription written for any brand name equivalent of a generic named drug product listed on the negative formulary or for a drug within the class of certain dosage forms as listed, is strictly prohibited. In cases where the prescription is written for a drug listed on the negative drug formulary but a brand name equivalent is not specified by the prescriber, the drug dispensed must be one obtained from a manufacturer or distributor holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, United States Department of Health and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying such medicinal drugs must show compliance with other applicable Federal Food and Drug Administration marketing requirements. The following are included on the negative drug formulary:

(1) Digitoxin.
(2) Conjugated Estrogen.
(3) Dicumarol.
(4) Chlorpromazine (Solid Oral Dosage Forms).
(5) Theophylline (Controlled Release).
(6) Pancrelipase (Oral Dosage Forms).

Rulemaking Authority 465.005, 465.025(6) FS., Ch. 2001-146, Laws of Florida. Law Implemented 465.025(6) FS., Ch. 2001-146, Laws of Florida. History–New 12-14-76, Amended 3-17-77, 7-2-79, 4-9-81, 9-14-82, 9-26-84, Formerly 21S-5.01, Amended 3-30-89, 7-1-90, Formerly 21S-5.001, Amended 12-25-90, 10-1-92, Formerly 21S-27.500, Amended 2-21-94, Formerly 61F10-27.500, 59X-27.500, Amended 12-4-01, 3-18-10.

64B16-27.510 Identification of Manufacturer.

Each formulary of generic and brand name drug products established by each community pharmacy pursuant to the provisions of Section 465.025, F.S., shall include the name of the manufacturer of the generic drug listed in said formulary.

Rulemaking Authority 465.005 FS. Law Implemented 465.025 FS. History–New 3-16-77, Formerly 21S-5.02, 21S-5.002, 21S-27.510, 61F10-27.510, 59X-27.510.

64B16-27.520 Positive Drug Formulary.

A positive formulary of generic and brand name drug products is required of each community pharmacy pursuant to subsection 465.025(5), F.S. Those medicinal drugs on the positive formulary shall be obtained from manufacturers or distributors holding an approved new drug application or abbreviated new drug application issued by the Food and Drug Administration, U.S. Department of Health, Education and Welfare permitting that manufacturer or distributor to market those medicinal drugs or when the former is non-applicable, those manufacturers or distributors supplying those medicinal drugs must show compliance with other applicable Federal Food and Drug Administration marketing requirements.

Rulemaking Authority 465.005 FS. Law Implemented 465.025(6) FS. History–New 12-7-77, Formerly 21S-5.03, 21S-5.003, 21S-27.520, 61F10-27.520, 59X-27.520.

64B16-27.530 Duty of Pharmacist to Inform Regarding Drug Substitution.

Prior to the delivery of the prescription, a pharmacist must inform the person presenting a prescription of any substitution of a generic drug product for a brand name drug product, of any retail price difference between the two, and of the person's right to refuse the substitution. This information must be communicated at a meaningful time such as to allow the person to make an informed choice as to whether to exercise the option to refuse substitution without undue inconvenience to the presenter of the prescription or to the consumer of the drug. This information shall be communicated to the person presenting the prescription in a manner determined to be appropriate by the pharmacist using professional discretion and judgment.

Rulemaking Authority 465.005 FS. Law Implemented 465.025(3)(a) FS. History–New 11-10-80, Formerly 21S-5.04, 21S-5.004, 21S-27.530, 61F10-27.530, 59X-27.530, Amended 11-18-07.

64B16-27.615 Possession and Disposition of Sample Medicinal Drugs.

(1) Pharmacies may not be in possession of sample medicinal drugs except:

(a) Pharmacies may possess the sample medicinal drugs that are listed within Rule 64B16-27.220, F.A.C., Medicinal Drugs That May be Ordered by Pharmacists.

(b) Institutional pharmacies may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(c) Those community pharmacies that are pharmacies of health care entities, as defined by Sections 499.003(3) and (14), F.S., may possess sample medicinal drugs upon the written request of the prescribing practitioner. Such possession must be in accordance with the provisions of Section 499.028(3)(e)2., F.S.

(2) Sample packages of medicinal drugs that are found to be unsuitable for dispensing by reason of physical condition or failure to meet requirements of state or federal law shall be returned to the company of origin in accordance with the requirements of Chapter 499, F.S.

Rulemaking Authority 465.005, 465.022, 499.028 FS. Law Implemented 465.018, 465.019, 465.022, 465.186, 499.028 FS. History–New 11-4-93, Formerly 61F10-27.615, 59X-27.615, Amended 11-18-07.

64B16-27.620 Disposition of Complimentary or Sample Medicinal Drugs Which Are Unsuitable for Dispensing.

Rulemaking Authority 465.005, 465.022, 499.028 FS. Law Implemented 465.022 FS. History–New 12-26-79, Formerly 21S-15.03, 21S-15.003, 21S-27.620, Amended 11-4-93, Formerly 61F10-27.620, 59X-27.620, Repealed 10-5-09.

64B16-27.700 Definition of Compounding.

"Compounding" is the professional act by a pharmacist or other practitioner authorized by law, employing the science or art of any branch of the profession of pharmacy, incorporating ingredients to create a finished product for dispensing to a patient or for administration by a practitioner or the practitioner's agent; and shall specifically include the professional act of preparing a unique finished product containing any ingredient or device defined by Sections 465.003(7) and (8), F.S. The term also includes the preparation of nuclear pharmaceuticals and diagnostic kits incident to use of such nuclear pharmaceuticals. The term "commercially available products," as used in this section, means any medicinal product as defined by Sections 465.003(7) and (8), F.S., that are legally distributed in the State of Florida by a drug manufacturer or wholesaler.

(1) Compounding includes:

(a) The preparation of drugs or devices in anticipation of prescriptions based on routine, regularly observed prescribing patterns.

(b) The preparation pursuant to a prescription of drugs or devices which are not commercially available.

(c) The preparation of commercially available products from bulk when the prescribing practitioner has prescribed the compounded product on a per prescription basis and the patient has been made aware that the compounded product will be prepared by the pharmacist. The reconstitution of commercially available products pursuant to the manufacturer's guidelines is permissible without notice to the practitioner.

(2) The preparation of drugs or devices for sale or transfer to pharmacies, practitioners, or entities for purposes of dispensing or distribution is not compounding and is not within the practice of the profession of pharmacy. Except that the supply of patient specific compounded prescriptions to another pharmacy under the provisions of Section 465.0265, F.S., and Rule 64B16-28.450, F.A.C., is authorized.

(3) Office use compounding, "Office use" means the provision and administration of a compounded drug to a patient by a practitioner in the practitioner's office or by the practitioner in a health care facility or treatment setting, including a hospital, ambulatory surgical center, or pharmacy. A pharmacist may dispense and deliver a quantity of a compounded drug to a practitioner for office use by the practitioner in accordance with this section provided:

(a) The quantity of compounded drug does not exceed the amount a practitioner anticipates may be used in the practitioner's office before the expiration date of the drug;

(b) The quantity of compounded drug is reasonable considering the intended use of the compounded drug and the nature of the practitioner's practice;

(c) The quantity of compounded drug for any practitioner and all practitioners as a whole, is not greater than an amount the pharmacy is capable of compounding in compliance with pharmaceutical standards for identity, strength, quality, and purity of the compounded drug that are consistent with United States Pharmacopoeia guidelines and accreditation practices.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(12), 465.0155, 465.0265 FS. History–New 10-1-92, Formerly 21S-27.700, 61F10-27.700, 59X-27.700, Amended 11-2-03, 10-7-08.

64B16-27.797 Standards of Practice for Compounding Sterile Preparations (CSPs).

The purpose of this section is to assure positive patient outcomes through the provision of standards for 1) pharmaceutical care; 2) the preparation, labeling, and distribution of sterile pharmaceuticals by pharmacies, pursuant to or in anticipation of a prescription drug order, and 3) product quality and characteristics. These standards are intended to apply to all sterile pharmaceuticals, notwithstanding the location of the patient (e.g., home, hospital, nursing home, hospice, doctor's office).

(1) Definitions:

(a) "Anteroom" means an area where personnel perform hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate generating activities. It is also a transition area that provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas. The Anteroom area is to be maintained within ISO Class 8 level of particulate contamination.

(b) "Antineoplastic" means a pharmaceutical agent that has the intent of causing cell death targeted to cancer cells, metastatic cells, or other cells involved in a severe inflammatory or autoimmune response.

(c) "Beyond-use-date" means the date after which a compounded preparation should not be used and is determined from the date the preparation was compounded.

(d) "Biological safety cabinet" means a containment unit suitable for the preparation of low, moderate, and high risk agents where there is a need for protection of the product, personnel, and environment.

(e) "Bulk Compounding" means the compounding of CSPs in increments of twenty-five (25) or more doses from a single source.

(f) "Buffer area" (Clean room) is an area where the activities of CSP take place; it shall not contain sinks or drains. In High-Risk compounding this must be a separate room. The Buffer area is to be maintained within ISO Class 7 level of particulate contamination.

(g) "Class 100 environment" means an atmospheric environment which contains no more than one hundred particles of 0.5 microns in diameter or larger per cubic foot of air. A class 100 environment is equivalent to ISO Class 5 level of particulate contamination.

(h) "Compounding Aseptic Isolator" (CAI) – is a form of barrier isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer process. Air exchange into the isolator from the surrounding environment should not occur unless it is first passed through a microbially retentive filter (HEPA minimum 0.2 microns).

(i) "High-Risk Level CSPs" – are products compounded under any of the following conditions are either non-sterile or at high risk to become non-sterile with infectious microorganisms.

1. Non-sterile ingredients, including manufactured products for routes of administration other than sterile parenteral administration are incorporated or a non-sterile device is employed before terminal sterilization.

2. Sterile contents of commercially manufactured products, CSP that lack effective antimicrobial preservatives, sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs are exposed to air quality worse than ISO Class 5 for more than one (1) hour.

3. Before sterilization, non-sterile procedures such as weighing and mixing are conducted in air quality worse than ISO Class 7, compounding personnel are improperly garbed and gloved, or water-containing preparations are stored for more than 6 hours.

4. For properly stored sterilized high-risk preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and exposed for not more than 24 hours at controlled room temperature, and for not more than 3 days at a cold temperature (2-8 degrees Celsius) and for not more than 45 days in solid frozen state at -20 degrees celsius or colder.

5. Examples of high-risk compounding include: (1) dissolving non-sterile bulk drug and nutrient powders to make solutions, which will be terminally sterilized; (2) exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 for more than one (1) hour; (3) measuring and mixing sterile ingredients in non-sterile devices before sterilization is performed; (4) assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

6. All high risk category products must be rendered sterile by heat sterilization, gas sterilization, or filtration sterilization in order to become a CSP.

7. Quality assurance practices for high-risk level CSPs include all those for low-risk level CSPs. In addition, each person authorized to compound high-risk level CSPs demonstrates competency by completing a media-filled test that represents high-level compounding semiannually.

(j) Immediate Use CSPs:

1. Requires only simple aseptic measuring and transfer manipulations are performed with not more than three (3) sterile non-hazardous drug or diagnostic radiopharmaceutical drug preparations, including an infusion or dilution solution.

2. The preparation procedure occurs continuously without delays or interruptions and does not exceed 1 hour.

3. At no point during preparation and prior to administration are critical surfaces and ingredients of the CSP directly exposed to contact contamination such as human touch, cosmetic flakes or particulates, blood, human body substances (excretions and secretions, e.g., nasal or oral) and non-sterile inanimate sources.

4. Administration begins not later than one (1) hour following the start of preparing the CSP.

5. When the CSP is not administered by the person who prepared it, or its administration is not witnessed by the person who prepared it, the CSP container shall bear a label listing patient identification information (name, identification numbers), and the names and amounts of all active ingredients, and the name or identifiable initials of the person who prepared the CSP, and one (1) hour beyond-use time and date.

6. If administration has not begun within one (1) hour following the start of preparing the CSP, the CSP is promptly and safely discarded. Immediate use CSPs shall not be stored for later use.

(k) ISO Class 5 guidelines are met when particulate contamination is measured at "not more than 3,520 particles 0.5 micron size or larger per cubic meter of air for any lamiar airflow workbench (LAWF), BSC, or CAI. (Also referred to as a "Class 100 environment.")

(l) ISO Class 7 guidelines are met when particulate contamination is measured at "not more than 352,000 particles 0.5 micron size or larger per cubic meter of air for any buffer area (room)."

(m) ISO Class 8 guidelines are met when particulate contamination is measured at "not more than 3,520,000 particles 0.5 micron size or larger per cubic meter of air for any anteroom (area)."

(n) Low-Risk Level CSPs compounded under all of the following are at a low risk of contamination:

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (class 100) or better air quality using only sterile ingredients, products, components, and devices.

2. The compounding involves only transfer, measuring, and mixing manipulations using no more than three commercially manufactured sterile products and entries into one container (e.g., bag, vial) of sterile product to make the CSP.

3. Manipulations are limited to aseptically opening ampoules, penetrating sterile stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers for storage and dispensing. The contents of ampoules shall be passed through a sterile filter to remove any particles.

4. For low-risk preparation, in the absence of passing a sterility test or a documented validated process, the storage periods cannot exceed the following time periods; before administration, the CSPs are properly stored and exposed for not more than 48

hours at controlled room temperature, and for not more than 14 days at a cold temperature (2-8 degrees celsius) and for 45 days in solid frozen state at -20 degrees celsius or colder.

5. Quality Assurance practices include, but are not limited to, the following: (1) routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 air quality; (2) Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments; (3) Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded; (4) Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and accuracy and thoroughness of labeling.

6. All compounding personnel are required to demonstrate competency by completing a media-filled test that represents low-level compounding annually. A media-filled test is a commercially available sterile fluid culture media that shall be able to promote exponential colonization of bacteria that are both likely to be transmitted to CSP from the compounding personnel and environment. Media filled vials are incubated at 25-35 degrees celsius for 14 days. Failure is indicated by visible turbidity in the medium on or before 14 days.

(o) Medium-Risk Level CSPs – When CSPs are compounded aseptically under Low-Risk Conditions, and one or more of the following conditions exist, such CSPs are at a medium risk of contamination:

1. CSPs containing more than three (3) commercial sterile drug products and those requiring complex manipulations and/or preparation methods.

2. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.

3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.

4. For Medium-risk preparation, in the absence of passing a sterility test or a documented validated process, the storage periods cannot exceed the following time periods; before administration, the CSPs are properly stored and exposed for not more than 30 hours at controlled room temperature, and for not more than 9 days at a cold temperature and for 45 days in solid frozen state at -20 degrees celsius or colder.

5. These include compounding of total parenteral nutrition (TPN) using either manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.

6. Filling of reservoirs of injection and infusion devices with more than three (3) sterile drug products and evacuation of air from those reservoirs before the filled devices are dispensed.

7. Transfer of volumes from multiple ampules or vials into one or more final sterile containers.

8. Quality assurance practices for medium-risk level CSPs include all those for low-risk level CSPs.

9. Demonstrates competency by completing a media-filled test that represents medium-level compounding annually.

(p) Parenteral means a sterile preparation of drugs for injection through one or more layers of the skin.

(q) Risk level of the sterile preparation means the level assigned to a sterile product by a pharmacist that represents the probability that the sterile product will be contaminated with microbial organisms, spores, endotoxins, foreign chemicals or other physical matter.

(r) Sterile preparation means any dosage form devoid of viable microorganisms, including but not limited to, parenterals, injectables, ophthalmics, and aqueous inhalant solutions for respiratory treatments.

(2) Compounded sterile preparations include, but are not limited, to the following:

(a) Total Parenteral Nutrition (TPN) solutions;

(b) Parenteral analgesic drugs;

(c) Parenteral antibiotics;

(d) Parenteral antineoplastic agents;

(e) Parenteral electrolytes;

(f) Parenteral vitamins;

(g) Irrigating fluids;

(h) Ophthalmic preparations; and

(i) Aqueous inhalant solutions for respiratory treatments.

(3) Sterile preparations shall not include commercially manufactured products that do not require compounding prior to dispensing.

(4) Policy & Procedure Manual. A policy and procedure manual shall be prepared and maintained for the compounding, dispensing, and delivery of sterile preparation prescriptions. The policy and procedure manual shall be available for inspection by the Department and include at a minimum:

(a) Use of single dose and multiple dose containers not to exceed United States Pharmacopeia 797 guidelines.

(b) Verification of compounding accuracy and sterility.

(c) Personnel training and evaluation in aseptic manipulation skills.

(d) Environmental quality and control:

1. Air particle monitoring for hoods (or Barrier Isolator), clean room and buffer area (or anteroom) when applicable;

2. Unidirectional airflow (pressure differential monitoring);

3. Cleaning and disinfecting the sterile compounding areas;

4. Personnel cleansing and garbing;

5. Environmental monitoring (air and surfaces).

(e) Personnel monitoring and validation.

(f) Finished product checks and tests.

(g) Method to identify and verify ingredients used in compounding.

(h) Labeling requirements for bulk compounded products:

1. Contents;

2. Beyond-Use-Date; and

3. Storage requirements.

(i) Packing, storage, and transportation conditions.

(5) Physical Requirements.

(a) The pharmacy shall have a designated area with entry restricted to designated personnel for preparing parenteral products. This area shall have a specified ante area and buffer area; in high risk compounding, this shall be separate rooms. This area shall be structurally isolated from other areas with restricted entry or access, and must be designed to avoid unnecessary traffic and interference with unidirectional airflow. It shall be used only for the preparation of these sterile preparations. It shall be of sufficient size to accommodate a laminar airflow hood and to provide for the proper storage of drugs and supplies under appropriate conditions of temperature, light, moisture, sanitation, ventilation, and security.

(b) The pharmacy compounding parenteral and sterile preparation shall have the following:

1. Appropriate environmental control devices capable of maintaining at least class 100 conditions in the work place where critical objects are exposed and critical activities are performed; furthermore, these devices must be capable of maintaining class 100 conditions during normal activity. Examples of appropriate devices include laminar airflow hoods and zonal laminar flow of high efficiency particulate air (HEPA) filtered air;

2. Appropriate disposal containers for used needles, syringes, and if applicable, for antineoplastic waste from the preparation of chemotherapy agents;

3. Appropriate environmental control including approved biohazard cabinetry when antineoplastic drug products are prepared;

4. Appropriate temperature and transport containers;

5. Infusion devices and equipment, if appropriate.

(c) The pharmacy shall maintain and use supplies adequate to preserve an environment suitable for the aseptic preparation of sterile preparations, such as:

1. Gloves, masks, shoe covers, head and facial hair covers, and non-shedding gowns;

2. Needles and syringes of various standard sizes;

3. Disinfectant cleaning agents;

4. Clean towels;

5. Hand washing materials with bactericidal properties;

6. Vacuum containers and various transfer sets;

7. "Spill kits" for antineoplastic agent spills.

(d) The pharmacy should have current reference material in hard copy or readily available on line:

1. USP Pharmacist Pharmacopeia (optional) or Handbook of Injectable Drugs by American Society of Hospital Pharmacists; or other nationally recognized standard reference; and

2. "Practice Guidelines for Personnel Dealing with Cytotoxic Drugs," or other nationally recognized standard cytotoxic reference if applicable.

(e) Barrier isolator is exempt from all physical requirements subject to manufacturer guidelines for proper placement.

(6) Antineoplastic Drugs. The following requirements are necessary for those pharmacies that prepare antineoplastic drugs to ensure the protection of the personnel involved:

(a) All antineoplastic drugs shall be compounded in a vertical flow, Class II, biological safety cabinet placed in negative pressure room unless using barrier isolators. Other preparations shall not be compounded in this cabinet.

(b) Protective apparel shall be worn by personnel compounding antineoplastic drugs. This shall include at least gloves and gowns with tight cuffs.

(c) Appropriate safety and containment techniques for compounding antineoplastic drugs shall be used in conjunction with the aseptic techniques required for preparing sterile products.

(d) Disposal of antineoplastic waste shall comply with all applicable local, state, and federal requirements.

(e) Written procedures for handling both major and minor spills of antineoplastic agents shall be developed and shall be included in the policy and procedure manual.

(f) Prepared doses of antineoplastic drugs shall be dispensed, labeled with proper precautions inside and outside, and shipped in a manner to minimize the risk of accidental rupture of the primary container.

(7) Quality Assurance:

(a) There shall be a documented, ongoing quality assurance control program that monitors personnel performance, equipment, and preparations. Appropriate samples of finished preparations shall be examined to assure that the pharmacy is capable of consistently preparing sterile preparations meeting specifications:

1. All clean rooms and laminar flow hoods shall be certified by an independent contractor or National Sanitation Foundation Standard 49, for operational efficiency at least semiannually for high risk CSPs and annually for low and medium risk CSPs or any time the hood is relocated or the structure is altered and records shall be maintained for two years.

2. There shall be written procedures developed requiring sampling if microbial contamination is suspected for batches greater than 25 units.

3. High risk greater than 25 units have antimicrobial testing prior to dispensing.

4. There shall be referenced written justification of the chosen beyond-use-dates for compounded products.

5. There shall be documentation of quality assurance audits at regular planned intervals, including infection control and sterile technique audits.

(b) Compounding personnel shall be adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:

1. Demonstrate by observation or test a functional understanding of USP Chapter 797 and definitions, to include Risk Category assessment;

2. Understand the characteristics of touch contamination and airborne microbial contaminants;

3. Perform antiseptic hand cleaning and disinfections of non-sterile compounding surfaces;

4. Select and appropriately don protective garb;

5. Demonstrate aseptic techniques and requirements while handling medications;

6. Maintain and achieve sterility of CSPs in ISO Class 5 (Class 100) primary engineering devices and protect personnel and compounding environments from contamination by antineoplastic and chemotoxic or other hazardous drugs or substances;

7. Manipulate sterile products aseptically, sterilize high-risk level CSPs (where applicable) and quality inspect CSPs;

8. Identify, weigh and measure ingredients;

9. Prepare product labeling requirements and "beyond use" requirements of product expiration;

10. Prepare equipment and barrier requirement work requirements to maintain sterility;

11. Prepare end point testing and demonstrated competencies for relevant risk levels;

12. Prepare media fills to test aseptic technique.

(8) Radiopharmaceuticals as Compounded Sterile Products

(a) Upon release of a Positron Emission Tomography (PET) radiopharmaceutical as a finished drug product from a PET production facility, the further manipulation, handling, or use of the product will be considered compounding and will be subject to the rules of this section.

(b) Radiopharmaceuticals compounded from sterile components in closed, sterile containers and with a volume of 100 ml or less for single dose injection or not more than 30 ml taken from a multiple dose container, shall be designated as, and conform to, the standards for low risk compounding.

(c) Radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning ISO Class 5 PEC (Primary Engineering Control), located in an ISO Class 8 or better buffer area environment in compliance with special handling, shielding, air flow requirements, and radiation safety programs to maintain radiation exposure as low as reasonably achievable.

(d) Radiopharmaceuticals designed for multi use, compounded with Tc-99m, exposed to an ISO Class 5 environment by components with no direct contact contamination, may be used up until the time indicated by manufacturers recommendations.

(e) Technetium 99/Molybdnenum 99 generator systems shall be stored and eluted in an ISO Class 8 or cleaner environment to permit special handling, shielding, and airflow requirements.

(f) Manipulation of blood or blood derived products (e.g. radiolabeling white blood cells) shall be conducted in an area that is clearly separated from routine material handling areas and equipment, and shall be controlled by specific standard operating procedures to avoid cross contamination of products. The buffer area for manipulation of blood or blood derived products shall be maintained as an ISO 7 environment and direct manipulations shall occur in an ISO 5 PEC suitable for these products (e.g. biological safety cabinet).

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.0155, 465.022 FS. History–New 6-18-08, Amended 1-7-10.

64B16-27.800 Requirement for Patient Records.

(1) A patient record system shall be maintained by all pharmacies for patients to whom new or refill prescriptions are dispensed. The patient record system shall provide for the immediate retrieval of information necessary for the dispensing pharmacist to identify previously dispensed drugs at the time a new or refill prescription is presented for dispensing. The pharmacist shall ensure that a reasonable effort is made to obtain, record and maintain the following information:

(a) Full name of the patient for whom the drug is intended;

(b) Address and telephone number of the patient;

(c) Patient's age or date of birth;

(d) Patient's gender;

(e) A list of all new and refill prescriptions obtained by the patient at the pharmacy maintaining the patient record during the two years immediately preceding the most recent entry showing the name of the drug or device, prescription number, name and strength of the drug, the quantity and date received, and the name of the prescriber; and

(f) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) The pharmacist shall ensure that a reasonable effort is made to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other drugs, including over-the-counter drugs, or devices currently being used by the patient which may relate to prospective drug review. The pharmacist shall record any related information indicated by a licensed health care practitioner.

(3) A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(4) Patient records shall be maintained for prescriptions dispensed subsequent to the effective date of this regulation.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.800, 61F10-27.800, 59X-27.800, Amended 6-15-98.

64B16-27.810 Prospective Drug Use Review.

(1) A pharmacist shall review the patient record and each new and refill prescription presented for dispensing in order to promote therapeutic appropriateness by identifying:

(a) Over-utilization or under-utilization;

(b) Therapeutic duplication;

(c) Drug-disease contraindications;

(d) Drug-drug interactions;

(e) Incorrect drug dosage or duration of drug treatment;

(f) Drug-allergy interactions;

(g) Clinical abuse/misuse.

(2) Upon recognizing any of the above, the pharmacist shall take appropriate steps to avoid or resolve the potential problems which shall, if necessary, include consultation with the prescriber.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.810, 61F10-27.810, 59X-27.810.

64B16-27.820 Patient Counseling.

(1) Upon receipt of a new or refill prescription, the pharmacist shall ensure that a verbal and printed offer to counsel is made to the patient or the patient's agent when present. If the delivery of the drugs to the patient or the patient's agent is not made at the pharmacy the offer shall be in writing and shall provide for toll-free telephone access to the pharmacist. If the patient does not refuse such counseling, the pharmacist, or the pharmacy intern, acting under the direct and immediate personal supervision of a licensed pharmacist, shall review the patient's record and personally discuss matters which will enhance or optimize drug therapy with each patient or agent of such patient. Such discussion shall be in person, whenever practicable, or by toll-free telephonic communication and shall include appropriate elements of patient counseling. Such elements may include, in the professional judgment of the pharmacist, the following:

(a) The name and description of the drug;

(b) The dosage form, dose, route of administration, and duration of drug therapy;

(c) Intended use of the drug and expected action (if indicated by the prescribing health care practitioner);

(d) Special directions and precautions for preparation, administration, and use by the patient;

(e) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;

(f) Techniques for self-monitoring drug therapy;

(g) Proper storage;

(h) Prescription refill information;

(i) Action to be taken in the event of a missed dose; and

(j) Pharmacist comments relevant to the individual's drug therapy, including any other information peculiar to the specific patient or drug.

(2) Patient counseling as described herein, shall not be required for inpatients of a hospital or institution where other licensed health care practitioners are authorized to administer the drug(s).

(3) A pharmacist shall not be required to counsel a patient or a patient's agent when the patient or patient's agent refuses such consultation.

Rulemaking Authority 465.022, 465.0155 FS. Law Implemented 465.0155 FS. History–New 8-18-93, Formerly 21S-27.820, 61F10-27.820, 59X-27.820.

64B16-27.830 Standards of Practice - Drug Therapy Management.

(1) "Prescriber Care Plan" means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. The Prescriber Care Plan shall be written by a physician licensed pursuant to Chapter 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication. The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.

(2) "Drug Therapy Management" means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.

(3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient's drug

therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:

(a) Drug therapy to be initially dispensed to the patient by the pharmacist; or

(b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist; or

(c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient; or

(d) The conditions under which the pharmacist shall contact or notify the physician.

(4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:

(a) A transferable patient care record that includes:

1. A Prescriber Care Plan that includes a section noted as "orders" from a duly licensed physician for each patient for whom a pharmacist provides Drug Therapy Management services;

2. Progress notes; and

(b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and

(c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(13), 465.0155, 465.022(1)(b) FS. History–New 4-4-00.

64B16-27.831 Standards of Practice for the Dispensing of Controlled Substances for Treatment of Pain.

(1) An order purporting to be a prescription that is not issued for a legitimate medical purpose is not a prescription and the pharmacist knowingly filling such a purported prescription shall be subject to penalties for violations of the law.

(2) The following criteria shall cause a pharmacist to question whether a prescription was issued for a legitimate medical purpose:

(a) Frequent loss of controlled substance medications,

(b) Only controlled substance medications are prescribed for a patient,

(c) One person presents controlled substance prescriptions with different patient names,

(d) Same or similar controlled substance medication is prescribed by two or more prescribers at same time,

(e) Patient always pays cash and always insists on brand name product.

(3) If any of the criteria in (2) is met, the pharmacist shall:

(a) Require that the person to whom the medication is dispensed provide picture identification and the pharmacist should photocopy such picture identification for the pharmacist's records. If a photocopier is not available, the pharmacist should document on the back of the prescription complete descriptive information from the picture identification. If the person to whom medication is dispensed has no picture identification, the pharmacist should confirm the person's identity and document on the back of the prescription complete information on which the confirmation is based.

(b) Verify the prescription with the prescriber. A pharmacist who believes a prescription for a controlled substance medication to be valid, but who has not been able to verify it with the prescriber, may determine not to supply the full quantity and may dispense a partial supply, not to exceed a 72 hour supply. After verification by the prescriber, the pharmacist may dispense the balance of the prescription within a 72 hour time period following the initial partial filling, unless otherwise prohibited by law.

(4) Every pharmacy permit holder shall maintain a computerized record of controlled substance prescriptions dispensed. A hard copy printout summary of such record, covering the previous 60 day period, shall be made available within 72 hours following a request for it by any law enforcement personnel entitled to request such summary under authority of Section 465.017(2), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substance medications being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substance medications being dispensed to a specific patient.

(5) Any pharmacist who has reason to believe that a prescriber of controlled substances is involved in the diversion of controlled substances shall report such prescriber to the Department of Health.

(6) Any pharmacist that dispenses a controlled substance subject to the requirements of this rule when dispensed by mail shall

be exempt from the requirements to obtain suitable identification.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 456.072(1)(i), 465.0155, 465.016(1)(i), (o), 465.017(2) FS. History–New 8-29-02, Amended 2-24-03, 11-18-07.

64B16-27.850 Standards of Practice for Orthotics and Pedorthics.

(1) Definitions.

(a) "Orthosis" means a medical device used to provide support, correction, or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury, or deformity, but does not include the following assistive technology devices: upper extremity adaptive equipment used to facilitate the activities of daily living, including specialized utensils, combs, and brushes; finger splints; wheelchair seating and equipment that is an integral part of the wheelchair and not worn by the patient; elastic abdominal supports that do not have metal or plastic reinforcing stays; arch supports; nontherapeutic accommodative inlays and nontherapeutic accommodative footwear, regardless of method of manufacture; unmodified, over-the-counter shoes; prefabricated foot care products; durable medical equipment such as canes, crutches, or walkers; dental appliances; or devices implanted into the body by a physician. For purposes of this subsection, "accommodative" means designed with the primary goal of conforming to the individual's anatomy and "inlay" means any removable material upon which the foot directly rests inside the shoe and which may be an integral design component of the shoe.

(b) "Orthotics" means the practice, pursuant to a licensed physician's written prescription, of evaluating, treatment formulating, measuring, designing, fabricating, assembling, fitting, adjusting, servicing, or providing the initial training necessary to accomplish the fitting of an orthosis or pedorthic device; however, the repair, replacement, adjustment, or servicing of any existing orthosis may be performed without an additional prescription from the patient's physician, unless the original prescription states otherwise. If a patient is under the care of a licensed occupational therapist or physical therapist, the pharmacist must consult with the therapist if the therapist has requested consultation regarding the fitting, design, or fabrication of an orthosis or regarding treatment with an orthosis.

(c) "Pedorthic device" means therapeutic shoes, shoe modifications made for therapeutic purposes, prosthetic fillers of the forefoot, and foot orthoses for use from the ankle and below, but does not include arch supports; nontherapeutic accommodative inlays and nontherapeutic accommodative footwear, regardless of method of manufacture; unmodified, over-the-counter shoes; or prefabricated foot care products. For purposes of this subsection, "accommodative" means designed with the primary goal of conforming to the individual's anatomy and "inlay" means any removable material upon which the foot directly rests inside the shoe and which may be an integral design component of the shoe.

(d) "Pedorthics" means the practice, pursuant to a licensed physician's written prescription, of evaluating, treatment formulating, measuring, designing, fabricating, assembling, fitting, adjusting, servicing, or providing the initial training necessary to accomplish the fitting of a pedorthic device; however, the repair, replacement, adjustment, or servicing of any existing pedorthic device may be performed without an additional prescription from the patient's physician, unless the original prescription states otherwise. If a patient is under the care of a licensed occupational therapist or physical therapist, the pharmacist must consult with the therapist if the therapist has requested consultation regarding the fitting, design, or fabrication of a pedorthic device or regarding treatment with a pedorthic device.

(2) Pursuant to a licensed physician's written prescription, the pharmacist shall assume the responsibility for assessing the patient, planning the patient's treatment program, and directing the program. No pharmacist shall implement a prescription that, in the pharmacist's judgment, is contraindicated. No change shall be made in the prescription without the authorization of the prescribing physician.

(3) The pharmacist's professional responsibilities include:

(a) Ongoing consultation with the prescribing physician regarding information that will impact the patient's medical and functional outcomes.

(b) Orthotic and/or pedorthic evaluation of the patient.

(c) Identification and documentation of precautions, special problems, or contraindications.

(d) Development of a treatment plan including the short and long terms goals.

(e) Implementation of a treatment plan.

(f) Periodic review and update of the treatment plan, including reassessment of the patient in reference to goals and, when necessary, modification of the treatment plan.

(g) Collaboration with members of the health care team when appropriate.

(h) Advising the patient, in terms which the patient can understand, of the nature and purpose of the services to be rendered and the techniques for use and care of an orthosis or pedorthic device.

(i) Determination of the appropriateness of proper fit and function of any orthosis or pedorthic device.

(4) A pharmacist may delegate duties to nonlicensed supportive personnel if those duties are performed under the supervision of the pharmacist. In such instances the supervising pharmacist is responsible for all acts performed by such persons. It is below the standard of practice and prohibited for a pharmacist to delegate or assign activities, tasks or procedures that fall within the scope of any practice defined in Section 468.812(3), F.S., to support personnel, without providing supervision for the performance of the activities, tasks or procedures.

Rulemaking Authority 468.812(3) FS. Law Implemented 465.0155, 468.812(3) FS. History–New 5-2-07.

64B16-27.851 Record-Keeping for Orthotics and Pedorthics.

(1) The pharmacist or supportive personnel shall prepare and maintain in a timely manner patient records which include, at a minimum, the following:

(a) The patient name, address and telephone number;

(b) The location and dates of all treatment, evaluation or consultation;

(c) The name of the prescribing physician;

(d) All prescriptions pertaining to services provided to the patient;

(e) A treatment or service plan;

(f) Progress notes for each session;

(2) The licensee may charge a fee for the reproduction of records, which shall be no greater than $ 1.00 per page for the first 25 pages, and $0.50 per page for every page after 25. In addition, the actual cost of postage may be added. Reasonable costs of reproducing radiographs and such other kinds of records shall be the actual costs. "Actual costs" means the cost of the material and supplies used to duplicate the record and the labor and overhead costs associated with the duplication.

(3) The licensee shall retain the patient record for at least two years from the date of last entry, unless otherwise provided by law.

Rulemaking Authority 468.802, 468.812(3) FS. Law Implemented 456.057(16), 465.0155, 465.022, 468.802, 468.812(3) FS. History-New 5-2-07.

CHAPTER 64B16-28
GENERAL REQUIREMENTS – PERMITS

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64B16-28.101 Prescription Area Accessible to Inspection.

(1) The prescription department compounding room or any other place where prescriptions are compounded, filled, processed, accepted, dispensed, or stored in each pharmacy shall be so situated and located that authorized agents and employees of the Department or other persons authorized by law to enter and inspect, can observe and survey the confines of said department, room or area and can enter into said department, room or area after identifying themselves, for the purpose of inspection at a reasonable hour or when the practice of the profession of pharmacy is being carried on, as defined in Section 465.003, F.S., without having been previously detained or announced. Such inspection may be routinely conducted at any time by authorized agents of the Department to determine whether Chapter 465, F.S., or provisions of these rules have been violated or for other lawful purposes, and need not be in response to a complaint filed with the Department. There shall be a minimum of one (1) inspection per year except as otherwise provided herein or directed by the Board.

(a) A pharmacy shall be inspected twice during the first year of operation.

(b) A pharmacy which has had passing inspections for the most current three years, and no discipline during the most current three years shall be inspected every two years.

(c) A pharmacy which fails to obtain a passing inspection or which is disciplined during the two year inspection cycle will be inspected annually until it achieves passing inspections for the most current three years, and no discipline during the most current three years as set forth in this subsection.

(2) Authorized agents and employees of the Department or other persons authorized by law shall have the right to inspect invoices, shipping tickets, or any other document pertaining to the transfer of drugs or drug preparations, from or to all pharmacies and a reasonable amount of time shall be allowed for said information to be made available.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017, 465.022 FS. History–Amended 5-19-72, 11-2-81, Formerly 21S-1.01, 21S-1.001, Amended 7-31-91, Formerly 21S-28.101, 61F10-28.101, 59X-28.101, Amended 5-4-05, 2-2-12.

64B16-28.102 Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment.

There shall be provided for the prescription department of each pharmacy:

(1) An adequate sink in workable condition and running water easily accessible to the prescription counter that shall be available during the hours when the prescription department is normally open for the business related to prescriptions.

(2) Sufficient shelf, drawer or cabinet space for the neat and orderly storage of pharmaceutical stock, prescription containers, prescription labels, the required equipment, and all other items, articles or equipment stored therein and there shall be sufficient walking space and sufficient work counter space within each prescription department of said establishment so as to allow employees or pharmacists employed therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(3) Adequate facilities for the proper storage of pharmaceuticals which require refrigeration, and such pharmaceuticals shall be stored therein, and in such manner as to preserve their therapeutic activity.

(4) Adequate sanitation to insure the prescription department is operating under clean, sanitary, uncrowded, and healthy conditions.

(5) The following items:

(a) A current pharmacy reference compendium such as the United States Pharmacopoeia/National Formulary, the U.S. Dispensatory, USP DI, (United States Pharmacopoeial Drug Information), the Remington Practice of Pharmacy, Facts and Comparisons or an equivalent thereof sufficient in scope to meet the professional practice needs of that pharmacy, and a current

copy of the laws and rules governing the practice of pharmacy in the State of Florida. It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

(b) Such other equipment as is necessary to meet the needs of the professional practice of pharmacy.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.02, 21S-1.002, 21S-28.102, 61F10-28.102, 59X-28.102, Amended 5-4-05.

64B16-28.103 Sufficient Space in Prescription Department.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.03, 21S-1.003, 21S-28.103, 61F10-28.103, 59X-28.103, Repealed 5-4-05.

64B16-28.1035 Patient Consultation Area.

A community pharmacy shall provide a private consultation area so all patients of the pharmacy will be able to obtain counseling without being overheard by others in the prescription dispensing area of the pharmacy. The consultation area must be accessible by the patient from the outside of the prescription dispensing area of the pharmacy without having to traverse a stockroom or the prescription dispensing area. In determining whether the area is suitable, consideration shall be given to the proximity of the counseling area to the check-out or cash register area, the volume of pedestrian traffic in and around the consultation area, and the presence of walls or other barriers between the counseling area and the prescription dispensing area of the pharmacy. The consultation area may consist of designated private counter space. The area shall be designated with a sign bearing "Patient Consultation Area", or words that are substantially similar.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History-New 9-20-99, Amended 5-4-05.

64B16-28.104 Refrigeration.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.04, 21S-1.004, 21S-28.104, 61F10-28.104, 59X-28.104, Repealed 5-4-05.

64B16-28.105 Sanitation.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 1-29-80, Formerly 21S-1.07, 21S-1.007, Amended 7-31-91, Formerly 21S-28.105, 61F10-28.105, 59X-28.105, Repealed 5-4-05.

64B16-28.106 Right to Inspect Invoices.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.017 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 4-30-85, Formerly 21S-1.008, 21S-28.106, 61F10-28.106, 59X-28.106, Repealed 5-4-05.

64B16-28.107 Pharmacy Equipment.

Rulemaking Authority 465.005, 465.022, 465.022(1)(h) FS. Law Implemented 465.022(1)(h) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 4-8-80, 4-26-84, Formerly 21S-1.10, Amended 4-4-88, Formerly 21S-1.010, Amended 7-31-91, Formerly 21S-28.107, 61F10-28.107, Amended 6-4-97, Formerly 59X-28.107, Amended 2-4-99, Repealed 5-4-05.

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.

Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.

(1) Definitions.

(a) "Controlled substance" means any substance named or described in Schedules II-V of Section 893.03, F.S.

(b) "Customized medication package" means a package that:

1. Is prepared by a pharmacist for a specific patient.

2. Is a series of containers.

3. Contains two (2) or more solid oral dosage forms.

(c) "Labeling" means a label or other written, printed, or graphic material upon an agent or product or any of its containers,

wrappers, drug carts, or compartments thereof, as well as a medication administration record (MAR) if a medication administration record is an integral part of the unit dose system.

(d) "Radiopharmaceutical" means any substance defined as a drug in section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any of those drugs intended to be made radioactive. This includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance, but does not include drugs which are carbon-containing compounds or potassium-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(e) "Serial number" means a prescription number or other unique number by which a particular prescription or drug package can be identified.

(2) The label affixed to each container dispensed to a patient shall include:

(a) Name and address of the pharmacy.

(b) Date of dispensing.

(c) Serial number.

(d) Name of the patient or, if the patient is an animal, the name of the owner and the species of animal.

(e) Name of the prescriber.

(f) Name of the drug dispensed (except where the prescribing practitioner specifically requests that the name is to be withheld).

(g) Directions for use.

(h) Expiration date.

(i) If the medicinal drug is a controlled substance, a warning that it is a crime to transfer the drug to another person.

(3) The label on the immediate container of a repackaged product or a multiple unit prepackaged drug product shall include:

(a) Brand or generic name.

(b) Strength.

(c) Dosage form.

(d) Name of the manufacturer.

(e) Expiration date.

(f) Lot number:

1. Manufacturer's lot number, or

2. Number assigned by the dispenser or repackager which references the manufacturer's lot number.

(4) A medicinal drug dispensed in a unit dose system by a pharmacist shall be accompanied by labeling. The requirement will be satisfied if, to the extent not included on the label, the unit dose system indicates clearly the name of the resident or patient, the prescription number or other means utilized for readily retrieving the medication order, the directions for use, and the prescriber's name.

(5) A unit dose system shall provide a method for the separation and identification of drugs for the individual resident or patient.

(6) A customized patient medication package may be utilized if:

(a) The consent of the patient or the patient's agent has been secured, and

(b) The label includes:

1. Name, address and telephone number of the pharmacy.

2. Serial number for the customized medication package and a separate serial number for each medicinal drug dispensed.

3. Date of preparation of the customized patient medication package.

4. Patient's name.

5. Name of each prescriber.

6. Directions for use and any cautionary statements required for each medicinal drug.

7. Storage instructions.

8. Name, strength, quantity and physical description of each drug product.

9. A beyond use date that is not more than 60 days from the date of preparation of the customized patient medication package but shall not be later than any appropriate beyond use date for any medicinal drug included in the customized patient medication package.

(c) The customized patient medication package can be separated into individual medicinal drug containers, then each container shall identify the medicinal drug product contained.

(7) The label affixed to the immediate outer container shield of a radiopharmaceutical shall include:
(a) Name and address of the pharmacy.
(b) Name of the prescriber.
(c) Date of the original dispensing.
(d) The standard radiation symbol.
(e) The words "Caution Radioactive Material."
(f) Name of the procedure.
(g) Prescription order number.
(h) Radionuclide and chemical form.
(i) Amount of radioactivity and the calibration date and time.
(j) Expiration date and time.
(k) If a liquid, the volume.
(l) If a solid, the number of items or weight.
(m) If a gas, the number of ampules or vials.
(n) Molybdenum 99 content to the United States Pharmacopeia (UPS) limits.
(o) Name of the patient or the words "Physician's Use Only."
(8) The label affixed to the immediate inner container of a radiopharmaceutical to be distributed shall include:
(a) The standard radiation symbol.
(b) The words "Caution Radioactive Material."
(c) Radionuclide and chemical form.
(d) Name of the procedure.
(e) Prescription order number of the radiopharmaceutical.
(f) Name of the pharmacy.
(9) The labeling on a carton or package containing a medicinal drug or product dispensed from an Extended Scope Renal Dialysis (ESRD) pharmacy shall include:
(a) "Use as Directed" statement.
(b) The name and address of the person to whom the products will be delivered.
(c) Name of the prescriber.
(d) Name and address of the ESRD pharmacy location from which the products were shipped.
(e) Prescription number.
(f) Any special instructions regarding delivery dates or locations.
(g) Beyond use date or, if the medicinal drug or product is dispensed in an unopened sealed package, the manufacturer's expiration date.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, 9-18-84, 1-20-85, Formerly 21S-1.13, Amended 10-2-88, Formerly 21S-1.013, Amended 7-31-91, 10-1-92, 4-19-93, 7-12-93, Formerly 21S-28.108, 61F10-28.108, 59X-28.108, Amended 3-31-05.

64B16-28.1081 Regulation of Daily Operating Hours.

Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment shall keep the prescription department of the establishment open for a minimum of forty (40) hours per week. The Board hereby approves exceptions to the requirements noted above and permits closing of the prescription department for the following holidays: New Year's Day, Memorial Day, Fourth of July (Independence Day), Labor Day, Veterans' Day, Thanksgiving, Christmas and any bona fide religious holiday provided that notice of such closing is given in a sign as set forth herein. A sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. The prescription department manager may petition the Board in writing to operate the prescription department for less than forty (40) hours per week, but no less than twenty (20) hours per week. Prior to approving reduced hours, the Board may require the prescription department manager to appear before the Board to explain in detail the services that will be performed. Any pharmacy open less than 40 hours shall have a policy and procedure that provides a mechanism for access to a

pharmacist during the time the pharmacy is not open for the remainder of the forty hour week. Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access. Any pharmacy open less than 40 hours shall also have a policy and procedure for transferring a prescription pursuant to Rule 64B16-27.105, F.A.C., or receiving an emergency dose pursuant to Section 465.0275, F.S. during the time the pharmacy is open less than 40 hours.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 4-10-05, Amended 2-1-12.

64B16-28.109 Prescription Department; Padlock; Sign: "Prescription Department Closed."

(1) The prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty. A sign with bold letters not less than two (2) inches in width and height, shall be displayed in a prominent place in the prescription department so that it may easily be read by patrons of that establishment. The sign shall contain the following language: "Prescription Department Closed."

(2) The term "not present and on duty" shall not be construed to prevent a pharmacist from exiting the prescription department for the purpose of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, taking a meal break pursuant to Rule 64B16-27.1001, F.A.C., or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist's responsibility to provide pharmacy services.

(3) At all times when the prescription department is closed, either because of the absence of a pharmacist or for any other reason, it shall be separated from the remainder of the establishment by partition or other means of enclosure, thereby preventing access to the prescription department by persons not licensed in Florida to practice the profession of pharmacy.

(4) The partition or other means of enclosure shall be securely locked or padlocked and only a pharmacist shall have the means to gain access to the prescription department.

(5) Whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter or remain in the prescription department.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 8-20-63, 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, Formerly 21S-1.14, 21S-1.014, Amended 7-31-91, Formerly 21S-28.109, 61F10-28.109, 59X-28.109, Amended 6-15-98, 4-10-05.

64B16-28.110 Outdated Pharmaceuticals.

Persons qualified to do so shall examine the stock of the prescription department of each pharmacy at a minimum interval of four months, and shall remove all deteriorated pharmaceuticals, or pharmaceuticals which bear upon the container an expiration date which date has been reached, and under no circumstances will pharmaceuticals or devices which bear upon the container an expiration date which has been reached be sold or dispensed to the public.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.17, 21S-1.017, 21S-28.110, 61F10-28.110, 59X-28.110.

64B16-28.111 Storage of Equipment.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–Repromulgated 12-18-74, Formerly 21S-1.19, 21S-1.019, 21S-28.111, 61F10-28.111, 59X-28.111, Repealed 4-10-05.

64B16-28.112 Violations.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-63, Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.23, 21S-1.023, Amended 7-31-91, Formerly 21S-28.112, 61F10-28.112, 59X-28.112, Repealed 4-10-05.

64B16-28.113 Permits; Single Entity; Single Location.

A Board of Pharmacy permit shall be issued only to a single entity at a single location. The service provided by the permit shall be consistent with the issued permit. A single location shall be defined as:

(1) A contiguous area under the control of the permit holder. For purposes of this section, a public thoroughfare will be considered to have not broken the area of contiguity; and

(2) An area not more than one-half mile from the central location of the permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(10)(a), 465.018, 465.019, 465.0193, 465.0196 FS. History–New 1-30-96, Formerly 59X-28.113.

64B16-28.1135 Change of Ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History–New 4-19-00, Amended 1-2-02, Transferred to 64B16-28.2021.

64B16-28.114 Prescription Refills.

Rulemaking Authority 465.005, 465.016(1), 465.022, 465.022(1)(a), 893.04 FS. Law Implemented 465.022 FS. History–New 12-18-74, Formerly 21S-1.28, 21S-1.028, Amended 7-31-91, Formerly 21S-28.114, 61F10-28.114, 59X-28.114, Amended 2-4-02, 7-1-02, Repealed 10-5-09.

64B16-28.118 Unit Dose and Customized Patient Medication Package Returns by In-patients.

No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions:

(1) In a closed drug delivery system in which unit dose or customized patient medication packages are dispensed to in-patients, the unused medication may be returned to the pharmacy for redispensing only if each unit dose or customized patient medication package is individually sealed and if each unit dose or the unit dose system, or the customized patient medication package container or the customized patient medication package unit of which it is clearly a part is labeled with the name of the drug, dosage strength, manufacturer's control number, and expiration date, if any.

(2) In the case of controlled substances, as it is allowed by Federal Law.

(3) A "unit dose system" to which this rule applies means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this section, a product in an unopened, sealed, manufacture's container is deemed to be a unit dose package.

(4) A "customized patient medication package" to which this rule applies means a system wherein all USP approved multi-dose units are physically connected and are referred to as a container. The use of customized patient medication packages must comply with the provisions of subsection 64B16-28.108(5), F.A.C.

(5) A "closed drug delivery system" to which this rule applies is a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient.

(6) All pharmacies utilizing unit dose or customized patient medication packages shall address specific policies and procedures regarding their preparation and use in their Policy and Procedures Manual.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.016(1)(l) FS. History–New 11-10-80, Formerly 21S-1.36, 21S-1.036, Amended 7-31-91, Formerly 21S-28.118, 61F10-28.118, 59X-28.118, Amended 9-23-99, 7-1-02.

64B16-28.119 Data Processing Systems in Pharmacy.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 9-21-83, Formerly 21S-1.38, 21S-1.038, Amended 7-31-91, Formerly 21S-28.119, Amended 3-16-94, Formerly 61F10-28.119, 59X-28.119, Repealed 7-15-99.

64B16-28.1191 Unclaimed Prescriptions.

Prescriptions that are unclaimed may be retained by a pharmacy and reused for a period up to one year from the date of filling; however, any product reaching the product's expiration date prior to one year or any product subject to a recall shall not be reused.

Rulemaking Authority 465.0255 FS. Law Implemented 465.0255 FS. History–New 4-10-05.

64B16-28.120 All Permits – Storage of Legend Drugs; Prepackaging.

(1) All medicinal drugs or drug preparations as defined by Section 465.003(8), F.S., shall be stored:

(a) Within the confines of the prescription department of a community pharmacy permittee as defined in Section 465.018, F.S.

(b) In a Class II Institutional pharmacy as defined by Section 465.019(2)(b), F.S., within the confines of the pharmacy provided,

however, that those medicinal drugs established by the consultant pharmacist as supportive to treatment procedures such as medical drugs, surgical, obstetrical, diagnostic, etc., may be permitted to be stored in those areas where such treatment is conducted consistent with proper control procedures as provided by the policy and procedure manual of the pharmacy.

(2) All medicinal drugs or drug preparations as defined in Section 465.003(8), F.S., within Class I Institutional permittees as defined in Section 465.019(2)(a), F.S., and Special ALF Permit 64B16-28.870, F.A.C., shall:

(a) Be administered from individual prescription containers to the individual patient; and

(b) Be prohibited within the confines of Class I Institutional pharmacies unless obtained upon a proper prescription and properly labeled in accordance with Chapter 499, F.S., and the rules and regulations contained in Chapter 59A-4, F.A.C., incorporated by reference and effective August 1, 2006, pertaining to the licensure of nursing homes and related facilities.

(3) Prepackaging of medication, whether a part of a unit dose system or a part of a multiple dose drug distribution system in an extended care facility or hospital holding a valid Class II Institutional pharmacy permit, must be done in accordance with procedures set up by the consultant pharmacist of record in the policy and procedure manual; and in the case of a pharmacy holding a valid community pharmacy permit must be done in accordance with procedures set up by the prescription department manager.

(4) Medicinal drugs and proprietary preparations as identified above that are stored in treatment areas must be accessible only to licensed staff (pharmacists, nurses, physicians, advanced registered nurse practitioners, physician assistants, respiratory and physical therapist, radiology technicians and registered pharmacy technicians, etc.) in accordance with their license, practice act, or to other personnel specifically authorized by the institution.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 435.019(2), 465.003(7), 465.022 FS. History–New 9-18-84, Formerly 21S-1.44, 21S-1.044, Amended 7-31-91, Formerly 21S-28.120, 61F10-28.120, 59X-28.120, Amended 2-8-07, 8-16-10.

64B16-28.121 Permit Fees.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History–New 7-31-91, Formerly 21S-28.121, 61F10-28.121, 59X-28.121, Amended 10-30-00, Repealed 4-10-05.

64B16-28.130 Transmission of Prescription Orders.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.130, 59X-28.130, Repealed 4-10-05.

64B16-28.140 Record Maintenance Systems for Community, Special-Limited Community, Special-Closed Systems, Special-Parenteral/Enteral, and Nuclear Permits.

(1) Requirements for records maintained in a data processing system.

(a) The pharmacy must comply with the provisions of 21 C.F.R. Section 1304.04 (a regulation of the Federal Drug Enforcement Administration), which is hereby incorporated by reference as of March 1, 1998, when such is applicable to operate such a data processing system if any controlled substances (as that term is used in Ch. 893, F.S.) are dispensed from the pharmacy.

(b) Any pharmacy using a data processing system must meet the requirements of 21 C.F.R. Section 1306.22, which is hereby incorporated by reference as of March 1, 1998.

(c) If a pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping system as specified in Rule 64B16-27.800, F.A.C., and Section 893.07, F.S.

(d) Original prescriptions, including prescriptions received as provided for in Rule 64B16-28.130, F.A.C., Transmission of Prescription Orders, shall be reduced to a hard copy if not received in written form. All original prescriptions shall be retained for a period of not less than two years from date of last filling. To the extent authorized by 21 C.F.R. Section 1304.04, a pharmacy may, in lieu of retaining the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than two years from the date of last filling.

(e) Original prescriptions shall be maintained in a two or three file system as specified in 21 C.F.R. 1304.04(h).

(f) Requirements for back-up systems.

1. The pharmacy shall maintain a back-up copy of information stored in the data processing system using disk, tape or other electronic back-up system and update this back-up copy on a regular basis, at least weekly, to assure that data is not lost due to

system failure.

2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding two years as specified in Rule 64B16-27.800, F.A.C.

(g) Change or discontinuance of a data processing system.

1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records of dispensing to the new data processing system; or

b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b) of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) All transfers of prescriptions must be strictly in accordance with the provisions of Section 465.026, F.S., and Rule 64B16-27.105, F.A.C.

(3) Records of dispensing.

(a) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(b) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

1. Unique identification number of the prescription;

2. Date of dispensing;

3. Patient name;

4. Prescribing practitioner's name;

5. Name and strength of the drug product actually dispensed, if generic name, the brand name or manufacturer of drug dispensed;

6. Quantity dispensed;

7. Initials or an identification code of the dispensing pharmacist; and

8. If not immediately retrievable via CRT display, the following shall also be included on the hard-copy printout:

a. Patient's address;

b. Prescribing practitioner's address;

c. Practitioner's DEA registration number, if the prescription drug order is for a controlled substance.

d. Quantity prescribed, if different from the quantity dispensed;

e. Date of issuance of the prescription drug order, if different from the date of dispensing; and

f. Total number of refills dispensed to date for that prescription drug order.

(c) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(d) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(e) In lieu of producing the printout described in paragraphs (b) and (c) of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department

of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(f) The prescription department manager and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection.

(g) Failure to provide the records set out in this section, either on site or within 48 hours for whatever reason, constitutes failure to keep and maintain records.

(h) In the event that a pharmacy which uses a data processing system experiences system downtime, the following is applicable;

1. An auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or that authorization from the prescribing practitioner has been obtained prior to dispensing a refill; and

2. All of the appropriate data shall be retained for on-line data entry as soon as the system is available for use again.

(4) Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:

(a) Date of compounding.

(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacture's lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacture's lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.

(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.

(d) A signature or initials of the pharmacist or pharmacy technician performing the compounding.

(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.

(g) The quantity in units of finished products or grams of raw materials.

(h) The package size and number of units prepared.

(i) The name of the patient who received the particular compounded product.

(5) Authorization of additional refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(a) On the daily hard-copy printout; or

(b) Via the CRT display.

(6) Any other records, policy and procedure manuals, or reference materials which are not specifically required by statute or rule to be kept in a hard copy may be kept in a readily retrievable data processing system which complies with the provisions of subparagraph (1)(f)1.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.003(14), 465.022, 465.026, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.140, Amended 3-12-97, 6-4-97, Formerly 59X-28.140, Amended 10-29-97, 6-15-98, 11-11-98, 10-15-01.

64B16-28.141 Requirements for an Automated Pharmacy System in a Community Pharmacy.

(1) Definitions. "Automated pharmacy system" means a mechanical system, located within or adjacent to the prescription department, that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.

2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.

3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system

including the product identification, lot number, and expiration date.

4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.

5. Compliance with a Continuous Quality Improvement Program.

6. A method to ensure that patient confidentiality is maintained.

7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(b) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.

(c) The system shall maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(d) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) Meets the requirements in subsection (2) above.

(b) The stocking or restocking of a medicinal drug shall only be completed by a Florida pharmacist, except as provided in paragraph (c) below.

(c) If the automated pharmacy system uses removable cartridges or container to store the drug, the stocking or restocking of the cartridges or containers may occur at a licensed repackaging facility and be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A Florida pharmacist verifies the cartridge or container has been properly filled and labeled.

2. The individual cartridge or container is transported to the provider pharmacy in a secure, tamper-evident container.

3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the cartridge or container is accurately loaded into the automated pharmacy system.

4. The Florida pharmacist verifying the filling and labeling is responsible if the cartridge or container is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(d) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from the automated system.

(e) The medication shall bear a patient specific label that complies with Rule 64B16-28.108, F.A.C.

(f) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.

2. Name, strength, and dosage form of the drug product dispensed.

3. Quantity of drug dispensed.

4. Date and time of dispensing.

5. Name of provider pharmacy.

6. Prescription number.

7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(4) The Florida pharmacist responsible for filling, verifying, or loading the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History–New 11-29-04, Amended 12-30-07, 1-1-10.

64B16-28.150 Record Maintenance Systems for Institutional and Animal Shelter Permits.

Rulemaking Authority 465.005, 465.0155, 465.022, 828.055 FS. Law Implemented 465.022, 465.019, 465.026, 893.07, 828.055 FS. History–New

4-12-95, Formerly 59X-28.150, Repealed 5-3-05.

64B16-28.201 Definitions.

Rulemaking Authority 465.005, 465.022, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Amended 4-28-83, 4-30-85, Formerly 21S-16.01, 21S-16.001, Amended 7-31-91, Formerly 21S-28.201, 61F10-28.201, 59X-28.201, Repealed 4-5-05.

64B16-28.202 Closing of a Pharmacy; Transfer of Prescription Files.

(1) The term "prescription files" as used herein shall mean the drug dispensing records of a pharmacy which shall include all orders for drugs or medicinal supplies as defined by Section 465.003(7), F.S., inclusive of dispensing records for medicinal drugs listed within the provisions of Section 893.03, F.S., issued by a duly licensed practitioner, which serve to transfer possession of medicinal drugs from the pharmacy to the ultimate consumer.

(2) The term "closing of a pharmacy" as used herein shall mean the cessation or termination of professional and business activities within a pharmacy for which a permit has been issued under Chapter 465, F.S.

(3) Prior to closure of a pharmacy the permittee shall notify the Board of Pharmacy in writing as to the effective date of closure, and shall:

(a) Return the pharmacy permit to the Board of Pharmacy office or arrange with the local Bureau of Investigative Services of the Department to have the pharmacy permit returned to the Board of Pharmacy;

(b) Advise the Board of Pharmacy which permittee is to receive the prescription files;

(4) On the date of closure of a pharmacy the former permittee shall:

(a) Physically deliver the prescription files to a pharmacy operating within reasonable proximity of the pharmacy being closed and within the same locality. This delivery of prescription files may occur prior to the return of the pharmacy permit to the Board of Pharmacy office; and

(b) Affix a prominent sign to the front entrance of the pharmacy advising the public of the new location of the former permittee's prescription files or otherwise provide a means by which to advise the public of the new location of their prescription files.

(5) After the closing of a pharmacy as defined herein, the custody of the prescription files of the pharmacy shall be transferred to the new permittee, unless the former permittee and the new permittee inform the Board in writing that custody of the prescription files have been or are to be transferred to a pharmacy other than the new permittee.

(6) A pharmacy receiving custody of prescription files from another pharmacy shall maintain the delivered prescriptions in separate files so as to prevent intermingling with the transferee pharmacy's prescription files.

Rulemaking Authority 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Formerly 21S-16.02, 21S-16.002, Amended 7-31-91, Formerly 21S-28.202, 61F10-28.202, 59X-28.202, Amended 4-5-05.

64B16-28.2021 Change of Ownership.

(1) A pharmacy permit is not transferable. Upon the sale of an existing pharmacy, a new application must be filed. In those cases where the permit is held by a corporation, the transfer of all the stock of said corporation to another person or entity does not constitute a change of ownership, provided that the initial corporation holding the permit continues to exist.

(2) A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an "opening inventory" for DEA purposes. Both the new permit and the old permit must keep appropriate records for two (2) years for the transfer of legend drugs and controlled substances.

(3) A change in the company or person who leases the building where the permit is housed or a change in the management company which contracts with the owner of the permit for the operation of the permit does not constitute a change in ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022(7) FS. History–New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05.

64B16-28.203 Transfer of Medicinal Drugs; Change of Ownership; Closing of a Pharmacy.

Ownership of medicinal drugs, including those medicinal drugs within the provisions of Section 893.03, F.S., may be transferred to a new owner upon the change of ownership of a pharmacy, as defined in Rule 64B16-28.2021, F.A.C., or upon the closing of a pharmacy, as defined in Rule 64B16-28.2021, F.A.C. The transferee entity acquiring ownership shall be authorized to prescribe, dispense or distribute such drugs. The transferor pharmacy shall provide the Florida Board of Pharmacy with the following information:

(1) The name, address, pharmacy permit number and D.E.A. registration number of the transferor pharmacy.

(2) The name, address, permit number, D.E.A. registration number (if available), and authorized business activity of the transferee entity.

(3) The date on which the transfer will occur.

(4) A complete inventory of all medicinal drugs within the provisions of Section 893.03, F.S., as of the date of transfer. If the medicinal drug is listed in Schedule II, the transferor shall make an exact count or measure of the contents. If the medicinal drugs are listed in Schedule III, IV, or V, the transferor shall make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case an exact count of the contents shall be made. This inventory shall serve as the final inventory of the permittee transferor and the transfer inventory of the transferee entity. The transferor and transferee shall each retain a copy of the inventory in their records and shall provide the Board of Pharmacy with a copy of such inventory. Transfer of any controlled substance in Schedule II shall require the use of order form, D.E.A. form number 222.

(5) Unless the permittee-transferor is informed by the Board of Pharmacy or the regional D.E.A. Administrator prior to the date on which the transfer was stated to occur, that the transfer may not occur, the permittee-transferor may proceed with the transfer.

(6) On the date of transfer of the medicinal drugs, all records required to be kept by the permittee-transferor of the transferred drugs which are listed in Section 893.03, F.S., shall be transferred to the permittee-transferor. Responsibility for the accuracy of records prior to the date of transfer remains with the permittee-transferor, but responsibility for custody and maintenance shall be upon the permittee-transferee. It is the responsibility of the permittee-transferor to return all unused Schedule II order forms (D.E.A. form no. 222) to the regional D.E.A. office.

Rulemaking Authority 465.005, 465.022(1)(g) FS. Law Implemented 465.022(1)(g) FS. History–New 12-26-79, Formerly 21S-16.03, 21S-16.003, 21S-28.203, 61F10-28.203, 59X-28.203, Amended 4-5-05.

64B16-28.301 Destruction of Controlled Substances – Institutional Pharmacies.

(1) Controlled substances that have been dispensed and not used by the patient shall not be returned to the pharmacy and shall be securely stored by the nursing home until destroyed.

(2) A document must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. This documentation, at the time of destruction, shall be witnessed and signed by the consultant pharmacist, director of nursing, and the administrator or his designee, which may include a licensed physician, pharmacists, mid-level practitioner, or nurse.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.019 FS. History–New 4-21-87, Formerly 21S-19.001, Amended 7-31-91, Formerly 21S-28.301, 61F10-28.301, Amended 1-30-96, Formerly 59X-28.301, Amended 7-21-09.

64B16-28.303 Destruction of Controlled Substances All Permittees (excluding Nursing Homes).

(1) Controlled substances that cannot be retained as usable shall be securely stored in the prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form 41. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction does not require prior approval from D.E.A., but does require that a copy of the completed and witnessed D.E.A. Form 41 be mailed to D.E.A. immediately after destruction.

(3) Another method of destruction shall be conducted by at least two persons who are either a licensed pharmacist, physician or nurse, or a sworn law enforcement officer or any combination thereof, to serve as the witnesses. A copy of the completed D.E.A. Form 41 and a letter providing the proposed date of destruction, the proposed method of destruction and the names and titles of the proposed witnesses must be received by D.E.A. at least two weeks prior to the proposed date of destruction which shall constitute a request for destruction. The drugs may not be destroyed until D.E.A. grants approval of the request for destruction. A copy of the

completed and witnessed D.E.A. Form 41 shall be mailed to D.E.A. immediately after destruction.

(4) In lieu of destruction on the premises, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.018 FS. History–New 4-21-87, Formerly 21S-19.003, Amended 7-31-91, Formerly 21S-28.303, 61F10-28.303, Amended 1-30-96, Formerly 59X-28.303, Amended 2-5-07, 10-27-09, 2-1-12.

64B16-28.402 Labels and Labeling of Medicinal Drugs – Community Pharmacy Permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1), 465.0255 FS. History–New 7-3-91, Formerly 21S-28.402, Amended 12-27-93, Formerly 61F10-28.402, 59X-28.402, Amended 9-17-97, Repealed 5-11-05.

64B16-28.404 Regulation of Daily Operating Hours.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.

64B16-28.404 Regulation of Daily Operating Hours (Repealed).

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 8-20-65, Amended 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, 3-31-81, Formerly 21S-1.24, Amended 7-14-88, Formerly 21S-1.024, Amended 7-31-91, 3-15-92, Formerly 21S-28.404, 61F10-28.404, Amended 9-21-94, Formerly 59X-28.404, 59X-28.404, Repealed 2-28-07.

64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

(1) As used herein:

(a) The term "originating pharmacy" means a pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented; and

(b) The term "central fill pharmacy" means a pharmacy which performs centralized prescription filling, delivering, and returning for one or more originating pharmacies.

(2) Pharmacies acting as the central fill pharmacy must be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto.

(3) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:

(a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;

(b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and

(c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

(4) All central fill and originating pharmacies engaged in centralized prescription filling shall create and keep current a Policy and Procedure Manual which shall:

(a) Be maintained at the locations of the central fill and originating pharmacies;

(b) Include the information required in Sections 465.0265(2)(a)-(f), F.S.

(5) Delivery of medications. Delivery of medications must be made in a timely manner. The originating and central fill pharmacies shall each be identified on the prescription container.

(a) Delivery by central fill pharmacy to ultimate consumer. A central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer's agent under the following conditions:

1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which each pharmacy will comply with federal and state laws, rules and regulations.

2. The pharmacies shall have a pharmacist available 40 hours a week, either in person or via two-way communication technology, such as a telephone, to provide patient counseling.

3. The pharmacies shall include a toll-free number that allows the patient to reach a pharmacist for the purposes of patient counseling.

4. The pharmacies shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy.

5. The central fill pharmacy shall only deliver via carrier to the ultimate consumer or the consumer's agent those medications which could have been delivered via carrier by the originating pharmacy.

6. The central fill pharmacy shall not deliver to the ultimate consumer or consumer's agent substances listed as controlled substances under Chapter 893, F.S.

(b) The delivery of a filled prescription by a central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in Section 465.003(6), F.S.

(c) Each pharmacist that performs a specific function within the processing of the prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(6) The supplying and receiving pharmacy shall each be identified on the prescription container label. The receiving pharmacy shall be identified with pharmacy name and address. The supplying pharmacy may be identified by a code available at the receiving pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:

(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:

1. Write the word "central fill" on the face of the original prescription and record the name, address, and DEA registration number if a controlled substance of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy's pharmacist transmitting the prescription, and the date of transmittal;

2. Ensure all the information required to be on a prescription pursuant to Sections 456.0392 and 893.04, F.S., is transmitted to the central fill pharmacy either on the face of the prescription or in the electronic transmission of information;

3. Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;

4. Maintain the original prescription for a period of two years from the date the prescription was last refilled.

5. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy's employee accepting delivery.

(b) The central fill pharmacy receiving the transmitted prescription must:

1. Keep a copy of the prescription if sent via facsimile, or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and DEA registration number, if a controlled substance, of the originating pharmacy transmitting the prescription;

2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;

3. Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (private, common or contract carrier).

4. A central fill pharmacy's pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the receiving pharmacy's name and address, a unique identifier (i.e. the supplying pharmacy's DEA registration number) indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.

Rulemaking Authority 465.005, 465.0265 FS. Law Implemented 465.003(16), 465.0265 FS. History–New 9-23-03, Amended 7-27-04, 4-28-08.

64B16-28.451 Pharmacy Common Database.

(1) A pharmacy licensed under this chapter may perform prescription drug processing for other pharmacies, provided that all pharmacies are under common ownership, utilize a common database, and are properly licensed, permitted or registered in this state or another state. Nothing in this subsection shall prohibit a pharmacist employee of said pharmacies who is licensed in Florida or in another state from remotely accessing the pharmacy's electronic database from outside the pharmacy in order to process prescriptions, provided the pharmacy establishes controls to protect the privacy and security of confidential records.

(2) Prescription drug processing shall include the following:

(a) Receiving, interpreting, or clarifying a prescription;

(b) Entering prescription data into the pharmacy's record;

(c) Verifying or validating a prescription;

(d) Performing prospective drug review as defined by the Board;

(e) Obtaining refill and substitution authorizations;

(f) Interpreting or acting on clinical data;

(g) Performing therapeutic interventions;

(h) Providing drug information concerning a patient's prescription; and

(i) Providing patient counseling.

(3) Each pharmacist that performs a specific function within the prescription drug processing process via use of a common database shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.

(4) Each pharmacy performing prescription drug processing pursuant to this section must maintain a policy and procedure manual, which shall be made available to the Board or its agent upon request. The policy and procedures manual shall include the following information:

(a) A description for how each pharmacy will comply with federal and state laws, rules and regulations;

(b) The procedure for maintaining appropriate records to identify the pharmacies and pharmacists responsible for the prescription drug processing and dispensing of the prescription;

(c) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information; and

(d) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.

(5) The prescription drug processing of a prescription by one pharmacy for another pursuant to this section shall not be construed as the transferring of a prescription as set forth in Section 465.026, F.S.

(6) In addition to all record requirements of Rule 64B16-28.140, F.A.C., all pharmacies participating in prescription drug processing, shall maintain appropriate records which identify, by prescription, the name(s), initials, or identification code(s) of each pharmacist or registered pharmacy technician who performs a processing function for a prescription. Such records shall be maintained:

(a) Separately by each pharmacy and pharmacist; or

(b) In a common electronic file, as long as the records are maintained in such a manner that the data processing system can produce a printout which lists the functions performed by each pharmacy, pharmacist, registered pharmacy intern and registered pharmacy technician.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0266 FS. History–New 3-24-08, Amended 1-1-10.

64B16-28.501 Institutional Permit – Consultant Pharmacist of Record.

Each facility holding a Class I, a Class II, or a Modified Class II Institutional permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record for a Class I, Modified Class II, or a Special ALF permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor monthly the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and or in the monthly facility inspection.

Rulemaking Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.019, 465.022 FS. History–New 7-18-94, Formerly 61F10-28.501, 59X-28.501, Amended 1-2-02, 12-30-07.

64B16-28.502 Class I Institutional Permit and Class II Institutional Permit – Labels and Labeling of Medicinal Drugs for Inpatients of a Nursing Home.

(1) The label affixed to a container used in conventional dispensing to a Class I Institutional permit or a Class II Institutional permit which, within the scope of its practice, services only the inpatients of a nursing home as defined by Section 400.021(5), F.S., shall contain at least the following information:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The name of the patient;

(d) The date of the original filling or the refill date;

(e) The prescription number or other prescription identification adequate to readily identify the prescription;

(f) The directions for use;

(g) The name of the medicinal drug dispensed (except where the health care practitioner prescribing the drug specifically denotes that the name is to be withheld).

(h) The quantity of the drug in the container.

(2) The label affixed to a container used in dispensing substances listed in any of the schedules appearing in Chapter 893, F.S., in regard to conventional dispensing shall contain at least the following information:

(a) All of the information required by subsection (1) of this rule;

(b) The number of the prescription as recorded in the prescription files of the pharmacy in which it is filled; and

(c) A clear, concise warning that it is a crime to transfer the controlled substance to any person other than the patient for whom prescribed.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.502, 61F10-28.502, 59X-28.502, Amended 8-16-10.

64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I Institutional or Modified II B Facilities.

(1) Definitions.

(a) "Vendor pharmacy" means a community pharmacy or special closed system pharmacy which has a contract to dispense a medicinal drug to a patient in a facility holding a Class I Institutional Permit or Modified II B Permit.

(b) "Starter dose pharmacy" means a pharmacy that dispenses a medicinal drug pursuant to a starter dose prescription to a patient in a facility served by the vendor pharmacy.

(c) "Starter dose prescription" means a prescription transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of initiating drug therapy for a patient in a facility served by the vendor pharmacy.

(2) A vendor pharmacy may transmit a starter dose prescription to a starter dose pharmacy if the vendor pharmacy:

(a) Has written authorization from the facility to utilize a starter dose pharmacy.

(b) Has a written contract with the starter dose pharmacy.

(c) Has written authorization from a prescribing practitioner to act as the practitioner's agent for the purpose of transmitting a starter dose prescription.

(d) Possess a valid prescription from the prescribing practitioner prior to transmitting the starter dose prescription.

(e) Maintains a record of each starter dose prescription.

(f) Maintains a policy and procedure manual that references starter dose prescriptions.

(3) A starter dose pharmacy may dispense a medicinal drug pursuant to a starter dose prescription for a patient in a facility that holds a Class I Institutional Permit or Modified II B Permit if the starter dose pharmacy:

(a) Has a written contract with the vendor pharmacy.

(b) Maintains a record of each starter dose prescription.

(c) Maintains a policy and procedure manual that references starter dose prescriptions.

(4) The contract between a vendor pharmacy and a prescribing practitioner shall:

(a) Be in writing.

(b) Identify each facility served by the vendor pharmacy for which the authorization is valid.

(c) Authorize the vendor pharmacy to transmit, as an agent of the practitioner, a starter dose prescription to a starter dose pharmacy.

(d) Be on file at the vendor pharmacy, at the facility served by the vendor pharmacy, and with the prescribing practitioner.

(e) Be available for inspection by agents of the Department of Health or the Board of Pharmacy.

(5) The contract between the vendor pharmacy and the starter dose pharmacy shall:

(a) Be in writing.

(b) Identify each facility served by the vendor pharmacy.

(c) Assign the responsibility for prospective drug use review required by Rule 64B16-27.810, F.A.C., to the vendor pharmacy.

(d) Assign the responsibility for patient counseling required by Rule 64B16-27.820, F.A.C., to the vendor pharmacy.

(e) Be referenced in the Policy and Procedure Manual of the vendor pharmacy and of the starter dose pharmacy.

(f) Be updated as necessary to identify facilities or practitioners.

(g) Be on file at the vendor pharmacy, at the starter dose pharmacy, and at the facility.

(h) Be available for inspection by authorized agents of the Department of Health and the Board of Pharmacy.

(6) A record of each starter dose prescription shall be:

(a) Readily retrievable.

(b) Maintained for two years.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.019, 465.022 FS. History–New 11-29-04.

64B16-28.602 Institutional Class II Dispensing.

(1) Pharmaceutical preparations which are administered to patients of a hospital by the personnel of such institution shall only be taken from the original container, or from a container which has been prepared by a Florida licensed pharmacist. Only single doses of such preparations shall be removed from the container, and then only after the preparation has been prescribed for a specific patient, and the order has been duly recorded upon the records of the institution. This requirement shall not apply to nor be construed as preventing the administration of treatment in bona fide emergency cases, or further as prohibiting any person who is a duly licensed physician from dispensing medicinal drugs as defined in Chapter 465, F.S. A single dose of medicinal drugs based upon a valid physician's drug order may also be obtained and administered under the supervision of the nurse in charge consistent with good institutional practice procedures as established by the consultant pharmacist of record and written in the policy and procedure manual which shall be available within the pharmacy.

(2) A Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

3. A pharmacist for the institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(b), 465.0196, 465.022(1) FS. History–Amended 5-19-72, Repromulgated 12-18-74, Amended 10-10-78, Formerly 21S-1.11, 21S-1.011, Amended 7-31-91, Formerly 21S-28.602, 61F10-28.602, Amended 9-4-96, Formerly 59X-28.602, Amended 8-16-10.

64B16-28.6021 Institutional Class II Pharmacy – Emergency Department Dispensing.

(1) Individuals licensed to prescribe medicinal drugs in this state may dispense from the emergency department of a hospital holding a class II institutional pharmacy permit. Such dispensing must meet the requirements provided in Section 465.019(4), F.S., and this section.

(2) The following records of prescribing and dispensing must be created by the prescriber/dispenser and maintained by the consultant pharmacist of record within the facility;

(a) Patient name and address.

(b) Drug and strength prescribed/dispensed.
(c) Quantity prescribed/dispensed.
(d) Directions for use.
(e) Prescriber/dispenser.
(f) Prescriber DEA registration, if applicable.
(g) Reason community pharmacy services were not readily accessible.
(3) Labeling of the prescription container must meet the requirements of Section 465.0276, F.S.
(4) Quantity dispensed must not exceed a 24-hour supply or the minimal dispensable quantity, whichever is greater.

Rulemaking Authority 465.005, 465.019(4), 465.022 FS. Law Implemented 465.019(2)(b), (4), 465.0196, 465.022(1) FS. History–New 9-20-99, Amended 8-16-10.

64B16-28.603 Class II Institutional Pharmacy Operating Hours.
Any person who receives a Class II Institutional permit pursuant to Section 465.019, F.S., and commences to operate such a pharmacy shall, for the benefit of the institutions' patients' health and welfare, keep the pharmacy of the establishment open for a sufficient number of daily operating hours required to provide adequate and quality pharmaceutical services to the patients of said institution.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 7-31-91, Formerly 21S-28.603, 61F10-28.603, 59X-28.603.

64B16-28.604 Class II Institutional Pharmacy Department Security.
The pharmacy department shall be considered closed whenever a Florida licensed pharmacist is not present and on duty. At all times when the pharmacy department is closed, either because of the absence of a Florida licensed pharmacist or for any other reason, it shall be secured to prevent access. When the pharmacy department is closed, no person other than a Florida licensed pharmacist shall enter, except as authorized by subsection 465.019(2)(b), F.S., and Rule 64B16-28.602, F.A.C.

Rulemaking Authority 465.005, 465.022(1), 465.019 FS. Law Implemented 465.019, 465.022(1) FS. History–New 9-21-94, Formerly 59X-28.604.

64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.
(1) Definitions.
(a) "Automated medication system" means a robotic, mechanical or computerized device that is not used for medication compounding and is designed to:
1. Distribute medications in a licensed health care facility; or
2. Package medications for final distribution by a pharmacist.
(b) "Centralized automated medication system" means an automated medication system located in a pharmacy department from which medication is distributed or packaged for final distribution by a pharmacist.
(c) "Decentralized automated medication system" means an automated medication system that is located outside of a pharmacy department but within the same institution.
(d) "Distribute" or "Distribution" means the process of providing a drug to an individual authorized to administer medications and licensed as a health care provider in the state of Florida pursuant to an order issued by an authorized prescriber.
(e) "Medication" means a medicinal drug or proprietary preparation.
(f) "Override medication" means a single dose of medication that may be removed from a decentralized automated medication system prior to pharmacist review because a practitioner licensed pursuant to Chapter 458, 459 or 466, F.S., determined that the clinical status of the patient would be significantly compromised by delay.
(g) "Low risk override medication" is a medication determined by a practitioner licensed pursuant to Chapters 458, 459, or 466, F.S., to have a low risk of drug allergy, drug interaction, dosing error, or adverse patient outcome, and may be removed from a decentralized automated medication system independent of a pharmacist's review of the medication order or clinical status of the patient.
(h) "Physician controlled medication" is medication distributed in an environment where a practitioner controls the order, preparation and administration of the medication.

(2) General Requirements for the Use of Automated Medication Systems.

(a) The consultant pharmacist of record shall be responsible for:

1. Maintaining a record of each transaction or operation;

2. Controlling access to the system;

3. Maintaining policies and procedures for;

a. Operation of the automated medication system;

b. Training personnel who use the automated medication system;

c. Maintaining patient services whenever the automated medication system is not operating; and

d. Defining a procedure for a pharmacist to grant or deny access to the medication in the system.

4. Security of the system;

5. Assuring that a patient receives the pharmacy services necessary for good pharmaceutical care in a timely manner;

6. Assuring that the system maintains the integrity of the information in the system and protects patient confidentiality;

7. Establishing a comprehensive Quality Assurance program;

8. Establishing a procedure for stocking or restocking the automated medication system; and

9. Ensuring compliance with all requirements for packaging and labeling.

(b) A pharmacist shall perform prospective drug use review and approve each medication order prior to administration of a medication except an override medication, a low risk override medication or a physician controlled medication.

(c) A pharmacist shall perform retrospective drug use review for an override medication.

(3) Multidisciplinary Committee for Decentralized Automated Medication Systems.

(a) The consultant pharmacist of record shall convene or identify a multidisciplinary committee, which is charged with oversight of the decentralized automated medication system.

(b) The Multidisciplinary Committee shall:

1. Include at least one pharmacist;

2. Establish the criteria and process for determining which medication qualifies as an override medication or a low risk override medication in a decentralized automated medication system;

3. Develop policies and procedures regarding the decentralized automated medication system; and

4. Have its decisions reviewed and approved by the consultant pharmacist of record.

(4) Stocking or Restocking of a Decentralized Automated Medication System.

(a) Medications in a decentralized Automated Medication System shall be stocked or restocked by a pharmacist, registered pharmacy intern, or by a registered pharmacy technician supervised by a pharmacist.

(b) The stocking or restocking of a decentralized automated medication system shall follow one of the following procedures to assure correct medication selection:

1. A pharmacist shall conduct a daily audit of medications placed or to be placed into an automated medication system that includes random sampling.

2. A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic, or similar verification technology shall require an initial quality assurance validation followed by a monthly quality assurance review by a pharmacist.

(5) Centralized Automated Medication Systems. A pharmacist utilizing a centralized medication system may distribute patient specific medications within the licensed health care facility without checking each individual medication selected or packaged by the system, if:

(a) The initial medication order has been reviewed and approved by a pharmacist; and

(b) The medication is distributed for subsequent administration by a health care professional permitted by Florida law to administer medication; and

(c) A bar code verification, electronic verification, or similar verification process shall be utilized to assure correct selection of medication placed or to be placed into an automated medication system. The utilization of a bar code, electronic verification, or similar verification technology shall require an initial quality assurance validation, followed by monthly quality assurance review by a pharmacist.

(6) Quality Assurance Program. The consultant pharmacist of record shall be responsible for establishing a quality assurance program for the automated medication system. The program shall provide for:

(a) Review of override and low risk override medication utilization;

(b) Investigation of a medication error related to the automated medication system;

(c) Review of a discrepancy or transaction reports and identify patterns of inappropriate use or access;

(d) Review of the operation of the system;

(e) Integration of the automated medication system quality assurance program with the overall continuous quality improvement of the pharmacy as defined in Rule 64B16-27.300, F.A.C.; and

(f) Assurance that individuals working with the automated medication system receive appropriate training on the operation of the system and procedures for maintaining pharmacy services when the system is not in operation.

(7) Record Keeping.

(a) The consultant pharmacist of record shall maintain records related to the automated medication system in a readily retrievable manner.

(b) The following records shall be maintained for at least 60 days:

1. Daily audits of stocking or restocking, if applicable;

2. Daily audits for the output of centralized automated medication system, if applicable; and

3. Transaction records for all non-controlled medications or devices distributed by the automated medication system.

(c) The following records shall be maintained for at least two (2) years:

1. Any report or analysis generated as part of the quality assurance program;

2. A report or database related to access to the system or any change in the access to the system or to medication in the system; and

3. Transaction records from the automated medication system for all controlled substances dispensed or distributed.

(8) Compliance. The consultant pharmacist of record shall assure compliance with all requirements of Chapter 465, F.S., and the rules of Chapter 64B16, F.A.C.

(9) Security. A decentralized automated medication system that contains controlled substances shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances, unless otherwise contained in labeled patient-specific form.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235, 465.026 FS. History–New 4-22-07, Amended 1-1-10.

64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.

(1) Definitions.

(a) "Remote Medication Order Processing" includes any of the following activities performed for a Class II Institutional Pharmacy from a remote location:

1. Receiving, interpreting, or clarifying medication orders.

2. Entering or transferring medication order data.

3. Performing prospective drug use review.

4. Obtaining substitution authorizations.

5. Interpreting and acting on clinical data.

6. Performing therapeutic interventions.

7. Providing drug information.

8. Authorizing the release of a medication for administration.

(b) "Medication" means a medicinal drug or proprietary preparation.

(c) "Prospective drug use review" means an evaluation of medication orders and patient medication records for:

1. Over-utilization or under-utilization of medication.

2. Therapeutic duplication of medication.

3. Drug-disease contraindications.

4. Drug interactions.

5. Incorrect drug dosage or duration of drug treatment.

6. Clinical abuse or misuse of medication.

(2) General requirements.

(a) All pharmacists participating in remote medication order processing shall be Florida licensed pharmacists.

(b) A Class II Institutional pharmacy may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(c) A pharmacist shall perform the final check of a medication order.

(d) If the pharmacist performing remote order processing is not an employee of the Class II Institutional pharmacy, the Class II Institutional pharmacy must have a written agreement or contract with the pharmacist or entity employing the pharmacist. The written agreement or contract shall:

1. Outline the services to be provided.

2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements.

3. Require that the parties adopt a policies and procedures manual.

4. Provide that the parties have access to or share a common electronic file such that the pharmacist performing remote medication order processing has sufficient patient information necessary for prospective drug use review and approval of medication orders.

(3) Policy and Procedures. A policy and procedures manual shall:

(a) Be accessible to each party involved in remote medication order processing.

(b) Be available for inspection by the Board or an authorized agent of the Department.

(c) Outline the responsibilities of each party involved in remote medication order processing.

(d) Include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing.

(e) Include policies and procedures for:

1. Protecting the confidentiality and integrity of patient information.

2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources.

3. Ensuring that medical and nursing staff understand how to contact a pharmacist.

4. Maintaining records to identify the name, initials, or identification code of each person who performs a processing function for a medication order.

5. Complying with federal and state laws and regulations.

6. Operating or participating in a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems.

7. Reviewing the written policies and procedures and documenting the review every year.

(4) Records.

(a) A Class II Institutional Pharmacy involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.

(b) The record may be maintained in a common electronic file if the record is maintained in such a manner that the data processing system can produce a printout which identifies every person who performed a processing function for a medication order.

(c) The record shall be readily retrievable for at least the past two (2) years.

(d) The record shall be available for inspection by the Board or an authorized agent of the Department.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.026 FS. History–New 11-29-04.

64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.

(1) Definitions.

(a) "Automated pharmacy system" means a mechanical system that performs operations or activities, other than compounding or administration, relative to the storage, packaging, counting, labeling, and delivery of a medicinal drug, and which collects, controls, and maintains a record of each transaction.

(b) "Provider pharmacy" means a pharmacy that provides pharmacy services by using an automated pharmacy system at a remote site.

(c) "Remote site" means a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., that is not located at the same location as the provider pharmacy, at which pharmacy services are provided using an automated pharmacy system.

(d) "Controlled substance" means a substance listed in Chapter 893, F.S., or 21 CFR Part 1308.

(2) Provider Pharmacy Requirements.

(a) A provider pharmacy may provide pharmacy services to a long term care facility or hospice licensed under Chapter 400, F.S., or a state correctional institution operated under Chapter 944, F.S., through the use of an automated pharmacy system.

(b) An automated pharmacy system shall only be used to provide pharmacy services to an inpatient or a resident of the remote site.

(c) Supervision of the automated pharmacy system shall be the responsibility of a Florida pharmacist employed by the provider pharmacy.

(d) Every medicinal drug stored in the automated pharmacy system shall be owned by the provider pharmacy.

(e) An automated pharmacy system shall be under the supervision of a pharmacist employed by the provider pharmacy. The pharmacist need not be physically present at the remote site if the system is supervised electronically.

(f) A provider pharmacy shall have policies and procedures to ensure adequate security.

(3) Prescription Department Manager Requirements.

(a) The prescription department manager shall ensure that the automated pharmacy system complies with Chapter 893, F.S., and 21 C.F.R., relating to the regulation of controlled substances, for each automated pharmacy system that contains a controlled substance.

(b) The prescription department manager shall ensure that the use of an automated pharmacy system does not compromise patient confidentiality.

(c) The prescription department manager or a designee shall:

1. Authorize or deny access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

2. Document the training of each person who has access to the data from an automated pharmacy system or to a drug stored inside the automated pharmacy system.

(4) Automated Pharmacy System Requirements.

(a) A medicinal drug stored in bulk or unit-of-use in an automated pharmacy system is part of the inventory of the provider pharmacy and is not part of the inventory of any other pharmacy permit for the facility.

(b) A medicinal drug may be removed from an automated pharmacy system for administration to a patient only after a prescription or order has been received and approved by a pharmacist at the provider pharmacy. This provision does not apply to a medication designated as an emergency medication if the automated pharmacy system is also used as an emergency medication kit in compliance with Section 400.142, F.S. and Rule 59A-4.112, F.A.C.

(c) A pharmacist at the provider pharmacy shall control all operations of the automated pharmacy system and approve release of the initial dose of a prescription or order. A subsequent dose from an approved prescription or order may be released without additional approval of a pharmacist. However, any change made in a prescription or order shall require a new approval by a pharmacist to release the drug.

(d) A pharmacist at the provider pharmacy shall comply with the patient record requirements in Rule 64B16-27.800, F.A.C., and prospective drug use review requirements in Rule 64B16-27.810, F.A.C., for every medicinal drug delivered through an automated pharmacy system.

(e) If the facility where pharmacy services are being provided maintains a medication administration record that includes directions for use of the medication, a unit dose medication may be utilized if the provider pharmacy or the automated pharmacy system identifies and records the dispensing pharmacy, the prescription or order number, the name of the patient, and the name of the prescribing practitioner for each medicinal drug delivered.

(f) Stocking or Restocking of an Automated Pharmacy System.

1. The stocking or restocking of a medicinal drug in an automated pharmacy system at the remote site shall be completed by a pharmacist or other licensed personnel, except as provided in subparagraph 2. below of this section.

2. If the automated pharmacy system uses removable cartridges or containers to store the drug, the stocking or restocking of the cartridges or containers may occur at the provider pharmacy and be sent to the remote site to be loaded by personnel designated by the pharmacist if:

a. A pharmacist verifies the cartridge or container has been properly filled and labeled.

b. The individual cartridge or container is transported to the remote site in a secure, tamper-evident container.

c. The automated pharmacy system uses bar code verification, electronic verification, or similar process to assure that the cartridge or container is accurately loaded into the automated pharmacy system.

(g) A medicinal drug that has been removed from the automated pharmacy system shall not be replaced into the system unless a pharmacist has examined the medication, the packaging, and the labeling and determined that reuse of the medication is appropriate.

(h) Medication to be returned to the provider pharmacy's stock shall meet the requirements of Rule 64B16-28.118, F.A.C.

(5) Security Requirements.

(a) If a provider pharmacy intends to store a controlled substance in an automated pharmacy system:

1. It shall maintain a separate DEA registration for each remote site at which a controlled substance is stored.

2. It may utilize one DEA registration to include multiple automated pharmacy systems located at a single address.

(b) A provider pharmacy shall only store a medicinal drug at a remote site within an automated pharmacy system which is locked by a mechanism that prevents access to a drug or to data by unauthorized personnel.

(c) Access to the drugs shall be limited to a pharmacist or a registered pharmacy technician employed by the provider pharmacy or licensed personnel in the facility or institution who are authorized to administer medication.

(d) An automated pharmacy system that contains a controlled substance shall prohibit simultaneous access to multiple drug entities, drug strengths, or dosage forms of controlled substances.

(6) Emergency medication. If an automated pharmacy system is utilized for both a medication ordered for a specific patient and an emergency medication for which the review of a pharmacist is not required:

(a) The emergency medication shall be stored separately from other patient medications.

(b) The record shall identify the storage location from which the medication was released.

(c) The record shall include the name of the medication, the patient, the prescriber, the person who accessed the automated pharmacy system, and the date and time of the release.

(7) Record Keeping Requirements.

(a) The record of transactions with the automated pharmacy system shall be maintained in a readily retrievable manner.

(b) The record shall be available to an authorized agent of the Department of Health or the Board of Pharmacy.

(c) The record shall include:

1. Name or identification of the patient or resident.

2. Name, strength and dosage form of the drug product released.

3. Quantity of drug released.

4. Date and time of each release of a drug.

5. Name of provider pharmacy.

6. Prescription number or order number.

7. Name of prescribing practitioner.

8. Identity of the pharmacist who approved the prescription or order.

9. Identity of the person to whom the drug was released.

(d) A record of every transaction with the automated pharmacy system shall be maintained for two (2) years.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.019, 465.022, 465.0235 FS. History–New 4-22-07, Amended 1-1-10.

64B16-28.702 Modified Class II Institutional Pharmacies.

(1) Modified Class II Institutional Pharmacies are those Institutional Pharmacies which provide specialized pharmacy services restricted in scope of practice and designed to provide certain health care pharmacy services that are not generally obtainable from other pharmacy permittees. These specialized institutional pharmacy practices are generally identifiable with short-term or primary care treatment modalities in entities such as primary alcoholism treatment centers, free-standing emergency rooms, rapid in/out surgical centers, certain county health programs, and correctional institutions. Medicinal drugs may not be administered, except to patients of the institution for use on the premises of the institution, in any facility which has been issued a Modified Class II

Institutional Pharmacy Permit. All medicinal drugs as defined by Section 465.003(7), F.S., which are stocked in these pharmacies are only to be administered on premises as defined by Section 465.003(1), F.S., to inpatients on an inpatient or in-program basis. In-program patients are defined as those patients who have met program admission criteria required by the institution.

(2) Modified Class II Institutional Pharmacies are categorized according to the type of specialized pharmaceutical delivery system utilized and the following criteria (Categories are designated as Type "A", Type "B" and Type "C"):

(a) The type of the medicinal drug delivery system utilized at the facility, either a patient-specific or bulk drug system, and, the quantity of the medicinal drug formulary at the facility,

(b) Type "A" Modified Class II Institutional Pharmacies provide pharmacy services in a facility which has a formulary of not more than 15 medicinal drugs, excluding those medicinal drugs contained in an emergency box, and in which the medicinal drugs are stored in bulk and in which the consultant pharmacist shall provide on-site consultations not less than once every month, unless otherwise directed by the Board after review of the policy and procedure manual.

(c) Type "B" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and in bulk form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(d) Type "C" Modified Class II Institutional Pharmacies provide pharmacy services in a facility in which medicinal drugs are stored in the facility in patient specific form and which has an expanded drug formulary, and in which the consultant pharmacist shall provide on-site consultations not less than once per month, unless otherwise directed by the Board after review of the policy and procedure manual.

(3) All Modified Class II Institutional Pharmacies shall be under the control and supervision of a certified consultant pharmacist.

(4) The consultant pharmacist of record for the Modified Class II Institutional Pharmacy shall be responsible for establishing a written protocol and a policy and procedure manual for the implementation of a drug delivery system to be utilized and the requirements of this rule.

(5) A copy of the permittee's policy and procedure manual as provided herein shall accompany the permit application. The original policy and procedure manual shall be kept within the Modified Class II Institutional Pharmacy and shall be available for inspection by the Department of Health.

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A" and Type "B" as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A" and Type "B" Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(a) The policy and procedure manual of facilities which are issued Type A Modified Class II Institutional Permits shall provide the following:

1. Definitive information as to drugs and strengths to be stored.
2. The establishment of a Pharmacy Services Committee which shall meet at least annually.
3. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
4. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
5. Provisions for the utilization of proof-of-use forms for all medicinal drugs within the facility.
6. A diagram of the facility and the security and storage of the medicinal drugs.
7. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.
2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
4. Provisions for the utilization of a perpetual inventory system for all controlled substances, injectables and other medicinal drugs as required by the Pharmacy Services Committee.
5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(c) The policy and procedure manual of facilities which are issued Type C Modified Class II Institutional Permit shall provide the following:

1. The establishment of a Pharmacy Services Committee which shall meet at least annually.

2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.

3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.

4. Provisions for the utilization of a Medication Administration Record (MAR) for all medicinal drugs administered to patients of the facility.

5. A diagram of the facility and the security and storage of the medicinal drugs.

6. Provisions for maintaining the records of consultations for not less than two (2) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

(7) Controlled drugs as defined in Chapter 893, F.S., stocked as provided herein within a Type "A" Modified Class II Institutional Pharmacy shall be stocked in unit size not to exceed 100 dosage units unless an exception thereto is granted by the Board of Pharmacy. Proof of use record sheets showing patient's name, date of administration, initials of person administering drug, and other pertinent control requirements are required for both controlled and noncontrolled substance medicinal drugs in Type "A" Modified Class II Institutional Pharmacies.

(8) A Modified Class II institutional pharmacy may contract with a Special Parenteral/Enteral Extended Scope pharmacy for the pharmacy services provided for by Rule 64B16-28.860, F.A.C.

(a) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity including the following provisions:

1. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

2. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

(b) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(c) Prior to contracting for such services the institutional pharmacy shall ensure that the Special Parenteral/Enteral Extended Scope pharmacy is licensed under the provisions of Rule 64B16-28.860, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019(2)(c) FS. History–New 4-22-82, Amended 11-5-85, Formerly 21S-1.37, Amended 4-16-86, Formerly 21S-1.037, Amended 7-31-91, Formerly 21S-28.702, 61F10-28.702, Amended 9-4-96, Formerly 59X-28.702, Amended 10-15-01.

64B16-28.800 Special Pharmacies.

(1) Special pharmacies are pharmacies providing miscellaneous specialized pharmacy service functions. The Board of Pharmacy, by this rule, provides for the establishment of the following special pharmacy permits:

(a) Special-Limited Community.

(b) Special-Parenteral and Enteral.

(c) Special-Closed System Pharmacy.

(d) Special-Non Resident (Mail Service).

(e) Special-End Stage Renal Disease.

(f) Special-Parenteral/Enteral Extended Scope.

(g) Special-ALF.

(2) An applicant for any special pharmacy permit shall provide the Board of Pharmacy with an application (Form DOH\PH105 Revised 7/23/98, effective 11/11/98, which is hereby incorporated by reference and which can be obtained from the Department of Health) and a Policy and Procedure Manual which sets forth a detailed description of the type of pharmacy services to be provided within the special pharmacy practice. The Policy and Procedure Manual shall contain detailed provisions for compliance with the provision of Section 465.0196, F.S., and other applicable requirements contained in this chapter.

(3) The Policy and Procedure Manual shall be prepared, maintained, and will be reviewed and is subject to approval by the Board of Pharmacy or its designee prior to the issuance of the permit and the initiation of the operation of the permittee. The policy and procedure manual is reviewed to determine if the operation of the facility will be in compliance with Chapters 465 and 893,

F.S., and Chapter 64B16, F.A.C. The Policy and Procedure Manual shall be made available upon request of the Board or its agents. The applicant who requests a special permit shall be subject to inspection prior to the issuance of the permit.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 2-21-84, Formerly 21S-1.39, 21S-1.039, Amended 7-31-91, 10-14-91, Formerly 21S-28.800, 61F10-28.800, Amended 3-10-96, 6-4-97, Formerly 59X-28.800, Amended 11-11-98, 10-15-01.

64B16-28.810 Special Pharmacy – Limited Community Permit.

A Special-Limited Community Permit shall be obtained by a Class II Institutional Pharmacy that dispenses medicinal drugs, including controlled substances to:

(1) Employees, medical staff and their dependents for their personal use,

(2) Patients of the hospital who are under a continuation of a course of therapy not to exceed a three (3) day supply,

(3) Patients obtaining medical services in the facility's emergency room and, whenever it is otherwise appropriate, as indicated in the applicant's policy and procedure manual.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196 FS. History–New 7-31-91, Formerly 21S-28.810, 61F10-28.810, 59X-28.810, Amended 7-17-05.

64B16-28.820 Sterile Products and Special Parenteral/Enteral Compounding.

(1) Sterile Products and Parenteral/Enteral Compounding.

(a) A sterile products and parenteral/enteral compounding pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to render sterile products and parenteral/enteral compounding functions. This pharmacy practice facilitates the utilization of certain institutional therapeutic measures by patients in the home environment or by patients in an institutional environment where such pharmacy service is unavailable. Pharmacy services, sterile products and parenteral/enteral products provided by a special sterile products and parenteral/enteral compounding pharmacy pursuant to prescription as defined by Section 465.003(13), F.S., shall be limited to the compounding and/or dispensing of:

1. Sterile preparations for parenteral therapy, parenteral nutrition, and/or
2. Sterile preparations for jejunostomy feeding and sterile irrigation solutions, and/or
3. Sterile preparations of cytotoxic or antineo-plastic agents, and/or
4. Sterile products (i.e., injectables, eye drops, etc.).

(b) Prior to engaging in a sterile products and parenteral/enteral compounding pharmacy practice an entity shall obtain a special sterile products and parenteral/enteral compounding pharmacy permit as provided herein.

(2) Pharmacy Environment. The compounding and dispensing of sterile products and parenteral/enteral prescription preparations within a special sterile products and parenteral/enteral compounding pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws of this state and in accordance with those requirements for the safe handling of drugs. The environment for this practice shall be set apart, and designed, and equipped to facilitate controlled aseptic conditions. Aseptic techniques shall prevail in this practice to minimize the possibility of microbial contamination.

(3) General Requirements.

(a) A special sterile products and parenteral/enteral compounding pharmacy shall be under the control and supervision of a licensed pharmacist, who shall be designated prescription department manager on the application for a special sterile products and parenteral/enteral compounding pharmacy. The prescription department manager or other licensed qualified pharmacist as provided herein shall be present on duty during all hours of operation of said pharmacy. Changes in prescription department manager shall be reported to the Board of Pharmacy office within 10 days by the permit holder and prescription department manager of record. A prescription department manager of a special sterile products and parenteral/enteral compounding pharmacy shall not be designated prescription department manager of record of more than one special sterile products and parenteral/enteral compounding pharmacy, unless otherwise approved by the Board. The Board will consider the proximity of the facility as well as the administrative workload created by the two permits, in determining whether or not it will approve the designation of someone as a prescription department manager of more than one special sterile products and parenteral/enteral compounding pharmacy.

(b) A special sterile products and parenteral/enteral compounding pharmacy shall provide special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. All such preparations shall include the time and/or date of expiration on the label. Delivery from the pharmacy to the patient shall be made within a reasonable time. A special sterile products and parenteral/enteral

compounding pharmacy shall provide telephone accessibility to its pharmacist(s) for its patients at all hours.

(c) A patient profile shall be maintained for each patient. The profile must contain available medical information consistent with prevailing pharmacy standards which shall be confidential.

(d) A Policy and Procedure Manual shall be prepared and maintained at each special sterile products and parenteral/enteral compounding pharmacy, and be available for inspection by authorized agents of the Board of Pharmacy and the Department. The Policy and Procedure Manual shall set forth in detail the objectives and operational guidelines of the permittee. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance, equipment facilities, and random production sampling consistent with recommended standards for compounding and dispensing intravenous admixtures as set forth by the Joint Commission on Accreditation of Health Organizations, the National Coordinating Committee and Large Volume Parenteral, and as provided by the Florida Board of Pharmacy.

(e) Compounding shall be conducted within an annually certified laminar air flow (LAF) hood, except in the existence of a Class 100 certified compounding environment, or certified mobile isolation chamber, in which case compounding may be conducted without the use of a certified laminar air flow hood. All cytotoxins must be compounded in a certified vertical laminar air flow hood or certified mobile isolation chamber. The use of a Type A or Type B LAF hood used shall be dependent upon the volume of work anticipated. All certifications shall be performed following manufacturer specification.

(f) Protective garb: gloves, face and eye, and gowns should be provided and used.

(g) Proper aseptic procedures must be used at all times to prevent bacterial contamination of the product as well as chemical contamination of the operator.

(h) All unused cytotoxic agents and material must be disposed of properly in accordance with accepted professional standards and applicable law.

(4) An applicant for a special sterile products and parenteral/enteral compounding pharmacy permit shall provide the Board of Pharmacy with the following:

(a) Completed Board of Pharmacy permit application form (Form DPR/PH/107/9-88).

(b) Copy of Policy and Procedure Manual.

(c) Permit fee as provided in Rule 64B16-28.121, F.A.C.

(5) Minimum Requirements for Space, Equipment, Supplies and Publications.

(a) To ensure compliance with the general requirements as set forth, the following minimum requirements for space, equipment, supplies and publications shall be met by a pharmacy which operates under the special permit of a sterile products and parenteral/enteral compounding pharmacy. These requirements are in addition to the minimum requirements for space and equipment required of other types of pharmacies when applicable. The minimum permit requirements are set forth as follows:

(b) Space:

1. The area for preparing sterile prescriptions as provided for by this rule referred to as the sterile admixture room shall be set apart from general work and storage areas. The room shall be adequately air conditioned or shall be under positive pressure.

2. The sterile admixture room shall provide space for a minimum of one laminar flow hood. Additionally, the space shall be of adequate size to accommodate other equipment as provided herein and sufficient space to allow pharmacists and other employees working therein to adequately, safely, and accurately fulfill their duties related to prescriptions.

(c) Equipment:

1. Laminar Air Flow Hood(s):

a. Horizontal and/or.

b. Vertical.

2. Refrigerator/freezer convenient to the clean room.

3. Sink and wash area convenient to the clean room.

4. Appropriate waste containers for:

a. Used needles and syringes.

b. All cytotoxic waste including apparel.

(d) Supplies:

1. Gloves, masks and gowns.

2. Needles and syringes of various standard sizes.

3. Disinfectant cleaning agents.

4. Clean towels.

5. Handwashing materials with bactericidal properties.

6. Vacuum containers and various transfer sets.

7. "Spill kits" for cytotoxic agent spills.

(e) Current References:

1. Chapter 465, F.S.

2. Chapter 499, F.S.

3. Chapter 893, F.S.

4. Title 64B16, F.A.C., Rules of the Florida Board of Pharmacy.

5. United States Pharmacopeia and National Formulary, or Remington Pharmaceutical Sciences, or the United States Dispensatory (along with the latest supplements), or an equivalent thereof sufficient in scope to meet the professional practice needs of the pharmacy, and a current authoritative therapeutic reference.

6. Handbook of Injectable Drugs by American Society of Hospital Pharmacists.

7. "Practice Guidelines For Personnel Dealing With Cytotoxic Drugs."

(6) A community pharmacy permittee may perform parenteral/enteral compounding or prepare sterile products without obtaining an additional permit under this section, so long as prior to entering into such activities, the community pharmacy meets the requirements of subsections (1)-(5) above and is inspected for compliance by the Department of Health. A community pharmacy permittee that was engaged in the preparation of sterile products other than parenteral/enteral products as of June 1, 2002 shall have until June 1, 2003 to meet the requirements of subsections (1)-(5) above for the preparation of sterile products other than parenteral/enteral products.

Rulemaking Authority 465.005, 465.007, 465.022 FS. Law Implemented 465.007, 465.018, 456.0196 FS. History–New 4-26-84, Formerly 21S-1.40, Amended 7-27-86, Formerly 21S-1.040, Amended 7-31-91, 10-14-91, Formerly 21S-28.820, 61F10-28.820, Amended 3-11-96, 6-4-97, Formerly 59X-28.820, Amended 7-1-02, 1-29-03.

64B16-28.830 Special – Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for by Section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-MR's (Intermediate Care Facility/Mentally Retarded) or other custodial care facilities when defined by AHCA rules which the Board may approve.

(2) A special – closed system pharmacy permittee shall maintain a policy and procedure manual including drug procurement, storage, handling, compounding, dispensing, record keeping and disposition.

(3) A special – closed system pharmacy permittee shall provide twenty-four hour emergency and on-call service.

(4) A special – closed system pharmacy permittee may dispense parenteral and enteral medications as provided by rule.

(5) A special – closed system pharmacy permittee shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records, providing security of the prescription department and following other rules as relate to the practice of pharmacy. The prescription department manager of a closed system pharmacy shall not be the prescription department manager of any other pharmacy permit except when the permit is within the premises of a community pharmacy permit.

(6) The utilization of registered pharmacy interns and registered pharmacy technicians is subject to the rules as provided by Rule 64B16-26.400, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 465.022 FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.830, 61F10-28.830, 59X-28.830, Amended 1-1-10.

64B16-28.840 Special – Non Resident (Mail Service).

(1) A Special – Non Resident (Mail Service) pharmacy is provided for by Section 465.0156, F.S. It is a pharmacy located outside this state delivering a dispensed medicinal drug in any manner into this state.

(2) The pharmacy and the pharmacist designated as the prescription department manager or equivalent, for dispensing into Florida, must be licensed in the state of location.

(3) Changes of location, corporate officers, and prescription department managers must be reported to the Board as required by Section 465.0156(1)(b), F.S.

(4) The pharmacy must have regular hours of operation of not less than six (6) days per week and not less than forty (40) hours per week. A toll-free telephone number must be available to patients.

(5) A pharmacy outside of this state and not registered as a Non Resident Pharmacy may make a one-time delivery of a dispensed medicinal drug to a patient in this state as provided by Section 465.0156(2), F.S.

Rulemaking Authority 465.005, 465.022, 465.0156 FS. Law Implemented 465.0156 FS. History–New 10-14-91, Formerly 21S-28.840, 61F10-28.840, 59X-28.840, Amended 10-27-09.

64B16-28.850 Special Pharmacy – ESRD.

(1) An ESRD Pharmacy is a type of special pharmacy as provided by Section 465.0196, F.S., which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address. Pharmacy services and dialysis supplies and products provided by an ESRD pharmacy shall be limited to the distribution and delivery of legend drugs included in schedule (3) below; or legend devices included in schedule (4) below; which are ordered by a physician for administration or delivery to a person with chronic kidney failure for self-administration at the person's home or specified address. All dialysis supplies and products provided by an ESRD pharmacy shall be prepackaged and shall be covered by an approved NDA or 510 (k) application issued by the Federal Food and Drug Administration.

(2) Prior to engaging in an ESRD pharmacy practice an entity shall obtain a special ESRD pharmacy permit as provided herein.

(3) Schedule of legend drugs:

(a) Saline Solutions.

(b) Porcine Heparin.

(c) Beef Heparin.

(d) Dextrose Solutions.

(e) Doxercalciferol.

(f) Epoetin Alfa.

(g) NACL INJ 50 MEQ/20 ML.

(h) Levocarnitine.

(i) Lidocaine.

(j) Vitamin Preparations (dialysate use only).

(k) Paricalcitrol.

(l) Peritoneal Dialysate Solutions.

(m) Protamine Sulfate.

(n) Potassium 20 MEQ/10ML (dialysate use only).

(o) Sodium Ferric Gluconate Complex or equivalent.

(p) Sterile Water for Irrigation.

(4) The schedule of legend devices includes:

(a) Hemodialyzers.

(b) Hemodialysis solutions.

(c) Bloodlines and Associated Connectology.

(d) Peritoneal Dialysis Tubing and Connectology.

(5) The provision of legend drugs and devices included in the schedule necessary to perform dialysis to a person with chronic kidney failure for self-administration at the person's home or specified address shall be under the professional supervision of an appropriate practitioner licensed under Florida law. The consultant pharmacist shall assure that the following occurs:

(a) The ESRD pharmacy receives a prescription from the prescribing practitioner directing the pharmacist to dispense and deliver to a person with chronic kidney failure (or such person's designee) any legend drugs and/or devices included in the formulary necessary for the self-administration of dialysis at such person's home or specified address.

(b) That no dispensing shall occur unless the person with chronic kidney failure has been trained in the proper use and administration of such products. Further, the consulting pharmacist shall ensure that the ESRD pharmacy has received records confirming the completion of such training.

(c) After the delivery of such products by the ESRD pharmacy, the ESRD pharmacy shall upon request therefor, make available to the prescribing practitioner documentation describing, in sufficient detail, the types and quantities of products dispensed and

delivered by the ESRD pharmacy. The ESRD pharmacy shall also, upon request, make available to the prescribing practitioner documentation confirming shipment of such products and receipt thereof by the person with chronic kidney failure.

(6) The licensed ESRD pharmacy shall comply with all applicable state and federal regulatory requirements and shall maintain in effect all applicable permits and licenses required to dispense and deliver legend drugs and/or devices included in the formulary described in this Section.

(7) The ESRD pharmacy shall deliver products to a person with chronic kidney failure only upon receipt of a valid prescription from a prescribing practitioner specifying or including:

(a) Documentation that the intended recipient of the products has been trained in home dialysis therapy and will require such products;

(b) The duration of prescribing practitioner's order; and

(c) The name and product code of each product prescribed and the quantity prescribed.

(d) The prescription may indicate the person with chronic kidney failure shall have the right to request refills of legend drugs, devices or both, included in the schedule and described in the order for a period of one year.

(8) The ESRD pharmacy shall assemble the products to be delivered pursuant to the prescribing practitioner's prescription. In assembling such products for delivery, the ESRD pharmacy shall take steps necessary to assure the following:

(a) The code numbers and quantities of the products assembled match the code numbers identified in the prescribing practitioner's prescription;

(b) With respect to any dated products, a minimum of three (3) full months of shelf-life remain; and

(c) All cartons and other packaging are properly labeled as noted below:

1. "Use as Directed" statement;

2. The name and address of the person to whom the products will be delivered;

3. The name of the prescribing practitioner;

4. The name and address of the ESRD pharmacy location from which the products were shipped;

5. The prescription number identifying the shipment to the order created by the prescribing practitioner; and

6. Any special instructions regarding delivery dates or locations.

7. The date after which the drug(s) and/or device(s) must be discarded. Notwithstanding any other rule, the ESRD pharmacy may use, in lieu of a discard after date, the manufactures expiration date when such is displayed in an unopened sealed package.

(d) All cartons and related packaging shall be visually inspected to confirm compliance with the specifications in paragraph (8)(c). Compliance with the requirements set forth in paragraph (8)(c) shall be conducted by the consulting pharmacist or independently by not less than two employees of the ESRD pharmacy trained in the performance of the foregoing activities, each of whom shall acknowledge in writing their completion of such activities with respect to each group of products assembled for delivery.

(9) The ESRD pharmacy permit holder shall assure through visual inspection and comparison of records that products assembled for delivery to persons with chronic kidney failure are consistent with the prescribing practitioner's order therefor.

(10) The products ordered by the prescribing practitioner under this Rule shall be delivered by either the ESRD pharmacy or a carrier authorized by the ESRD pharmacy.

(11) Upon delivery of the products by the ESRD pharmacy or its carrier to the person identified on the prescribing practitioner's order, the ESRD pharmacy or its carrier shall confirm receipt by the patient or the patient's designee that the number of units delivered equals the number of units identified on the appropriate documentation. Compliance with the foregoing requirements set forth above shall be conducted by an employee or agent of the ESRD pharmacy trained in the performance of such activities, who shall acknowledge in writing the delivery of the products and the completion of such activities with respect to each delivery.

(12) In addition to the foregoing operation requirements, an ESRD pharmacy shall comply with the following:

(a) The ESRD pharmacy license shall be displayed at each ESRD pharmacy location.

(b) The Board of Pharmacy shall be notified in writing of the Consulting Pharmacist responsible, at the time of application for the permit, for supervising the ESRD pharmacy operations and within 10 days, if the Consultant Pharmacist of record changes.

(c) The ESRD pharmacy's hours of business shall be posted. The ESRD pharmacy shall be open such hours as are necessary to safely and effectively dispense and deliver supplies to those persons designated by the applicable prescribing practitioner. An ESRD pharmacy shall provide twenty-four hour emergency and on-call service.

(d) The ESRD pharmacy shall have sufficient space and storage capabilities as are necessary to carry out its operation.

(e) All legend drugs and/or legend devices included in the formulary subject to this Rule shall be properly identified.

(f) The ESRD pharmacy shall maintain a current copy of the Florida pharmacy laws and rules.

(g) The ESRD pharmacy shall comply with patient counseling requirements of Rules 64B16-27.800-.810 and 64B16-27.820, F.A.C.

(13) ESRD Pharmacy Application Requirements. An applicant for an ESRD pharmacy permit shall provide the Board of Pharmacy with a Policy and Procedure Manual setting forth in detail the operational guidelines of the applicant. The Policy and Procedure Manual shall include a Quality Assurance Program which monitors personnel qualifications, training and performance.

(14) An ESRD pharmacy shall be under the control and supervision of licensed Consultant Pharmacist licensed under Section 465.0125, F.S. The Consulting Pharmacist shall be responsible for the drug/device delivery system.

(15) The Consultant Pharmacist of record for the ESRD Pharmacy shall be responsible for establishing a written protocol and Policy and Procedure Manual for the implementation of a delivery system to be utilized in compliance with the requirements of this Rule.

(16) The Consultant Pharmacist shall inspect the permitted ESRD pharmacy on a monthly basis.

(17) A copy of the ESRD pharmacy's Policy and Procedure Manual as provided above shall accompany the permit application, shall be kept within the ESRD Pharmacy, and shall be available for inspection by the Department of Health. Changes in the Policy and Procedure Manual shall be approved by the Consulting Pharmacist.

Rulemaking Authority 465.005, 465.0125 FS. Law Implemented 465.0196, 465.022 FS. History–New 10-2-94, Formerly 59X-28.850, Amended 9-20-99, 7-17-05, 6-24-08.

64B16-28.860 Special Pharmacy – Parenteral/Enteral Extended Scope Permit.

(1)(a) A Special Parenteral/Enteral Extended Scope permit, as authorized by Section 465.0196, F.S., is required for pharmacies to compound patient specific enteral/parenteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied. Prior to engaging in a parenteral/enteral compounding pharmacy practice as described in this section, an entity shall obtain a Special Parenteral/Enteral Extended Scope pharmacy permit.

(b) Special Parenteral/Enteral Extended Scope pharmacies and institutional pharmacy permits shall create and comply with Policy and Procedure Manuals that delineate duties and responsibilities of each entity, including the following provisions:

1. When dispensing patient specific prescriptions provided by an institutional pharmacy permit, the Special Parenteral/Enteral Extended Scope pharmacy shall confirm accuracy of the prescription and dosage.

2. The institutional pharmacy permit shall maintain records appropriate to ensure the provision of proper patient care.

3. The institutional pharmacy permit designee shall inspect and log in all medicinal drugs provided by the Special Parenteral/Enteral Extended Scope pharmacy.

4. A pharmacist for the Class II institutional pharmacy shall provide drug utilization review and shall review each prescription order prior to transmission to the Special Parenteral/Enteral Extended Scope pharmacy.

5. The Policy and Procedure Manual for a Special Parenteral/Enteral Extended Scope pharmacy shall also meet the policy and procedure manual requirements of paragraph 64B16-28.820(3)(d), F.A.C.

(c) Such Policy and Procedure manuals shall be made available to the Board or Department upon request.

(2) Facilities obtaining this permit may also provide services described in paragraph 64B16-28.820(1)(a), F.A.C., without obtaining an additional permit. Pharmacy services and parenteral/enteral products provided by a Special Parenteral/Enteral Extended Scope pharmacy shall be limited to the compounding and/or dispensing of sterile:

(a) Preparations for parental therapy, parenteral nutrition, and/or

(b) Preparations for enteral feeding and sterile irrigation solutions, and/or

(c) Preparations of cytotoxic or antineoplastic agents.

(3) Facilities operating under this permit may provide all necessary supplies and delivery systems so that the medicinal drugs listed herein may be properly administered.

(4) Pharmacy Environment. The compounding and dispensing of sterile parenteral/enteral prescription preparations within a Special Parenteral/Enteral Extended Scope pharmacy shall be accomplished in a pharmacy environment subject to the pharmacy permit laws contained in Chapter 465, F.S., and in accordance with those requirements for the safe handling of drugs. Special Parenteral/Enteral Extended Scope permittees shall comply with the requirements contained in subsections 64B16-28.820(3) through (4), F.A.C., and the following:

(a) Shall include an active and ongoing end product testing program to ensure stability, sterility, and quantitative integrity of finished prescriptions.

(b) Shall insure each compounding process undergoes an initial and thereafter annual sterility validation utilizing media fill to ensure the integrity and validity of the compounding process.

(5) Records.

(a) Special Parenteral/Enteral Extended Scope pharmacies shall comply with the record maintenance requirements as contained in Rule 64B16-28.140, F.A.C.

(b) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients under the provisions of paragraph 64B16-28.820(1)(a), F.A.C., or to patients of Modified Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall comply with the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(c) Special Parenteral/Enteral Extended Scope pharmacies dispensing medicinal products to patients of Class II institutional pharmacies under the provisions of Rule 64B16-28.860, F.A.C., shall be exempt from the records, utilization review, and patient counseling requirements of Rules 64B16-27.800, 64B16-27.810 and 64B16-27.820, F.A.C.

(d) Compounding records shall be organized in such a manner as to include: lot number traceability of components used during compounding, documentation of any equipment used during compounding, documentation of staff performing compounding, and records recording ultimate dispensing of the compounded product.

Rulemaking Authority 465.005 FS. Law Implemented 465.0196, 465.022 FS. History–New 9-4-96, Formerly 59X-28.860, Amended 7-17-05.

64B16-28.870 Special-ALF.

The Special-ALF permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging. All medicinal drugs must be maintained in individual prescription containers for the individual patient. Medicinal drugs may not be dispensed on the premises. Medicinal drugs dispensed to patients of Special-ALF permits may be returned to the dispensing pharmacy's stock under the provisions of Rule 64B16-28.118, F.A.C. Dispensed controlled substances that have been discontinued shall be disposed of under the provisions of Rule 64B16-28.301, F.A.C. Medicinal drugs dispensed to the residents of a Special-ALF permit shall meet the labeling requirements of Rule 64B16-28.502 and paragraph 64B16-28.402(1)(h), F.A.C. Each facility holding a Special-ALF permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within 10 days of any change in the consultant pharmacist of record. The consultant pharmacist of record shall be responsible for the preparation of the Policy and Procedure Manual required by subsection 64B16-28.800(2), F.A.C. Policy and Procedure Manuals must provide for the appropriate storage conditions and security of the medicinal drugs stored at the facility. The consultant pharmacist of record shall inspect the facility and prepare a written report to be filed at the permitted facility at least monthly.

Rulemaking Authority 465.022 FS. Law Implemented 465.0196 FS. History–New 2-23-98.

64B16-28.900 Definitions – Nuclear Pharmacy.

(1) A "nuclear pharmacy" is a pharmacy which provides radiopharmaceutical services.

(2) A "nuclear pharmacist" is a pharmacist who has met the training qualifications as described in Rule 64B16-28.903, F.A.C., and has been licensed by the Board of Pharmacy.

(3) A "radiopharmaceutical service" shall include, but shall not be limited to, the procurement, storage, preparation, labeling, quality assurance testing, distribution, record keeping and disposal of radiopharmaceuticals.

(4) A "radiopharmaceutical" is any substance defined as a drug by section 201(g)(1) of the Federal Food, Drug and Cosmetic Act which exhibits spontaneous disintegration of unstable nuclei with the emission of nuclear particles or photons and includes any such drug which is intended to be made radioactive. This definition includes nonradioactive reagent kits and nuclide generators which are intended to be used in the preparation of any such substance but does not include drugs such as carbon-containing compounds or potassium-containing salts which contain trace quantities of naturally occurring radionuclides.

(5) "Radiopharmaceutical quality assurance" includes, but is not limited to, the performance of appropriate chemical, biological and physical tests on radiopharmaceuticals, and the interpretation of the resulting data to determine their suitability for use in humans and animals, including internal test assessment, authentication of product history and the keeping of proper records.

(6) "Authentication of product history" includes, but is not limited to, identifying the purchasing source, the ultimate fate, and

intermediate handling of any component of a radiopharmaceutical or other drug.

Rulemaking Authority 465.005 FS. Law Implemented 465.003(14), 465.022(1)(e) FS. History–New 1-7-76, Formerly 21S-3.01, Amended 4-4-88, Formerly 21S-3.001, Amended 7-31-91, 4-15-92, 10-1-92, Formerly 21S-28.900, 61F10-28.900, 59X-28.900, Amended 4-5-05.

64B16-28.901 Nuclear Pharmacy – General Requirements.

The process employed by any permit holder in this state concerning the handling of radioactive materials must involve appropriate procedures for the purchase, receipt, storage, manipulation, compounding, distribution and disposal of radioactive materials. In order to insure the public health and safety in this respect, a nuclear pharmacy in this state shall meet the following general requirements:

(1) Each nuclear pharmacy shall designate a nuclear pharmacist as the prescription department manager who shall be responsible for compliance with all laws and regulations, both state and federal pertaining to radiopharmaceuticals and radiopharmaceutical services. A nuclear pharmacist must personally supervise the operation of only one nuclear pharmacy during all times when radiopharmaceutical services are being performed.

(2) The nuclear pharmacy area shall be secured from access by unauthorized personnel.

(3) Each nuclear pharmacy shall maintain accurate records of the acquisition, inventory, distribution, and disposal of all radiopharmaceuticals.

(4) All nuclear pharmacies shall provide a secured radioactive storage and decay area.

(5) Nuclear pharmacies shall comply with all applicable laws and regulations of federal and state agencies for the procurement, secure storage, inventory, preparation, distribution and disposal of radiopharmaceuticals and other drugs.

(6) Radiopharmaceuticals are to be distributed only upon a prescription order from an authorized licensed medical practitioner or through the practitioner's agent.

(7) A nuclear pharmacist may transfer radioactive materials in accordance with all applicable laws and regulations.

(8) A nuclear pharmacist upon receiving an oral prescription order for a radiopharmaceutical shall immediately have the prescription order reduced to writing. The pharmacist may delegate this duty to a registered pharmacy technician only as authorized by Rule 64B16-27.410, F.A.C. The prescription order shall contain at least the following:

(a) The name of the user or his agent;

(b) The date of distribution and the time of administration of the radiopharmaceutical;

(c) The name of the procedure;

(d) The name of the radiopharmaceutical;

(e) The dose or quantity of the radiopharmaceutical;

(f) The serial number assigned to the prescription order for the radiopharmaceutical;

(g) Any specific instructions; and

(h) The initials of the person who received the prescription order.

(i) The patient's name must be obtained and recorded prior to dispensing, if the prescription order is for a therapeutic or blood product radiopharmaceutical.

(9) The immediate outer container shield of a radiopharmaceutical to be dispensed shall be labeled with:

(a) The name of and address of the pharmacy;

(b) The name of the prescriber;

(c) The date of the original filling;

(d) The standard radiation symbol;

(e) The words "Caution Radioactive Material";

(f) The name of the procedure;

(g) The prescription order number of the radiopharmaceutical;

(h) The radionuclide and chemical form;

(i) The amount of radioactivity and the calibration date and time;

(j) The expiration date and time;

(k) The volume if a liquid;

(l) The number of items or weight, if a solid;

(m) The number of ampules or vials, if a gas;

(n) Molybdenum 99 content to USP limits, applies only to TC 99M products; and

(o) The name of the patient or the words "Physician's Use Only" in the absence of a patient name. If the prescription order is for a therapeutic or blood-product radiopharmaceutical, the patient's name must be obtained and recorded prior to dispensing. The requirements of this subsection shall be met when the name of the patient is readily retrievable from the physician upon demand.

(p) The initials of the pharmacist who dispensed the medication.

(10) The immediate inner container label of a radiopharmaceutical to be distributed shall be labeled with:

(a) The standard radiation symbol;

(b) The words "Caution Radioactive Material";

(c) The radionuclide;

(d) The chemical form;

(e) The prescription order number of the radiopharmaceutical.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.0126, 465.014 FS. History–New 1-7-76, Formerly 21S-3.03, Amended 12-11-86, 4-4-88, Formerly 21S-3.003, 21S-28.901, 61F10-28.901, Amended 2-26-95, Formerly 59X-28.901, Amended 4-5-05, 1-1-10.

64B16-28.902 Nuclear Pharmacy – Minimum Requirements.

In order to insure compliance with the general safety requirements as previously set forth above, the following minimum requirements shall be met by a nuclear pharmacy. These requirements are in addition to the general requirements for space and equipment for other types of pharmacies, the requirements of the Department of Health for the control of radiation hazards, and the applicable requirements of the Federal Food and Drug Administration. Such minimum permit requirements are set forth as follows:

(1) Space:

(a) The area for the storage, compounding, distribution and disposal of radiopharmaceuticals shall be adequate to completely separate such radioactive pharmaceuticals from pharmacy areas which contain non-radioactive medicinal drugs;

(b) The Hot lab, storage area, and compounding and dispensing area shall be a minimum of 150 square feet.

(2) Equipment:

(a) Fume hood with appropriate air sampling equipment;

(b) Shielded radiation containment drawing station;

(c) Dose calibrator;

(d) Well scintillation counters;

(e) Area rate meters;

(f) Geiger-Mueller (GM) Survey meters;

(g) Refrigerator;

(h) Microscope;

(i) Syringe shields; and

(j) Personnel radiation detection devices.

(3) Supplies:

(a) Syringes and vials required to perform practice;

(b) Disposable gloves and protective lab coats;

(c) Appropriate supplies to ensure sterile practices for I.V. solutions;

(d) Appropriate supplies to perform thin layer chromotography;

(e) Lead transport shields for syringes and vials. No person shall utilize reusable unit dose transport containers for radioactive doses without either an effective process to decontaminate the transport container of blood and other biohazardous substances or an effective mechanism to avoid contamination of the transport container. No person shall re-use a unit dose transport container that remains contaminated with blood or other biohazardous subtances. Any unit dose transport container that is returned with the tamper-evident seal broken and the unit dose syringe included shall be considered to be contaminated.

(f) D.O.T. Type 7A approved transport containers and other labels and supplies for shipping radioactive materials.

(4) Current references:

(a) Chapter 465, F.S.;

(b) Chapter 404, F.S.;

(c) Chapter 893, F.S.;

(d) Chapters 64B16-26 and 64B16-28, F.A.C., Rules of the Florida Board of Pharmacy;

(e) Chapter 64E-5, F.A.C., Rules of the Department of Health;
(f) Title 10 C.F.R., Code of Federal Regulations, FDA Regulations;
(g) Title 49 C.F.R., Code of Federal Regulations, Department of Transportation Regulations;
(h) United States Pharmacopeia/National Formulary;
(i) USP-DI.

It shall be acceptable, in lieu of an actual hard copy, to maintain these materials in a readily available electronic data format.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0193, 465.022(1) FS. History–New 1-7-76, Formerly 21S-3.04, Amended 12-11-86, 4-4-88, Formerly 21S-3.004, Amended 7-31-91, Formerly 21S-28.902, 61F10-28.902, Amended 2-26-95, Formerly 59X-28.902, Amended 4-26-01, 4-5-05.

64B16-28.903 Training Qualifications.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(14), 465.0126 FS. History–New 4-17-76, Amended 4-8-80, 6-23-83, Formerly 21S-3.05, Amended 8-11-86, 4-4-88, Formerly 21S-3.005, Amended 7-31-91, Formerly 21S-28.903, 61F10-28.903, Amended 6-12-96, Formerly 59X-28.903, Repealed 1-18-05.

64B16-28.904 Nuclear Pharmacist – Continuing Education.

Rulemaking Authority 465.0126, 465.022 FS. Law Implemented 465.009(5), 465.0126 FS. History–New 10-28-91, Formerly 21S-28.904, 61F10-28.904, 59X-28.904, Amended 1-12-03, 10-19-03, Repealed 1-18-05.

CHAPTER 64B16-29
ANIMAL CONTROL SHELTER PERMITS

64B16-29.001 Definition
64B16-29.002 General Requirements
64B16-29.003 Drug Requirement (Repealed)
64B16-29.004 Records
64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits
64B16-29.005 Storage

64B16-29.001 Definition.

An "animal control shelter" is a county or municipal animal control agency or Humane Society registered with the Secretary of State which holds a modified Class II Institutional Pharmacy permit issued by the Department of Health pursuant to certification of compliance with Rule 64B16-29.002, F.A.C., by the Board of Pharmacy. An animal control shelter is issued a pharmacy permit for the sole purpose of obtaining the drugs, sodium pentobarbital and sodium pentobarbital with lidocaine, for euthanization of animals within their lawful possession.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.01, Amended 4-24-88, Formerly 21S-14.001, 21S-29.001, 61F10-29.001, 59X-29.001.

64B16-29.002 General Requirements.

(1) Application for an Animal Control Shelter Pharmacy permit shall be made on Board of Pharmacy approved form DOH-MQA/PH/107 "Animal Control Pharmacy Permit Application and Information," effective October 2009, which is incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254, or (850) 488-0595, or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(a) The application fee for animal shelters applying for the Modified Class II Institutional permit shall be fifty dollars ($50).

(b) The biennial permit renewal fee for animal shelters holding the Modified Class II Institutional permit shall be fifty dollars ($50).

(2) The applicant shall apply to the Drug Enforcement Administration, United States Department of Justice, by the appropriate DEA form, for Registration as a practitioner, to be designated as "Animal Shelter" on the appropriate DEA form.

(3) The applicant shall be certified by the Board of Pharmacy to the Department as having met the requirements of this rule chapter prior to issuance of a permit. The certification process shall require prior inspection of the facility by authorized persons.

(4) The consultant pharmacist requirement of Section 465.019(5), F.S., is waived as being inapplicable to this special restricted permit.

(5) Authorized employees of the Department shall inspect animal control shelters not less than twice per year to determine compliance with this rule.

(6) Each animal control shelter permittee shall designate an on-site manager of the shelter. The on-site manager and permittee shall notify the Department within ten (10) days of any change in the on-site manager of the shelter.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.02, Amended 4-24-88, Formerly 21S-14.002, Amended 10-1-92, Formerly 21S-29.002, Amended 7-18-94, Formerly 61F10-29.002, 59X-29.002, Amended 5-11-10.

64B16-29.003 Drug Requirement.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.03, Amended 4-24-88, Formerly 21S-14.003, 21S-29.003, 61F10-29.003, 59X-29.003, Repealed 3-28-12.

64B16-29.004 Records.

Animal control shelter permittees shall maintain records of purchases and administration of sodium pentobarbital and sodium pentobarbital with lidocaine for a period of not less than two (2) years. Records of administration shall contain:

(1) The date of use;

(2) Identification of the animal;

(3) The amount of the drug used;

(4) The signature of the person administering the drug;

(5) The signature of the on-site manager certifying the accuracy of the administration of sodium pentobarbital and sodium pentobarbital with lidocaine not less than once per month; and

(6) The signature of the on-site manager certifying to the accuracy of the records. These records are subject to audit by the Drug Enforcement Administration or authorized employees of the Department to determine adequacy, accuracy and validity of the record keeping.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.04, Amended 4-24-88, Formerly 21S-14.004, 21S-29.004, 61F10-29.004, 59X-29.004.

64B16-29.0041 Record Maintenance Systems for Animal Shelter Permits.

(1) General requirements for records maintained in an electronic system.

(a) If a permitted animal shelter's data processing system is not in compliance with the Board's data processing requirements, the facility must maintain a manual recordkeeping system meeting the requirements of Rule 64B16-29.004, F.A.C.

(b) Requirements for back-up systems. The facility shall maintain a back-up copy of information stored in the data processing system using disk, tape, or other electronic back-up and up-date this back-up copy on a regular basis, at least monthly, to assure that data is not lost due to system failure.

(c) Change or discontinuance of a data processing system.

1. Records of dispensed and returned medicinal drugs. A permitted animal shelter that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains the same information as required on the audit trail printout as specified in Rule 64B16-29.004, F.A.C.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(d) Loss of data. The shelter manager for permitted animal shelters shall report to the Board in writing any significant loss of information from the data processing system within 10 days of discovery of the loss.

(2) The permitted animal shelter shall maintain a system(s) which can produce the information required in Rule 64B16-29.004, F.A.C., for the preceding two years. The information required in this paragraph shall be supplied by the permitted animal shelter within seven working days if requested.

(3) Failure to maintain records. Failure to provide records set out in this subsection, either on site or within 7 working days for whatever reason, constitutes failure to keep and maintain records.

(4) Data processing system downtime. In the event that a permitted animal shelter which uses a data processing system experiences system downtime, the permitted animal shelter must have an auxiliary procedure which will ensure that all data is retained.

Rulemaking Authority 465.005, 465.0155, 465.022, 828.055 FS. Law Implemented 465.019, 465.022, 465.026, 893.07, 828.055 FS. History–New 3-31-05.

64B16-29.005 Storage.

Sodium pentobarbital and sodium pentobarbital with lidocaine shall be stored in a safe place. At a minimum, this shall require that the drugs be kept in a securely locked cabinet within a locked storage room. Schedule II order forms are to be stored under the same conditions. Records of purchases of sodium pentobarbital and sodium pentobarbital with lidocaine shall be maintained in a separate file from the records of administration. The records of purchases and administration shall be maintained at the location.

Rulemaking Authority 465.005, 828.055 FS. Law Implemented 828.055 FS. History–New 10-17-79, Formerly 21S-14.05, Amended 4-24-88, Formerly 21S-14.005, 21S-29.005, 61F10-29.005, 59X-29.005.

CHAPTER 64B16-30
DISCIPLINARY GUIDELINES

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances
64B16-30.002 Minor Violations
64B16-30.003 Citations
64B16-30.0035 Mediation

64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.

(1) The board sets forth below a range of disciplinary guidelines from which disciplinary penalties will be imposed upon licensees guilty of violating Chapter 465, F.S. The purpose of the disciplinary guidelines is to give notice to licensees of the range of penalties which will normally be imposed upon violations of particular provisions of Chapter 465, F.S. The term license means any permit, registation, certificate, or license, including a provisional license, issued by the Department. The minimum penalty range is based upon a first time single count violation of each provision listed. The maximum penalty range is based upon multiple or repeated violations of the same provision of Chapter 465, F.S., or the rules promulgated thereto. All penalties at the upper range of the sanctions set forth in the guidelines, i.e., suspension, revocation, etc., include lesser penalties, i.e., fine, probation or reprimand which may be included in the final penalty at the board's discretion. Probation may be subject to conditions, including restriction from practice in certain settings, restricting the licensee to working only under designated conditions or in certain settings, requiring continuing or remedial education, or any other restriction found to be necessary for the protection of the public health, safety and welfare. In addition to any other discipline imposed under these guidelines, the board shall assess costs relating to the investigation and prosecution of the case.

(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees and permittees for violation of the below mentioned statutes and rules. For the purposes of this rule, the descriptions of the violations are abbrieviated and the full statute or rule cited should be consulted to determine the prohibited conduct.

	PENALTY RANGE	
VIOLATION	MINIMUM	MAXIMUM
(a) Obtaining a license or permit by misrepresentation, fraud or error (Section 465.016(1)(a), F.S.) (Section 465.023(1)(a), F.S.)	$10,000 fine for each count and Revocation	$10,000 fine for each count and Revocation
(b) Procuring a license or permit by false representation (Section 465.016(1)(b), F.S.) (Section 465.023(1)(b), F.S.	$10,000 fine for each count and Revocation	$10,000 fine for each count and Revocation
(c) Permitting unlicensed persons to practice pharmacy (Section 465.016(1)(c), F.S.)	$2,500 fine and 12 hours Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE)	Revocation
(d) Being unfit or incompetent to practice pharmacy (Section 465.016(1)(d), (m), F.S.)	$250 fine, indefinite suspension with PRN review and board appearance	Revocation or, at the licensee's discretion, voluntarily relinquishment with reinstatement under the terms and conditions approved by the board
(e) Violating laws		

governing the practice of pharmacy (Section 465.016(1)(e), F.S.) (Section 465.023(1)(c), F.S.)		
1. Chapter 465, F.S.:		
a. Failure to supervise registered pharmacy technician (Section 465.014, F.S.)	$250 fine and one (1) year probation and 12 hour Laws & Rules Course or MPJE	Revocation
b. Operating a pharmacy that is not registered (Section 465.015(1)(a), F.S.)	$500 per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice)	Revocation
c. Operating a pharmacy where an unlicensed and unsupervised person practices pharmacy (Section 465.015(1)(b), F.S.)	$5,000 fine and one (1) year probation	Revocation
d. Making a false or fraudulent statement to the board (Section 465.015(2)(a), F.S.)	$10,000 fine for each count	$10,000 fine for each count and Revocation
e. Practicing pharmacy as an inactive licensee (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $500/month	Revocation
f. Selling or dispensing drugs without a prescription (Section 465.015(2)(c), F.S.)		
(i) Non-scheduled legend drugs	$1,500 fine	Revocation
(ii) Scheduled (controlled substances) legend drugs	$5,000 fine and one (1) year probation	Revocation
g. Selling samples or complimentary drugs (Section 465.015(2)(d), F.S.)		
(i) Non-scheduled legend drugs	$1,500 fine	Revocation
(ii) Scheduled (controlled Substances) legend drugs	$5,000 fine and one (1) year probation	Revocation

h. Failure to notify the board of or not to have a prescription department manager or consultant pharmacist Sections 465.018, .019, .0193, .0196, or .0197, F.S. (Section 465.022(10), (11), F.S.)		
(i) Failure to notify (Section 465.018, F.S.)	Fine based on length of time prior to notifying board. $500 per month	$7,500 maximum (penalty requires notification or ceasing practice)
(ii) Failure to have prescription department manager or consultant pharmacist of record	Fine based on length of time prior to notifying board, $750 per month and one (1) year probation	Revocation
i. Failure to comply with required substitution of legend drug requirements (Sections 465.025(2), (3), (4), F.S.)	$500 fine and 12 hour Laws & Rules Course or MPJE	$2,500 fine
j. Failure to follow negative formulary requirements (Section 465.025(6), F.S.) (Rule 64B16-27.500, F.A.C.)	$1,000 fine and 12 hours Laws & Rules Course or MPJE	$2,500 fine and one (1) year probation
k. Failure to follow emergency prescription requirements (Section 465.0275, F.S.)	$500 fine	$1,000 fine and one (1) year probation
l. Engage in prohibited rebate scheme (Section 465.185, F.S.)	$1,500 fine	Revocation
m. Failure to comply with pharmacist dispensing requirements (Section 465.186, F.S.)		
(i) Failure to follow procedure, but dispense drug appearing on formulary (Section 465.186(3), F.S.) (Rule 64B16-27.210, F.A.C.)	$500 fine	$1,000 fine, one (1) year probation and suspension of right to dispense
(ii) Dispensing drug not on the formulary (Section 465.186(2), F.S.)	$1,500 fine	Revocation

(Rules 64B16-27.220, .230, F.A.C.)		
2. Chapter 499, F.S.		
a. Adulteration of a drug (Section 499.005(2), (3), F.S.) (Section 499.006, F.S.)	$1,000 fine	Revocation
b. Misbranding a drug (Section 499.005(2), (3), F.S.) (Section 499.007, F.S.)		
(i) Incomplete or inaccurate labeling (Section 499.007, F.S.) (Rule 64B16-28.108, F.A.C.)	$250 fine and 12 hour Laws & Rules Course or MPJE	$2,500 fine and one (1) year probation
(ii) Fraudulent misbranding of legend drugs (Section 499.007, F.S.)	$2,500 fine and one (1) year suspension	Revocation
c. Prescriptions Drug Pedigree	$500 fine and 12 hour Laws & Rules Course or MPJE	Revocation
d. Recordkeeping requirement	$500 fine and 12 hour Laws & Rules Course or MPJE	Revocation
e. Storage of drugs	$500 fine and 12 hour Laws & Course or MPJE	Revocation
3. Chapter 893, F.S. (Controlled substances)		
a. Filling a prescription for controlled substances that does not meet the requirements of Chapter 893, F.S. (Section 893.04(1)(b), F.S.)	$1,500 fine	$5,000 fine and one (1) year probation
b. Failing to retain prescription records for two (2) years (Section 893.04(1)(d), F.S.)	$1,000 fine	Revocation
c. Failing to appropriately label (Section 893.04(1)(e), F.S.)	$250 fine and 12 hour Laws & Rules Course or MPJE	$2,500 fine and one (1) year probation
d. Dispensing a Schedule II drug inappropriately with a	$5,000 fine and one (1) year probation	Revocation

non-written prescription (Section 893.04(1)(f), F.S.)		
e. Inappropriate refilling of Schedule III, IV, or V drugs (Section 893.04(1)(g), F.S.)	$1,750 fine and one (1) year probation	One (1) year suspension
f. Receiving controlled substances without an appropriate order form (Section 893.06(1), F.S.)	$2,500 fine	Revocation
g. Unlawful possession of controlled substances (Section 893.06(2), F.S.)	$2,500 fine and one (1) year probation	Revocation
h. Failure to take a biennial inventory (Section 893.07(1)(a), (2), (3), (4), (5), F.S.)	$1,000 fine	$2,500 fine and one (1) year probation
i. Failure to maintain a complete and accurate record of controlled substances (Section 893.07(1)(b), (2), (3), (4), (5), F.S.)	$1,000 fine and one (1) year probation	Revocation
j. Dispensing controlled substances in other than good faith (Section 893.08(3)(b), F.S.)	$5,000 fine and one (1) year probation	Revocation
k. Inappropriate selling of Schedule V controlled substance (Section 893.08(3)(c), F.S.)	$1,500 fine and one (1) year probation	One (1) year suspension
l. Unlawful possession of controlled substance (Section 893.13, F.S.)	$5,000 fine and two (2) years probation	Revocation
4. Violation of Federal Drug Abuse Act 21 U. S. C. 821 et seq.	$500 fine and one (1) year probation	Revocation
(f) Criminal conviction related to pharmacy (Section 465.016(1)(f), F.S.) (Section 465.023(1)(d), F.S.)		

(i) Misdemeanor	$1,000 fine	Revocation
(ii) Felony	One (1) year suspension, two (2) years probation & $5,000 fine	Revocation
(g) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6), F.S. or Section 465.025, F.S., or compounding,dispensing or distributing legend drugs outside professional practice of pharmacy (Section 465.016(1)(g), F.S.) (Section 465.016(1)(i), F.S.)	$250 fine and and complete approved CE course in the prevention of medication errors of no less than eight (8) hours	Revocation
(h) Filing a false report or failing to file a report required by law		
1. Knowing violation	$2,000 fine and one (1) year probation	Revocation
2. Negligent violation	Reprimand	One (1) year probation and $1,000 fine
(i) Failure to make prescription price information available (Section 465.016(1)(k), F.S.)	$250 fine and 12 hour Laws & Rules Course or MPJE	$1,000 fine and one (1) year probation
(j) Improperly placing returned drugs into the stock of a pharmacy (Section 465.016(1)(l), F.S.)	$1,500 fine	$3,000 fine and one (1) year probation
(k) Violating a rule or order of the board or Department (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy		
a. Rules 64B16-28.101 to 64B16-28.1035, F.A.C. Rule 64B16-27.100, F.A.C. Rule 64B16-28.109, F.A.C.	$500 fine and 12 hour Laws & Rules or MPJE	One (1) year probation and $2,000 fine

Rule 64B16-27.103, F.A.C. Rule 64B16-27.104, F.A.C. Rule 64B16-26.400, F.A.C. Rule 64B16-26.2032, F.A.C. Rule 64B16-28.1081, F.A.C. Rule 64B16-26.301, F.A.C. Rule 64B16-28.114, F.A.C. Rule 64B16-27.105, F.A.C. Rule 64B16-27.211, F.A.C. Rule 64B16-28.113, F.A.C. Rule 64B16-28.2021, F.A.C. Rule 64B16-28.603, F.A.C.		
b. Rule 64B16-28.102, F.A.C.	Suspension until compliance	Revocation
c. Rule 64B16-27.101, F.A.C. (counterfeit drugs)	$1,000 fine for dispensing	Revocation
d. Rule 64B16-28.110, F.A.C. (outdated pharmaceuticals)	$500 fine for possession $1,000 fine for dispensing	Revocation
e. Rules 64B16-28.301, 64B16-28.303, F.A.C. (destruction of controlled substances) (violations)	$500 fine and 12 hour Laws & Rules or MPJE	Revocation
f. Rule 64B16-26.300, F.A.C (Serving as consultant pharmacist without being licensed as a consultant pharmacist)	$500 per month up to $5,000 fine (fine based upon the length of time the person is serving as a consultant without being licensed as a consultant pharmacist)	Revocation
g. Rule 64B16-28.140, F.A.C. (Data processing systems)	$1,000 fine	Revocation
h. Rule 64B16-28.120, F.A.C. (Location of legend drugs)	$1,000 fine	Revocation
i. Practicing nuclear pharmacy without being licensed as a nuclear pharmacist (Rule 64B16-26.303, F.A.C.)	$500 per month up to $5,000 fine (fine based upon the length of time the person is practicing without being licensed as a nuclear pharmacist)	Revocation
j. Failure to follow technical requirements (Rules 64B16-28.901 and 64B16-28.902, F.A.C.)	One (1) year probation and $1,000 fine	Revocation
k. Rules 64B16-28.202 and	$1,500 fine	Revocation

64B16-28.203, F.A.C. (transfer of prescription files and drugs)		
l. Failure to complete the required continuing education during the biennial licensure period. (Rule 64B16-26.103, F.A.C.)		
1. Failure to complete less than ten (10) hours	$500 fine	$1,500 fine
2. Failure to complete ten (10) or more hours In addition, licensees shall take two additional hours of continuing edcuation for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.	$1,000 fine	$2,500 fine
m. Failure to maintain program requirements for certification, training, or continuing education programs or providers. (Rule 64B16-26.601, F.A.C.)	$500 fine	Revocation
n. Failure to retain continuing education records. (Rule 64B16-26.603, F.A.C.)	$250 fine	$1,500 fine
o. Failure to practice in accordance with established practice standards. (Rules 64B16-27.1001, .104, F.A.C.)		
1. Pharmacist	$500 fine	Revocation
2. Pharmacy Intern	$250 fine	Revocation
3. Permittee	$500 fine	Revocation
p. Failure to have current policies and procedures. (Rules 64B16-28.141, .450, F.A.C.)	$500 fine	Revocation
q. Failure to have or maintain standards for an automated pharmacy system in a community	$500 fine and 12 hours Laws & Rules MJPE	Revocation

pharmacy. (Rule 64B16-28.141, F.A.C.)		
r. Failure to have or maintain standards for a central fill pharmacy. (Rule 64B16-28.450, F.A.C.)	$500 fine and 12 hour Laws & Rules or MJPE	Revocation
s. Failure to have or maintain standards for an institutional pharmacy. (Rules 64B16-28.602, .6021, .605, .606, .702, F.A.C.)	$500 fine and 12 hour Laws & Rules or MJPE	
t. Failuare to maintain or have standards for a special pharmacy. (Rules 64B16-28.800, .810, .820, .840, .850, .860, .870, F.A.C.)	$500 fine and 12 hour Laws & Rules or MJPE	
u. Failure to maintain standards for animal control shelters	$500 Fine	Revocation
2. Violation of orders of Board or Department	$2,500 fine and one (1) year probation	Revocation
(l) License disciplined by another jurisdiction (Section 465.016(1)(h), F.S.)	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes	
(m) Failure to comply with Board's rule on patient counseling (Rules 64B16-27.800, .810, .820, F.A.C.)	$750 fine	$2,500 fine and, one year probation
(n) Abandoning or allowing permit to become null and void after notice of disciplinary proceedings. (Section 465.018(3), F.S.)	Revocation	Revocation
(o) Violating 456.072, F.S.		
1. Making misleading, deceptive, or fraudulent representations in or related to the practice of the licensee's profession.	$1,500 fine and one (1) year probation	Revocation
2. Intentionally violating	$2,500 fine and two (2) years	Revocation

any rule adopted by the Board or the Department.	probation	
3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession.		
(i) Misdemanor	$1,000 fine	Revocation
(ii) Felony	$3,000 fine and one (1) year probation	Revocation
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors.	$500 fine	$1,000 fine
5. Having a license or the authority to practice the regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure, stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license.	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation	
6. Having been found liable in a civil proceeding for	$3,000 fine	Revocation

knowingly filing a false report or complaint with the Department against another licensee.		
7. Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the Department or the Board.	Revocation or denial of license application	
8. Except as provided in Section 465.016, F.S., failing to report to the Department any person who the licensee knows is in violation of this part, the chapter regulating the alleged violator, or the rules of the Department or the Board.	$500 fine and one (1) year probation	Revocation
9. Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this part, the chapter regulating the profession, or the rules of the Department or the Board.	$2,000 fine	Revocation
10. Failing to perform any statutory or legal obligation placed upon a licensee.	$2,000 fine	Revocation
11. Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the	$2,500 fine and two (2) years probation	Revocation

capacity of a licensee.		
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession.	$10,000 fine and two (2) years probation	Revocation $10,000 fine and one (1) year suspension
13. Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party.	$3,000 fine and two (2) years probation	Revocation
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform.	$2,000 fine and two (2) years probation	Revocation
15. Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when required to perform them.	$2,000 fine and two (2) years probation	Revocation
16. Violating any provision of this part, the applicable professional practice act, a rule of the Department or the Board, or a lawful order of the Department or the Board, or failing to comply with a lawfully issued subpoena of the Department.	$1,000 fine	Revocation
17. Improperly interfering	$2,500 fine and two (2) years	Revocation

with an investigation or inspection authorized by statute, or with any disciplinary proceeding.	probation	
18. Failing to report to the board in writing within 30 days after the licensee has been convicted or found guilty or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction.	$1,000 fine	Revocation
19. Testing positive for any drug, as defined in Section 112.0455, F.S., on any confirmed preemployment or employer ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug.	$1,500 fine PRN evaluvation and two (2) years probation or compliance with PRN contract	Revocation
20. Being terminated from or failing to successfully complete an impaired practitioners treatment program. (Section 456.072(1)(hh), F.S.)	Suspension until successful completion or receipt of written confirmation of compliance with ongoing treatment and a fine of up to $1,000.	Revocation
21. Being convicted of, or entering a plea of guilty or nolo contendere to any misdemeanor or felony, regardless of adjudication, under 18 USC s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 USC ss. 1320a-7b, relating to the Medicaid program. (Section 456.072(1)(ii), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	
22. Failing to remit the sum owed to the state for overpayment from the Medicaid program pursuant to a final order, judgment, or settlement.	From a letter of concern to probation, and a fine of $500 to $5,000.	From a reprimand to revocation, and a fine of $2,500 to $5,000.

(Section 456.072(1)(jj), F.S.)		
23. Being terminated from the state Medicaid program, or any other state Medicaid program, or the federal Medicare program. (Section 456.072(1)(kk), F.S.)	From a letter of concern to suspension, and a fine of $1,000 to $5,000.	From a reprimand to revocation, and a fine of $5,000 to $10,000.
24. Being convicted of, or entering into a plea of guilty or nolo contendere to any misdemeanor or felony, regardless of adjudication, which relates to health care fraud. (Section 456.072(1)(ll), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license.	

(3) The board shall be entitled to deviate from the above-mentioned guidelines upon a showing of aggravating or mitigating circumstances by clear and convincing evidence presented to the board prior to the imposition of a final penalty. The fact that an Administrative Law Judge of the Division of Administrative Hearings may or may not have been aware of the below-mentioned aggravating or mitigating circumstances prior to a recommendation of penalty in a Recommended Order shall not obviate the duty of the board to consider aggravating and mitigating circumstances brought to its attention prior to the issuance of a Final Order.

(a) Aggravating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the enhancement of a penalty beyond the maximum level of discipline in the guidelines shall include but not be limited to the following:

1. History of previous violations of the practice act and the rules promulgated thereto.

2. In the case of negligent acts, the magnitude and scope of the damage or potential damage inflicted upon the patient or the general public by the licensee's misfeasance.

3. Evidence of violation of professional practice acts in other jurisdictions wherein the licensee has been disciplined by the appropriate regulatory authority.

4. Violation of the provision of the practice act wherein a letter of guidance as provided in Section 456.073(3), F.S., has previously been issued to the licensee.

(b) Mitigating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the lessening of a penalty beyond the minimum level of discipline in the guidelines shall include but not be limited to the following:

1. In cases of negligent acts, the minor nature of the damage or potential damage to the patient's or the public's health, safety and welfare resulting from the licensee's misfeasance.

2. Lack of previous disciplinary history in this or any other jurisdiction wherein the licensee practices his profession.

3. Restitution of any monetary damage suffered by the patient.

4. The licensee's professional standing among his peers.

5. Steps taken by the licensee to insure the non-occurrence of similar violations in the future including continuing education.

6. The degree of financial hardship incurred by a licensee as a result of the imposition of fines or the suspension of his practice.

(4) All fines imposed by the Board shall be paid within a period of niney (90) days from the date of the final ordered entered by the Board. This time limitation may be modified by the Board for good cause shown in order to prevent undue hardship.

Rulemaking Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079 FS. History–New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, 9-26-12.

64B16-30.002 Minor Violations.

(1) The Board sets forth the following guidelines for use by Department investigators when a licensee is in noncompliance of an initial offense of a minor violation. The Board deems the following violations, depending upon severity, to be consistent with

Section 456.073(3), F.S.

(a) Outdated pharmaceuticals – Rule 64B16-28.110, F.A.C.

(b) Failure to meet regulation of daily operating hours – Rule 64B16-28.404, F.A.C.

(c) Generic substitution sign not displayed – Section 465.025(7), F.S.

(d) Information required on controlled substance prescriptions: practitioner's address, practitioner's DEA registration number, patient's address – Section 893.04, F.S.

(e) Failure to have certified by dispensing pharmacists the daily hard-copy printout or daily log – paragraph 64B16-28.140(3)(c) or (e), F.A.C.

(f) Failure to have pharmacy minimally equipped i.e. references, compounding equipment, and a current copy of the laws and rules governing the practice of pharmacy in the State of Florida – Rule 64B16-28.107, F.A.C.

(g) Failure to properly identify pharmacy technicians – Rule 64B16-27.410, F.A.C.

(h) Results of P&E quality assurance program not documented or available for inspection – paragraph 64B16-28.820(3)(d), F.A.C.

(i) Improper storage of legend drugs – Rule 64B16-28.120, F.A.C.

(j) Improper documentation of destruction of controlled substances – Rules 64B16-28.301, 64B16-28.303, F.A.C.

(k) Consultant pharmacist's monthly reports not current or available for inspection – Rule 64B16-28.501, subsection 64B16-28.702(2), F.A.C.

(l) Controlled substance prescription labels lack transfer crime warning labeling – paragraph 64B16-28.502(2)(c), F.A.C.

(2) The Department's investigator may issue a Notice of Deficiencies when the above conditions occur and the requirements of Section 456.073(3), F.S., are met. In such cases licensees shall correct the violation and respond to the investigator on forms provided by the Department and with other evidence of compliance as may be necessary, within 30 days, to certify current compliance. Failure to do so shall subject the licensee to further proceedings.

Rulemaking Authority 456.073(3), 465.005 FS. Law Implemented 456.073(3) FS. History–New 11-12-90, Formerly 21S-17.002, 21S-30.002, 61F10-30.002, 59X-30.002, Amended 12-9-98, 8-26-02.

64B16-30.003 Citations.

(1) Pursuant to Section 456.077, F.S., the Board sets forth in (3) of this rule those violations for which there is no substantial threat to the public health, safety and welfare; or, if there is a substantial threat to the public health, safety and welfare, such potential for harm has been removed prior to the issuance of the citation. Next to each violation is the fine to be imposed.

(2) Prior to issuance of the citation, the Department must confirm that the violation has been corrected or is in the process of being corrected. If the violation is a substantial threat to the public health, safety and welfare, such potential for harm must be removed prior to issuance of the citation.

(3) The following violations with accompanying fines may be disposed of by citation:

(a) Practicing pharmacy as an inactive licensee (465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $200/month or $5,000 maximum (penalty will require licensee to renew license or cease practice).
(b) Operating a pharmacy with an inactive permit (465.015(1)(a), F.S.)	$500 per month to a maximum of $5000 (penalty will require permittee to renew permit or cease practice).

(c) First time failure to complete the required continuing education during the biennial licensure period.(456.072(3), F.S.)

Failure to complete less than 10 hours	$500
Failure to complete 10 or more hours	$1000

In addition, licensees shall take two additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.

(d) Failure to timely pay a fine or costs imposed by a final order.	$500 per month late to a maximum of $5,000 (penalty will require permittee or licensee to also pay the original fine and/or costs).

(e) Failure to display any sign, license or permit required by statute or rule.	$500
(f) Failure to have any reference material required by statute or rule available.	$500
(g) Failure to notify the board of a change in a prescription department manager or consultant pharmacist.	Fine based on the length of time prior to notifying board. $200 a month to $5,000 maximum.
(h) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed, except as authorized in Section 465.019(6) or 465.025, F.S.; or dispensing a medication with dosage instructions different in any way than prescribed, provided that the medication was not used or ingested.	$250 fine, Completion of an approved CE course in the prevention of medication errors of no less than 8 hours.
(i) Tendering a check payable to the Board of Pharmacy or to the Department of Health that is dishonored by the Institution upon which it is drawn.	$100 fine plus payment of the check within 30 days.
(j) Failing to comply with the Educational course requirements for Human immunodeficiency virus and Aquired immune deficiency syndrome (HIV/AIDS), or medical errors	$500
(k) Failure to correct Minor violation as listed in Rule 64B16-30.002, F.A.C.	$250
(l) Failure to retain continuing education records	$250

(4) Once the citation becomes a final order, the citation and complaint become a public record pursuant to Chapter 119, F.S., unless otherwise exempt from the provisions thereof. The citation and complaint may be considered as aggravating circumstances in future disciplinary actions pursuant to paragraph 64B16-30.001(3)(a), F.A.C.

(5) The procedures described herein apply only for an initial offense of the alleged violation. Subsequent violation(s) of the same rule or statute shall require the procedures of Section 456.073, F.S., to be applied. In addition, should an initial offense for which a citation could be issued occur in conjunction with violations not described herein, then the procedures of Section 456.073, F.S., shall apply.

Rulemaking Authority 456.073, 456.077, 465.005 FS. Law Implemented 456.077 FS. History–New 12-22-91, Formerly 21S-30.003, 61F10-30.003, 59X-30.003, Amended 4-3-00, 1-2-02, 8-26-02, 1-12-03, 2-1-12.

64B16-30.0035 Mediation.

(1) "Mediation" means a process whereby a mediator appointed by the Department acts to encourage and facilitate resolution of a legally sufficient complaint. It is an informal and nonadversarial process with the objective of assisting the parties to reach a mutually acceptable agreement.

(2) The Board finds that mediation is an acceptable method of dispute resolution for the following violation as it is economic in

nature or can be remedied by the licensee: failure of the licensee to timely pay any assessed administrative fines or costs.

(3) A "mediator" means a person who is certified in mediation by the Florida Bar, the Florida Supreme Court, or the Division of Administrative Hearings.

Rulemaking Authority 456.078 FS. Law Implemented 456.078 FS. History–New 11-21-94, Formerly 59X-30.0035.

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Pharmaceutical Compounding—Sterile Preparations

U.S. PHARMACOPEIA
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⟨797⟩ PHARMACEUTICAL COMPOUNDING–STERILE PREPARATIONS

INTRODUCTION

The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from (1) microbial contamination (nonsterility), (2) excessive bacterial endotoxins, (3) variability in the intended strength of correct ingredients that exceeds either monograph limits for official articles (see "official" and "article" in the *General Notices and Requirements*) or 10% for nonofficial articles, (4) unintended chemical and physical contaminants, and (5) ingredients of inappropriate quality in compounded sterile preparations (CSPs). Contaminated CSPs are potentially most hazardous to patients when administered into body cavities, central nervous and vascular systems, eyes, and joints, and when used as baths for live organs and tissues. When CSPs contain excessive bacterial endotoxins (see *Bacterial Endotoxins Test* ⟨85⟩), they are potentially most hazardous to patients when administered into the central nervous system.

Despite the extensive attention in this chapter to the provision, maintenance, and evaluation of air quality, the avoidance of direct or physical contact contamination is paramount. It is generally acknowledged that direct or physical contact of critical sites of CSPs with contaminants, especially microbial sources, poses the greatest probability of risk to patients. Therefore, compounding personnel must be meticulously conscientious in precluding contact contamination of CSPs both within and outside ISO Class 5 (see *Table 1*) areas.

To achieve the above five conditions and practices, this chapter provides minimum practice and quality standards for CSPs of drugs and nutrients based on current scientific information and best sterile compounding practices. The use of technologies, techniques, materials, and procedures other than those described in this chapter is not prohibited so long as they have been proven to be equivalent or superior with statistical significance to those described herein. The standards in this chapter do not pertain to the *clinical administration* of CSPs to patients via application, implantation, infusion, inhalation, injection, insertion, instillation, and irrigation, which are the routes of administration. Four specific categories of CSPs are described in this chapter: low-risk level, medium-risk level, and high-risk level, and immediate use. Sterile compounding differs from nonsterile compounding (see *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩ and *Good Compounding Practices* ⟨1075⟩) primarily by requiring the maintenance of sterility when compounding exclusively with sterile ingredients and components (i.e., with immediate-use CSPs, low-risk level CSPs, and medium-risk level CSPs) and the achievement of sterility when compounding with nonsterile ingredients and components (i.e., with high-risk level CSPs). Some differences between standards for sterile compounding in this chapter and those for nonsterile compounding in *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩ include, but are not limited to, ISO-classified air environments (see *Table 1*); personnel garbing and gloving; personnel training and testing in principles and practices of aseptic manipulations and sterilization; environmental quality specifications and monitoring; and disinfection of gloves and surfaces of ISO Class 5 (see *Table 1*) sources.

Table 1. ISO Classification of Particulate Matter in Room Air
(limits are in particles of 0.5 µm and larger per cubic meter [current ISO] and cubic feet [former Federal Standard No. 209E, FS 209E])*

Class Name		Particle Count	
ISO Class	U.S. FS 209E	ISO, m^3	FS 209E, ft^3
3	Class 1	35.2	1
4	Class 10	352	10
5	Class 100	3,520	100
6	Class 1,000	35,200	1,000
7	Class 10,000	352,000	10,000
8	Class 100,000	3,520,000	100,000

*Adapted from former Federal Standard No. 209E, General Services Administration, Washington, DC, 20407 (September 11, 1992) and ISO 14644-1:1999, Cleanrooms and associated controlled environments—Part 1: Classification of air cleanliness. For example, 3,520 particles of 0.5 µm per m^3 or larger (ISO Class 5) is equivalent to 100 particles per ft^3 (Class 100) (1 m^3 = 35.2 ft^3).

The standards in this chapter are intended to apply to all persons who prepare CSPs and all places where CSPs are prepared (e.g., hospitals and other healthcare institutions, patient treatment clinics, pharmacies, physicians' practice facilities, and other locations and facilities in which CSPs are prepared, stored, and transported). Persons who perform sterile compounding include pharmacists, nurses, pharmacy technicians, and physicians. These terms recognize that most sterile compounding is performed by or under the supervision of pharmacists in pharmacies and also that this chapter applies to all healthcare personnel who prepare, store, and transport CSPs. For the purposes of this chapter, CSPs include any of the following:

(1) Compounded biologics, diagnostics, drugs, nutrients, and radiopharmaceuticals, including but not limited to the following dosage forms that must be sterile when they are administered to patients: aqueous bronchial and nasal inhalations, baths and soaks for live organs and tissues, injections (e.g., colloidal dispersions, emulsions, solutions, suspensions), irrigations for wounds and body cavities, ophthalmic drops and ointments, and tissue implants.

(2) Manufactured sterile products that are either prepared strictly according to the instructions appearing in manufacturers' approved labeling (product package inserts) or prepared differently than published in such labeling. [NOTE—The FDA states that "Compounding does not include mixing, reconstituting, or similar acts that are performed in accordance with the directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling" [21 USC 321 (k) and (m)]. However, the FDA-approved labeling (product package insert) rarely describes environmental quality (e.g., ISO Class air designation, exposure durations to non-ISO classified air, personnel garbing and gloving, and other aseptic precautions by which sterile products are to be prepared for administration). Beyond-use exposure and storage dates or times (see *General Notices and Requirements* and *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩) for sterile products that have been either opened or prepared for administration are not specified in all package inserts for all sterile products. Furthermore, when such durations are specified, they may refer to chemical stability and not necessarily to microbiological purity or safety.]

ORGANIZATION OF THIS CHAPTER

The sections in this chapter are organized to facilitate the practitioner's understanding of the fundamental accuracy and quality practices for preparing CSPs. They provide a

foundation for the development and implementation of essential procedures for the safe preparation of low-risk, medium-risk, and high-risk level CSPs and immediate-use CSPs, which are classified according to the potential for microbial, chemical, and physical contamination. The chapter is divided into the following main sections:

- Definitions
- Responsibility of Compounding Personnel
- CSP Microbial Contamination Risk Levels
- Personnel Training and Evaluation in Aseptic Manipulation Skills
- Immediate-Use CSPs
- Single-Dose and Multiple-Dose Containers
- Hazardous Drugs as CSPs
- Radiopharmaceuticals as CSPs
- Allergen Extracts as CSPs
- Verification of Compounding Accuracy and Sterility
- Environmental Quality and Control
- Suggested Standard Operating Procedures (SOPs)
- Elements of Quality Control
- Verification of Automated Compounding Devices (ACDs) for Parenteral Nutrition Compounding
- Finished Preparation Release Checks and Tests
- Storage and Beyond-Use Dating
- Maintaining Sterility, Purity, and Stability of Dispensed and Distributed CSPs
- Patient or Caregiver Training
- Patient Monitoring and Adverse Events Reporting
- Quality Assurance (QA) Program
- Abbreviations and Acronyms
- Appendices I–V

The requirements and recommendations in this chapter are summarized in *Appendix I*. A list of abbreviations and acronyms is included at the end of the main text, before the *Appendices*.

All personnel who prepare CSPs shall be responsible for understanding these fundamental practices and precautions, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

DEFINITIONS

Ante-Area—An ISO Class 8 (see *Table 1*) or better area where personnel hand hygiene and garbing procedures, staging of components, order entry, CSP labeling, and other high-particulate-generating activities are performed. It is also a transition area that (1) provides assurance that pressure relationships are constantly maintained so that air flows from clean to dirty areas and (2) reduces the need for the heating, ventilating, and air-conditioning (HVAC) control system to respond to large disturbances.[1]

Aseptic Processing (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩)—A mode of processing pharmaceutical and medical products that involves the separate sterilization of the product and of the package (containers–closures or packaging material for medical devices) and the transfer of the product into the container and its closure under at least ISO Class 5 (see *Table 1*) conditions.

Beyond-Use Date (BUD) (see *General Notices and Requirements* and *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩)—For the purpose of this chapter, the date or time after which a CSP shall not be stored or transported. The date is determined from the date or time the preparation is compounded.

Biological Safety Cabinet (BSC)—A ventilated cabinet for CSPs, personnel, product, and environmental protection having an open front with inward airflow for personnel protection, downward high-efficiency particulate air (HEPA)-filtered laminar airflow for product protection, and HEPA-filtered exhausted air for environmental protection.

Buffer Area—An area where the primary engineering control (PEC) is physically located. Activities that occur in this area include the preparation and staging of components and supplies used when compounding CSPs.

Clean Room (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩ and also the definition of *Buffer Area*)—A room in which the concentration of airborne particles is controlled to meet a specified airborne particulate cleanliness class. Microorganisms in the environment are monitored so that a microbial level for air, surface, and personnel gear are not exceeded for a specified cleanliness class.

Compounding Aseptic Containment Isolator (CACI)—A compounding aseptic isolator (CAI) designed to provide worker protection from exposure to undesirable levels of airborne drug throughout the compounding and material transfer processes and to provide an aseptic environment for compounding sterile preparations. Air exchange with the surrounding environment should not occur unless the air is first passed through a microbial retentive filter (HEPA minimum) system capable of containing airborne concentrations of the physical size and state of the drug being compounded. Where volatile hazardous drugs are prepared, the exhaust air from the isolator should be appropriately removed by properly designed building ventilation.

Compounding Aseptic Isolator (CAI)—A form of isolator specifically designed for compounding pharmaceutical ingredients or preparations. It is designed to maintain an aseptic compounding environment within the isolator throughout the compounding and material transfer processes. Air exchange into the isolator from the surrounding environment should not occur unless the air has first passed through a microbially retentive filter (HEPA minimum).[2]

Critical Area—An ISO Class 5 (see *Table 1*) environment.

Critical Site—A location that includes any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral and mucosal secretions), or touch contamination. Risk of microbial particulate contamination of the critical site increases with the size of the openings and exposure time.

Direct Compounding Area (DCA)—A critical area within the ISO Class 5 (see *Table 1*) primary engineering control (PEC) where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.

Disinfectant—An agent that frees from infection, usually a chemical agent but sometimes a physical one, and that destroys disease-causing pathogens or other harmful microorganisms but may not kill bacterial and fungal spores. It refers to substances applied to inanimate objects.

First Air—The air exiting the HEPA filter in a unidirectional air stream that is essentially particle free.

Hazardous Drugs—Drugs are classified as hazardous if studies in animals or humans indicate that exposures to them have a potential for causing cancer, development or reproductive toxicity, or harm to organs. (See current NIOSH publication.)

Labeling [see *General Notices and Requirements* and 21 USC 321 (k) and (m)]—A term that designates all labels and other written, printed, or graphic matter on an immediate container of an article or preparation or on, or in, any package or wrapper in which it is enclosed, except any outer shipping container. The term "label" designates that part of the labeling on the immediate container.

[1] See *American Society of Heating, Refrigerating and Air-Conditioning Engineers, Inc. (ASHRAE), Laboratory Design Guide.*

[2] *CETA Applications Guide for the Use of Compounding Isolators in Compounding Sterile Preparations in Healthcare Facilities,* CAG-001-2005, Controlled Environment Testing Association (CETA), November 8, 2005.

Media-Fill Test (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩)—A test used to qualify aseptic technique of compounding personnel or processes and to ensure that the processes used are able to produce sterile product without microbial contamination. During this test, a microbiological growth medium such as Soybean–Casein Digest Medium is substituted for the actual drug product to simulate admixture compounding.[3] The issues to consider in the development of a media-fill test are media-fill procedures, media selection, fill volume, incubation, time and temperature, inspection of filled units, documentation, interpretation of results, and possible corrective actions required.

Multiple-Dose Container (see *General Notices and Requirements* and *Containers for Injections* under *Injections* ⟨1⟩)—A multiple-unit container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives. The beyond-use date (BUD) for an opened or entered (e.g., needle-punctured) multiple-dose container with antimicrobial preservatives is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩), unless otherwise specified by the manufacturer.

Negative Pressure Room—A room that is at a lower pressure than the adjacent spaces and, therefore, the net flow of air is *into* the room.[1]

Pharmacy Bulk Package (see *Containers for Injections* under *Injections* ⟨1⟩)—A container of a sterile preparation for parenteral use that contains many single doses. The contents are intended for use in a pharmacy admixture program and are restricted to the preparation of admixtures for infusion or, through a sterile transfer device, for the filling of empty sterile syringes. The closure shall be penetrated only one time after constitution with a suitable sterile transfer device or dispensing set, which allows measured dispensing of the contents. The pharmacy bulk package is to be used only in a suitable work area such as a laminar flow hood (or an equivalent clean air compounding area).

Where a container is offered as a pharmacy bulk package, the label shall (a) state prominently "Pharmacy Bulk Package—Not for Direct Infusion," (b) contain or refer to information on proper techniques to help ensure safe use of the product, and (c) bear a statement limiting the time frame in which the container may be used once it has been entered, provided it is held under the labeled storage conditions.

Primary Engineering Control (PEC)—A device or room that provides an ISO Class 5 (see *Table 1*) environment for the exposure of critical sites when compounding CSPs. Such devices include, but may not be limited to, laminar airflow workbenches (LAFWs), biological safety cabinets (BSCs), compounding aseptic isolators (CAIs), and compounding aseptic containment isolators (CACIs).

Preparation—A preparation, or a CSP, that is a sterile drug or nutrient compounded in a licensed pharmacy or other healthcare-related facility pursuant to the order of a licensed prescriber; the article may or may not contain sterile products.

Product—A commercially manufactured sterile drug or nutrient that has been evaluated for safety and efficacy by the FDA. Products are accompanied by full prescribing information, which is commonly known as the FDA-approved manufacturer's labeling or product package insert.

Positive Pressure Room—A room that is at a higher pressure than the adjacent spaces and, therefore, the net airflow is *out of* the room.[1]

Single-Dose Container (see *General Notices and Requirements* and *Containers for Injections* under *Injections* ⟨1⟩)—A single-dose container is a single-unit container for articles (see *General Notices and Requirements*) or preparations intended for parenteral administration only. It is intended for a single use. A single-dose container is labeled as such. Examples of single-dose containers include prefilled syringes, cartridges, fusion-sealed containers, and closure-sealed containers when so labeled.

Segregated Compounding Area—A designated space, either a demarcated area or room, that is restricted to preparing low-risk level CSPs with 12-hour or less BUD. Such area shall contain a device that provides unidirectional airflow of ISO Class 5 (see *Table 1*) air quality for preparation of CSPs and shall be void of activities and materials that are extraneous to sterile compounding.

Sterilizing Grade Membranes—Membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* per square centimeter of membrane surface under a pressure of not less than 30 psi (2.0 bar). Such filter membranes are nominally at 0.22-µm or 0.2-µm nominal pore size, depending on the manufacturer's practice.

Sterilization by Filtration—Passage of a fluid or solution through a sterilizing grade membrane to produce a sterile effluent.

Terminal Sterilization—The application of a lethal process (e.g., steam under pressure or autoclaving) to sealed containers for the purpose of achieving a predetermined sterility assurance level of usually less than 10^{-6}, or a probability of less than one in one million of a nonsterile unit.[3]

Unidirectional Flow (see footnote 3)—An airflow moving in a single direction in a robust and uniform manner and at sufficient speed to reproducibly sweep particles away from the critical processing or testing area.

RESPONSIBILITY OF COMPOUNDING PERSONNEL

Compounding personnel are responsible for ensuring that CSPs are accurately identified, measured, diluted, and mixed and are correctly purified, sterilized, packaged, sealed, labeled, stored, dispensed, and distributed. These performance responsibilities include maintaining appropriate cleanliness conditions and providing labeling and supplementary instructions for the proper clinical administration of CSPs.

Compounding supervisors shall ensure, through either direct measurement or appropriate information sources, that specific CSPs maintain their labeled strength within monograph limits for *USP* articles, or within 10% if not specified, until their BUDs. All CSPs are prepared in a manner that maintains sterility and minimizes the introduction of particulate matter.

A written quality assurance procedure includes the following in-process checks that are applied, as appropriate, to specific CSPs: accuracy and precision of measuring and weighing; the requirement for sterility; methods of sterilization and purification; safe limits and ranges for strength of ingredients, bacterial endotoxins, and particulate matter; pH; labeling accuracy and completeness; BUD assignment; and packaging and storage requirements. The dispenser shall, when appropriate and practicable, obtain and evaluate results of testing for identity, strength, purity, and sterility before a CSP is dispensed. Qualified licensed healthcare professionals who supervise compounding and dispensing of CSPs shall ensure that the following objectives are achieved:

1. Compounding personnel are adequately skilled, educated, instructed, and trained to correctly perform and document the following activities in their sterile compounding duties:
   a. perform antiseptic hand cleansing and disinfection of nonsterile compounding surfaces;
   b. select and appropriately don protective garb;
   c. maintain or achieve sterility of CSPs in ISO Class 5 (see *Table 1*) PEC devices and protect personnel and compounding environments from contamination by radioactive, cytotoxic, and chemotoxic

[3] U.S. Food and Drug Administration, Guidance for Industry, *Sterile Drug Products Produced by Aseptic Processing—Current Good Manufacturing Practice*, September 2004.

drugs (see *Hazardous Drugs as CSPs* and *Radiopharmaceuticals as CSPs*);
   d. identify, weigh, and measure ingredients; and
   e. manipulate sterile products aseptically, sterilize high-risk level CSPs, and label and quality inspect CSPs.
2. Ingredients have their correct identity, quality, and purity.
3. Opened or partially used packages of ingredients for subsequent use in CSPs are properly stored under restricted access conditions in the compounding facility. Such packages cannot be used when visual inspection detects unauthorized breaks in the container, closure, and seal; when the contents do not possess the expected appearance, aroma, and texture; when the contents do not pass identification tests specified by the compounding facility; and when either the BUD or expiration date has been exceeded.
4. Water-containing CSPs that are nonsterile during any phase of the compounding procedure are sterilized within 6 hours after completing the preparation in order to minimize the generation of bacterial endotoxins.
5. Sterilization methods achieve sterility of CSPs while maintaining the labeled strength of active ingredients and the physical integrity of packaging.
6. Measuring, mixing, sterilizing, and purifying devices are clean, appropriately accurate, and effective for their intended use.
7. Potential harm from added substances and differences in rate and extent of bioavailability of active ingredients for other than oral route of administration are carefully evaluated before such CSPs are dispensed and administered.
8. Packaging selected for CSPs is appropriate to preserve the sterility and strength until the BUD.
9. While being used, the compounding environment maintains the sterility or the presterilization purity, whichever is appropriate, of the CSP.
10. Labels on CSPs list the names and amounts or concentrations of active ingredients, and the labels or labeling of injections (see *Preservation, Packaging, Storage, and Labeling* in the *General Notices and Requirements*) list the names and amounts or concentrations of all ingredients (see *Injections* ⟨1⟩). Before being dispensed or administered, the clarity of solutions is visually confirmed; also, the identity and amounts of ingredients, procedures to prepare and sterilize CSPs, and specific release criteria are reviewed to ensure their accuracy and completeness.
11. BUDs are assigned on the basis of direct testing or extrapolation from reliable literature sources and other documentation (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).
12. Procedures for measuring, mixing, dilution, purification, sterilization, packaging, and labeling conform to the correct sequence and quality established for the specified CSP.
13. Deficiencies in compounding, labeling, packaging, and quality testing and inspection can be rapidly identified and corrected.
14. When time and personnel availability so permit, compounding manipulations and procedures are separated from postcompounding quality inspection and review before CSPs are dispensed.

This chapter emphasizes the need to maintain high standards for the quality and control of processes, components, and environments and for the skill and knowledge of personnel who prepare CSPs. The rigor of in-process quality-control checks and of postcompounding quality inspection and testing increases with the potential hazard of the route of administration. For example, nonsterility, excessive bacterial endotoxin contamination, large errors in strength of correct ingredients, and incorrect ingredients in CSPs are potentially more dangerous to patients when the CSPs are administered into the vascular and central nervous systems than when administered by most other routes.

CSP MICROBIAL CONTAMINATION RISK LEVELS

The three contamination categories for CSPs described in this section are assigned primarily according to the potential for microbial contamination during the compounding of low-risk level CSPs and medium-risk level CSPs or the potential for not sterilizing high-risk level CSPs, any of which would subject patients to risk of harm, including death. High-risk level CSPs must be sterilized before being administered to patients. The appropriate risk level—low, medium, or high—is assigned according to the corresponding probability of contaminating a CSP with (1) microbial contamination (e.g., microbial organisms, spores, endotoxins) and (2) chemical and physical contamination (e.g., foreign chemicals, physical matter). Potential sources of contamination include, but are not limited to, solid and liquid matter from compounding personnel and objects; nonsterile components employed and incorporated before terminal sterilization; inappropriate conditions within the restricted compounding environment; prolonged presterilization procedures with aqueous preparations; and nonsterile dosage forms used to compound CSPs.

The characteristics described below for low-, medium-, and high-risk level CSPs are intended as a guide to the breadth and depth of care necessary in compounding, but they are neither exhaustive nor prescriptive. The licensed healthcare professionals who supervise compounding are responsible for determining the procedural and environmental quality practices and attributes that are necessary for the risk level they assign to specific CSPs.

These risk levels apply to the quality of CSPs immediately after the final aseptic mixing or filling or immediately after the final sterilization, unless precluded by the specific characteristics of the preparation. Upon subsequent storage and shipping of freshly finished CSPs, an increase in the risks of chemical degradation of ingredients, contamination from physical damage to packaging, and permeability of plastic and elastomeric packaging is expected. In such cases, compounding personnel are responsible for considering the potential additional risks to the integrity of CSPs when assigning BUDs. The pre-administration storage duration and temperature limits specified in the following subsections apply in the absence of direct sterility testing results that justify different limits for specific CSPs.

Low-Risk Level CSPs

CSPs compounded under all the following conditions are at a low risk of contamination.

Low-Risk Conditions—

1. The CSPs are compounded with aseptic manipulations entirely within ISO Class 5 (see *Table 1*) or better air quality using only sterile ingredients, products, components, and devices.
2. The compounding involves only transfer, measuring, and mixing manipulations using not more than three commercially manufactured packages of sterile products and not more than two entries into any one sterile container or package (e.g., bag, vial) of sterile product or administration container/device to prepare the CSP.
3. Manipulations are limited to aseptically opening ampuls, penetrating disinfected stoppers on vials with sterile needles and syringes, and transferring sterile liquids in sterile syringes to sterile administration devices, package containers of other sterile products, and containers for storage and dispensing.

4. For a low-risk level preparation, in the absence of passing a sterility test (see *Sterility Tests* ⟨71⟩), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 48 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 14 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between –25° and –10°.

Examples of Low-Risk Compounding—

1. Single-volume transfers of sterile dosage forms from ampuls, bottles, bags, and vials using sterile syringes with sterile needles, other administration devices, and other sterile containers. The solution content of ampuls should be passed through a sterile filter to remove any particles.
2. Simple aseptic measuring and transferring with not more than three packages of manufactured sterile products, including an infusion or diluent solution to compound drug admixtures and nutritional solutions.

Low-Risk Level CSPs with 12-Hour or Less BUD—If the PEC is a CAI or CACI that does not meet the requirements described in *Placement of Primary Engineering Controls* or is a laminar airflow workbench (LAFW) or a biological safety cabinet (BSC) that cannot be located within an ISO Class 7 (see *Table 1*) buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician's order for a specific patient may be prepared, and administration of such CSPs shall commence within 12 hours of preparation or as recommended in the manufacturers' package insert, whichever is less. Low-risk level CSPs with a 12-hour or less BUD shall meet all of the following four criteria:

1. PECs (LAFWs, BSCs, CAIs, CACIs,) shall be certified and maintain ISO Class 5 (see *Table 1*) as described in *Facility Design and Environmental Controls* for exposure of critical sites and shall be in a segregated compounding area restricted to sterile compounding activities that minimize the risk of CSP contamination.
2. The segregated compounding area shall not be in a location that has unsealed windows or doors that connect to the outdoors or high traffic flow, or that is adjacent to construction sites, warehouses, or food preparation. Note that this list is not intended to be all inclusive.
3. Personnel shall follow the procedures described in *Personnel Cleansing and Garbing* and *Additional Personnel Requirements* prior to compounding. Sinks should not be located adjacent to the ISO Class 5 (see *Table 1*) PEC. Sinks should be separated from the immediate area of the ISO Class 5 (see *Table 1*) PEC device.
4. The specifications in *Cleaning and Disinfecting the Sterile Compounding Areas, Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures,* and *Viable and Nonviable Environmental Sampling (ES) Testing* shall be followed as described in the chapter.

Compounding personnel must recognize that the absence of an ISO Class 7 (see *Table 1*) buffer area environment in a general uncontrolled environment increases the potential of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization, and thus for patient harm, especially in critically ill or immunocompromised patients.

Quality Assurance—Quality assurance practices include, but are not limited to the following:

1. Routine disinfection and air quality testing of the direct compounding environment to minimize microbial surface contamination and maintain ISO Class 5 (see *Table 1*) air quality.
2. Visual confirmation that compounding personnel are properly donning and wearing appropriate items and types of protective garments, including eye protection and face masks.
3. Review of all orders and packages of ingredients to ensure that the correct identity and amounts of ingredients were compounded.
4. Visual inspection of CSPs to ensure the absence of particulate matter in solutions, the absence of leakage from vials and bags, and the accuracy and thoroughness of labeling.

Media-Fill Test Procedure—This test or an equivalent test is performed at least annually by each person authorized to compound in a low-risk level environment under conditions that closely simulate the most challenging or stressful conditions encountered during compounding of low-risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see *Table 1*) air quality environment, three sets of four 5-mL aliquots of sterile Soybean–Casein Digest Medium (also known as trypticase soy broth or trypticase soy agar [TSA]) are transferred with the same sterile 10-mL syringe and vented needle combination into separate sealed, empty, sterile 30-mL clear vials (i.e., four 5-mL aliquots into each of three 30-mL vials). Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*

Medium-Risk Level CSPs

When CSPs are compounded aseptically under *Low-Risk Conditions* and one or more of the following conditions exists, such CSPs are at a medium risk of contamination.

Medium-Risk Conditions—

1. Multiple individual or small doses of sterile products are combined or pooled to prepare a CSP that will be administered either to multiple patients or to one patient on multiple occasions.
2. The compounding process includes complex aseptic manipulations other than the single-volume transfer.
3. The compounding process requires unusually long duration, such as that required to complete dissolution or homogeneous mixing.
4. For a medium-risk preparation, in the absence of passing a sterility test (see *Sterility Tests* ⟨71⟩), the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 30 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 9 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between –25° and –10°.

Examples of Medium-Risk Compounding—

1. Compounding of total parenteral nutrition fluids using manual or automated devices during which there are multiple injections, detachments, and attachments of nutrient source products to the device or machine to deliver all nutritional components to a final sterile container.
2. Filling of reservoirs of injection and infusion devices with more than three sterile drug products and evacuation of air from those reservoirs before the filled device is dispensed.
3. Transfer of volumes from multiple ampuls or vials into one or more final sterile containers.

Quality Assurance—Quality assurance procedures for medium-risk level CSPs include all those for low-risk level CSPs, as well as a more challenging media-fill test passed annually or more frequently.

Media-Fill Test Procedure—This test or an equivalent test is performed at least annually under conditions that closely simulate the most challenging or stressful conditions encountered during compounding. Once begun, this test is completed without interruption. *Example of test procedure:* within an ISO Class 5 (see *Table 1*) air quality environment, six 100-mL aliquots of sterile Soybean–Casein Digest Medium are aseptically transferred by gravity through separate tubing sets into separate evacuated sterile containers. The six containers are then arranged as three pairs, and a sterile 10-mL syringe and 18-gauge needle combination is used to exchange two 5-mL aliquots of medium from one container to the other container in the pair. For example, after a 5-mL aliquot from the first container is added to the second container in the pair, the second container is agitated for 10 seconds, then a 5-mL aliquot is removed and returned to the first container in the pair. The first container is then agitated for 10 seconds, and the next 5-mL aliquot is transferred from it back to the second container in the pair. Following the two 5-mL aliquot exchanges in each pair of containers, a 5-mL aliquot of medium from each container is aseptically injected into a sealed, empty, sterile 10-mL clear vial, using a sterile 10-mL syringe and vented needle. Sterile adhesive seals are aseptically affixed to the rubber closures on the three filled vials, then the vials are incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*

High-Risk Level CSPs

CSPs compounded under any of the following conditions are either contaminated or at a high risk to become contaminated.

High-Risk Conditions—

1. Nonsterile ingredients, including manufactured products not intended for sterile routes of administration (e.g., oral), are incorporated or a nonsterile device is employed before terminal sterilization.
2. Any of the following are exposed to air quality worse than ISO Class 5 (see *Table 1*) for more than 1 hour (see *Immediate-Use CSPs*):
   - sterile contents of commercially manufactured products,
   - CSPs that lack effective antimicrobial preservatives, and
   - sterile surfaces of devices and containers for the preparation, transfer, sterilization, and packaging of CSPs.
3. Compounding personnel are improperly garbed and gloved (see *Personnel Cleansing and Use of Barrier Protective Equipment*).
4. Nonsterile water-containing preparations are stored for more than 6 hours before being sterilized.
5. It is assumed, and not verified by examination of labeling and documentation from suppliers or by direct determination, that the chemical purity and content strength of ingredients meet their original or compendial specifications in unopened or in opened packages of bulk ingredients (see *Ingredient Selection* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩).

For a sterilized high-risk level preparation, in the absence of passing a sterility test, the storage periods cannot exceed the following time periods: before administration, the CSPs are properly stored and are exposed for not more than 24 hours at controlled room temperature (see *General Notices and Requirements*), for not more than 3 days at a cold temperature (see *General Notices and Requirements*), and for 45 days in solid frozen state between –25° and –10°. [NOTE—Sterility tests for autoclaved CSPs are not required unless they are prepared in batches of more than 25 units.]

All nonsterile measuring, mixing, and purifying devices are rinsed thoroughly with sterile, pyrogen-free water, and then thoroughly drained or dried immediately before use for high-risk compounding. All high-risk level CSP solutions subjected to terminal sterilization are prefiltered by passing through a filter with a nominal pore size not larger than 1.2 µm preceding or during filling into their final containers to remove particulate matter. Sterilization of high-risk level CSPs by filtration shall be performed with a sterile 0.2-µm or 0.22-µm nominal pore size filter entirely within an ISO Class 5 (see *Table 1*) or superior air quality environment.

Examples of High-Risk Conditions—

1. Dissolving nonsterile bulk drug and nutrient powders to make solutions that will be terminally sterilized.
2. Exposing the sterile ingredients and components used to prepare and package CSPs to room air quality worse than ISO Class 5 (see *Table 1*) for more than 1 hour (see *Immediate-Use CSPs*).
3. Measuring and mixing sterile ingredients in nonsterile devices before sterilization is performed.
4. Assuming, without appropriate evidence or direct determination, that packages of bulk ingredients contain at least 95% by weight of their active chemical moiety and have not been contaminated or adulterated between uses.

Quality Assurance—Quality assurance procedures for high-risk level CSPs include all those for low-risk level CSPs. In addition, a media-fill test that represents high-risk level compounding is performed semiannually by each person authorized to compound high-risk level CSPs.

Media-Fill Test Procedure for CSPs Sterilized by Filtration—This test or an equivalent test is performed under conditions that closely simulate the most challenging or stressful conditions encountered when compounding high-risk level CSPs. Once begun, this test is completed without interruption. *Example of test procedure* (in the following sequence):

1. Dissolve 3 g of nonsterile commercially available Soybean–Casein Digest Medium in 100 mL of nonbacteriostatic water to make a 3% nonsterile solution.
2. Draw 25 mL of the medium into each of three 30-mL sterile syringes. Transfer 5 mL from each syringe into separate sterile 10-mL vials. These vials are the positive controls to generate exponential microbial growth, which is indicated by visible turbidity upon incubation.
3. Under aseptic conditions and using aseptic techniques, affix a sterile 0.2-µm or 0.22-µm nominal pore size filter unit and a 20-gauge needle to each syringe. Inject the next 10 mL from each syringe into three separate 10-mL sterile vials. Repeat the process for three more vials. Label all vials, affix sterile adhesive seals to the closure of the nine vials, and incubate them at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Inspect for microbial growth over 14 days as described in *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*

PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATION SKILLS

Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through audio–video instructional sources and professional publications in the theoretical principles and practical skills of aseptic manipulations and in achieving and maintaining ISO Class 5 (see *Table 1*) environmental conditions before they begin to prepare CSPs. Compounding personnel shall perform didactic review and pass written and media-fill testing of aseptic manipulative skills initially, at least annually thereafter for low- and medium-risk level compounding, and semiannually for high-risk level compounding. Compounding personnel who fail written tests or whose media-fill test vials result in gross microbial colonization shall be immediately re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

Media-Fill Challenge Testing—The skill of personnel to aseptically prepare CSPs may be evaluated using sterile fluid bacterial culture media-fill verification[3] (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare particular risk level CSPs and when sterilizing high-risk level CSPs. Media-fill challenge tests that simulate high-risk level compounding are also used to verify the capability of the compounding environment and process to produce a sterile preparation.

Commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see *Sterility Tests* ⟨71⟩), shall be able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Failure is indicated by visible turbidity in the medium on or before 14 days.

IMMEDIATE-USE CSPs

The immediate-use provision is intended only for those situations where there is a need for emergency or immediate patient administration of a CSP. Such situations may include cardiopulmonary resuscitation, emergency room treatment, preparation of diagnostic agents, or critical therapy where the preparation of the CSP under conditions described for *Low-Risk Level CSPs* subjects the patient to additional risk due to delays in therapy. Immediate-use CSPs are not intended for storage for anticipated needs or batch compounding. Preparations that are medium-risk level and high-risk level CSPs shall not be prepared as immediate-use CSPs.

Immediate-use CSPs are exempt from the requirements described for *Low-Risk Level CSPs* only when all of the following criteria are met:

1. The compounding process involves simple transfer of not more than three commercially manufactured packages of sterile nonhazardous products or diagnostic radiopharmaceutical products from the manufacturers' original containers and not more than two entries into any one container or package (e.g., bag, vial) of sterile infusion solution or administration container/device. For example, anti-neoplastics shall not be prepared as immediate-use CSPs because they are hazardous drugs.
2. Unless required for the preparation, the compounding procedure is a continuous process not to exceed 1 hour.
3. During preparation, aseptic technique is followed and, if not immediately administered, the finished CSP is under continuous supervision to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, mix-ups with other CSPs, and direct contact of outside surfaces.
4. Administration begins not later than 1 hour following the start of the preparation of the CSP.
5. Unless immediately and completely administered by the person who prepared it or immediate and complete administration is witnessed by the preparer, the CSP shall bear a label listing patient identification information, the names and amounts of all ingredients, the name or initials of the person who prepared the CSP, and the exact 1-hour BUD and time.
6. If administration has not begun within 1 hour following the start of preparing the CSP, the CSP shall be promptly, properly, and safely discarded.

Compounding in worse than ISO Class 5 (see *Table 1*) conditions increases the likelihood of microbial contamination, and administration durations of microbially contaminated CSPs exceeding a few hours increase the potential for clinically significant microbial colonization and thus for patient harm, especially in critically ill or immunocompromised patients.

SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS

Opened or needle-punctured single-dose containers, such as bags, bottles, syringes, and vials of sterile products and CSPs shall be used within 1 hour if opened in worse than ISO Class 5 (see *Table 1*) air quality (see *Immediate-Use CSPs*), and any remaining contents must be discarded. Single-dose vials exposed to ISO Class 5 (see *Table 1*) or cleaner air may be used up to 6 hours after initial needle puncture. Opened single-dose ampuls shall not be stored for any time period. Multiple-dose containers (e.g., vials) are formulated for removal of portions on multiple occasions because they usually contain antimicrobial preservatives. The BUD after initially entering or opening (e.g., needle-punctured) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩) unless otherwise specified by the manufacturer.

HAZARDOUS DRUGS AS CSPs

Although the potential therapeutic benefits of compounded sterile hazardous drug preparations generally outweigh the risks of their adverse effects in ill patients, exposed healthcare workers risk similar adverse effects with no therapeutic benefit. Occupational exposure to hazardous drugs can result in (1) acute effects, such as skin rashes; (2) chronic effects, including adverse reproductive events; and (3) possibly cancer (see Appendix A of NIOSH Publication no. 2004-165).

Hazardous drugs shall be prepared for administration only under conditions that protect the healthcare workers and other personnel in the preparation and storage areas. Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure. Many hazardous drugs have sufficient vapor pressures that allow volatilization at room temperature; thus storage is preferably within a containment area such as a negative pressure room. The storage area should have sufficient gen-

eral exhaust ventilation, at least 12 air changes per hour (ACPH)[4] to dilute and remove any airborne contaminants.

Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparation for administration, and disposal. Hazardous drugs shall be prepared in an ISO Class 5 (see *Table 1*) environment with protective engineering controls in place and following aseptic practices specified for the appropriate contamination risk levels defined in this chapter. Access shall be limited to areas where drugs are stored and prepared to protect persons not involved in drug preparation.

All hazardous drugs shall be prepared in a BSC[5] or a CACI that meets or exceeds the standards for CACI in this chapter. The ISO Class 5 (see *Table 1*) BSC or CACI shall be placed in an ISO Class 7 (see *Table 1*) area that is physically separated (i.e., a different area from other preparation areas) and optimally has not less than 0.01-inch water column negative pressure to adjacent positive pressure ISO Class 7 (see *Table 1*) or better ante-areas, thus providing inward airflow to contain any airborne drug. A pressure indicator shall be installed that can be readily monitored for correct room pressurization. The BSC and CACI optimally should be 100% vented to the outside air through HEPA filtration.

If a CACI that meets the requirements of this chapter is used outside of a buffer area, the compounding area shall maintain a minimum negative pressure of 0.01-inch water column and have a minimum of 12 ACPHs.

When closed-system vial-transfer devices (CSTDs) (i.e., vial-transfer systems that allow no venting or exposure of hazardous substance to the environment) are used, they shall be used within the ISO Class 5 (see *Table 1*) environment of a BSC or CACI. The use of a CSTD is preferred because of their inherent closed system process. In facilities that prepare a low volume of hazardous drugs, the use of two tiers of containment (e.g., CSTD within a BSC or CACI that is located in a non-negative pressure room) is acceptable.

Appropriate personnel protective equipment (PPE) shall be worn when compounding in a BSC or CACI and when using CSTD devices. PPE should include gowns, face masks, eye protection, hair covers, shoe covers or dedicated shoes, double gloving with sterile chemo-type gloves, and compliance with manufacturers' recommendations when using a CACI.

All personnel who compound hazardous drugs shall be fully trained in the storage, handling, and disposal of these drugs. This training shall occur prior to preparing or handling hazardous CSPs, and its effectiveness shall be verified by testing specific hazardous drugs preparation techniques. Such verification shall be documented for each person at least annually. This training shall include didactic overview of hazardous drugs, including mutagenic, teratogenic, and carcinogenic properties, and it shall include ongoing training for each new hazardous drug that enters the marketplace. Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs. The training shall include at least the following: (1) safe aseptic manipulation practices; (2) negative pressure techniques when utilizing a BSC or CACI; (3) correct use of CSTD devices; (4) containment, cleanup, and disposal procedures for breakages and spills; and (5) treatment of personnel contact and inhalation exposure.

NOTE—*Because standards of assay and unacceptable quantities of contamination of each drug have not been established in the literature, the following paragraph is a recommendation only. Future standards will be adopted as these assay methods are developed and proven.*

In order to ensure containment, especially in operations preparing large volumes of hazardous drugs, environmental sampling to detect uncontained hazardous drugs should be performed routinely (e.g., initially as a benchmark and at least every 6 months or more often as needed to verify containment). This sampling should include surface wipe sampling of the working area of BSCs and CACIs; counter tops where finished preparations are placed; areas adjacent to BSCs and CACIs, including the floor directly under the working area; and patient administration areas. Common marker hazardous drugs that can be assayed include cyclophosphamide, ifosfamide, methotrexate, and fluorouracil. If any measurable contamination (cyclophosphamide levels greater than 1.00 ng per cm^2 have been found to cause human uptake) is found by any of these quality assurance procedures, practitioners shall make the decision to identify, document, and contain the cause of contamination. Such action may include retraining, thorough cleaning (utilizing high-pH soap and water), and improving engineering controls. Examples of improving engineering controls are (1) venting BSCs or CACIs 100% to the outside, (2) implementing a CSTD, or (3) re-assessing types of BSCs or CACIs.

Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations. All personnel who perform routine custodial waste removal and cleaning activities in storage and preparation areas for hazardous drugs shall be trained in appropriate procedures to protect themselves and prevent contamination.

RADIOPHARMACEUTICALS AS CSPs

In the case of production of radiopharmaceuticals for positron emission tomography (PET), general test chapter *Radiopharmaceuticals for Positron Emission Tomography—Compounding* ⟨823⟩ supersedes this chapter. Upon release of a PET radiopharmaceutical as a finished drug product from a production facility, the further handling, manipulation, or use of the product will be considered compounding, and the content of this section and chapter is applicable.

For the purposes of this chapter, radiopharmaceuticals compounded from sterile components in closed sterile containers and with a volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container (see *Injections* ⟨1⟩) shall be designated as, and conform to, the standards for *Low-Risk Level CSPs.*

These radiopharmaceuticals shall be compounded using appropriately shielded vials and syringes in a properly functioning and certified ISO Class 5 (see *Table 1*) PEC located in an ISO Class 8 (see *Table 1*) or cleaner air environment to permit compliance with special handling, shielding, and negative air flow requirements.

Radiopharmaceutical vials designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 (see *Table 1*) environment, and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations. Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

Technetium-99m/molybdenum-99 generator systems shall be stored and eluted (operated) under conditions recommended by manufacturers and applicable state and federal regulations. Such generator systems shall be eluted in an ISO Class 8 (see *Table 1*) or cleaner air environment to permit special handling, shielding, and air flow requirements. To limit acute and chronic radiation exposure of inspecting personnel to a level that is as low as reasonably achievable (ALARA), direct visual inspection of radiopharmaceutical CSPs containing high concentrations of doses of radioactivity shall be conducted in accordance with ALARA.

Radiopharmaceuticals prepared as *Low-Risk Level CSPs with 12-Hour or Less BUD* shall be prepared in a segregated compounding area. A line of demarcation defining the segregated compounding area shall be established. Materials and garb exposed in a patient care and treatment area shall not

[4] Guidelines for Environmental Infection Control in Health-Care Facilities, Recommendations of CDC and the Healthcare Infection Control Practices Advisory Committee (HICPAC), MMWR, vol. 52, no. RR-10, June 6, 2003, figure 3, pg. 12.

[5] NSF/ANSI 49.

cross a line of demarcation into the segregated compounding area.

ALLERGEN EXTRACTS AS CSPs

Allergen extracts as CSPs are single-dose and multiple-dose *intradermal or subcutaneous injections* that are prepared by specially trained physicians and personnel under their direct supervision. Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all *CSP Microbial Contamination Risk Levels* in this chapter only when all of the following criteria are met:

1. The compounding process involves simple transfer via sterile needles and syringes of commercial sterile allergen products and appropriate sterile added substances (e.g., glycerin, phenol in sodium chloride injection).
2. All allergen extracts as CSPs shall contain appropriate substances in effective concentrations to prevent the growth of microorganisms. Nonpreserved allergen extracts shall comply with the appropriate CSP risk level requirements in the chapter.
3. Before beginning compounding activities, personnel perform a thorough hand-cleansing procedure by removing debris from under fingernails using a nail cleaner under running warm water followed by vigorous hand and arm washing to the elbows for at least 30 seconds with either nonantimicrobial or antimicrobial soap and water.
4. Compounding personnel don hair covers, facial hair covers, gowns, and face masks.
5. Compounding personnel perform antiseptic hand cleansing with an alcohol-based surgical hand scrub with persistent activity.
6. Compounding personnel don powder-free sterile gloves that are compatible with sterile 70% isopropyl alcohol (IPA) before beginning compounding manipulations.
7. Compounding personnel disinfect their gloves intermittently with sterile 70% IPA when preparing multiple allergen extracts as CSPs.
8. Ampul necks and vial stoppers on packages of manufactured sterile ingredients are disinfected by careful wiping with sterile 70% IPA swabs to ensure that the critical sites are wet for at least 10 seconds and allowed to dry before they are used to compound allergen extracts as CSPs.
9. The aseptic compounding manipulations minimize direct contact contamination (e.g., from glove fingertips, blood, nasal and oral secretions, shed skin and cosmetics, other nonsterile materials) of critical sites (e.g., needles, opened ampuls, vial stoppers).
10. The label of each multiple-dose vial (MDV) of allergen extracts as CSPs lists the name of one specific patient and a BUD and storage temperature range that is assigned based on manufacturers' recommendations or peer-reviewed publications.
11. Single-dose allergen extracts as CSPs shall not be stored for subsequent additional use.

Personnel who compound allergen extracts as CSPs must be aware of greater potential risk of microbial and foreign material contamination when allergen extracts as CSPs are compounded in compliance with the foregoing criteria instead of the more rigorous standards in this chapter for *CSP Microbial Contamination Risk Levels*. Although contaminated allergen extracts as CSPs can pose health risks to patients when they are injected *intradermally or subcutaneously*, these risks are substantially greater if the extract is inadvertently injected *intravenously*.

VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY

The compounding procedures and sterilization methods for CSPs correspond to correctly designed and verified written documentation in the compounding facility. Verification requires planned testing, monitoring, and documentation to demonstrate adherence to environmental quality requirements, personnel practices, and procedures critical to achieving and maintaining sterility, accuracy, and purity of finished CSPs. For example, sterility testing (see *Test for Sterility of the Product To Be Examined* under *Sterility Tests* ⟨71⟩) may be applied to specimens of low- and medium-risk level CSPs, and standard self-contained biological indicators (BI) shall be added to nondispensable specimens of high-risk level CSPs before terminal sterilization for subsequent evaluation to determine whether the sterilization cycle was adequate (see *Biological Indicators for Sterilization* ⟨1035⟩). Packaged and labeled CSPs shall be visually inspected for physical integrity and expected appearance, including final fill amount. The accuracy of identities, concentrations, amounts, and purities of ingredients in CSPs shall be confirmed by reviewing labels on packages, observing and documenting correct measurements with approved and correctly standardized devices, and reviewing information in labeling and certificates of analysis provided by suppliers. When the correct identity, purity, strength, and sterility of ingredients and components of CSPs cannot be confirmed (in cases of, for example, unlabeled syringes, opened ampuls, punctured stoppers of vials and bags, containers of ingredients with incomplete labeling), such ingredients and components shall be discarded immediately.

Some individual ingredients, such as bulk drug substances, are not labeled with expiration dates when they are stable indefinitely in their commercial packages under their labeled storage conditions. However, despite retaining full chemical stability, such ingredients may gain or lose moisture during storage and use. Changes in moisture content may require testing (see *Loss on Drying* ⟨731⟩) to determine the correct amount to weigh for accurate content of active chemical moieties in CSPs (see *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩).

Although not required, a quantitative stability-indicating chemical assay is recommended to ensure compounding accuracy of CSPs, especially those that contain drug ingredients with a narrow therapeutic plasma concentration range.

Sterilization Methods

The licensed healthcare professionals who supervise compounding shall be responsible for determining that the selected sterilization method (see *Methods of Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩) both sterilizes and maintains the strength, purity, quality, and packaging integrity of CSPs. The selected sterilization process is obtained from experience and appropriate information sources (e.g., see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩)—and, preferably, verified wherever possible—to achieve sterility in the particular CSPs. General guidelines for matching CSPs and components to appropriate sterilization methods include the following:

1. CSPs have been ascertained to remain physically and chemically stable when subjected to the selected sterilization method.
2. Glass and metal devices may be covered tightly with aluminum foil, then exposed to dry heat in an oven at a mean temperature of 250° for 30 minutes to achieve sterility and depyrogenation (see *Dry-Heat Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Bacterial Endotoxins Test* ⟨85⟩). Such items are either used immediately or stored until use in an environment suitable for com-

pounding *Low-Risk Level CSPs* and *Medium-Risk Level CSPs*.

3. Personnel ascertain from appropriate information sources that the sterile microporous membrane filter used to sterilize CSP solutions, during either compounding or administration, is chemically and physically compatible with the CSP.

STERILIZATION OF HIGH-RISK LEVEL CSPS BY FILTRATION

Commercially available sterile filters shall be approved for human-use applications in sterilizing pharmaceutical fluids. Sterile filters used to sterilize CSPs shall be pyrogen free and have a nominal pore size of 0.2 or 0.22 µm. They shall be certified by the manufacturer to retain at least 10^7 microorganisms of a strain of *Brevundimonas (Pseudomonas) diminuta* on each square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be sterilized (see *High-Risk Conditions* in *High-Risk Level CSPs*).

The compounding supervisor shall ensure, directly or from appropriate documentation, that the filters are chemically and physically stable at the pressure and temperature conditions to be used, that they have enough capacity to filter the required volumes, and that they will achieve sterility and maintain prefiltration pharmaceutical quality, including strength of ingredients of the specific CSP. The filter dimensions and liquid material to be sterile-filtered shall permit the sterilization process to be completed rapidly, without the replacement of the filter during the process. When CSPs are known to contain excessive particulate matter, a prefilter of larger nominal pore size membrane is placed upstream from the sterilizing filter to remove gross particulate contaminants in order to maximize the efficiency of the sterilizing filter.

Filter units used to sterilize CSPs shall also be subjected to manufacturers' recommended integrity test, such as the bubble point test.

Compounding personnel shall ascertain that selected filters will achieve sterilization of the particular CSPs being sterilized. Large deviations from usual or expected chemical and physical properties of CSPs (e.g., water-miscible alcohols) may cause undetectable damage to filter integrity and shrinkage of microorganisms to sizes smaller than filter nominal pore size.

STERILIZATION OF HIGH-RISK LEVEL CSPS BY STEAM

The process of thermal sterilization employing saturated steam under pressure, or autoclaving, is the preferred method to terminally sterilize aqueous preparations that have been verified to maintain their full chemical and physical stability under the conditions employed (see *Steam Sterilization* under *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩). To achieve sterility, all materials are to be exposed to steam at 121° under a pressure of about 1 atmosphere or 15 psi for the duration verified by testing to achieve sterility of the items, which is usually 20 to 60 minutes for CSPs. An allowance shall be made for the time required for the material to reach 121° before the sterilization exposure duration is timed.

Not directly exposing items to pressurized steam may result in survival of microbial organisms and spores. Before their sterilization, plastic, glass, and metal devices are tightly wrapped in low-particle-shedding paper or fabrics or sealed in envelopes that prevent poststerilization microbial penetration. Immediately before filling ampuls and vials that will be steam sterilized, solutions are passed through a filter having a nominal pore size not larger than 1.2 µm for removal of particulate matter. Sealed containers shall be able to generate steam internally; thus, stoppered and crimped empty vials shall contain a small amount of moisture to generate steam.

The description of steam sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of steam sterilization shall be verified using appropriate BIs of *Bacillus stearothermophilus* (see *Biological Indicators* ⟨1035⟩) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Sterility Tests* ⟨71⟩).

STERILIZATION OF HIGH-RISK LEVEL CSPS BY DRY HEAT

Dry heat sterilization is usually done as a batch process in an oven designed for sterilization. Heated filtered air shall be evenly distributed throughout the chamber by a blower device. The oven should be equipped with a system for controlling temperature and exposure period. Sterilization by dry heat requires higher temperatures and longer exposure times than does sterilization by steam. Dry heat shall be used only for those materials that cannot be sterilized by steam, when either the moisture would damage the material or the material is impermeable. During sterilization, sufficient space shall be left between materials to allow for good circulation of the hot air. The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate BIs of *Bacillus subtilis* (see *Biological Indicators* ⟨1035⟩) and other confirmation methods such as temperature-sensing devices (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Sterility Tests* ⟨71⟩). [NOTE—Dry heat sterilization may be performed at a lower temperature than may be effective for depyrogenation].

Depyrogenation by Dry Heat

Dry heat depyrogenation shall be used to render glassware or containers such as vials free from pyrogens as well as viable microbes. A typical cycle would be 30 minutes at 250°. The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility. The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs). The bacterial endotoxin test should be performed on the ECVs to verify that the cycle is capable of achieving a 3-log reduction in endotoxin (see *Sterilization and Sterility Assurance of Compendial Articles* ⟨1211⟩ and *Bacterial Endotoxins Test* ⟨85⟩).

ENVIRONMENTAL QUALITY AND CONTROL

Achieving and maintaining sterility and overall freedom from contamination of a CSP is dependent on the quality status of the components incorporated, the process utilized, personnel performance, and the environmental conditions under which the process is performed. The standards required for the environmental conditions depend on the amount of exposure of the CSP to the immediate environment anticipated during processing. The quality and control of environmental conditions for each risk level of operation are explained in this section. In addition, operations using nonsterile components require the use of a method of preparation designed to produce a sterile preparation.

Exposure of Critical Sites

Maintaining the sterility and cleanliness (i.e., freedom from sterile foreign materials) of critical sites is a primary safeguard for CSPs. Critical sites are locations that include any component or fluid pathway surfaces (e.g., vial septa, injection ports, beakers) or openings (e.g., opened ampuls, needle hubs) exposed and at risk of direct contact with air (e.g., ambient room or HEPA filtered), moisture (e.g., oral

and mucosal secretions), or touch contamination. The risk of, or potential for, critical sites to be contaminated with microorganisms and foreign matter increases with increasing exposed area of the critical sites, the density or concentration of contaminants, and exposure duration to worse than ISO Class 5 (see *Table 1*) air. Examples include an opened ampul or vial stopper on a 10-mL or larger vial or an injection port on a package of intravenous solution having an area larger than the point of a needle or the tip of a syringe.

The nature of a critical site also affects the risk of contamination. The relatively rough, permeable surface of an elastomeric closure retains microorganisms and other contaminants after swabbing with a sterile 70% IPA pad more readily than does the smoother glass surface of the neck of an ampul. Therefore, the surface disinfection can be expected to be more effective for an ampul.

Protection of critical sites by precluding physical contact and airborne contamination shall be given the highest priority in sterile compounding practice. Airborne contaminants, especially those generated by sterile compounding personnel, are much more likely to reach critical sites than are contaminants that are adhering to the floor or other surfaces below the work level. Furthermore, large and high-density particles that are generated and introduced by compounding manipulations and personnel have the potential to settle on critical sites even when those critical sites are exposed within ISO Class 5 (see *Table 1*) air.

ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas

The most common sources of ISO Class 5 (see *Table 1*) air quality for exposure of critical sites are horizontal and vertical LAFWs, CAIs, and CACIs. A clean room (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩) is a compounding environment that is supplied with HEPA or HEPA-filtered air that meets ISO Class 7 (see *Table 1*), the access to which is limited to personnel trained and authorized to perform sterile compounding and facility cleaning. A buffer area is an area that provides at least ISO Class 7 (see *Table 1*) air quality.

Figure 1 is a conceptual representation of the placement of an ISO Class 5 (see *Table 1*) PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD. This plan depicts the most critical operation area located within the PEC in a designated area (see definition of *Segregated Compounding Area*) separated from activities not essential to the preparation of CSPs. Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in the segregated area should be restricted or limited, depending on their effect on air quality in the ISO Class 5 (see *Table 1*) PEC.

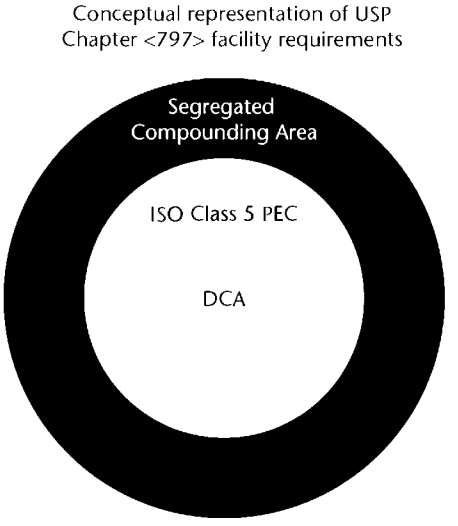

Figure 1. Conceptual representation of the placement of an ISO Class 5 PEC in a segregated compounding area used for low-risk level CSPs with 12-hour or less BUD.

Figure 2 is a conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level. The quality of the environmental air increases with movement from the outer boundary to the direct compounding area (DCA). Placement of devices in ante-areas and buffer areas is dictated by their effect on the designated environmental quality of atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that each source of ISO Class 5 (see *Table 1*) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

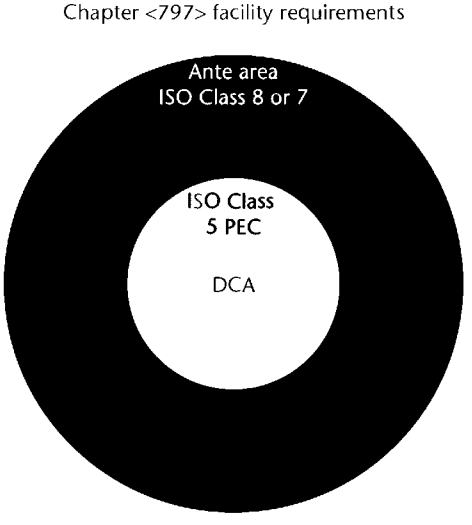

Figure 2. Conceptual representation of the arrangement of a facility for preparation of CSPs categorized as low-, medium-, and high-risk level.

Placement of devices (e.g., computers, printers) and objects (e.g., carts, cabinets) that are not essential to compounding in buffer areas is dictated by their effect on the required environmental quality of air atmospheres and surfaces, which shall be verified by monitoring (see *Viable and Nonviable Environmental Sampling (ES) Testing*). It is the responsibility of each compounding facility to ensure that

each source of ISO Class 5 (see *Table 1*) environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

Facility Design and Environmental Controls

Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites. These facilities shall also provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler, to maintain comfortable conditions for compounding personnel to perform flawlessly when attired in the required aseptic compounding garb. PECs typically include, but are not limited to, LAFWs, BSCs, CAIs, and CACIs, which provide an ISO Class 5 (see *Table 1*) environment for the exposure of critical sites. PECs shall maintain ISO Class 5 (see *Table 1*) or better conditions for 0.5-μm particles (dynamic operating conditions) while compounding CSPs. Secondary engineering controls such as buffer areas and ante-areas generally serve as a core for the location of the PEC. Buffer areas are designed to maintain at least ISO Class 7 (see *Table 1*) conditions for 0.5-μm particles under dynamic conditions and ISO Class 8 (see *Table 1*) conditions for 0.5-μm and larger particles under dynamic conditions for the ante-areas. Airborne contamination control is achieved in the PEC through the use of HEPA filters. The airflow in the PEC shall be unidirectional (laminar flow), and because of the particle collection efficiency of the filter, the "first air" at the face of the filter is, for the purposes of aseptic compounding, free from airborne particulate contamination. HEPA-filtered air shall be supplied in critical areas (ISO Class 5, see *Table 1*) at a velocity sufficient to sweep particles away from the compounding area and maintain unidirectional airflow during operations. Proper design and control prevents turbulence and stagnant air in the critical area. In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.

The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions. Policies and procedures for maintaining and working within the PEC area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities utilized during the preparation of the CSPs. The CSP work environment is designed to have the cleanest work surfaces (PEC) located in a buffer area. The buffer area shall maintain at least ISO Class 7 (see *Table 1*) conditions for 0.5-μm and larger particles under dynamic operating conditions. The room shall be segregated from surrounding, unclassified spaces to reduce the risk of contaminants being blown, dragged, or otherwise introduced into the filtered unidirectional airflow environment, and this segregation shall be continuously monitored. For rooms providing a physical separation through the use of walls, doors, and pass-throughs, a minimum differential positive pressure of 0.02- to 0.05-inch water column is required. For buffer areas not physically separated from the ante-areas, the principle of displacement airflow shall be employed. This concept utilizes a low pressure differential, high airflow principle. Using displacement airflow typically requires an air velocity of 40 ft per minute or more from the buffer area across the line of demarcation into the ante-area.

The displacement concept shall not be used for high-risk compounding.[6] The PEC shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation. For example, strong air currents from opened doors, personnel traffic, or air streams from the HVAC systems can disrupt the unidirectional airflow in open-faced workbenches. The operators may also create disruptions in airflow by their own movements and by the placement of objects onto the work surface. The PEC shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts. Room air exchanges are typically expressed as ACPHs. Adequate HEPA-filtered airflow supplied to the buffer area and ante-area is required to maintain cleanliness classification during operational activity through the number of ACPHs. Factors that should be considered when determining air-change requirements include number of personnel working in the room and compounding processes that generate particulates, as well as temperature effects. An ISO Class 7 (see *Table 1*) buffer area and ante-area supplied with HEPA-filtered air shall receive an ACPH of not less than 30. The PEC is a good augmentation to generating air changes in the air supply of an area but cannot be the sole source of HEPA-filtered air. If the area has an ISO Class 5 (see *Table 1*) recirculating device, a minimum of 15 ACPHs through the area supply HEPA filters is adequate, providing the combined ACPH is not less than 30. More air changes may be required, depending on the number of personnel and processes. HEPA-filtered supply air shall be introduced at the ceiling, and returns should be mounted low on the wall, creating a general top-down dilution of area air with HEPA-filtered make-up air. Ceiling-mounted returns are not recommended. All HEPA filters should be efficiency tested using the most penetrating particle size and should be leak tested at the factory and then leak tested again in situ after installation.[7]

Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment. Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the area, and they shall be nonpermeable, nonshedding, cleanable, and resistant to disinfectants. Whenever such items are brought into the area, they shall first be cleaned and disinfected. Whenever possible, equipment and other items used in the buffer area shall not be taken out of the area except for calibration, servicing, or other activities associated with the proper maintenance of the item.

The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability and minimizing spaces in which microorganisms and other contaminants may accumulate. The surfaces shall be resistant to damage by disinfectant agents. Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate. If ceilings consist of inlaid panels, the panels shall be impregnated with a polymer to render them impervious and hydrophobic, and they shall be caulked around each perimeter to seal them to the support frame. Walls may be constructed of flexible material (e.g., heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board. Preferably, floors are overlaid with wide sheet vinyl flooring with heat-welded seams and coving to the sidewall. Dust-collecting overhangs, such as ceiling utility pipes, and ledges, such as windowsills, should be avoided. The exterior lens surface of ceiling lighting fixtures should be smooth, mounted flush, and sealed. Any other penetrations through the ceiling or walls shall be sealed. The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected. Carts should be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility. Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshed-

[6] ISO 14644-4:2001 Cleanrooms and associated controlled environments—Design, construction, and start-up, *Case Postale 56*, CH-1211 Geneve 20, Switzerland, tel. +41 22 749 01 11.

[7] By definition (IEST RP CC 001.4), HEPA filters are a minimum of 99.97% efficient when tested using 0.3-μm thermally generated particles and a photometer or rated at their most penetrating particle size using a particle counter.

ding, cleanable, and disinfectable; their number, design, and manner of installation shall promote effective cleaning and disinfection.

Placement of Primary Engineering Controls

PECs (LAFWs, BSCs, CAIs, and CACIs) shall be located within a restricted access ISO Class 7 (see *Table 1*) buffer area (see *Figure 1*), with the following CAI/CACI exceptions below:

- Only authorized personnel and materials required for compounding and cleaning shall be permitted in the buffer area.
- Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 (see *Table 1*) environment.
- PECs shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

CAIs and CACIs shall be placed in an ISO Class 7 (see *Table 1*) buffer area *unless* they meet all of the following conditions:

- The isolator shall provide isolation from the room and maintain ISO Class 5 (see *Table 1*) during dynamic operating conditions, including transferring ingredients, components, and devices into and out of the isolator and during preparation of CSPs.
- Particle counts sampled approximately 6 to 12 inches upstream of the critical exposure site shall maintain ISO Class 5 (see *Table 1*) levels during compounding operations.
- Not more than 3520 particles (0.5 µm and larger) per m^3 shall be counted during material transfer, with the particle counter probe located as near to the transfer door as possible without obstructing the transfer.[8]

It is incumbent on the compounding personnel to obtain documentation from the manufacturer that the CAI/CACI will meet this standard when located in environments where the background particle counts exceed ISO Class 8 (see *Table 1*) for 0.5-µm and larger particles. When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 (see *Table 1*) air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

If the PEC is a CAI or CACI that does not meet the requirements above or is a LAFW or BSC that cannot be located within an ISO Class 7 (see *Table 1*) buffer area, then only low-risk level nonhazardous and radiopharmaceutical CSPs pursuant to a physician order for a specific patient may be prepared, and administration of the CSP shall commence within 12 hours of preparation or as recommended in the manufacturer's package insert, whichever is less.

Viable and Nonviable Environmental Sampling (ES) Testing

The ES program should provide information to staff and leadership to demonstrate that the PEC is maintaining an environment within the compounding area that consistently ensures acceptably low viable and nonviable particle levels. The compounding area includes the ISO Class 5 (see *Table 1*) PEC (LAFWs, BSCs, CAIs, and CACIs), buffer areas, ante-areas, and segregated compounding areas.

Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally under any of the following conditions:

- as part of the commissioning and certification of new facilities and equipment;
- following any servicing of facilities and equipment;
- as part of the re-certification of facilities and equipment (i.e., every 6 months);
- in response to identified problems with end products or staff technique; or
- in response to issues with CSPs, observed compounding personnel work practices, or patient-related infections (where the CSP is being considered as a potential source of the infection).

ENVIRONMENTAL NONVIABLE PARTICLE TESTING PROGRAM

A program to sample nonviable airborne particles differs from that for viable particles in that it is intended to directly measure the performance of the engineering controls used to create the various levels of air cleanliness, for example, ISO Class 5, 7, or 8 (see *Table 1*).

Engineering Control Performance Verification—PECs (LAFWs, BSCs, CAIs, and CACIs) and secondary engineering controls (buffer and ante-areas) are essential components of the overall contamination control strategy for aseptic compounding. As such, it is imperative that they perform as designed and that the resulting levels of contamination be within acceptable limits. Certification procedures such as those outlined in *Certification Guide for Sterile Compounding Facilities* (CAG-003-2006)[9] shall be performed by a qualified individual no less than every 6 months and whenever the device or room is relocated or altered or major service to the facility is performed.

Total Particle Counts—Certification that each ISO classified area, for example, ISO Class 5, 7, and 8 (see *Table 1*), is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer area or ante-area has been altered. Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results of the following:

- ISO Class 5: not more than 3520 particles 0.5 µm and larger size per cubic meter of air for any LAFW, BSC, CAI, and CACI;
- ISO Class 7: not more than 352,000 particles of 0.5 µm size and larger per cubic meter of air for any buffer area;
- ISO Class 8: not more than 3,520,000 particles or 0.5 µm size and larger per cubic meter of air for any ante-area.

All certification records shall be maintained and reviewed by supervising personnel or other designated employees to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and ACPHs.

PRESSURE DIFFERENTIAL MONITORING

A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and the ante-area and between the ante-area and the general environment outside the compounding area. The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device. The pressure between the ISO Class 7 (see *Table 1*) and the general pharmacy area shall not be less than 5 Pa (0.02 inch water column). In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meters per second (40 feet per minute) between buffer area and ante-area.

[8] Sample procedures are detailed in CETA Applications Guide CAG-002-2006–section 2.09.

[9] Controlled Environment Testing Association, 1500 Sunday Drive, Ste. 102, Raleigh, NC 27607; www.CETAinternational.org.

ENVIRONMENTAL VIABLE AIRBORNE PARTICLE TESTING PROGRAM

The risk of contaminating a CSP prepared under low-risk level and medium-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see *Table 1*) PEC and secondary engineering controls, ISO Class 7 (see *Table 1*) buffer area, and ISO Class 8 (see *Table 1*) ante-area. High-risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility.

A sampling program in conjunction with an observational audit is designed to evaluate the competency of compounding personnel work practices, allowing for the implementation of corrective actions on an ongoing basis (see *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).

Sampling Plan—An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.

Selected sampling sites shall include locations within each ISO Class 5 (see *Table 1*) environment and in the ISO Class 7 and 8 (see *Table 1*) areas and in the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 [see *Table 1*] environment, counters near doors, pass-through boxes). The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

Review of the data generated during a sampling event may detect elevated amounts of airborne microbial bioburden; such changes may be indicative of adverse changes within the environment. It is recommended that compounding personnel refer to *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩ and the CDC's "Guidelines for Environmental Infection Control in Healthcare Facilities, 2003" for more information.

Growth Medium—A general microbiological growth medium such as Soybean–Casein Digest Medium shall be used to support the growth of bacteria. Malt extract agar or some other media that supports the growth of fungi shall be used in high-risk level compounding environments. Media used for surface sampling must be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

Viable Air Sampling—Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments (LAFWs, CAIs, clean room or buffer areas, and ante-areas) shall be performed by properly trained individuals for all compounding risk levels.

Impaction shall be the preferred method of volumetric air sampling. Use of settling plates for qualitative air sampling may not be able to determine adequately the quality of air in the controlled environment. The settling of particles by gravity onto culture plates depends on the particle size and may be influenced by air movement. Consequently, the number of colony-forming units (cfu) on a settling plate may not always relate to the concentrations of viable particles in the sampled environment.

For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities such as staging, labeling, gowning, and cleaning. Locations shall include zones of air backwash turbulence within LAFW and other areas where air backwash turbulence may enter the compounding area (doorways, in and around ISO Class 5 [see *Table 1*] PEC and environments). Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.

For low-risk level CSPs with 12-hour or less BUD prepared in a PEC (LAFWs, BSCs, CAIs) that maintains an ISO Class 5 (see *Table 1*), air sampling shall be performed at locations inside the ISO Class 5 (see *Table 1*) environment and other areas that are in close proximity to the ISO Class 5 (see *Table 1*) environment during the certification of the PEC.

Air Sampling Devices—There are a number of manufacturers of electronic air sampling equipment. It is important that personnel refer to the manufacturer's recommended procedures when using the equipment to perform volumetric air sampling procedures. The instructions in the manufacturer's user's manual for verification and use of electric air samplers that actively collect volumes of air for evaluation must be followed. A sufficient volume of air (400 to 1000 liters) shall be tested at each location in order to maximize sensitivity. The volumetric air sampling devices need to be serviced and calibrated as recommended by the manufacturer.

It is recommended that compounding personnel also refer to *Methodology and Instrumentation for Quantitation of Viable Airborne Microorganisms* under *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩, which provides more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.

Air Sampling Frequency and Process—Air sampling shall be performed at least semiannually (i.e., every 6 months) as part of the re-certification of facilities and equipment. If compounding occurs in multiple locations within an institution (e.g., main pharmacy, satellites), environmental sampling is required for each individual compounding area. A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed. Any facility construction or equipment servicing may require that air sampling be performed during these events.

Incubation Period—At the end of the designated sampling or exposure period for air sampling activities, the microbial growth media plates are recovered and their covers secured (e.g., taped), and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA should be incubated at 30° to 35° for 48 to 72 hours. Malt extract agar or other suitable fungal media should be incubated at 26° to 30° for 5 to 7 days. The number of discrete colonies of microorganisms are counted and reported as cfu and documented on an environmental sampling form. Counts from air sampling need to be transformed into cfu per cubic meter of air and evaluated for adverse trends.

Action Levels, Documentation, and Data Evaluation—The value of viable microbial sampling of the air in the compounding environment is realized when the data are used to identify and correct an unacceptable situation. Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

Any cfu count that exceeds its respective action level (see *Table 2*) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or work practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in *Table 2* should be used only as guidelines. Regardless of the number of cfu identified in the pharmacy, further corrective ac-

tions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bioburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and must be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

Table 2. Recommended Action Levels for Microbial Contamination*

†(cfu per cubic meter [1000 liters] of air per plate)

Classification	Air Sample†
ISO Class 5	> 1
ISO Class 7	> 10
ISO Class 8 or worse	> 100

* Guidance for Industry–Sterile Drug Products Produced by Aseptic Processing–Current Good Manufacturing Practice–US HHS, FDA September 2004.

Additional Personnel Requirements

Food, drinks, and materials exposed in patient care and treatment areas shall not enter ante-areas, buffer areas, or segregated compounding areas where components and ingredients of CSPs are present. When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific SOPs in order to avoid any cross-contamination. Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA), when possible in an ante-area of ISO Class 8 (see *Table 1*) air quality, before being passed into the buffer areas. Personnel hand hygiene and garbing procedures are also performed in the ante-area, which may contain a sink that enables hands-free use with a closed system of soap dispensing to minimize the risk of extrinsic contamination. There shall be some demarcation designation that separates the ante-area from the buffer area. Adequate provision for performing antiseptic hand cleansing using an alcohol-based surgical hand scrub with persistent activity followed by the donning of sterile gloves should be provided after entry into the buffer area.

Cleaning and Disinfecting the Compounding Area

Environmental contact is a major source of microbial contamination of CSPs. Consequently, scrupulous attention to cleaning and disinfecting the sterile compounding areas is required to minimize this as a source of CSP contamination.

The cleaning and disinfecting practices and frequencies in this section apply to ISO Class 5 (see *Table 1*) compounding areas for exposure of critical sites as well as buffer areas, ante-areas, and segregated compounding areas. Compounding personnel are responsible for ensuring that the frequency of cleaning is in accordance with the requirements stated in *Table 3* and determining the cleaning and disinfecting products to be used (see *Appendix II*). Any organizational or institutional policies regarding disinfectant selection should be considered by compounding personnel. All cleaning and disinfecting practices and policies for the compounding of CSPs shall be included in written SOPs and shall be followed by all compounding personnel.

The selection and use of disinfectants in healthcare facilities is guided by several properties, such as microbicidal activity, inactivation by organic matter, residue, and shelf life (see *Appendix II*). In general, highly toxic disinfectants, such as glutaraldehyde, are not used on housekeeping surfaces (e.g., floors, countertops). Many disinfectants registered by the EPA are one-step disinfectants. This means that the disinfectant has been formulated to be effective in the presence of light to moderate soiling without a pre-cleaning step.

Surfaces in LAFWs, BSCs, CAIs, and CACIs, which are intimate to the exposure of critical sites, require disinfecting more frequently than do housekeeping surfaces such as walls and ceilings. Disinfecting sterile compounding areas shall occur on a regular basis at the intervals noted in *Table 3* when spills occur, when the surfaces are visibly soiled, and when microbial contamination is known to have been or is suspected of having been introduced into the compounding areas.

When the surface to be disinfected has heavy soiling, a cleaning step is recommended prior to the application of the disinfectant. Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs. Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills; for example, water-soluble solid residues are removed with sterile water (for injection or irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent such as sterile 70% IPA, which is allowed to dry before compounding begins.

Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs are the most critical practices before the preparation of CSPs. Consequently, such surfaces shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.

Work surfaces in the ISO Class 7 (see *Table 1*) buffer areas and ISO Class 8 (see *Table 1*) ante-areas as well as segregated compounding areas shall be cleaned and disinfected at least daily, and dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies using a method that does not degrade the ISO Class 7 or 8 (see *Table 1*) air quality (see *Disinfectants and Antiseptics* ⟨1072⟩).

Table 3. Minimum Frequency of Cleaning and Disinfecting Compounding Areas

Site	Minimum Frequency
ISO Class 5 (see *Table 1*) Primary Engineering Control (e.g., LAFW, BSC, CAI, CACI)	At the beginning of each shift, before each batch, not longer than 30 minutes following the previous surface disinfection when ongoing compounding activities are occurring, after spills, and when surface contamination is known or suspected
Counters and easily cleanable work surfaces	Daily
Floors	Daily
Walls	Monthly
Ceilings	Monthly
Storage shelving	Monthly

Floors in the buffer or clean area, ante-area, and segregated compounding area are cleaned by mopping with a cleaning and disinfecting agent once daily at a time when no aseptic operations are in progress. Mopping shall be performed by trained personnel using approved agents and

procedures described in the written SOPs. It is incumbent on compounding personnel to ensure that such cleaning is performed properly. In the buffer or clean area, ante-area, and segregated compounding area, walls, ceilings, and shelving shall be cleaned and disinfected monthly. Cleaning and disinfecting agents are to be used with careful consideration of compatibilities, effectiveness, and inappropriate or toxic residues (see *Appendix II*). Their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial or compounding personnel.

All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer or clean area, ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal. Floor mops may be used in both the buffer or clean area and ante-area, but only in that order. Ideally, all cleaning tools are discarded after one use by collection in suitable plastic bags and removed with minimal agitation. If cleaning materials (e.g., mops) are reused, procedures shall be developed (based on manufacturers' recommendations) that ensure that the effectiveness of the cleaning device is maintained and that repeated use does not add to the bioburden of the area being cleaned.

Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method. After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, during which time the item shall not be used for compounding purposes.

Wiping with small sterile 70% IPA swabs that are commercially available in individual foil-sealed packages (or a comparable method) is preferred for disinfecting entry points on bags and vials, allowing the IPA to dry before piercing stoppers with sterile needles and breaking necks of ampuls. The surface of the sterile 70% IPA swabs used for disinfecting entry points of sterile packages and devices shall not contact any other object before contacting the surface of the entry point. Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.

When sterile supplies are received in sealed pouches designed to keep them sterile until opening, the sterile supplies may be removed from the covering pouches as the supplies are introduced into the ISO Class 5 (see *Table 1*) PEC (LAFW, BSC, CAI, CACI) without the need to disinfect the individual sterile supply items. No shipping or other external cartons may be taken into the buffer or clean area or segregated compounding area.

Personnel Cleansing and Garbing

The careful cleansing of hands and arms and the correct donning of PPE by compounding personnel constitute the first major step in preventing microbial contamination in CSPs. Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs. Squamous cells are normally shed from the human body at a rate of 10^6 or more per hour, and those skin particles are laden with microorganisms.[10, 11] When individuals are experiencing rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, as well as when they wear cosmetics, they shed these particles at even higher rates. Particles shed from compounding personnel pose an increased risk of microbial contamination of critical sites of CSPs. Therefore, compounding personnel with such conditions as mentioned above shall be excluded from working in ISO Class 5 (see *Table 1*) and ISO Class 7 (see *Table 1*) compounding areas until their conditions are remedied.

Before entering the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), compounding personnel shall remove personal outer garments (e.g., bandannas, coats, hats, jackets, scarves, sweaters, vests); all cosmetics, because they shed flakes and particles; and all hand, wrist, and other visible jewelry or piercings (e.g., earrings, lip or eyebrow piercings) that can interfere with the effectiveness of PPE (e.g., fit of gloves and cuffs of sleeves). The wearing of artificial nails or extenders is prohibited while working in the sterile compounding environment. Natural nails shall be kept neat and trimmed.

Personnel shall don the following PPE in an order that proceeds from those activities considered the dirtiest to those considered the cleanest. Garbing activities considered the dirtiest include donning of dedicated shoes or shoe covers, head and facial hair covers (e.g., beard covers in addition to face masks), and face masks/eye shields. Eye shields are optional unless working with irritants such as germicidal disinfecting agents or when preparing hazardous drugs.

After donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner under running warm water followed by vigorous hand washing. Hands and forearms shall be washed to the elbows for at least 30 seconds with soap (either nonantimicrobial or antimicrobial) and water while in the ante-area. The use of antimicrobial scrub brushes is not recommended because they can cause skin irritation and skin damage. Hands and forearms to the elbows will be completely dried using either lint-free disposable towels or an electronic hand dryer. After completion of hand washing, a nonshedding gown with sleeves that fit snugly around the wrists and enclosed at the neck is donned. Gowns designated for buffer area use shall be worn, and preferably they should be disposable. If reusable gowns are worn, they should be laundered appropriately for buffer area use.

Once inside the buffer area or segregated compounding area (see *Low-Risk Level CSPs with 12-Hour or Less BUD*), and prior to donning sterile powder-free gloves, antiseptic hand cleansing shall be performed using a waterless alcohol-based surgical hand scrub with persistent activity[12] following manufacturers' recommendations. Hands are allowed to dry thoroughly before donning sterile gloves.

Sterile gloves shall be the last item donned before compounding begins. Gloves become contaminated when they contact nonsterile surfaces during compounding activities. Disinfection of contaminated gloved hands may be accomplished by wiping or rubbing sterile 70% IPA to all contact surface areas of the gloves and letting the gloved hands dry thoroughly. Only use gloves that have been tested for compatibility with alcohol disinfection by the manufacturer. Routine application of sterile 70% IPA shall occur throughout the compounding process and whenever nonsterile surfaces (e.g. vials, counter tops, chairs, carts) are touched. Gloves on hands shall also be routinely inspected for holes, punctures, or tears and replaced immediately if such are detected. Antiseptic hand cleansing shall be performed as indicated above. Compounding personnel shall be trained and evaluated in the avoidance of touching critical sites.

When compounding personnel exit the compounding area during a work shift, the exterior gown may be removed and retained in the compounding area if not visibly soiled, to be re-donned during that same work shift only. However, shoe covers, hair and facial hair covers, face masks/eye shields, and gloves shall be replaced with new ones before re-entering the compounding area, and proper hand hygiene shall be performed.

During high-risk compounding activities that precede terminal sterilization, such as weighing and mixing of nonster-

[10] Agalloco J, Akers JE. Aseptic Processing: A Vision of the Future. *Pharmaceutical Technology*, 2005. Aseptic Processing supplement, s16.

[11] Eaton T. Microbial Risk Assessment for Aseptically Prepared Products. *Am Pharm Rev.* 2005; 8 (5, Sep/Oct): 46–51.

[12] *Guideline for Hand Hygiene in Health care Settings*, MMWR, October 25, 2002, vol. 51, No. RR-16 available on the Internet at http://www.cdc.gov/handhygiene/.

ile ingredients, compounding personnel shall be garbed and gloved the same as when performing compounding in an ISO Class 5 (see *Table 1*) environment. Properly garbed and gloved compounding personnel who are exposed to air quality that is either known or suspected to be worse than ISO Class 7 (see *Table 1*) shall re-garb PPE along with washing their hands properly, performing antiseptic hand cleansing with a waterless alcohol-based surgical hand scrub, and donning sterile gloves upon re-entering the ISO Class 7 (see *Table 1*) buffer area. When CAIs and CACIs are the source of the ISO Class 5 (see *Table 1*) environment, the garbing and gloving requirements for compounding personnel should be as described above, unless the isolator manufacturer can provide written documentation based on validated environmental testing that any component(s) of PPE or personnel cleansing are not required.

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices, and Cleaning/Disinfection Procedures

Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel and through multimedia instructional sources and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 (see *Table 1*) environmental conditions, and cleaning and disinfection procedures. This training shall be completed and documented before any compounding personnel begin to prepare CSPs. Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing (see *Appendices III–V*).

Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding and semiannually for high-risk level compounding.

Compounding personnel who fail written tests or observational audits or whose media-fill test vials have one or more units showing visible microbial contamination shall be re-instructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies. Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations. In addition to didactic evaluation and aseptic media fill, compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures.

In the event that cleaning and disinfecting procedures are also performed by other support personnel (e.g., institutional environmental services, housekeeping), thorough training of proper hand hygiene, garbing, and cleaning and disinfection procedures shall be done by a qualified aseptic compounding expert. After completion of training, support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.

COMPETENCY EVALUATION OF GARBING AND ASEPTIC WORK PRACTICE

The risk of contaminating a CSP prepared under low-risk level and medium-risk level conditions is highly dependent on proper hand hygiene and garbing practices, compounding personnel aseptic technique, and the presence of surface contamination, assuming that all work is performed in a certified and properly functioning ISO Class 5 (see *Table 1*) PEC and secondary engineering controls, ISO Class 7 (see *Table 1*) buffer area, and ISO Class 8 (see *Table 1*) ante-area. High-risk level CSPs pose the greatest threat to patients because compounding personnel are tasked with the requirement of processing nonsterile components and devices in order to achieve sterility. Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see *Appendix III*) and the personnel glove fingertip sampling procedures indicated below.

Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling—Sampling of compounding personnel glove fingertips shall be performed for all CSP risk level compounding because direct touch contamination is the most likely source of introducing microorganisms into CSPs prepared by humans. Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices, which include frequent and repeated glove disinfection using sterile 70% IPA during actual compounding of CSPs. All personnel shall demonstrate competency in proper hand hygiene and garbing procedures and in aseptic work practices (e.g., disinfection of component surfaces, routine disinfection of gloved hands).

Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing in order to assess garbing competency and after completing the media-fill preparation (without applying sterile 70% IPA) in order to assess the adequacy of aseptic work practices prior to being initially allowed to prepare CSPs for human use and for more experienced personnel to maintain their qualifications to prepare CSPs for human use.

Garbing And Gloving Competency Evaluation—Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures (see *Personnel Cleansing and Garbing* under *Personnel Training and Evaluation in Aseptic Manipulation Skills* above). The visual observation shall be documented on a form such as the *Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel* (see *Appendix III*) and maintained to provide a permanent record and long-term assessment of personnel competency.

Gloved Fingertip Sampling—All compounding personnel shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (zero cfu) no less than three times before initially being allowed to compound CSPs for human use. Immediately after the compounding employee completes the hand hygiene and garbing procedure (e.g., donning of sterile gloves prior to any disinfection with sterile 70% IPA), the evaluator will collect a gloved fingertip and thumb sample from both hands of the compounding employee onto appropriate agar plates by lightly pressing each fingertip into the agar. The plates will be incubated for the appropriate incubation period and at the appropriate temperature (see *Incubation Period*). After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel for this competency shall occur at least annually for personnel who compound low- and medium-risk level CSPs and semiannually for personnel who compound high-risk level CSPs using one or more sample collections during any media-fill test procedure before they are allowed to continue compounding CSPs for human use.

Immediately prior to sampling, gloves shall not be disinfected with sterile 70% IPA. Disinfecting gloves immediately before sampling will provide false negative results. Plates filled with nutrient agar with neutralizing agents such as lecithin and polysorbate 80 added shall be used when sampling personnel fingertips. Personnel shall "touch" the agar with the fingertips of both hands in separate plates in a manner to create a slight impression in the agar. The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below (see *Incubation Period*). Results should be reported separately as number of cfu per employee per hand (left hand, right hand). The cfu action

level for gloved hands will be based on the total number of cfu on both gloves, not per hand.

Incubation Period—At the end of the designated sampling period for compounding personnel competency assessment activities (surface or personnel), the agar plates are recovered and covers secured and they are inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. TSA with lecithin and polysorbate 80 shall be incubated at 30° to 35° for 48 to 72 hours.

Aseptic Manipulation Competency Evaluation—After successful completion of an initial Hand Hygiene and Garbing Competency Evaluation, all compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the *Media-Fill Test Procedure* and subsequent annual or semi-annual *Media-Fill Test Procedures*. Records of these evaluations will be maintained using a form such as the *Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel* (see *Appendix IV*) and maintained to provide a permanent record of and long-term assessment of personnel competency.

Media-Fill Test Procedure—The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media-fill verification, (i.e., sterile bacterial culture medium transfer via a sterile syringe and needle). Media-fill testing is used to assess the quality of the aseptic skill of compounding personnel. Media-fill tests shall represent the most challenging or stressful conditions actually encountered by the personnel being evaluated when they prepare low- and medium-risk level CSPs and when sterilizing high-risk level CSPs. Media-fill challenge tests are also used to verify the capability of the compounding environment and processes to produce sterile preparations.

A commercially available sterile fluid culture media, such as Soybean–Casein Digest Medium (see *Sterility Tests* ⟨71⟩), that is able to promote exponential colonization of bacteria that are most likely to be transmitted to CSPs from the compounding personnel and environment is commonly used. For high-risk level CSPs nonsterile commercially available Soybean–Casein Digest Medium may be used to make a 3% solution. Normal processing steps, including filter sterilization, shall be mimicked. Media-filled vials shall be incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩). Failure is indicated by visible turbidity in any one of the media-fill units on or before 14 days. Other methodologies recommended by a competent microbiologist to enhance recovery time and sensitivity to detect microbial contamination may be considered (see *CSP Microbial Contamination Risk Levels* for examples of media-fill procedures).

SURFACE CLEANING AND DISINFECTION SAMPLING AND ASSESSMENT

Surface sampling is an important component of the maintenance of a suitable microbially controlled environment for compounding CSPs, especially since transfer of microbial contamination from improperly disinfected work surfaces via inadvertent touch contact by compounding personnel can be a potential source of contamination into CSPs. It is useful for evaluating facility and work surface cleaning and disinfecting procedures and employee competency in work practices such as disinfection of component/vial surface cleaning. Surface sampling shall be performed in all ISO classified areas on a periodic basis. Sampling can be accomplished using contact plates or swabs, and it shall be done at the conclusion of compounding. Locations to be sampled shall be defined in a sample plan or on a form. The size of the plate to be used for each sampled location usually ranges from 24 to 30 cm^2. Contact plates are filled with general solid agar growth medium and neutralizing agents above the rim of the plate, and they are used for sampling regular or flat surfaces. Swabs may be used for sampling irregular surfaces, especially for equipment (see *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩).

Cleaning and Disinfecting Competency Evaluation—Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures, during initial personnel training on cleaning procedures, during changes in cleaning staff, and at the completion of any media-fill test procedure (see *Cleaning and Disinfecting of Compounding Areas*).

The visual observation shall be documented using a form such as the *Sample Form for Assessing Cleaning and Disinfection Procedures* (see *Appendix V*) and maintained to provide a permanent record and long-term assessment of personnel competency.

Surface Collection Methods—To sample surfaces using a contact plate, gently touch the sample area with the agar surface and roll the plate across the surface to be sampled. The contact plate will leave a growth media residue behind; therefore, immediately after sampling with the contact plate, the sampled area shall be thoroughly wiped with a nonshedding wipe soaked in sterile 70% IPA.

If an area is sampled via the swab method, collection of the sample is processed by using appropriate procedures that will result in the surface location equivalent to that of a contact plate. After swabbing the surface to be sampled, swabs are placed in an appropriate diluent; an aliquot is planted on or in the specified nutrient agar. Results should be reported as cfu per unit of surface area.

Action Levels, Documentation, and Data Evaluation

The value of viable microbial monitoring of gloved fingertips and surfaces of components and the compounding environment are realized when the data are used to identify and correct an unacceptable work practice. Sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment. If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

Any cfu count that exceeds its respective action level (see *Table 4*) should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location. An investigation into the source of the contamination shall be conducted. Sources could include HVAC systems, damaged HEPA filters, and changes in personnel garbing or working practices. The source of the problem shall be eliminated, the affected area cleaned, and resampling performed.

When gloved fingertip sample results exceed action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented. Employee training may be required to correct the source of the problem.

Counts of cfu are to be used as an approximate measure of the environmental microbial bioburden. Action levels are determined on the basis of cfu data gathered at each sampling location and trended over time. The numbers in *Table 4* should be used only as guidelines. Regardless of the number of cfu identified in the compounding facility, further corrective actions will be dictated by the identification of microorganisms recovered (at least the genus level) by an appropriate credentialed laboratory of any microbial bi-

oburden captured as a cfu using an impaction air sampler. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds and yeasts) can be potentially fatal to patients receiving CSPs and shall be immediately remedied, regardless of cfu count, with the assistance of a competent microbiologist, infection control professional, or industrial hygienist.

Table 4. Recommended Action Levels for Microbial Contamination*

Classification	Fingertip Sample	Surface Sample (Contact Plate) (cfu per plate)
ISO Class 5	> 3	> 3
ISO Class 7	N/A	> 5
ISO Class 8 or worse	N/A	> 100

* Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guide to Good Manufacturing Practice for Medicinal Products Annexes PE 009-6, 5 April 2007.

SUGGESTED STANDARD OPERATING PROCEDURES (SOPs)

The compounding facility shall have written, properly approved SOPs designed to ensure the quality of the environment in which a CSP is prepared. The following procedures are recommended:

1. Access to the buffer area is restricted to qualified personnel with specific responsibilities or assigned tasks in the compounding area.
2. All cartoned supplies are decontaminated in the area by removing them from shipping cartons and wiping or spraying them with a nonresidue-generating disinfecting agent while they are being transferred to a clean and properly disinfected cart or other conveyance for introduction into the buffer area. Manufacturers' directions or published data for minimum contact time will be followed. Individual pouched sterile supplies need not be wiped because the pouches can be removed as these sterile supplies are introduced into the buffer area.
3. Supplies that are required frequently or otherwise needed close at hand but not necessarily needed for the scheduled operations of the shift are decontaminated and stored on shelving in the ante-area.
4. Carts used to bring supplies from the storeroom cannot be rolled beyond the demarcation line in the ante-area, and carts used in the buffer area cannot be rolled outward beyond the demarcation line unless cleaned and disinfected before returning.
5. Generally, supplies required for the scheduled operations of the shift are wiped down with an appropriate disinfecting agent and brought into the buffer area, preferably on one or more movable carts. Supplies that are required for back-up or general support of operations may be stored on the designated shelving in the buffer area, but excessive amounts of supplies are to be avoided.
6. Nonessential objects that shed particles shall not be brought into the buffer area, including pencils, cardboard cartons, paper towels, and cotton items (e.g., gauze pads).
7. Essential paper-related products (e.g., paper syringe overwraps, work records contained in a protective sleeve) shall be wiped down with an appropriate disinfecting agent prior to being brought into the buffer area.
8. Traffic flow in and out of the buffer area shall be minimized.
9. Personnel preparing to enter the buffer area shall remove all personal outer garments, cosmetics (because they shed flakes and particles), and all hand, wrist, and other visible jewelry or piercings that can interfere with the effectiveness of PPE.
10. Personnel entering the ante-area shall don attire as described in *Personnel Cleansing and Garbing* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures.*
11. Personnel shall then thoroughly wash hands and forearms to the elbow with soap and water for at least 30 seconds. An air dryer or disposable nonshedding towels are used to dry hands and forearms after washing.
12. Personnel entering the buffer area shall perform antiseptic hand cleansing prior to donning sterile gloves using a waterless alcohol-based surgical hand scrub with persistent activity.
13. Chewing gum, drinks, candy, or food items shall not be brought into the buffer area or ante-area. Materials exposed in patient care and treatment areas shall never be introduced into areas where components and ingredients for CSPs are present.
14. At the beginning of each compounding activity session, and whenever liquids are spilled, the surfaces of the direct compounding environment are first cleaned with USP Purified Water to remove water-soluble residues. Immediately thereafter, the same surfaces are disinfected with a nonresidue-generating agent using a nonlinting wipe.
15. Primary engineering controls shall be operated continuously during compounding activity. When the blower is turned off and before other personnel enter to perform compounding activities, only one person shall enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and disinfecting the work surfaces.
16. Traffic in the area of the DCA is minimized and controlled.
17. Supplies used in the DCA for the planned procedures are accumulated and then decontaminated by wiping or spraying the outer surface with sterile 70% IPA or removing the outer wrap at the edge of the DCA as the item is introduced into the aseptic work area.
18. All supply items are arranged in the DCA so as to reduce clutter and provide maximum efficiency and order for the flow of work.
19. After proper introduction into the DCA of supply items required for and limited to the assigned operations, they are so arranged that a clear, uninterrupted path of HEPA-filtered air will bathe all critical sites at all times during the planned procedures. That is, no objects may be placed between the first air from HEPA filters and an exposed critical site.
20. All procedures are performed in a manner designed to minimize the risk of touch contamination. Gloves are disinfected with adequate frequency with an approved disinfectant such as sterile 70% IPA.
21. All rubber stoppers of vials and bottles and the necks of ampuls are disinfected by wiping with sterile 70% IPA and waiting for at least 10 seconds before they are used to prepare CSPs.
22. After the preparation of every CSP, the contents of the container are thoroughly mixed and then inspected for the presence of particulate matter, evidence of incompatibility, or other defects.
23. After procedures are completed, used syringes, bottles, vials, and other supplies are removed, but with a minimum of exit and re-entry into the DCA so as to minimize the risk of introducing contamination into the aseptic workspace.

ELEMENTS OF QUALITY CONTROL

A written description of specific training and performance evaluation program for individuals involved in the use of aseptic techniques for the preparation of sterile products shall be developed for each site. This program equips personnel with the appropriate knowledge and trains them in the required skills necessary to perform the assigned tasks. Each person assigned to the aseptic area in the preparation of sterile products shall successfully complete specialized training in aseptic techniques and aseptic area practices prior to preparing CSPs (see *Personnel Training and Evaluation in Aseptic Manipulation Skills* and *Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures*).

Ingredients and Devices

Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality using the following information: vendor labels, labeling, certificates of analysis, direct chemical analysis, and knowledge of compounding facility storage conditions.

STERILE INGREDIENTS AND DEVICES

Commercially available sterile drug products, sterile ready-to-use containers, and devices are examples of sterile components. A written procedure for unit-by-unit physical inspection preparatory to use is followed to ensure that these components are sterile, free from defects, and otherwise suitable for their intended use.

NONSTERILE INGREDIENTS AND DEVICES

If any nonsterile components, including containers and ingredients, are used to make a CSP, such CSPs must be high risk. Nonsterile active ingredients and added substances or excipients for CSPs should preferably be official *USP* or *NF* articles. When nonofficial ingredients are used, they shall be accompanied by certificates of analysis from their suppliers to aid compounding personnel in judging the identity, quality, and purity in relation to the intended use in a particular CSP. Physical inspection of a package of ingredients is necessary in order to detect breaks in the container, looseness in the cap or closure, and deviation from the expected appearance, aroma, and texture of the contents.

Bulk or unformulated drug substances and added substances or excipients shall be stored in tightly closed containers under temperature, humidity, and lighting conditions that are either indicated in official monographs or approved by suppliers. The date of receipt by the compounding facility shall be clearly and indelibly marked on each package of ingredient. After receipt by the compounding facility, packages of ingredients that lack a supplier's expiration date cannot be used after 1 year unless either appropriate inspection or testing indicates that the ingredient has retained its purity and quality for use in CSPs.

Careful consideration and evaluation of nonsterile ingredient sources is especially warranted when the CSP will be administered into the vascular system, central nervous system, or eyes.

Upon receipt of each lot of the bulk drug substance or excipient used for CSPs, the individual compounding the preparation performs a visual inspection of the lot for evidence of deterioration, other types of unacceptable quality, and wrong identification. For bulk drug substances or excipients, visual inspection is performed on a routine basis as described in the written protocol.

Equipment

It is necessary that equipment, apparatus, and devices used to compound a CSP be consistently capable of operating properly and within acceptable tolerance limits. Written procedures outlining required equipment calibration, annual maintenance, monitoring for proper function, and controlled procedures for use of the equipment and specified time frames for these activities are established and followed. Routine maintenance and frequencies shall be outlined in these SOPs. Results from the equipment calibration, annual maintenance reports, and routine maintenance are kept on file for the lifetime of the equipment. Personnel are prepared through an appropriate combination of specific training and experience to operate or manipulate any piece of equipment, apparatus, or device they may use when preparing CSPs. Training includes gaining the ability to determine whether any item of equipment is operating properly or is malfunctioning.

VERIFICATION OF AUTOMATED COMPOUNDING DEVICES (ACDs) FOR PARENTERAL NUTRITION COMPOUNDING

ACDs for the preparation of parenteral nutrition admixtures are widely used by pharmacists in hospitals and other healthcare settings. They are designed to streamline the labor-intensive processes involved in the compounding of these multiple-component formulations by automatically delivering the individual nutritional components in a predetermined sequence under computerized control. Parenteral nutrition admixtures often contain 20 or more individual additives representing as many as 50 or more individual components (e.g., 15 to 20 crystalline amino acids, dextrose monohydrate, and lipids; 10 to 12 electrolyte salts; 5 to 7 trace minerals; and 12 vitamins). Thus, ACDs can provide improved accuracy and precision of the compounding process over the traditional manual compounding methods.

Accuracy

The accuracy of an ACD can be determined in various ways to ensure that the correct quantities of nutrients, electrolytes, or other nutritional components are delivered to the final infusion container. Initially, the ACD is tested for its volume and weight accuracy. For volume accuracy, a suitable volume of Sterile Water for Injection, USP, which represents a typical additive volume (e.g., 40 mL for small-volume range of 1 to 100 mL, 300 mL for large-volume range of 100 to 1000 mL), is programmed into the ACD and delivered to the appropriate volumetric container. The compounding personnel should then consult *Volumetric Apparatus* ⟨31⟩ for appropriate parameters to assess the volumetric performance of the ACD. For gravimetric accuracy, the balance used in conjunction with the ACD is tested using various weight sizes that represent the amounts typically used to deliver the various additives. Compounding personnel should consult *Weights and Balances* ⟨41⟩ for acceptable tolerances of the weights used. In addition, the same volume of *Sterile Water for Injection* used to assess volumetric accuracy is then weighed on the balance used in conjunction with the ACD. For example, if 40 mL of water was used in the volumetric assessment, its corresponding weight should be about 40 g (assuming the relative density of water is 1.0). In addition, during the use of the ACD, certain additives, such as potassium chloride (corrected for density differences), can also be tested in the same manner as with an in-process test.

Finally, additional tests of accuracy may be employed that determine the content of certain ingredients in the final volume of the parenteral nutrition admixture. Generally, pharmacy departments do not have the capability to routinely

perform chemical analyses such as analyses of dextrose or electrolyte concentrations. Consequently, hospital or institutional laboratories may be called upon to perform these quality assurance tests. However, the methods in such laboratories are often designed for biological, not pharmaceutical, systems. Thus, their testing procedures shall be verified to meet the *USP* requirements stated in the individual monograph for the component being tested. For example, under *Dextrose Injection*, the following is stated: It contains not less than 95.0% and not more than 105.0% of the labeled amount of $C_6H_{12}O_6 \cdot H_2O$. The hospital or institutional chemistry laboratories must validate their methods to apply to this range and correct for their typical measurement of anhydrous dextrose versus dextrose monohydrate. Similar ranges and issues exist, for example, for injections of calcium gluconate, magnesium sulfate, and potassium chloride. The critical point is the use of *USP* references and possible laboratory procedural differences.

Precision

The intermediate precision of the ACD can be determined on the basis of the day-to-day variations in performance of the accuracy measures. Thus, compounding personnel shall keep a daily record of the above-described accuracy assessments and review the results over time. This review shall occur at least at weekly intervals to avoid potentially clinically significant cumulative errors over time. This is especially true for additives with a narrow therapeutic index, such as potassium chloride.

FINISHED PREPARATION RELEASE CHECKS AND TESTS

The following quality metrics shall be performed for all CSPs before they are dispensed or administered.

Inspection of Solution Dosage Forms and Review of Compounding Procedures

All CSPs that are intended to be solutions shall be visually examined for the presence of particulate matter and not administered or dispensed when such matter is observed. The prescription orders, written compounding procedure, preparation records, and expended materials used to make CSPs at all contamination risk levels are inspected for accuracy of correct identities and amounts of ingredients, aseptic mixing and sterilization, packaging, labeling, and expected physical appearance before they are administered or dispensed.

PHYSICAL INSPECTION

Finished CSPs are individually inspected in accordance with written procedures after compounding. If not distributed promptly, these CSPs are individually inspected just prior to leaving the storage area. Those CSPs that are not immediately distributed are stored in an appropriate location as described in the written procedures. Immediately after compounding, and as a condition of release, each CSP unit, where possible, should be inspected against lighted white or black background or both for evidence of visible particulates or other foreign matter. Prerelease inspection also includes container–closure integrity and any other apparent visual defect. CSPs with observed defects should be immediately discarded or marked and segregated from acceptable products in a manner that prevents their administration. When CSPs are not distributed promptly after preparation, a predistribution inspection is conducted to ensure that a CSP with defects, such as precipitation, cloudiness, and leakage, which may develop between the time of release and the time of distribution, is not released.

Compounding Accuracy Checks

Written procedures for double-checking compounding accuracy shall be followed for every CSP during preparation and immediately prior to release. The double-check system should meet state regulations and include label accuracy and accuracy of the addition of all drug products or ingredients used to prepare the finished product and their volumes or quantities. The used additive containers and, for those additives for which the entire container was not expended, the syringes used to measure the additive should be quarantined with the final products until the final product check is completed. Compounding personnel shall visually confirm that ingredients measured in syringes match the written order being compounded. Preferably, a person other than the compounder can verify that correct volumes of correct ingredients were measured to make each CSP. For example, compounding personnel would pull the syringe plunger back to the volume measured.

When practical, the accuracy of measurements is confirmed by weighing a volume of the measured fluid, then calculating that volume by dividing the weight by the accurate value of the density, or specific gravity, of the measured fluid. Correct density or specific gravity values programmed in ACDs, which measure by weight using the quotient of the programmed volume divided by the density or specific gravity, shall be confirmed to be accurate before and after delivering volumes of the liquids assigned to each channel or port. These volume accuracy checks and the following additional safety and accuracy checks in this section shall be included in the SOP manual of the CSP facility.

Sterility Testing

All high-risk level CSPs that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in multiple-dose vials (MDVs) for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall meet the sterility test (see *Sterility Tests* ⟨71⟩) before they are dispensed or administered. The *Membrane Filtration* method is the method of choice where feasible (e.g., components are compatible with the membrane). A method not described in the *USP* may be used if verification results demonstrate that the alternative is at least as effective and reliable as the *USP Membrane Filtration* method or the *USP Direct Inoculation of the Culture Medium* method where the *Membrane Filtration* method is not feasible.

When high-risk level CSPs are dispensed before receiving the results of their sterility tests, there shall be a written procedure requiring daily observation of the incubating test specimens and immediate recall of the dispensed CSPs when there is any evidence of microbial growth in the test specimens. In addition, the patient and the physician of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. Positive sterility test results should prompt a rapid and systematic investigation of aseptic technique, environmental control, and other sterility assurance controls to identify sources of contamination and correct problems in the methods or processes.

Bacterial Endotoxin (Pyrogen) Testing

All high-risk level CSPs, except those for inhalation and ophthalmic administration, that are prepared in groups of more than 25 identical individual single-dose packages (e.g., ampuls, bags, syringes, vials) or in MDVs for administration to multiple patients or that are exposed longer than 12 hours at 2° to 8° and longer than 6 hours at warmer than 8° before they are sterilized shall be tested to ensure that they do not contain excessive bacterial endotoxins (see

Bacterial Endotoxins Test ⟨85⟩ and *Pyrogen Test* ⟨151⟩). In the absence of a bacterial endotoxins limit in the official monograph or other CSP formula source, the CSP shall not exceed the amount of USP Endotoxin Units (per hour per kilogram of body weight or square meters of body surface area) specified in *Bacterial Endotoxins Test* ⟨85⟩ referenced above for the appropriate route of administration.

Identity and Strength Verification of Ingredients

Compounding facilities shall have at least the following written procedures for verifying the correct identity and quality of CSPs before they are dispensed and administered:

1. That labels of CSPs bear correct names and amounts or concentrations of ingredients, the total volume, the BUD, the appropriate route(s) of administration, the storage conditions, and other information for safe use.
2. That there are correct identities, purities, and amounts of ingredients by comparing the original written order with the written compounding record for the CSP.
3. That correct fill volumes in CSPs and correct quantities of filled units of the CSPs were obtained. When the strength of finished CSPs cannot be confirmed to be accurate, based on the above three inspections, the CSPs shall be assayed by methods that are specific for the active ingredients.

STORAGE AND BEYOND-USE DATING

BUDs for compounded preparations are usually assigned on the basis of professional experience, which should include careful interpretation of appropriate information sources for the same or similar formulations (see *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩). BUDs for CSPs are rarely based on preparation-specific chemical assay results, which are used with the Arrhenius equation to determine expiration dates (see *General Notices and Requirements*) for manufactured products. The majority of CSPs are aqueous solutions in which hydrolysis of dissolved ingredients is the most common chemical degradation reaction. The extent of hydrolysis and other heat-catalyzed degradation reactions at any particular time point in the life of a CSP represents the thermodynamic sum of exposure temperatures and durations. Such lifetime stability exposure is represented in the mean kinetic temperature calculation (see *Pharmaceutical Calculations in Prescription Compounding* ⟨1160⟩). Drug hydrolysis rates increase exponentially with arithmetic temperature increase; thus, exposure of a beta-lactam antibiotic solution for 1 day at controlled room temperature (see *General Notices and Requirements*) will have an equivalent effect on the extent of hydrolysis of approximately 3 to 5 days in cold temperatures (see *General Notices and Requirements*).

Personnel who prepare, dispense, and administer CSPs shall store them strictly in accordance with the conditions stated on the label of ingredient products and finished CSPs. When CSPs are known to have been exposed to temperatures warmer than the warmest labeled limit or to temperatures exceeding 40° (see *General Notices and Requirements*) for more than 4 hours, such CSPs should be discarded unless direct assay data or appropriate documentation confirms their continued stability.

Determining Beyond-Use Dates

BUDs and expiration dates are not the same (see *General Notices and Requirements*). Expiration dates for the chemical and physical stability of manufactured sterile products are determined from results of rigorous analytical and performance testing, and they are specific for a particular formulation in its container and at stated exposure conditions of illumination and temperature. When CSPs deviate from conditions in the approved labeling of manufactured products contained in CSPs, compounding personnel may consult the manufacturer of particular products for advice on assigning BUDs based on chemical and physical stability parameters. BUDs for CSPs that are prepared strictly in accordance with manufacturers' product labeling shall be those specified in that labeling or from appropriate literature sources or direct testing. BUDs for CSPs that lack justification from either appropriate literature sources or by direct testing evidence shall be assigned as described in *Stability Criteria and Beyond-Use Dating* under *Pharmaceutical Compounding—Nonsterile Preparations* ⟨795⟩.

In addition, compounding personnel may refer to applicable publications to obtain relevant stability, compatibility, and degradation information regarding the drug or its congeners. When assigning a beyond-use date, compounding personnel should consult and apply drug-specific and general stability documentation and literature where available, and they should consider the nature of the drug and its degradation mechanism, the container in which it is packaged, the expected storage conditions, and the intended duration of therapy (see *Expiration Date and Beyond-Use Date* under *Labeling* in the *General Notices and Requirements*). Stability information must be carefully interpreted in relation to the actual compounded formulation and conditions for storage and use. Predictions based on other evidence, such as publications, charts, and tables, would result in theoretical BUDs. Theoretically predicted beyond-use dating introduces varying degrees of assumptions and, hence, a likelihood of error or at least inaccuracy. The degree of error or inaccuracy would be dependent on the extent of differences between the CSPs' characteristics (e.g., composition, concentration of ingredients, fill volume, container type and material) and the characteristics of the products from which stability data or information is to be extrapolated. The greater the doubt of the accuracy of theoretically predicted beyond-use dating, the greater the need to determine dating periods experimentally. Theoretically predicted beyond-use dating periods should be carefully considered for CSPs prepared from nonsterile bulk active ingredients having therapeutic activity, especially where these CSPs are expected to be compounded routinely. When CSPs will be distributed to and administered in residential locations other than healthcare facilities, the effect of potentially uncontrolled and unmonitored temperature conditions shall be considered when assigning BUDs. It must be ascertained that CSPs will not be exposed to warm temperatures (see *General Notices and Requirements*) unless the compounding facility has evidence to justify stability of CSPs during such exposure.

It should be recognized that the truly valid evidence of stability for predicting beyond-use dating can be obtained only through product-specific experimental studies. Semiquantitative procedures such as thin-layer chromatography (TLC) may be acceptable for many CSPs. However, quantitative stability-indicating assays such as high-performance liquid chromatographic (HPLC) assays would be more appropriate for certain CSPs. Examples include CSPs with a narrow therapeutic index, where close monitoring or dose titration is required to ensure therapeutic effectiveness and to avoid toxicity; where a theoretically established beyond-use dating period is supported by only marginal evidence; or where a significant margin of safety cannot be verified for the proposed beyond-use dating period. In short, because beyond-use dating periods established from product-specific data acquired from the appropriate instrumental analyses are clearly more reliable than those predicted theoretically, the former approach is strongly urged to support dating periods exceeding 30 days.

To ensure consistent practices in determining and assigning BUDs, the compounding facility should have written policies and procedures governing the determination of the BUDs for all compounded products. When attempting to

predict a theoretical BUD, a compounded or an admixed preparation should be considered as a unique system that has physical and chemical properties and stability characteristics that differ from its components. For example, antioxidant, buffering, or antimicrobial properties of a sterile vial for injection (SVI) might be lost upon its dilution, with the potential of seriously compromising the chemical stability of the SVI's active ingredient or the physical or microbiological stability of the SVI formulation in general. Thus, the properties stabilized in the SVI formulation usually cannot be expected to be carried over to the compounded or admixed preparation. Preparation-specific, experimentally determined stability data evaluation protocols are preferable to published stability information. Compounding personnel should consult general information chapter *Pharmaceutical Stability* ⟨1150⟩ for the appropriate stability parameters to be considered when initiating or evaluating a preparation-specific stability study.

Compounding personnel who assign BUDs to CSPs when lacking direct chemical assay results must critically interpret and evaluate the most appropriate available information sources to determine a conservative and safe BUD. The SOP manual of the compounding facility and each specific CSP formula record shall describe the general basis used to assign the BUD and storage conditions.

When manufactured MDVs (see *Multiple-Dose Container* under *Preservation, Packaging, Storage,* and *Labeling* in the *General Notices and Requirements*) of sterile ingredients are used in CSPs, the stoppers of the MDVs are inspected for physical integrity and disinfected by wiping with a sterile 70% IPA swab before each penetration with a sterile withdrawal device. When contaminants or abnormal properties are suspected or observed in MDVs, such MDVs shall be discarded. The BUD after initially entering or opening (e.g., needle puncturing) multiple-dose containers is 28 days (see *Antimicrobial Effectiveness Testing* ⟨51⟩) unless otherwise specified by the manufacturer.

Proprietary Bag and Vial Systems

The sterility storage and stability beyond-use times for attached and activated (where activated is defined as allowing contact of the previously separate diluent and drug contents) container pairs of drug products for intravascular administration (e.g., ADD-Vantage®, Mini Bag Plus®) shall be applied as indicated by the manufacturer. In other words, follow manufacturers' instructions for handling and storing ADD-Vantage®, Mini Bag Plus®, Add A Vial®, Add-Ease® products, and any others.

Monitoring Controlled Storage Areas

To ensure that product potency is retained through the manufacturer's labeled expiration date, compounding personnel shall monitor the drug storage areas within the compounding facility. Controlled temperature areas in compounding facilities include controlled room temperature, 20° to 25° with mean kinetic temperature 25°; controlled cold temperature, 2° to 8° with mean kinetic temperature 8°; cold temperature, 2° to 8°; freezing temperature, –25° and –10° (see *General Notices and Requirements)* if needed to achieve freezing, and the media-specific temperature range for microbial culture media. A controlled temperature area shall be monitored at least once daily and the results documented on a temperature log. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberrations. Suitable temperature recording devices may include a calibrated continuous recording device or a National Institute of Standards and Technology (NIST) calibrated thermometer that has adequate accuracy and sensitivity for the intended purpose, and it shall be properly calibrated at suitable intervals. If the compounding facility uses a continuous temperature recording device, compounding personnel shall verify at least once daily that the recording device itself is functioning properly.

The temperature-sensing mechanisms shall be suitably placed in the controlled temperature storage space to reflect accurately its true temperature. In addition, the compounding facility shall adhere to appropriate procedures of all controlled storage spaces to ensure that such spaces are not subject to significantly prolonged temperature fluctuations as may occur, for example, by leaving a refrigerator door open too long.

MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs

This section summarizes the responsibilities of compounding facilities for maintaining quality and control of CSPs that are dispensed and administered within their parent healthcare organizations.

Compounding personnel shall ensure proper storage and security of CSPs prepared by or dispensed from the compounding facility until either their BUDs are reached or they are administered to patients. In fulfilling this general responsibility, the compounding facility is responsible for the proper packaging, handling, transport, and storage of CSPs prepared by or dispensed from it, including the appropriate education, training, and supervision of compounding personnel assigned to these functions. The compounding facility should assist in the education and training of noncompounding personnel responsible for carrying out any aspect of these functions.

Establishing, maintaining, and ensuring compliance with comprehensive written policies and procedures encompassing these responsibilities is a further responsibility of the compounding facility. Where noncompounding personnel are assigned tasks involving any of these responsibilities, the policies and procedures encompassing those tasks should be developed by compounding supervisors. The quality and control activities related to distribution of CSPs are summarized in the following five subsections. Activities or concerns that should be addressed as the compounding facility fulfills these responsibilities are as follows.

Packaging, Handling, and Transport

Inappropriate processes or techniques involved with packaging, handling, and transport can adversely affect quality and package integrity of CSPs. Although compounding personnel routinely perform many of the tasks associated with these functions, some tasks, such as transport, handling, and placement into storage, may be fulfilled by noncompounding personnel who are not under the direct administrative control of the compounding facility. Under these circumstances, appropriate SOPs shall be established by the compounding facility with the involvement of other departments or services whose personnel are responsible for carrying out those CSP-related functions for which the compounding facility has a direct interest. The performance of the noncompounding personnel is monitored for compliance to established policies and procedures.

The critical requirements that are unique to CSPs and that are necessary to ensure CSP quality and packaging integrity shall be addressed in SOPs. For example, techniques should be specified to prevent the depression of syringe plungers or dislodging of syringe tips during handling and transport. Additionally, disconnection of system components (e.g., where CSPs are dispensed with administration sets attached to them) shall be prevented through the BUD of the CSP. Foam padding or inserts are particularly useful where CSPs are transported by pneumatic tube systems. Regardless of the methods used, the compounding facility must evaluate their effectiveness and the reliability of the intended protec-

tion. Evaluation should be continuous—for example, through a surveillance system, including a system of problem reporting to the compounding facility.

Inappropriate transport and handling can adversely affect the quality of certain CSPs having unique stability concerns. For example, the physical shaking that might occur during pneumatic tube transport or undue exposure to heat or light must be addressed on a preparation-specific basis. Alternative transport modes or special packaging measures might be needed for the proper assurance of quality of these CSPs. The use of tamper-evident closures and seals on CSP ports can add an additional measure of security to ensure product integrity regardless of the transport method used.

Chemotoxic and other hazardous CSPs require safeguards to maintain the integrity of the CSP and to minimize the exposure potential of these products to the environment and to personnel who may come in contact with them. Transportation by pneumatic tube should be discouraged because of potential breakage and contamination. Special requirements associated with the packaging, transport, and handling of these agents include the prevention of accidental exposures or spills and the training of personnel in the event of an exposure or spill. Examples of special requirements of these agents also include exposure-reducing strategies such as the use of Luer lock syringes and connections, syringe caps, the capping of container ports, sealed plastic bags, impact-resistant containers, and cautionary labeling.

Use and Storage

The compounding facility is responsible for ensuring that CSPs in the patient-care setting maintain their quality until administered. The immediate labeling of the CSP container will display prominently and understandably the requirements for proper storage and expiration dating. Delivery and patient-care-setting personnel shall be properly trained to deliver the CSP to the appropriate storage location. Outdated and unused CSPs shall be returned to the compounding facility for disposition.

SOPs must exist to ensure that storage conditions in the patient-care setting are suitable for the CSP-specific storage requirements. Procedures include daily monitoring and documentation of drug storage refrigerators to ensure temperatures between 2° and 8° and the monthly inspection of all drug storage locations by compounding personnel. Inspections shall confirm compliance with appropriate storage conditions, separation of drugs and food, proper use of MDVs, and the avoidance of using single-dose products as MDVs. CSPs, as well as all other drug products, shall be stored in the patient-care area in such a way as to secure them from unauthorized personnel, visitors, and patients.

Readying for Administration

Procedures essential for generally ensuring quality, especially sterility assurance, when readying a CSP for its subsequent administration include proper hand washing, aseptic technique, site care, and change of administration sets. Additional procedures may also be essential for certain CSPs, devices, or techniques. Examples where such special procedures are needed include in-line filtration, the operation of automated infusion control devices, and the replenishment of CSPs into the reservoirs of implantable or portable infusion pumps. When CSPs are likely to be exposed to warmer than 30° for more than 1 hour during their administration to patients, the maintenance of their sterility and stability should be confirmed from either relevant and reliable sources or direct testing.

Redispensed CSPs

The compounding facility shall have the sole authority to determine when unopened, returned CSPs may be redispensed. Returned CSPs may be redispensed only when personnel responsible for sterile compounding can ensure that such CSPs are sterile, pure, and stable (contain labeled strength of ingredients). The following may provide such assurance: the CSPs were maintained under continuous refrigeration and protected from light, if required, and no evidence of tampering or any readying for use outside the compounding facility exists. Assignment of new storage times and BUDs that exceed the original dates for returned CSPs is permitted only when there is supporting evidence from sterility testing and quantitative assay of ingredients. Thus, initial preparation and thaw times should be documented and reliable measures should have been taken to prevent and detect tampering. Compliance with all procedures associated with maintaining product quality is essential. The CSPs shall not be redispensed if there is not adequate assurance that preparation quality and packaging integrity (including the connections of devices, where applicable) were continuously maintained between the time the CSPs left and the time they were returned. Additionally, CSPs shall not be redispensed if redispensing cannot be supported by the originally assigned BUD.

Education and Training

The assurance of CSPs' quality and packaging integrity is highly dependent on the proper adherence of all personnel to the pertinent SOPs. Compounding personnel shall design, implement, and maintain a formal education, training, and competency assessment program that encompasses all the functions and tasks addressed in the foregoing sections and all personnel to whom such functions and tasks are assigned. This program includes the assessment and documentation of procedural breaches, administration mishaps, side effects, allergic reactions, and complications associated with dosage or administration, such as extravasation. This program should be coordinated with the institution's adverse-events and incident reporting programs.

Packing and Transporting CSPs

The following sections describe how to maintain sterility and stability of CSPs until they are delivered to patient care locations for administration.

PACKING CSPS FOR TRANSIT

When CSPs are distributed to locations outside the premises in which they are compounded, compounding personnel select packing containers and materials that are expected to maintain physical integrity, sterility, and stability of CSPs during transit. Packing is selected that simultaneously protects CSPs from damage, leakage, contamination, and degradation, and protects personnel who transport packed CSPs from harm. The SOP manual of the compounding facility specifically describes appropriate packing containers and insulating and stuffing materials, based on information from product specifications, vendors, and experience of compounding personnel. Written instructions that clearly explain how to safely open containers of packed CSPs are provided to patients and other recipients.

TRANSIT OF CSPs

Compounding facilities that ship CSPs to locations outside their own premises shall select modes of transport that are expected to deliver properly packed CSPs in undamaged, sterile, and stable condition to recipients.

Compounding personnel should ascertain that temperatures of CSPs during transit by the selected mode will not exceed the warmest temperature specified on the storage temperature range on CSP labels. It is recommended that compounding personnel communicate directly with the couriers to learn shipping durations and exposure conditions that CSPs may encounter.

Compounding personnel shall include specific handling and exposure instructions on the exteriors of containers packed with CSPs to be transported and obtain reasonable assurance of compliance therewith from transporters. Compounding personnel shall periodically review the delivery performance of couriers to ascertain that CSPs are being efficiently and properly transported.

Storage in Locations Outside Compounding Facilities

Compounding facilities that ship CSPs to patients and other recipients outside their own premises shall ascertain or provide, whichever is appropriate, the following assurances:

1. Labels and accessory labeling for CSPs include clearly readable BUDs, storage instructions, and disposal instructions for out-of-date units.
2. Each patient or other recipient is able to store the CSPs properly, including the use of a properly functioning refrigerator and freezer if CSPs are labeled for such storage.

PATIENT OR CAREGIVER TRAINING

A formal training program is provided as a means to ensure understanding and compliance with the many special and complex responsibilities placed on the patient or caregiver for the storage, handling, and administration of CSPs. The instructional objectives for the training program include all home care responsibilities expected of the patient or caregiver and is specified in terms of patient or caregiver competencies.

Upon the conclusion of the training program, the patient or caregiver should, correctly and consistently, be able to do the following:

1. Describe the therapy involved, including the disease or condition for which the CSPs are prescribed, goals of therapy, expected therapeutic outcome, and potential side effects of the CSPs.
2. Inspect all drug products, CSPs, devices, equipment, and supplies on receipt to ensure that proper temperatures were maintained during transport and that goods received show no evidence of deterioration or defects.
3. Handle, store, and monitor all drug products, CSPs, and related supplies and equipment in the home, including all special requirements related to same.
4. Visually inspect all drug products, CSPs, devices, and other items the patient or caregiver is required to use immediately prior to administration in a manner to ensure that all items are acceptable for use. For example, CSPs must be free from leakage, container cracks, particulates, precipitate, haziness, discoloration, or other deviations from the normal expected appearance, and the immediate packages of sterile devices must be completely sealed, with no evidence of loss of package integrity.
5. Check labels immediately prior to administration to ensure the right drug, dose, patient, and time of administration.
6. Clean the in-home preparation area, scrub hands, use proper aseptic technique, and manipulate all containers, equipment, apparatus, devices, and supplies used in conjunction with administration.
7. Employ all techniques and precautions associated with CSP administration; for example, preparing supplies and equipment, handling of devices, priming the tubing, and discontinuing an infusion.
8. Care for catheters, change dressings, and maintain site patency as indicated.
9. Monitor for and detect occurrences of therapeutic complications such as infection, phlebitis, electrolyte imbalance, and catheter misplacement.
10. Respond immediately to emergency or critical situations such as catheter breakage or displacement, tubing disconnection, clot formation, flow blockage, and equipment malfunction.
11. Know when to seek and how to obtain professional emergency services or professional advice.
12. Handle, contain, and dispose of wastes, such as needles, syringes, devices, biohazardous spills or residuals, and infectious substances.

Training programs include a hands-on demonstration and practice with actual items that the patient or caregiver is expected to use, such as CSP containers, devices, and equipment. The patient or caregiver practices aseptic and injection technique under the direct observation of a health professional.

The compounding facility, in conjunction with nursing or medical personnel, is responsible for ensuring initially and on an ongoing basis that the patient or caregiver understands, has mastered, and is capable of and willing to comply with all of these home care responsibilities. This is achieved through a formal, written assessment program. All specified competencies in the patient or caregiver training program are formally assessed. The patient or caregiver is expected to demonstrate to appropriate healthcare personnel mastery of assigned activities before being allowed to administer CSPs unsupervised by a health professional.

Printed material such as checklists or instructions provided during training may serve as continuing post-training reinforcement of learning or as reminders of specific patient or caregiver responsibilities. Post-training verbal counseling can also be used periodically, as appropriate, to reinforce training and to ensure continuing correct and complete fulfillment of responsibilities.

PATIENT MONITORING AND ADVERSE EVENTS REPORTING

Compounding facilities shall clinically monitor patients treated with CSPs according to the regulations and guidelines of their respective state healthcare practitioner licensure boards or of accepted standards of practice. Compounding facilities shall provide patients and other recipients of CSPs with a way to address their questions and report any concerns that they may have with CSPs and their administration devices.

The SOP manuals of compounding facilities shall describe specific instructions for receiving, acknowledging, and dating receipts, and for recording, or filing, and evaluating reports of adverse events and of the quality of preparation claimed to be associated with CSPs. Reports of adverse events with CSPs shall be reviewed promptly and thoroughly by compounding supervisors to correct and prevent future occurrences. Compounding personnel are encouraged to participate in adverse event reporting and product defects programs of the FDA and USP.

QUALITY ASSURANCE (QA) PROGRAM

A provider of CSPs shall have in place a formal QA program intended to provide a mechanism for monitoring, evaluating, correcting, and improving the activities and processes described in this chapter. Emphasis in the QA program is placed on maintaining and improving the quality of systems and the provision of patient care. In addition, the QA program ensures that any plan aimed at correcting identified problems also includes appropriate follow-up to make certain that effective corrective actions were performed.[13]

Characteristics of a QA program include the following:

1. Formalization in writing;
2. Consideration of all aspects of the preparations and dispensing of products as described in this chapter, including environmental testing and verification results;
3. Description of specific monitoring and evaluation activities;
4. Specification of how results are to be reported and evaluated;
5. Identification of appropriate follow-up mechanisms when action limits or thresholds are exceeded; and
6. Delineation of the individuals responsible for each aspect of the QA program.

In developing a specific plan, focus is on establishing objective, measurable indicators for monitoring activities and processes that are deemed high risk, high volume, or problem prone. In general, the selection of indicators and the effectiveness of the overall QA program is reassessed on an annual basis.

ABBREVIATIONS AND ACRONYMS

ACD	automated compounding device
ACPH	air changes per hour
ALARA	as low as reasonably achievable
ASHRAE	American Society of Heating, Refrigerating and Air-Conditioning Engineers
BI	biological indicator
BSC	biological safety cabinet
BUD	beyond-use date
CACI	compounding aseptic containment isolator
CAI	compounding aseptic isolator
CDC	Centers for Disease Control and Prevention
CETA	Controlled Environment Testing Association
cfu	colony-forming unit(s)
CSP	compounded sterile preparation
CSTD	closed-system vial-transfer device
DCA	direct compounding area
ECV	endotoxin challenge vial
EU	Endotoxin Unit
FDA	Food and Drug Administration
HEPA	high efficiency particulate air
HICPAC	Healthcare Infection Control Practices Advisory Committee
HVAC	heating, ventilation, and air conditioning
IPA	isopropyl alcohol
ISO	International Organization for Standardization
LAFW	laminar airflow workbench
MDVs	multiple-dose vials
MMWR	Morbidity and Mortality Weekly Report
NIOSH	National Institute for Occupational Safety and Health
NIST	National Institute of Standards and Technology
PEC	primary engineering control
PET	positron emission tomography
PPE	personnel protective equipment
psi	pounds per square inch
QA	quality assurance
SOP	standard operating procedure
SVI	sterile vial for injection
TSA	trypticase soy agar
USP	United States Pharmacopeia

[13] The use of additional resources, such as the Accreditation Manual for Home Care from the Joint Commission on Accreditation of Healthcare Organizations, may prove helpful in the development of a QA plan.

APPENDICES

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩

NOTE—This tabular appendix selectively abstracts and condenses the full text of ⟨797⟩ for rapid reference only. Compounding personnel are responsible for reading, understanding and complying with the full text and all official USP terminology, content, and conditions therein.

INTRODUCTION

‡ Chapter purpose is to prevent harm and death to patients treated with CSPs.

† Chapter pertains to preparation, storage, and transportation, but not administration, of CSPs.

† Personnel and facilities to which ⟨797⟩ applies; therefore, for whom and which it may be enforced by regulatory and accreditation authorities.

† Types of preparations designated to be CSPs according to their physical forms, and their sites and routes of administration to patients.

† Compounding personnel must be meticulously conscientious to preclude contact contamination of CSPs both within and outside ISO Class 5 areas.

ORGANIZATION

† All compounding personnel shall be responsible for understanding fundamental practices and precautions within USP ⟨797⟩, for developing and implementing appropriate procedures, and for continually evaluating these procedures and the quality of final CSPs to prevent harm.

DEFINITIONS

† Twenty-eight terms are defined and integral to complying with USP ⟨797⟩.

RESPONSIBILITY OF COMPOUNDING PERSONNEL

† Practices and quality assurances required to prepare, store, and transport CSPs that are sterile, and acceptably accurate, pure, and stable.

CSP MICROBIAL CONTAMINATION RISK LEVELS

† Proper training and evaluation of personnel, proper cleansing and garbing of personnel, proper cleaning and disinfecting of compounding work environments, and proper maintenance and monitoring of controlled environmental locations (all of which are detailed in their respective sections).

Low-Risk Level CSPs

† Aseptic manipulations within an ISO Class 5 environment using three or fewer sterile products and entries into any container.

† In absence of passing sterility test, store not more than 48 hours at controlled room temperature, 14 days at cold temperature, and 45 days in solid frozen state at –25° to –10° or colder.

† Media-fill test at least annually by compounding personnel.

Low-Risk Level CSPs with 12-Hour or Less BUD

† Fully comply with all four specific criteria.

‡ Sinks should not be located adjacent to the ISO Class 5 primary engineering control.

‡ Sinks should be separated from the immediate area of the ISO Class 5 primary engineering control device.

Medium-Risk Level CSPs

† Aseptic manipulations within an ISO Class 5 environment using prolonged and complex mixing and transfer, more than three sterile products and entries into any container, and pooling ingredients from multiple sterile products to prepare multiple CSPs.

† In absence of passing sterility test, store not more than 30 hours at controlled room temperature, 9 days at cold temperature, and 45 days in solid frozen state at –25° to –10° or colder.

†Media-fill test at least annually by compounding personnel.

High-Risk Level CSPs

† Confirmed presence of nonsterile ingredients and devices, or confirmed or suspected exposure of sterile ingredients for more than one hour to air quality inferior to ISO Class 5 before final sterilization.

† Sterilization method verified to achieve sterility for the quantity and type of containers.

† Meet allowable limits for bacterial endotoxins.

† Maintain acceptable strength and purity of ingredients and integrity of containers after sterilization.

† In absence of passing sterility test, store not more than 24 hours at controlled room temperature, 3 days at cold temperature, and 45 days in solid frozen state at –25° to –10° or colder.

† Media-fill test at least semiannually by compounding personnel.

PERSONNEL TRAINING AND EVALUATION IN ASEPTIC MANIPULATIONS SKILLS

† Pass didactic, practical skill assessment and media-fill testing initially, followed by an annual assessment for a low- and medium-risk level compounding and semi-annual assessment for high-risk level compounding.

† Compounding personnel who fail written tests, or whose media-fill test vials result in gross microbial colonization, shall be immediately reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic practice deficiencies.

IMMEDIATE-USE CSPs

† Fully comply with all six specified criteria.

APPENDICES

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

SINGLE-DOSE AND MULTIPLE-DOSE CONTAINERS

† Beyond-use date 28 days, unless specified otherwise by the manufacturer, for closure sealed multiple-dose containers after initial opening or entry.

† Beyond-use time of 6 hours, unless specified otherwise by the manufacturer, for closure sealed single-dose containers in ISO Class 5 or cleaner air after initial opening or entry.

† Beyond-use time of 1 hour for closure sealed single-dose containers after being opened or entered in worse than ISO Class 5 air.

† Storage of opened single-dose ampuls is not permitted.

HAZARDOUS DRUGS AS CSPs

† Appropriate personnel protective equipment.

† Appropriate primary engineering controls (BSCs and CACIs) are used for concurrent personnel protection and exposure of critical sites.

† Hazardous drugs shall be stored separately from other inventory in a manner to prevent contamination and personnel exposure.

† At least 0.01 inch water column negative pressure and 12 air changes per hour in non-cleanrooms in which CACIs are located.

† Hazardous drugs shall be handled with caution at all times using appropriate chemotherapy gloves during receiving, distribution, stocking, inventorying, preparing for administration, and disposal.

† Hazardous drugs shall be prepared in an ISO Class 5 environment with protective engineering controls in place, and following aseptic practices specified for the appropriate contamination risk levels.

† Access to drug preparation areas shall be limited to authorized personnel.

† A pressure indicator shall be installed that can readily monitor room pressurization, which is documented daily.

† Annual documentation of full training of personnel regarding storage, handling, and disposal of hazardous drugs.

† When used, a CSTD shall be used in an ISO Class 5 primary engineering control device.

† At least 0.01 inch water column negative pressure is required for compounding of hazardous drugs.

‡ Negative-pressure buffer area is not required for low-volume compounding operations when CSTD is used in BSC or CACI.

† Compounding personnel of reproductive capability shall confirm in writing that they understand the risks of handling hazardous drugs.

† Disposal of all hazardous drug wastes shall comply with all applicable federal and state regulations.

‡ Total external exhaust of primary engineering controls.

‡ Assay of surface wipe samples every 6 months.

RADIOPHARMACEUTICALS AS CSPs

† Positron Emission Tomography is according to USP chapter ⟨823⟩.

† Appropriate primary engineering controls and radioactivity containment and shielding.

† Radiopharmaceuticals compounded from sterile components, in closed sterile containers, with volume of 100 mL or less for a single-dose injection or not more than 30 mL taken from a multiple-dose container shall be designated as and conform to the standards for low-risk level CSPs.

† Radiopharmaceutical vials, designed for multi-use, compounded with technetium-99m, exposed to ISO Class 5 environment and punctured by needles with no direct contact contamination may be used up to the time indicated by manufacturers' recommendations.

† Location of primary engineering controls permitted in ISO Class 8 controlled environment.

† Technetium-99m/Molybdenum-99 generators used according to manufacturer, state, and federal requirements.

† Radiopharmaceuticals prepared as low-risk level CSPs with 12-hour or less BUD shall be prepared in a segregated compounding area.

† Materials and garb exposed in patient-care and treatment area shall not cross a line of demarcation into the segregated compounding area.

† Technetium-99m/Molybdenum-99 generators must be eluted in ISO Class 8 conditions.

† Segregated compounding area will be designated with a line of demarcation.

‡ Storage and transport of properly shielded vials of radiopharmaceutical CSPs may occur in a limited access ambient environment without a specific ISO class designation.

ALLERGEN EXTRACTS AS CSPs

† Allergen extracts as CSPs are not subject to the personnel, environmental, and storage requirements for all CSP Microbial Contamination Risk Levels when certain criteria are met.

VERIFICATION OF COMPOUNDING ACCURACY AND STERILITY

† Review labels and document correct measurements, aseptic manipulations, and sterilization procedures to confirm correct identity, purity, and strength of ingredients in, and sterility of, CSPs.

‡ Assay finished CSPs to confirm correct identity and, or, strength of ingredients.

‡ Sterility test finished CSPs.

Sterilization Methods

† Verify that methods achieve sterility while maintaining appropriate strength, purity, quality, and packaging integrity.

‡ Prove effectiveness by USP chapter ⟨71⟩, equivalent, or superior sterility testing.

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

Sterilization of High-Risk Level CSPs by Filtration

† Nominal 0.2-µm pore size sterile membranes that are chemically and physically compatible with the CSP.

† Complete rapidly without filter replacement.

† Subject filter to manufacturer's recommended integrity test (e.g., bubble point test) after filtering CSPs.

Sterilization of High-Risk Level CSPs by Steam

† Test to verify the mass of containers to be sterilized will be sterile after the selected exposure duration in the particular autoclave.

† Ensure live steam contacts all ingredients and surfaces to be sterilized.

† Pass solutions through a 1.2-µm or smaller nominal pore size filter into final containers to remove particulates before sterilization.

† Heated filtered air shall be evenly distributed throughout the chamber by a blower device.

† Dry heat shall only be used for those materials that cannot be sterilized by steam, when the moisture would either damage or be impermeable to the materials.

† Sufficient space shall be left between materials to allow for good circulation of the hot air.

† The description of dry heat sterilization conditions and duration for specific CSPs shall be included in written documentation in the compounding facility. The effectiveness of dry heat sterilization shall be verified using appropriate biological indicators and other confirmation.

‡ The oven should be equipped with a system for controlling temperature and exposure period.

Depyrogenation by Dry Heat

† Dry heat depyrogenation shall be used to render glassware or containers, such as vials free from pyrogens as well as viable microbes.

† The description of the dry heat depyrogenation cycle and duration for specific load items shall be included in written documentation in the compounding facility.

† The effectiveness of the dry heat depyrogenation cycle shall be verified using endotoxin challenge vials (ECVs).

‡ The bacterial endotoxin test should be performed on the ECVs to verify the cycle is capable of achieving a 3 log reduction in endotoxin.

ENVIRONMENTAL QUALITY AND CONTROL

Exposure of Critical Sites

† ISO Class 5 or better air.

† Preclude direct contact (e.g., touch and secretions) contamination.

ISO Class 5 Air Sources, Buffer Areas, and Ante-Areas

† A buffer area is an area that provides at least ISO Class 7 air quality.

† New representations of facility layouts.

† Each compounding facility shall ensure that each source of ISO Class 5 environment for exposure of critical sites and sterilization by filtration is properly located, operated, maintained, monitored, and verified.

† Devices (e.g., computers and printers) and objects (e.g., carts and cabinets) can be placed in buffer areas and shall be verified by testing or monitoring.

Viable and Nonviable Environmental Sampling (ES) Testing

† Environmental sampling shall occur as part a comprehensive quality management program and shall occur minimally when several conditions exist.

‡ The ES program should provide information to staff and leadership to demonstrate that the engineering controls are maintaining an environment within the compounding area that consistently maintains acceptably low viable and nonviable particle levels.

Environmental Nonviable Particle Testing Program

† Certification and testing of primary (LAFWs, BSCs, CAIs and CACIs) and secondary engineering controls (buffer and ante areas) shall be performed by a qualified individual no less than every six months and whenever the device or room is relocated, altered, or major service to the facility is performed. Certification procedures such as those outlined in the CETA Certification Guide for Sterile Compounding Facilities (CAG-003-2006) shall be used.

Total Particle Counts

† Certification that each ISO classified area (e.g., ISO Class 5, 7 and 8) is within established guidelines shall be performed no less than every 6 months and whenever the LAFW, BSC, CAI, or CACI is relocated or the physical structure of the buffer room or ante-area has been altered.

† Testing shall be performed by qualified operators using current, state-of-the-art electronic equipment with results meeting ISO Class 5, 7, or 8 depending on the requirements of the area.

† All certification records shall be maintained and reviewed by supervising personnel or other designated employee to ensure that the controlled environments comply with the proper air cleanliness, room pressures, and air changes per hour.

Pressure Differential Monitoring

† A pressure gauge or velocity meter shall be installed to monitor the pressure differential or airflow between the buffer area and ante-area, and the ante-area and the general environment outside the compounding area.

† The results shall be reviewed and documented on a log at least every work shift (minimum frequency shall be at least daily) or by a continuous recording device.

† The pressure between the ISO Class 7 and general pharmacy area shall not be less than 5 Pa (0.02 inch water column (w.c.)).

† In facilities where low- and medium-risk level CSPs are prepared, differential airflow shall maintain a minimum velocity of 0.2 meter/second (40 fpm) between buffer area and ante-area.

Environmental Viable Airborne Particle Testing Program—Sampling Plan

† An appropriate environmental sampling plan shall be developed for airborne viable particles based on a risk assessment of compounding activities performed.

† Selected sampling sites shall include locations within each ISO Class 5 environment and in the ISO Class 7 and 8 areas, and the segregated compounding areas at greatest risk of contamination (e.g., work areas near the ISO Class 5 environment, counters near doors, pass-through boxes).

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

† The plan shall include sample location, method of collection, frequency of sampling, volume of air sampled, and time of day as related to activity in the compounding area and action levels.

‡ It is recommended that compounding personnel refer to USP Chapter *Microbiological Evaluation of Clean Rooms and Other Controlled Environments* ⟨1116⟩ and the CDC Guidelines for Environmental Infection Control in Healthcare Facilities-2003 for more information.

Growth Media

† A general microbiological growth medium such as Soybean–Casein Digest Medium (also known as trypticase soy broth (TSB) or agar (TSA)) shall be used to support the growth of bacteria.

† Malt extract agar (MEA) or some other media that supports the growth of fungi shall be used in high-risk level compounding environments.

† Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with lecithin and polysorbate 80).

Viable Air Sampling

† Evaluation of airborne microorganisms using volumetric collection methods in the controlled air environments shall be performed by properly trained individuals for all compounding risk levels.

† Impaction shall be the preferred method of volumetric air sampling.

† For low-, medium-, and high-risk level compounding, air sampling shall be performed at locations that are prone to contamination during compounding activities and during other activities like staging, labeling, gowning, and cleaning.

† Locations shall include zones of air backwash turbulence within laminar airflow workbench and other areas where air backwash turbulence may enter the compounding area.

† For low-risk level CSPs with 12-hour or less BUD, air sampling shall be performed at locations inside the ISO Class 5 environment and other areas that are in close proximity to the ISO class 5 environment, during the certification of the primary engineering control.

‡ Consideration should be given to the overall effect the chosen sampling method will have on the unidirectional airflow within a compounding environment.

Air Sampling Devices

† The instructions in the manufacturer's user manual for verification and use of electric air samplers that actively collect volumes of air for evaluation shall be followed.

† A sufficient volume of air (400–1000 liters) shall be tested at each location in order to maximize sensitivity.

‡ It is recommended that compounding personnel also refer to USP Chapter ⟨1116⟩, which can provide more information on the use of volumetric air samplers and volume of air that should be sampled to detect environmental bioburden excursions.

Air Sampling Frequency and Process

† Air sampling shall be performed at least semiannually (i.e. every 6 months), as part of the re-certification of facilities and equipment for area where primary engineering controls are located.

† A sufficient volume of air shall be sampled and the manufacturer's guidelines for use of the electronic air sampling equipment followed.

‡ Any facility construction or equipment servicing may require the need to perform air sampling during these events.

Incubation Period

† The microbial growth media plates used to collect environmental sampling are recovered, covers secured (e.g., taped), inverted, and incubated at a temperature and for a time period conducive to multiplication of microorganisms.

† The number of discrete colonies of microorganisms shall be counted and reported as colony-forming units (cfu) and documented on an environmental monitoring form. Counts from air monitoring need to be transformed into cfu/cubic meter of air and evaluated for adverse trends.

‡ TSA should be incubated at 35° ± 2 ° for 2–3 days.

‡ MEA or other suitable fungal media should be incubated at 28° ± 2 ° for 5–7 days.

Action Levels, Documentation and Data Evaluation

† Sampling data shall be collected and reviewed on a periodic basis as a means of evaluating the overall control of the compounding environment.

† Competent microbiology personnel shall be consulted if an environmental sampling consistently shows elevated levels of microbial growth.

† An investigation into the source of the environmental contamination shall be conducted.

‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.

‡ Table titled, Recommended Action Levels for Microbial Contamination should only be used as a guideline

Facility Design and Environmental Controls

† Compounding facilities are physically designed and environmentally controlled to minimize airborne contamination from contacting critical sites.

† Compounding facilities shall provide a comfortable and well-lighted working environment, which typically includes a temperature of 20° or cooler to maintain comfortable conditions for compounding personnel when attired in the required aseptic compounding garb.

† Primary engineering controls provide unidirectional (i.e., laminar) HEPA air at a velocity sufficient to prevent airborne particles from contacting critical sites.

† In situ air pattern analysis via smoke studies shall be conducted at the critical area to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions.

† Policies and procedures for maintaining and working within the primary engineering control area shall be written and followed. The policies and procedures will be determined by the scope and risk levels of the aseptic compounding activities used during the preparation of the CSPs.

† The principles of HEPA-filtered unidirectional airflow in the work environment shall be understood and practiced in the compounding process in order to achieve the desired environmental conditions.

† Clean rooms for nonhazardous and nonradioactive CSPs are supplied with HEPA that enters from ceilings with return vents low on walls, and that provides not less than 30 air changes per hour.

† Buffer areas maintain 0.02- to 0.05-inch water column positive pressure, and do not contain sinks or drains.

† Air velocity from buffer rooms or zones to ante-areas is at least 40 feet/minute.

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

† The primary engineering controls shall be placed within a buffer area in such a manner as to avoid conditions that could adversely affect their operation.

† The primary engineering controls shall be placed out of the traffic flow and in a manner to avoid disruption from the HVAC system and room cross-drafts.

† HEPA-filtered supply air shall be introduced at the ceiling.

† All HEPA filters shall be efficiency tested using the most penetrating particle size and shall be leak tested at the factory and then leak tested again in situ after installation.

† Activities and tasks carried out within the buffer area shall be limited to only those necessary when working within a controlled environment.

† Only the furniture, equipment, supplies, and other material required for the compounding activities to be performed shall be brought into the room.

† Surfaces and essential furniture in buffer rooms or zones and clean rooms shall be nonporous, smooth, nonshedding, impermeable, cleanable, and resistant to disinfectants.

† The surfaces of ceilings, walls, floors, fixtures, shelving, counters, and cabinets in the buffer area shall be smooth, impervious, free from cracks and crevices, and nonshedding, thereby promoting cleanability, and minimizing spaces in which microorganisms and other contaminants may accumulate.

† The surfaces shall be resistant to damage by disinfectant agents.

† Junctures of ceilings to walls shall be coved or caulked to avoid cracks and crevices where dirt can accumulate.

† Ceiling tiles shall be caulked around each perimeter to seal them to the support frame.

† The exterior lens surface of ceiling lighting fixtures shall be smooth, mounted flush, and sealed.

† Any other penetrations through the ceiling or walls shall be sealed.

† The buffer area shall not contain sources of water (sinks) or floor drains. Work surfaces shall be constructed of smooth, impervious materials, such as stainless steel or molded plastic, so that they are easily cleaned and disinfected.

† Carts shall be of stainless steel wire, nonporous plastic, or sheet metal construction with good quality, cleanable casters to promote mobility.

† Storage shelving, counters, and cabinets shall be smooth, impervious, free from cracks and crevices, nonshedding, cleanable, and disinfectable.

† Their number, design, and manner of installation the itmes above shall promote effective cleaning and disinfection.

‡ If ceilings consist of inlaid panels, the panels should be impregnated with a polymer to render them impervious and hydrophobic.

‡ Dust-collecting overhangs, such as ceiling utility pipes, or ledges, such as windowsills, should be avoided.

‡ Air returns should be mounted low on the wall creating a general top-down dilution of room air with HEPA-filtered make-up air.

Placement of Primary Engineering Controls Within ISO Class 7 Buffer Areas

† Primary engineering controls for nonhazardous and nonradioactive CSPs are located in buffer areas, except for CAIs that are proven to maintain ISO Class 5 air when particle counts are sampled 6 to 12 inches upstream of critical site exposure areas during performance of normal inward and outward transfer of materials, and compounding manipulations when such CAIs are located in air quality worse than ISO Class 7.

† Presterilization procedures for high-risk level CSPs, such as weighing and mixing, shall be completed in no worse than an ISO Class 8 environment.

† Primary engineering controls shall be located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns.

† When isolators are used for sterile compounding, the recovery time to achieve ISO Class 5 air quality shall be documented and internal procedures developed to ensure that adequate recovery time is allowed after material transfer before and during compounding operations.

† When compounding activities require the manipulation of a patient's blood-derived or other biological material (e.g., radiolabeling a patient's or a donor's white blood cells), the manipulations shall be clearly separated from routine material-handling procedures and equipment used in CSP preparation activities, and they shall be controlled by specific standard operating procedures in order to avoid any cross-contamination.

† Food, drinks, and items exposed in patient care areas, and unpacking of bulk supplies and personnel cleansing and garbing are prohibited from buffer areas or rooms.

† Demarcation designation between buffer areas or rooms and ante-areas.

† Antiseptic hand cleansing and sterile gloves in buffer areas or rooms.

‡ Packaged compounding supplies and components, such as needles, syringes, tubing sets, and small- and large-volume parenterals, should be uncartoned and wiped down with a disinfectant that does not leave a residue (e.g., sterile 70% IPA) when possible in an ante-area, of ISO Class 8 air quality, before being passed into the buffer areas.

Cleaning and Disinfecting the Sterile Compounding Areas

† Trained personnel write detailed procedures including cleansers, disinfectants, and non-shedding wipe and mop materials.

† Cleaning and disinfecting surfaces in the LAFWs, BSCs, CAIs, and CACIs shall be cleaned and disinfected frequently, including at the beginning of each work shift, before each batch preparation is started, every 30 minutes during continuous compounding periods of individual CSPs, when there are spills, and when surface contamination is known or suspected from procedural breaches.

† Trained compounding personnel are responsible for developing, implementing, and practicing the procedures for cleaning and disinfecting the DCAs written in the SOPs.

† Cleaning and disinfecting shall occur before compounding is performed. Items shall be removed from all areas to be cleaned, and surfaces shall be cleaned by removing loose material and residue from spills, e.g., water-soluble solid residues are removed with Sterile Water (for Injection or Irrigation) and low-shedding wipes. This shall be followed by wiping with a residue-free disinfecting agent, such as sterile 70% IPA, which is allowed to dry before compounding begins.

† Work surfaces in ISO Class 7 and 8 areas and segregated compounding areas are cleaned at least daily.

† Dust and debris shall be removed when necessary from storage sites for compounding ingredients and supplies, using a method that does not degrade the ISO Class 7 or 8 air quality.

† Floors in ISO Class 7 and 8 areas are cleaned daily when no compounding occurs.

† IPA (70% isopropyl alcohol) remains on surfaces to be disinfected for at least 30 seconds before such surfaces are used to prepare CSPs.

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Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

† Emptied shelving, walls, and ceilings in ante-areas are cleaned and disinfected at least monthly.

† Mopping shall be performed by trained personnel using approved agents and procedures described in the written SOPs.

† Cleaning and disinfecting agents, their schedules of use and methods of application shall be in accordance with written SOPs and followed by custodial and/or compounding personnel.

† All cleaning materials, such as wipers, sponges, and mops, shall be nonshedding, preferably composed of synthetic micro fibers, and dedicated to use in the buffer area, or ante-area, and segregated compounding areas and shall not be removed from these areas except for disposal.

† If cleaning materials are reused (e.g., mops), procedures shall be developed (based on manufacturer recommendations) that ensure that the effectiveness of the cleaning device is maintained and repeated use does not add to the bioburden of the area being cleaned.

† Supplies and equipment removed from shipping cartons shall be wiped with a suitable disinfecting agent (e.g., sterile 70% IPA) delivered from a spray bottle or other suitable delivery method.

† After the disinfectant is sprayed or wiped on a surface to be disinfected, the disinfectant shall be allowed to dry, and during this time the item shall not be used for compounding purposes.

† Sterile 70% IPA wetted gauze pads or other particle-generating material shall not be used to disinfect the sterile entry points of packages and devices.

Personnel Cleansing and Garbing

† Personnel shall also be thoroughly competent and highly motivated to perform flawless aseptic manipulations with ingredients, devices, and components of CSPs.

† Personnel with rashes, sunburn, weeping sores, conjunctivitis, active respiratory infection, and cosmetics are prohibited from preparing CSPs.

† Compounding personnel shall remove personal outer garments; cosmetics; artificial nails; hand, wrist, and body jewelry that can interfere with the fit of gowns and gloves; and visible body piercing above the neck.

† Order of compounding garb and cleansing in ante-area: shoes or shoe covers, head and facial hair covers, face mask, fingernail cleansing, hand and forearm washing and drying; non-shedding gown.

† Order of cleansing and gloving in buffer room or area: hand cleansing with a persistently active alcohol-based product with persistent activity; allow hands to dry; don sterile gloves.

† Routinely disinfect gloves with sterile 70% IPA after contacting nonsterile objects.

† Inspect gloves for holes and replace when breaches are detected.

† Personnel repeat proper procedures after they are exposed to direct contact contamination or worse than ISO Class 8 air.

† These requirements are exempted only for immediate-use CSPs and CAIs for which manufacturers provide written documentation based on validated testing that such personnel practices are not required to maintain sterility in CSPs.

Personnel Training and Competency Evaluation of Garbing, Aseptic Work Practices and Cleaning/Disinfection Procedures

† Personnel who prepare CSPs shall be trained conscientiously and skillfully by expert personnel, multi-media instructional sources, and professional publications in the theoretical principles and practical skills of garbing procedures, aseptic work practices, achieving and maintaining ISO Class 5 environmental conditions, and cleaning and disinfection procedures.

† This training shall be completed and documented before any compounding personnel begin to prepare CSPs.

† Compounding personnel shall complete didactic training, pass written competence assessments, undergo skill assessment using observational audit tools, and media-fill testing.

† Media-fill testing of aseptic work skills shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level compounding; and semiannually for high-risk level compounding.

† Compounding personnel who fail written tests, observational audits, or whose media-fill test vials have one or more units showing visible microbial contamination, shall be reinstructed and re-evaluated by expert compounding personnel to ensure correction of all aseptic work practice deficiencies.

† Compounding personnel shall pass all evaluations prior to resuming compounding of sterile preparations.

† Compounding personnel must demonstrate proficiency of proper hand hygiene, garbing, and consistent cleaning procedures in addition to didactic evaluation and aseptic media fill.

† Cleaning and disinfecting procedures performed by other support personnel shall be thoroughly trained in proper hand hygiene, and garbing, cleaning, and disinfection procedures by a qualified aseptic compounding expert.

† Support personnel shall routinely undergo performance evaluation of proper hand hygiene, garbing, and all applicable cleaning and disinfecting procedures conducted by a qualified aseptic compounding expert.

Competency Evaluation of Garbing and Aseptic Work Practices

† Compounding personnel shall be evaluated initially prior to beginning compounding CSPs and whenever an aseptic media fill is performed using a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and the personnel glove fingertip sampling procedures.

Aseptic Work Practice Assessment and Evaluation via Personnel Glove Fingertip Sampling

† Monitoring of compounding personnel glove fingertips shall be performed for all CSP risk level compounding.

† Glove fingertip sampling shall be used to evaluate the competency of personnel in performing hand hygiene and garbing procedures in addition to educating compounding personnel on proper work practices.

† All personnel shall demonstrate competency in proper hand hygiene and garbing procedures in addition to aseptic work practices.

† Sterile contact agar plates shall be used to sample the gloved fingertips of compounding personnel after garbing to assess garbing competency and after completing the media-fill preparation.

† Gloves shall not be disinfected with sterile 70% IPA immediately prior to sampling.

APPENDICES

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

Garbing and Gloving Competency Evaluation

† Compounding personnel shall be visually observed during the process of performing hand hygiene and garbing procedures.

† The visual observation shall be documented on a Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel and maintained to provide a permanent record of and long-term assessment of personnel competency.

Gloved Fingertip Sampling

† Immediately after the compounder completes the hand hygiene and garbing procedure, the evaluator shall collect a gloved fingertip and thumb sample from both hands of the compounder onto appropriate agar plates by lightly pressing each finger tip into the agar.

† The plates shall be incubated for the appropriate incubation period and at the appropriate temperature.

† All employees shall successfully complete an initial competency evaluation and gloved fingertip/thumb sampling procedure (0 cfu) no less than three times before initially being allowed to compound CSPs for human use.

† After completing the initial gowning and gloving competency evaluation, re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk level CSPs before being allowed to continue compounding CSPs.

† Gloves shall not be disinfected with sterile 70% IPA prior to testing.

† The sampled gloves shall be immediately discarded and proper hand hygiene performed after sampling. The nutrient agar plates shall be incubated as stated below.

† The cfu action level for gloved hands shall be based on the total number of cfu on both gloves and not per hand.

‡ Results should be reported separately as number of cfu per employee per hand (left hand, right hand).

Incubation Period

† At the end of the designated sampling period, the agar plates are recovered, covers secured, inverted and incubated at a temperature and for a time period conducive to multiplication of microorganisms. Trypticase soy agar (TSA) with lecithin and polysorbate 80 shall be incubated at 35°± 2° for 2–3 days.

Aseptic Manipulation Competency Evaluation

† All compounding personnel shall have their aseptic technique and related practice competency evaluated initially during the media-fill test procedure and subsequent annual or semiannual media-fill test procedures on the Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel.

Media-Fill Test Procedure

† The skill of personnel to aseptically prepare CSPs shall be evaluated using sterile fluid bacterial culture media-fill verification.

† Media-filled vials shall be incubated within a range of 35° ± 2° for 14 days.

Surface Cleaning and Disinfection Sampling and Assessment

† Surface sampling shall be performed in all ISO classified areas on a periodic basis and can be accomplished using contact plates and/or swabs and shall be done at the conclusion of compounding.

† Locations to be sampled shall be defined in a sample plan or on a form.

Cleaning and Disinfecting Competency Evaluation

† Compounding personnel and other personnel responsible for cleaning shall be visually observed during the process of performing cleaning and disinfecting procedures during initial personnel training on cleaning procedures, changes in cleaning staff and at the completion of any Media-Fill Test Procedure.

† Visual observation shall be documented on a Sample Form for Assessing Cleaning and Disinfection Procedures and maintained to provide a permanent record of, and long-term assessment of, personnel competency.

Surface Collection Methods

† Immediately after sampling a surface with the contact plate, the sampled area shall be thoroughly wiped with a non-shedding wipe soaked in sterile 70% IPA.

‡ Results should be reported as cfu per unit of surface area.

Action Levels, Documentation, and Data Evaluation

† Environmental sampling data shall be collected and reviewed on a routine basis as a means of evaluating the overall control of the compounding environment.

† If an activity consistently shows elevated levels of microbial growth, competent microbiology personnel shall be consulted.

† An investigation into the source of the contamination shall be conducted.

† When gloved fingertip sample results exceeds action levels after proper incubation, a review of hand hygiene and garbing procedures as well as glove and surface disinfection procedures and work practices shall be performed and documented.

‡ Any cfu count that exceeds its respective action level should prompt a re-evaluation of the adequacy of personnel work practices, cleaning procedures, operational procedures, and air filtration efficiency within the aseptic compounding location.

SUGGESTED STANDARD OPERATING PROCEDURES

† All facilities are required to have these, and they must include at least the items enumerated in this section.

FINISHED PREPARATION RELEASE CHECKS AND TESTS

Inspection of Solution Dosage Forms and Review of Compounding Procedures

† Review procedures and documents to ensure sterility, purity, correct identities and amounts of ingredients, and stability.

† Visually inspect for abnormal particulate matter and color, and intact containers and seals.

Sterility Testing

† High-risk level CSPs prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8° before being sterilized.

APPENDICES

Appendix I. Principal Competencies, Conditions, Practices, and Quality Assurances That Are Required († "shall") and Recommended (‡ "should") in USP Chapter ⟨797⟩ *(Continued)*

Bacterial Endotoxin (Pyrogen) Testing

† High-risk level CSPs, excluding those for inhalation and ophthalmic administration, prepared in batches of more than 25 identical containers, or exposed longer than 12 hours at 2° to 8°, and 6 hours at warmer than 8°, before being sterilized.

Identity and Strength Verification of Ingredients

† Written procedures to verify correct identity, quality, amounts, and purities of ingredients used in CSPs.

† Written procedures to ensure labels of CSPs contain correct names and amounts or concentrations of ingredients, total volumes, beyond-use dates, storage conditions, and route(s) of administration.

STORAGE AND BEYOND-USE DATING

Determining Beyond-Use Dates

† Use the general criteria in USP ⟨795⟩ in the absence of direct stability-indicating assays or authoritative literature that supports longer durations.

MAINTAINING STERILITY, PURITY, AND STABILITY OF DISPENSED AND DISTRIBUTED CSPs

† Written procedures for proper packaging, storage, and transportation conditions to maintain sterility, quality, purity, and strength of CSPs.

Redispensed CSPs

† When sterility, and acceptable purity, strength, and quality can be ensured.

† Assignment of sterility storage times and stability beyond-use dates that occur later than those of originally dispensed CSPs must be based on results of sterility testing and quantitative assay of ingredients.

Packaging and Transporting CSPs

† Packaging maintains physical integrity, sterility, stability, and purity of CSPs.

† Modes of transport that maintain appropriate temperatures and prevent damage to CSPs.

PATIENT OR CAREGIVER TRAINING

† Multiple component formal training program to ensure patients and caregivers understand the proper storage, handling, use, and disposal of CSPs.

PATIENT MONITORING AND ADVERSE EVENTS REPORTING

† Written standard procedures describe means for patients to ask questions and report concerns and adverse events with CSPs, and for compounding supervisors to correct and prevent future problems.

‡ Adverse events and defects with CSPs reported to FDA's MedWatch and USP's MEDMARX programs.

Appendix II. Common Disinfectants Used in Health Care for Inanimate Surfaces and Noncritical Devices, and Their Microbial Activity and Properties[1]

		Chemical Category of Disinfectant					
		Isopropyl alcohol	**Accelerated hydrogen peroxide**	**Quaternary Ammonium (e.g., dodecyl dimethyl ammonium chloride)**	**Phenolics**	**Chlorine (e.g., sodium hypochlorite)**	**Iodophors (e.g., povidone-iodine)**
Concentration Used		**60–95%**	**0.5%[3]**	**0.4–1.6% aq**	**0.4–1.6% aq**	**100–5000 ppm**	**30–50 ppm**
Microbial Inactivation[2]	Bacteria	+	+	+	+	+	+
	Lipophilic viruses	+	+	+	+	+	+
	Hydrophilic viruses	±	+	±	±	+	±
	M.tuberculosis	+	+	±	+	+	±
	Mycotic agents (fungi)	+	+	+	+	+	±
	Bacterial Spores	–	–	–	–	+	–
Important Chemical & Physical Properties	Shelf life >1 week	+	+	+	+	+	+
	Corrosive or deleterious effects	±	–	–	–	±	±
	Non-evaporable residue	–	–	+	+	–	+
	Inactivated by organic matter	+	±	+	±	+	+
	Skin irritant	±	–	+	+	+	±
	Eye irritant	+	–	+	+	+	+
	Respiratory irritant	–	–	–	–	+	–
	Systemic toxicity	+	–	+	+	+	+

Key to abbreviation and symbols: aq = diluted with water; ppm = parts per million; + = yes; – = no; ± = variable results.

[1] Modified from World Health Organization, Laboratory Bio Safety Manual 1983 and Rutala WA, "Antisepsis, disinfection and sterilization in the hospital and related institutions," *Manual of Clinical Microbiology*, American Society for Microbiology, Washington, DC, 1995, pages 227-245.

[2] Inactivation of the most common microorganisms (i.e., bacteria) occurs with a contact time of ≤1 minute; inactivation of spores requires longer contact times (e.g., 5-10 minutes for 5,000 ppm chlorine solution against *C. difficile spores*). *Reference: Perez J, Springthorpe VS, Sattar SA, "Activity of selected oxidizing microbicides against the spores of Clostridium difficile: Relevance to environmental control," American Journal of Infection Control, August 2005, pages 320-325.*

[3] *Accelerated* hydrogen peroxide is a new generation of hydrogen peroxide-based germicides in which the potency and performance of the active ingredient have been enhanced and accelerated through the use of appropriate acids and detergents.

Appendix III. Sample Form for Assessing Hand Hygiene and Garbing Related Practices of Compounding Personnel

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Hand Hygiene and Garbing Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

_____ Presents in a clean appropriate attire and manner.

_____ Wears no cosmetics or jewelry (watches, rings, earrings, etc. piercing jewelry included) upon entry into ante-areas.

_____ Brings no food or drinks into or stored in the ante-areas or buffer areas.

_____ Is aware of the line of demarcation separating clean and dirty sides and observes required activities.

_____ Dons shoe covers or designated clean-area shoes one at a time, placing the covered or designated shoe on clean side of the line of demarcation, as appropriate.

_____ Dons beard cover if necessary.

_____ Dons head cover assuring that all hair is covered.

_____ Dons face mask to cover bridge of nose down to include chin.

_____ Performs hand hygiene procedure by wetting hands and forearms and washing using soap and warm water for at least 30 seconds.

_____ Dries hands and forearms using lint-free towel or hand dryer.

_____ Selects the appropriate sized gown examining for any holes, tears, or other defects.

_____ Dons gown and ensures full closure.

_____ Disinfects hands again using a waterless alcohol-based surgical hand scrub with persistent activity and allows hands to dry thoroughly before donning sterile gloves.

_____ Dons appropriate sized sterile gloves ensuring that there is a tight fit with no excess glove material at the fingertips.

_____ Examines gloves ensuring that there are no defects, holes, or tears.

_____ While engaging in sterile compounding activities, routinely disinfects gloves with sterile 70% IPA prior to work in the direct compounding area (DCA) and after touching items or surfaces that may contaminate gloves.

_____ Removes PPE on the clean side of the ante-area.

_____ Removes gloves and performs hand hygiene.

_____ Removes gown and discards it, or hangs it on hook if it is to be reused within the same work day.

_____ Removes and discards mask, head cover, and beard cover (if used).

_____ Removes shoe covers or shoes one at a time, ensuring that uncovered foot is placed on the dirty side of the line of demarcation and performs hand hygiene again. (Removes and discards shoe covers every time the compounding area is exited).

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

Appendix IV. Sample Form for Assessing Aseptic Technique and Related Practices of Compounding Personnel

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Aseptic Technique, Safety, and Quality Assurance Practices: The qualified evaluator checks each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

_____ Completes the Hand Hygiene and Garbing Competency Assessment Form.
_____ Performs proper hand hygiene, garbing, and gloving procedures according to SOPs.
_____ Disinfects ISO Class 5 device surfaces with an appropriate agent.
_____ Disinfects components/vials with an appropriate agent prior to placing into ISO Class 5 work area.
_____ Introduces only essential materials in a proper arrangement in the ISO Class 5 work area.
_____ Does not interrupt, impede, or divert flow of first-air to critical sites.
_____ Ensures syringes, needles, and tubing remain in their individual packaging and are only opened in ISO Class 5 work area.
_____ Performs manipulations only in the appropriate DCA of the ISO Class 5 device.
_____ Does not expose critical sites to contact contamination or worse than ISO Class 5 air.
_____ Disinfects stoppers, injection ports, and ampul necks by wiping with sterile 70% IPA and allows sufficient time to dry.
_____ Affixes needles to syringes without contact contamination.
_____ Punctures vial stoppers and spikes infusion ports without contact contamination.
_____ Labels preparation(s) correctly.
_____ Disinfects sterile gloves routinely by wiping with sterile 70% IPA during prolonged compounding manipulations.
_____ Cleans, sets up, and calibrates automated compounding device (e.g., "TPN compounder") according to manufacturer's instructions.
_____ Disposes of sharps and waste according to institutional policy or recognized guidelines.

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

Appendix V. Sample Form for Assessing Cleaning and Disinfection Procedures

Printed name and position/title of person assessed: _____

Name of facility or location: _____

Cleaning and Disinfection Practices: The qualified evaluator will check each space for which the person being assessed has acceptably completed the described activity, prints N/A if the activity is not applicable to the assessment session or N/O if the activity was not observed.*

Daily Tasks:

_____ Prepares correct concentration of disinfectant solution according to manufacturer's instructions.

_____ Uses appropriately labeled container for the type of surface to be cleaned (floor, wall, production bins, etc.).

_____ Documents disinfectant solution preparation.

_____ Follows garbing procedures when performing any cleaning activities.

_____ At the beginning of each shift, cleans all ISO Class 5 devices prior to compounding in the following order: walls, IV bar, automated compounders, and work surface.

_____ Uses a lint free wipe soaked with sterile 70% IPA or other approved disinfectant solution and allows to dry completely.

_____ Removes all compounder components and cleans all ISO Class 5 areas as stated above at the end of each shift.

_____ Cleans all counters and easily cleanable work surfaces.

_____ Mops floors, using the mop labeled "floors," starting at the wall opposite the room entry door; mops floor surface in even strokes toward the operator. Moves carts as needed to clean entire floor surface. Use of a microfiber cleaning system is an acceptable alternative to mops.

_____ In the ante-area, cleans sink and all contact surfaces; cleans floor with a disinfectant solution or uses microfiber cleaning system.

Monthly Tasks:

_____ Performs monthly cleaning on a designated day. Prepares a disinfectant solution as stated in daily tasks that is appropriate for the surfaces to be cleaned.

_____ Cleans buffer area and ante-area ceiling, walls, and storage shelving with a disinfectant solution and a mop or uses a microfiber cleaning system.

_____ Once ISO Class 5 area is clean, cleans compounding room ceiling, followed by walls and ending with the floor. Uses appropriate labeled mops or microfiber cleaning system.

_____ Cleans all buffer area totes and storage shelves by removing contents and using a germicidal detergent soaked lint free wipe, cleans the inside surfaces of the tote and then the entire exterior surfaces of the tote. Allows totes to dry. Prior to replacing contents into tote, wipes tote with sterile 70% IPA to remove disinfectant residue. Uses new wipe as needed.

_____ Cleans all buffer area carts by removing contents and using germicidal detergent soaked lint free wipe, cleans all carts starting with the top shelf and top of post, working down to wheels. Cleans the under side of shelves in a similar manner. Uses a new wipe for each cart. Allows to dry. Wipes carts with sterile 70% IPA wetted lint-free wipe to remove any disinfectant residue. Uses new wipe as needed.

_____ Cleans buffer area chairs, the interior and exterior of trash bins, and storage bins using disinfectant solution soaked lint free wipe.

_____ Documents all cleaning activities as to who performed such activities with date and time noted.

***The person assessed is immediately informed of all unacceptable activities (i.e., spaces lacking check marks, N/A, or N/O) and shown and informed of specific corrections.**

Signature of Person Assessed	Printed Name	Date
Signature of Qualified Evaluator	Printed Name	Date

of frauds against American manufacturers and has provided the cover for the importation of foreign counterfeit drugs.

"(6) The existing system of providing drug samples to physicians through manufacturer's representatives has been abused for decades and has resulted in the sale to consumers of misbranded, expired, and adulterated pharmaceuticals.

"(7) The bulk resale of below wholesale priced prescription drugs by health care entities, for ultimate sale at retail, helps fuel the diversion market and is an unfair form of competition to wholesalers and retailers that must pay otherwise prevailing market prices.

"(8) The effect of these several practices and conditions is to create an unacceptable risk that counterfeit, adulterated, misbranded, subpotent, or expired drugs will be sold to American consumers."

§ 353a. Pharmacy compounding

(a) In general

Sections 351(a)(2)(B), 352(f)(1), and 355 of this title shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the unsolicited receipt of a valid prescription order or a notation, approved by the prescribing practitioner, on the prescription order that a compounded product is necessary for the identified patient, if the drug product meets the requirements of this section, and if the compounding—

(1) is by—

(A) a licensed pharmacist in a State licensed pharmacy or a Federal facility, or

(B) a licensed physician,

on the prescription order for such individual patient made by a licensed physician or other licensed practitioner authorized by State law to prescribe drugs; or

(2)(A) is by a licensed pharmacist or licensed physician in limited quantities before the receipt of a valid prescription order for such individual patient; and

(B) is based on a history of the licensed pharmacist or licensed physician receiving valid prescription orders for the compounding of the drug product, which orders have been generated solely within an established relationship between—

(i) the licensed pharmacist or licensed physician; and

(ii)(I) such individual patient for whom the prescription order will be provided; or

(II) the physician or other licensed practitioner who will write such prescription order.

(b) Compounded drug

(1) Licensed pharmacist and licensed physician

A drug product may be compounded under subsection (a) of this section if the licensed pharmacist or licensed physician—

(A) compounds the drug product using bulk drug substances, as defined in regulations of the Secretary published at section 207.3(a)(4) of title 21 of the Code of Federal Regulations—

(i) that—

(I) comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(II) if such a monograph does not exist, are drug substances that are components of drugs approved by the Secretary; or

(III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, that appear on a list developed by the Secretary through regulations issued by the Secretary under subsection (d) of this section;

(ii) that are manufactured by an establishment that is registered under section 360 of this title (including a foreign establishment that is registered under section 360(i) of this title); and

(iii) that are accompanied by valid certificates of analysis for each bulk drug substance;

(B) compounds the drug product using ingredients (other than bulk drug substances) that comply with the standards of an applicable United States Pharmacopoeia or National Formulary monograph, if a monograph exists, and the United States Pharmacopoeia chapter on pharmacy compounding;

(C) does not compound a drug product that appears on a list published by the Secretary in the Federal Register of drug products that have been withdrawn or removed from the market because such drug products or components of such drug products have been found to be unsafe or not effective; and

(D) does not compound regularly or in inordinate amounts (as defined by the Secretary) any drug products that are essentially copies of a commercially available drug product.

(2) Definition

For purposes of paragraph (1)(D), the term "essentially a copy of a commercially available drug product" does not include a drug product in which there is a change, made for an identified individual patient, which produces for that patient a significant difference, as determined by the prescribing practitioner, between the compounded drug and the comparable commercially available drug product.

(3) Drug product

A drug product may be compounded under subsection (a) only if—

(A) such drug product is not a drug product identified by the Secretary by regulation as a drug product that presents demonstrable difficulties for compounding that reasonably demonstrate an adverse effect on the safety or effectiveness of that drug product; and

(B) such drug product is compounded in a State—

(i) that has entered into a memorandum of understanding with the Secretary which addresses the distribution of inordinate amounts of compounded drug products interstate and provides for appropriate investigation by a State agency of complaints relating to compounded drug products distributed outside such State; or

(ii) that has not entered into the memorandum of understanding described in clause (i) and the licensed pharmacist, licensed pharmacy, or licensed physician distributes (or causes to be distributed) compounded drug products out of the State in which they are compounded in quantities that do not exceed 5 percent of the total prescription orders dispensed or distributed by such pharmacy or physician.

The Secretary shall, in consultation with the National Association of Boards of Pharmacy, develop a standard memorandum of understanding for use by the States in complying with subparagraph (B)(i).

(c) Advertising and promotion

A drug may be compounded under subsection (a) of this section only if the pharmacy, licensed pharmacist, or licensed physician does not advertise or promote the compounding of any particular drug, class of drug, or type of drug. The pharmacy, licensed pharmacist, or licensed physician may advertise and promote the compounding service provided by the licensed pharmacist or licensed physician.

(d) Regulations

(1) In general

The Secretary shall issue regulations to implement this section. Before issuing regulations to implement subsections (b)(1)(A)(i)(III), (b)(1)(C), or (b)(3)(A) of this section, the Secretary shall convene and consult an advisory committee on compounding unless the Secretary determines that the issuance of such regulations before consultation is necessary to protect the public health. The advisory committee shall include representatives from the National Association of Boards of Pharmacy, the United States Pharmacopoeia, pharmacy, physician, and consumer organizations, and other experts selected by the Secretary.

(2) Limiting compounding

The Secretary, in consultation with the United States Pharmacopoeia Convention, Incorporated, shall promulgate regulations identifying drug substances that may be used in compounding under subsection (b)(1)(A)(i)(III) of this section for which a monograph does not exist or which are not components of drug products approved by the Secretary. The Secretary shall include in the regulation the criteria for such substances, which shall include historical use, reports in peer reviewed medical literature, or other criteria the Secretary may identify.

(e) Application

This section shall not apply to—

(1) compounded positron emission tomography drugs as defined in section 321(ii) of this title; or

(2) radiopharmaceuticals.

(f) "Compounding" defined

As used in this section, the term "compounding" does not include mixing, reconstituting, or other such acts that are performed in accordance with directions contained in approved labeling provided by the product's manufacturer and other manufacturer directions consistent with that labeling.

(June 25, 1938, ch. 675, § 503A, as added Pub. L. 105–115, title I, § 127(a), Nov. 21, 1997, 111 Stat. 2328.)

EFFECTIVE DATE

Section 127(b) of Pub. L. 105–115 provided that: "Section 503A of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353a], added by subsection (a), shall take effect upon the expiration of the 1-year period beginning on the date of the enactment of this Act [Nov. 21, 1997]."

§ 353b. Prereview of television advertisements

(a) In general

The Secretary may require the submission of any television advertisement for a drug (including any script, story board, rough, or a completed video production of the television advertisement) to the Secretary for review under this section not later than 45 days before dissemination of the television advertisement.

(b) Review

In conducting a review of a television advertisement under this section, the Secretary may make recommendations with respect to information included in the label of the drug—

(1) on changes that are—

(A) necessary to protect the consumer good and well-being; or

(B) consistent with prescribing information for the product under review; and

(2) if appropriate and if information exists, on statements for inclusion in the advertisement to address the specific efficacy of the drug as it relates to specific population groups, including elderly populations, children, and racial and ethnic minorities.

(c) No authority to require changes

Except as provided by subsection (e), this section does not authorize the Secretary to make or direct changes in any material submitted pursuant to subsection (a).

(d) Elderly populations, children, racially and ethnically diverse communities

In formulating recommendations under subsection (b), the Secretary shall take into consideration the impact of the advertised drug on elderly populations, children, and racially and ethnically diverse communities.

(e) Specific disclosures

(1) Serious risk; safety protocol

In conducting a review of a television advertisement under this section, if the Secretary determines that the advertisement would be false or misleading without a specific disclosure about a serious risk listed in the labeling of the drug involved, the Secretary may require inclusion of such disclosure in the advertisement.

(2) Date of approval

In conducting a review of a television advertisement under this section, the Secretary

THE COMMITTEE ON ENERGY AND COMMERCE

November 12, 2012

MAJORITY MEMORANDUM

TO: Members, Subcommittee on Oversight and Investigations

FROM: Subcommittee on Oversight and Investigations Staff

RE: Hearing on "The Fungal Meningitis Outbreak: Could It Have Been Prevented?"

On Wednesday, November 14, 2012, at 10:00 a.m. in room 2123 of the Rayburn House Office Building, the Subcommittee on Oversight and Investigations will hold a hearing entitled "The Fungal Meningitis Outbreak: Could It Have Been Prevented?"

This hearing will examine the facts surrounding the recent outbreak of fungal meningitis and other infections linked to contaminated injectable products made and distributed by the New England Compounding Center (NECC) in Framingham, Massachusetts. This hearing will also examine the history of complaints associated with NECC and its affiliated entities as well as related inspections and actions taken by the U.S. Food and Drug Administration (FDA) and the Massachusetts Department of Public Health (MDPH).

I. WITNESSES

Panel One

Ms. Joyce Lovelace

Panel Two

Mr. Barry J. Cadden
President, Co-Owner and Director of Pharmacy
New England Compounding Center

Panel Three

The Honorable Margaret A. Hamburg, MD
Commissioner
U.S. Food and Drug Administration (FDA)

Dr. Lauren Smith, MD, MPH
Interim Commissioner
Massachusetts Department of Public Health (MDPH)

II. BACKGROUND – THE CURRENT OUTBREAK

This section of the memorandum details the facts surrounding the current outbreak and the investigation of the outbreak by State and Federal regulators. In Part III, the memorandum describes the history of Federal and State inspections of NECC and resulting regulatory actions since the Massachusetts Board of Registration in Pharmacy (MBP or Massachusetts Board of Pharmacy) approved the company's pharmacy license in 1998.

A. The Fungal Meningitis Outbreak

As of November 9, 2012, the Centers for Disease Control and Prevention (CDC) has confirmed that 32 people have died and 438 people have been sickened across 19 states after receiving contaminated injectable products made and distributed by NECC .

The first case of meningitis connected to this outbreak was confirmed on September 18, 2012, in Tennessee. On September 21, 2012, CDC was notified by the Tennessee Department of Health (TDH) of a patient with the onset of meningitis approximately 19 days after receiving an epidural steroid injection at an ambulatory surgical center in Nashville. By September 24, 2012, TDH officials contacted MDPH informing them that it was investigating an outbreak of fungal meningitis in six patients at the same Nashville facility, with onsets between July 30 and September 18, 2012. All six patients had received the same injectable steroid, preservative-free methylprednisolone acetate (80 mg/ml), compounded and distributed by NECC.

On September 25, 2012, CDC informed FDA of the situation and that three lots of methylprednisolone acetate were suspected. Methylprednisolone acetate is a type of injectable steroid suspension often used to treat pain and swelling. MDPH convened a multi-agency teleconference with CDC, FDA, and Tennessee officials. Mr. Barry Cadden and Mr. Gregory Conigliaro, principal owners of NECC, joined the call as well. Mr. Cadden and Mr. Conigliaro immediately provided documentation of all facilities that had received shipments from the three suspect lots of methylprednisolone acetate. On September 26, 2012, NECC instituted a voluntary recall of the suspect lots. In total, 17,676 doses had been shipped to customers in 23 states. More than 14,000 patients had already received a potentially contaminated injection. Based on surveillance efforts, CDC soon identified a patient in North Carolina displaying symptoms of meningitis after receiving an injection from one of the suspect lots.

From September 26, 2012, through October 5, 2012, investigators from FDA's New England District Office (FDA NWE-DO) and MDPH inspected the NECC facility. During their inspection, State and Federal investigators observed visible black particulate matter in sealed vials of purportedly sterile methylprednisolone acetate that had been returned to NECC. MDPH noted that NECC's records showed inconsistencies in sterilization processes. The Massachusetts Board of Pharmacy voted to obtain a voluntary surrender of NECC's license, which NECC

agreed to on October 3. NECC also agreed to a voluntary recall of all products intended for injection into the area around the spinal cord or brain. On October 4, FDA and MDPH confirmed that fungal contamination had been identified in a vial from one of the suspect lots. FDA and CDC recommended that all health care professionals cease use and remove any material produced by NECC from their facilities.[1] On October 6, NECC announced a voluntary recall of all NECC products currently in circulation. On October 8, Mr. Cadden and Mr. Glenn Chin[2] voluntarily ceased practice as pharmacists pending completion of the investigation.[3] In addition to the evidence of contamination, investigators also found evidence that the NECC had not been compounding drugs for patient-specific prescriptions. Instead, the NECC accepted patient lists generated by a clinical facility and provided to NECC for the purpose of obtaining its products. On October 16, agents from FDA's Office of Criminal Investigations, along with local authorities, raided the NECC Framingham, Massachusetts facility.

The MDPH and FDA also inspected two other companies owned by Barry Cadden, Ameridose, LLC (Ameridose) and Alaunus Pharmaceutical, LLC (Alaunus) on October 10, 2012, and October 14, 2012, respectively. NECC, Ameridose, and Alaunus share common ownership and corporate structures. Cadden is a co-owner of Ameridose, a pharmacy and wholesaler based in Westborough, Massachusetts, and Alaunus, a wholesaler located next to NECC in Framingham. Cadden, his wife, Lisa Conigliaro-Cadden, her brother, Gregory Conigliaro, and his wife, Carla Conigliaro, serve as directors of all three companies. Based on their shared ownership, MDPH requested that Ameridose and Alaunus cease all pharmacy operations and the manufacturing and distribution of any products. According to MDPH, Mr. Cadden agreed to immediately resign as manager, director and from any other management position at NECC, Ameridose, and Alaunus.

The FDA's investigation of the fungal meningitis outbreak has expanded beyond NECC's methylprednisolone acetate product. For example, FDA confirmed the report of a patient with meningitis-like symptoms potentially caused by epidural injection of a different NECC product, triamcinolone acetonide. In addition, one transplant patient developed a fungal infection after having been administered NECC-produced cardioplegic solution during surgery. Based on these reports, FDA announced that the sterility of any injectable drugs, including ophthalmic drugs that are injectable or used in conjunction with eye surgery, and cardioplegic solutions produced by NECC are of significant concern. FDA recommended that patients who received these products on or after May 21, 2012, be alerted to the potential risk of infection.

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[1] FDA subsequently released definitive laboratory confirmation of the presence of fungal contaminants in sealed vials of methylprednisolone acetate in two of the three suspected lots from NECC. As of November 3, 2012, testing of the third lot, as well as other NECC products, was ongoing.

[2] MDPH referred to Mr. Chin as a "leader[ ] at NECC" in its preliminary investigative report. MASS. DEP'T OF PUB. HEALTH, NEW ENGLAND COMPOUNDING CENTER (NECC) PRELIMINARY INVESTIGATION FINDINGS: BD. OF REGISTRATION IN PHARMACY REPORT, at 7 (Oct. 23, 2012) [hereinafter, "MDPH OCT. 23, 2012 REPORT"]. In a discussion with Committee staff, Mr. Chin's counsel stated that he started with the company on April 21, 2004 and was the compounding pharmacist in one of NECC's clean rooms until the company ceased operations.

[3] On October 22, 2012, MBP authorized MDPH staff to request voluntary permanent surrender of the licenses of Barry Cadden, Glenn Chin, and Lisa Conigliaro-Cadden, as well as NECC. According to MDPH, in response to an inquiry from Committee staff on November 4, this process is ongoing.

FDA reported on October 31, 2012, that Ameridose was voluntarily recalling all of its unexpired products in circulation. While the investigation remained open at the time of the announcement, FDA stated that its preliminary findings raised sterility concerns. The agency further clarified that the recall was not based on reports of patients with infections associated with any Ameridose product.

On November 1, 2012, FDA and CDC released laboratory results that confirmed contaminants in two other NECC products: preservative-free betamethasone repository injection and cardioplegia solution. Bacteria were present in three separate lots of betamethasone and in a single lot of cardioplegia solution. CDC continues to investigate reports of potential infections in patients receiving NECC products. As of November 1, CDC had not received reports of laboratory-confirmed cases of infection due to bacteria present in betamethasone or cardioplegia solution from NECC.

B. Preliminary Findings Released by State and Federal Regulators Regarding the Outbreak

On October 23, 2012, MDPH issued a Board of Registration in Pharmacy Report setting forth its preliminary findings relating to the ongoing investigation into the outbreak.[4] In addition, on October 26, 2012, FDA released its inspectional observations as well as a corresponding Form FDA 483 (483) to NECC.[5]

As previously discussed, investigators from FDA NWE-DO and MDPH first visited the NECC facility in connection with this outbreak on September 26, 2012. According to MDPH, upon arriving at NECC, investigators found NECC employees cleaning sterile compounding areas. They also detected signs of bleach decontamination.[6] Despite NECC's apparent attempt to present the facility as compliant, State investigators still identified "serious deficiencies and significant violations of pharmacy law and regulations that clearly placed the public's health and safety at risk."[7]

During the facility inspections, MDPH documented numerous deficiencies and violations, including the following:

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[4] *See* MDPH OCT. 23, 2012 REPORT, *supra* note 2. MDPH noted that this report constitutes early findings that may be subject to revision as the investigation unfolds. *Id.* at 2.

[5] *See* U.S. FOOD & DRUG ADMIN., NEW ENGLAND COMPOUNDING CENTER FORM FDA 483 (Oct. 26, 2012), *available at* http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM325980.pdf [hereinafter, "FDA OCT. 26, 2012 FORM 483"]. FDA issues a Form 483 at the end of an inspection when the investigators believe that the observed conditions or practices, in their judgment, may indicate violations of the Food, Drug, and Cosmetic Act or any related regulations. FDA has stated that its goal in issuing a 483 is to have the company act quickly to correct potential violations. The FDA considers the 483 along with an Establishment Inspection Report (EIR), prepared by FDA investigators, and any other information, including any responses received from the company. The agency then considers whether further action is appropriate.

[6] MDPH OCT. 23, 2012 REPORT, *supra* note 2, at 6.

[7] *Id.* at 2.

- NECC distributed large batches of compounded sterile products directly to facilities for apparent general use rather than requiring a prescription for an individual patient.[8]

- NECC distributed two of the recalled lots of methylprednisolone acetate prior to receiving results of sterility testing.[9]

- Final sterilization of product did not follow proper standards pursuant to United States Pharmacopeia Standard 797 (USP 797) and NECC's own Standard Operating Procedures.[10]

- NECC failed to test its autoclaves to ensure proper function. [11]

- Visible black particulate matter was seen in several recalled sealed vials of methylprednisolone acetate.[12]

- "Tacky" mats located outside the clean room were visibly soiled with assorted debris, violating USP 797.[13]

- A leaking boiler adjacent to the clean room had created a pool of water, an environment susceptible to contaminant growth.[14]

FDA investigators documented similar observations in the 483, as well as additional problems with NECC's ability to maintain its clean room and ensure the sterility of its products, as further supported by sample testing results. FDA's observations included the following:

- Eighty-three vials out of a bin containing 321 vials of methylprednisolone acetate from one of the suspect lots contained what appeared to be greenish black foreign matter. Seventeen vials from the same bin were observed to contain what appeared to be white filamentous material. Fifty of these vials were sent to an FDA laboratory for testing and all 50 tested positive for microbial contamination.[15]

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[8] *Id.* at 3.
[9] *Id.* at 4. MDPH noted that while NECC's records showed that the sterility tests found no contamination, the adequacy of NECC's sterility testing methods remained under examination.
[10] *Id.*
[11] *Id.* An autoclave is a device used to sterilize equipment by subjecting it to high pressure steam. If done properly, all bacteria and fungi would be inactivated.
[12] *Id.*
[13] *Id.* A clean room is an enclosed space that is designed and maintained to have a controlled environment with low levels of airborne particles and surface contamination. Production of sterile drug products in a properly functioning and maintained clean room reduces the risk of the introduction of microbial contamination into the drug during processing, including filling into its final container.
[14] *Id.* at 5.
[15] FDA OCT. 26, 2012 FORM 483, *supra* note 5, at 1.

- NECC provided no documentation or evidence to support that the autoclave used to sterilize suspensions formulated using non-sterile active pharmaceutical ingredients and raw materials was effective.[16]

- NECC is abutted to the rear by a recycling facility producing airborne particulates. NECC rooftop HVAC units were estimated to be located approximately 100 feet from the recycling facility.[17]

- NECC's air conditioning was turned off at night, including in the clean rooms, despite the importance of maintaining a consistent temperature and level of humidity.[18]

- NECC's own environmental monitoring program yielded violative levels of bacteria and mold in clean rooms used for the production of sterile drug products, between January 2012 and September 2012. Despite the company's action limits having been exceeded, there was no investigation conducted by the company, no identification of the isolates, no product impact assessments conducted, and no documented corrective actions taken to remove the microbial contamination from the facility.[19]

Further, according to Steven Lynn, Director of FDA's Office of Manufacturing and Product Quality, on an October 26, 2012, media call describing FDA's observations and test results, there was overgrowth of bacteria or fungi in at least one sample testing dish. When asked to clarify what he meant, Mr. Lynn stated, "Think of a plant just growing out of control."[20]

III. HISTORY OF STATE AND FEDERAL INVESTIGATIONS OF NECC

While investigating the meningitis outbreak over the last six weeks, FDA and MDPH investigators have observed many serious deficiencies and significant violations of law and good compounding practices. These violations, however, were not a first for NECC. Documents produced to the Committee by the FDA and the Massachusetts Board show that NECC has a long history of very similar, if not identical, underlying misconduct. Some of the violations observed by regulators as early as 2002 include the company's failure to maintain adequate safeguards for sterile injectable products – the very issue at the center of the current meningitis outbreak. In fact, since the company's formation, FDA conducted three prior series of inspections of NECC, each based on a separate set of allegations or events, issuing two Form 483s in 2002 and 2003 and one Warning Letter in 2006. The Massachusetts Board of Pharmacy has an even more extensive history with NECC. Prior to this outbreak, the Board had investigated at least twelve separate complaints concerning NECC or Mr. Cadden, issued at least

[16] *Id.*
[17] *Id.* at 7.
[18] *Id.* at 1.
[19] *Id.*
[20] Media Call, U.S. Food & Drug Admin., FDA Media Call: Fungal Meningitis Outbreak – FDA Inspection Observations (Form 483) at NECC (Oct. 26, 2012) (statement of SteVen Lynn, Dir., Office of Mfg. & Product Quality, Office of Compliance, Ctr. for Drug EValuation & Research, FDA).

four advisory letters and/or informal reprimands, and entered into a consent agreement with the company in 2006.

Set forth below is the chronology of FDA's and the Massachusetts Board's inspections and involvement with the NECC, including any resulting administrative actions.

A. Formation of NECC

On May 12, 1998, MBP approved NECC's pharmacy license. Mr. Barry Cadden was listed as the managing pharmacist. Less than a year later, in April 1999, MBP filed a complaint against Mr. Cadden for providing a practitioner with blank prescription pads referring to NECC, in clear violation of MBP regulations.[21] The MBP Complaint Committee reviewed the complaint on October 19, 1999, and voted to issue an informal reprimand to Mr. Cadden and NECC and dismiss the case.

NECC's efforts to market its products were the subject of additional complaints starting in 2001. On June 27, 2001, MBP staff completed an investigation into a report submitted by the Idaho Board of Pharmacy that NECC was soliciting business for drug products which should have been discontinued by the manufacturer. In addition, on April 18, 2002, MBP received a letter from the Nevada Board of Pharmacy describing allegations of NECC selling non FDA-approved products to physicians in Nevada. Committee staff is unaware of any additional administrative or disciplinary actions taken as a result of these reports.

Further, based on various complaints of unprofessional conduct and failure to adhere to standards of practice between 2002 and 2004, MBP issued three advisory letters to Mr. Cadden and NECC on September 30, 2004. Each of the advisory letters addressed complaints made by out-of-state pharmacists or practitioners in Texas, South Dakota, Iowa, and Wisconsin. Each of these complaints related to NECC's solicitation of out-of-state prescriptions for office use. The three advisory letters issued by the Massachusetts Board stated that the letters did not constitute disciplinary action but communicated the Board's concern regarding the conduct that was the basis for the complaint. The letters requested that NECC adopt "quality assurance measures . . . to reduce the risk of recurrence."[22]

B. 2002 Inspections Related to Betamethasone Repository Injection

In March 2002, two adverse events were reported to FDA through its MedWatch system.[23] Both adverse events involved epidural betamethasone repository injections

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[21] 247 CMR § 9.01(1),(13).

[22] Advisory Letter from James T. Devita, President, Mass. Bd. of Registration in Pharmacy, to Barry Cadden, Manager of Record, New England Compounding Ctr. (Sept. 30, 2004) (Docket Nos. DS-03-060, PH-03-070 – Texas). *See also* Advisory Letter from James T. Devita, President, Mass. Bd. of Registration in Pharmacy, to Barry Cadden, Manager of Record, New England Compounding Ctr. (Sept. 30, 2004) (Docket Nos. DS-04-062, PH-04-161 – Iowa and Wisconsin) *and* Advisory Letter from James T. Devita, President, Mass. Bd. of Registration in Pharmacy, to Barry Cadden, Manager of Record, New England Compounding Ctr. (Sept. 30, 2004) (Docket Nos. DS-03-036, PH-03-042 – South Dakota).

[23] The investigative report corresponding to an April 16, 2002 FDA Form 483 states that FDA investigators contacted the MedWatch reporter who informed them that "a total of probably 5 incidents occurred after using

(betamethasone acetate and betamethasone sodium phosphate suspension 6 mg/ml), from the same lot compounded and distributed by NECC. Like methylprednisolone acetate, betamethasone repository injections are steroid solutions often used to treat pain and swelling. FDA alerted the MBP and invited them to participate in an inspection commencing April 9, 2002. FDA noted in its investigative report that the agency had no previous investigation or inspection history with the firm, though MBP had inspected NECC in the past.

While the investigation was underway, FDA investigators were informed of the fact that this was the same formulation compounded by a pharmacy in California that was associated with numerous hospitalizations (including five cases of meningitis, three of which were fatal) in Walnut Creek, California the previous year. Before detailing areas of concern and related discussions with NECC management, FDA's investigative report states, "Very similar operational problems existed with the California Compounding Pharmacy that were encountered with NEC[C]."[24]

On the day the inspection began, Barry Cadden was identified as the Owner and Director of Pharmacy at NECC. He identified his wife, Lisa Cadden, as Vice President and introduced her to investigators on the second day of the inspection. According to the report, Mr. Cadden stated that NECC had eight employees, three of whom were involved in compounding, though he was the only individual who compounded sterile product. He informed investigators that "they fill patient specific prescriptions only, and that they have no wholesale functions.[25]

According to FDA's inspection report, on the first day of the inspection, "Mr. Cadden was cooperative [and] supplied some documents. The second day of the inspection, Mr. Cadden had a complete change in attitude [and] basically would not provide any additional information either by responding to questions or providing records. Mr. Cadden challenged FDA jurisdiction/authority to be at his pharmacy."[26] FDA investigators were initially "allowed to review and were furnished with copies of records related to the compounding of Betamethasone Repository Injection," though by the second day, "Mr. Cadden stated that he was no longer willing to provide us with any additional records, unless we would identify the specific lot . . .

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subject Betamethasone on patients." U.S. FOOD & DRUG ADMIN., FDA INSPECTION REPORT OF NEW ENGLAND COMPOUNDING PHARMACY, INC., at 4 (Apr. 16, 2002) [hereinafter, "FDA APR. 16, 2002 INSPECTION REPORT"]. In a February 2003 presentation to MBP, FDA identified the adverse events as "dizziness, shortness of breath, diaphoresis, drop in blood pressure to 55/44." U.S. Food & Drug Admin., *Inspectional History of New England Compounding Center (NECC)*, Presentation to Bd. of Registration in Pharmacy, Div. of Health Professions Licensure, Dep't of Pub. Health, Commonwealth of Mass. (Feb. 5, 2003) [hereinafter, "Feb. 5, 2003 FDA Presentation"].

[24] FDA APR. 16, 2002 INSPECTION REPORT, *supra* note 23, at 3.

[25] *Id.* at 6.

[26] *Id.* at 2. Questions and discussion regarding issues related to FDA's jurisdiction and authority are addressed in detail later in this memorandum. With respect to the April 2002 inspection, the FDA investigative report cites § 704(a) of the FDCA, which describes the nature of FDA inspectional authority with regard to drug manufacturers, pharmacies, and other entities, and specifically excludes traditional retail pharmacies, operating in accordance with local pharmacy laws, from being obligated to furnish certain records. The report summarizes, that the investigators' inspectional authority at pharmacies operating in a retail capacity consists of being able to "enter, at reasonable times (Section 704(a)(1)(A), and inspect, at reasonable times, and within reasonable limits and in a reasonable manner (Section 704(a)(1)(b), the establishment and its equipment and operations. However, the owner of the pharmacy is not obligated to furnish records, as is normally the case when a facility that processes drug products is being inspected." *Id.*

that was the focus of this investigation. Since we had been specifically directed by [FDA's Office of Compliance in the Center for Drug Evaluation and Research (CDER)] not to divulge this lot number, we were not in a position to comply with Mr. Cadden's request. From this point on, no additional records were provided or collected."[27]

Nonetheless, FDA investigators had managed to obtain a printout of the betamethasone products compounded by NECC in 2002 and identified the suspect lot on the list, which according to the lot number was compounded on February 1, 2002. Mr. Cadden informed FDA that there were no compounding records associated with the suspect lot number. According to FDA's report, Mr. Cadden stated that he did not believe betamethasone was ever compounded for that lot number, although FDA noted that Mr. Cadden "could not provide any documents to support his belief, such as a cancelled lot etc."[28] Further, FDA investigators contacted the healthcare professional who reported the adverse events to confirm that the suspect lot existed. That individual informed FDA that he had returned the betamethasone product to NECC and, in fact, had spoken by telephone to Mr. Cadden about the incident.[29]

While FDA's investigative report did not mention any test results of the suspect lot in question, the MBP report stated, "The FDA was concerned regarding a specific date the Batch of Betamethasone Repository 6mg/ml was compounded. The error was first reported in March 2002. The unnamed facility conducted sterility and Endotoxin tests on the product prepared by NECC, the results indicated a positive test for Endotoxin."[30] While FDA did not include this specific test result in its investigative report, FDA did discuss other positive endotoxin test results of betamethasone samples from NECC lots.

According to the FDA report, on April 9, 2002, "Mr. Cadden stated on/about 3/19/02 through 4/6/02 he received ARL [(Analytical Research Laboratories)] results positive for endotoxin (greater than 100 ppb). . . . He stated these lots (about 4 lots total) were awaiting disposal at his facility."[31] After changing the suspending agent based on research he conducted, Mr. Cadden informed investigators that he made an additional lot on April 6, 2002. He stated that he "sent his samples to ARL, then left the product beaker covered with aluminum foil on the magnetic stirrer in the hood awaiting lab results" and that it "could take anywhere from seven to ten days to obtain lab results."[32] When questioned about this practice, "Mr. Cadden stated he didn't want to waste the money on vials or the effort in transfilling the vials if the 4/6/02 lot failed testing. He stated he would transfill the vials upon receiving satisfactory lab results."[33] FDA investigators "discussed with Mr. Cadden that this was not an acceptable process for maintaining product sterility."[34] When FDA investigators returned to NECC on April 10, "the

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[27] *Id.* at 3.
[28] *Id.* at 4.
[29] *Id.*
[30] MASS. DEP'T OF PUB. HEALTH, INVESTIGATION REPORT OF NEW ENGLAND COMPOUNDING CENTER & BARRY CADDEN, at 5 (Mar. 4, 2004) [hereinafter, "MDPH MAR. 4, 2004 INVESTIGATION REPORT"].
[31] FDA APR. 16, 2002 INSPECTION REPORT, *supra* note 23, at 7. Analytical Research Laboratories (ARL) is a third-party analytical testing lab located in Oklahoma City, Oklahoma that NECC has sent samples to for sterility and endotoxin testing since at least 2002.
[32] *Id.*
[33] *Id.*
[34] *Id.*

hood was clean and Mr. Cadden was asked the whereabouts of the 4/06/02 lot. He stated he received negative lab results the night before, and had transfilled the lot into vials that morning. He accredited the positive endotoxins to the previous suspending agent."[35] FDA did not comment on this assertion, nor is it known how long Mr. Cadden had been using the previous suspending agent. According to the report, "The FDA investigator suggested to Mr. Cadden that he retest the 4/6/02 lot again after transfilling the vials since the product sat in a beaker for 5 days," which he agreed to do.[36]

After completing the inspection, FDA investigators concluded that "[d]ue to jurisdiction/confidentiality restrictions, this FDA investigation could not proceed to any definitive resolution of issues raised in the [FDA] Headquarters assignment" and that individuals in CDER's Office of Compliance "were fully informed of problems/barriers that were encountered throughout the inspection."[37] FDA's investigative report was finalized on April 16, 2002. Prior to concluding the investigation, FDA investigators spoke with officials in CDER's Office of Compliance and FDA NWE-DO about NECC's "poor practices and areas of concern" and "impressed upon [them] that due to limitations on information gathering and access to records, the FD-483 observations could not/would not be supported with documentation."[38] Nonetheless, "FDA Investigators were directed to issue the 483 (even in light of the lack of documentation)."[39] The observations in the 483 focused primarily on two violations: the sterility of the betamethasone product and NECC's failure to account for records related to the suspect lot of betamethasone, which subsequently tested positive for endotoxin.[40]

After issuing the 483, Mr. Cadden was given an opportunity to respond to FDA investigators' observations during an exit interview. With regard to the sterility of the beaker, and keeping the solution in the beaker for seven to ten days while waiting for test results, Mr. Cadden claimed that this was not his usual practice.[41] FDA's report also indicated that Mr. Cadden provided contradictory information to the agency. During the exit interview, Mr. Cadden claimed that the beaker capped with foil "didn't contain the betamethasone repository."[42]

The report completed by the Massachusetts Board substantiated FDA's observations about NECC's practices. Specifically, it noted that the beaker remained in the hood capped with foil while tests were conducted, a process which could take up to seven days.[43]

In February 2003, following the April 2002 inspections with FDA, the MBP filed formal complaints against NECC and Mr. Cadden "based on the failure to adhere to standards of practice for compounding prescriptions. Specifically, the pharmacy and pharmacist engaged in unprofessional conduct as exhibited by[:] failing to follow guidelines, sterility procedures, record

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[35] *Id.*
[36] *Id.*
[37] *Id.* at 5.
[38] *Id.*
[39] *Id.*
[40] *See* U.S. FOOD & DRUG ADMIN., NEW ENGLAND COMPOUNDING PHARMACY, INC. FORM FDA 483 (Apr. 16, 2002) [hereinafter, "FDA APR. 16, 2002 FORM 483"].
[41] *See* FDA APR. 16, 2002 INSPECTION REPORT, *supra* note 23, at 10.
[42] *Id.*
[43] *See* MDPH MAR. 4, 2004 INVESTIGATION REPORT, *supra* note 30, at 6.

keeping requirements, [and] batch records [requirements], [and] failing to provide certificates of analysis, proof of sterility testing, Endotoxin test results, batch numbers and prescriptions upon request."[44]

On February 7, 2003, the MBP investigator requested that NECC provide responses to certain questions raised during the investigation. Documents produced to the Committee show that the Massachusetts Board found that NECC took certain corrective measures in February 2003, including hiring a consultant to develop policy and procedures.[45] The MBP subsequently conducted follow-up inspections on February 20, 2003, and one year later on February 20, 2004. According to the MBP report, the investigator found the facility was in compliance.[46] Even so, the MBP investigator recommended that the Board issue a formal reprimand to NECC. According to the report, which was signed by the investigator and her supervisor on March 4, 2004, the investigator based her decision on NECC's "history as it relate[d] to prior concerns of the Board agents since 1999[.]"[47]

One particular concern, which was raised between the investigator's April 2002 inspections with FDA and her recommendation for formal reprimand, may have informed her decision. In October 2002, FDA investigators informed the MBP that a second incident with NECC had occurred, this one involving methylprednisolone acetate.[48]

C. 2002 Inspections Related to Methylprednisolone Acetate

On October 2, 2002, CDER's Office of Compliance requested an FDA NWE-DO investigation to obtain information regarding three MedWatch reports associated with the use of methylprednisolone acetate that was compounded by NECC in May 2002. According to FDA's investigative report, the three MedWatch reports were reported by a physician and the chief pharmacist at a hospital in Rochester, New York and detailed adverse events that occurred in two patients on July 17, 2002, after they had received inrathecal injections. After speaking with hospital staff, FDA documented that both patients were hospitalized with meningitis-like symptoms, received antibiotics, and fully recovered. Hospital staff reported that the vials from the same lot distributed by NECC were tested at the hospital and confirmed positive for bacteria. When asked about actions taken by the hospital, the hospital's chief pharmacist stated that he "instructed his staff to remove all the methylprednisolone acetate injectable with the affected lot number from the hospital floors."[49] The hospital's quality assurance supervisor stated that she first contacted Mr. Cadden on or about July 23, 2002, "to make him aware of the adverse events."[50] She informed the FDA investigator that "she does not believe [the hospital] returned any of the vials to NECC" and that "[s]he believes they were all retained for FDA sampling and hospital investigative purpose."[51]

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[44] *Id.* at 4.
[45] *Id.* at 6.
[46] *See id.* at Attachment 1.
[47] *Id.* at 9.
[48] *Id.* at 7.
[49] U.S. FOOD & DRUG ADMIN., FDA INSPECTION REPORT OF NEW ENGLAND COMPOUNDING CENTER, at 4 (Feb. 10, 2003) [hereinafter, "FDA FEB. 10, 2003 INSPECTION REPORT"].
[50] *Id.* at 5.
[51] *Id.*

On September 9, 2002, FDA's New York District Office collected a sample from the hospital, purportedly from the suspect lot. The sample was then sent to FDA's Northeast Regional Lab (NRL) for sterility and endotoxin testing. However, according to FDA's report, NRL "was unable to perform the sample analysis until 4 days after the compounded product's expiration date" and the sample collected from the hospital was from "a different lot than the MedWatch reports."[52]

FDA and MBP investigators first visited NECC in relation to the adverse events associated with methylprednisolone acetate on October 24, 2002. FDA's investigation report noted that FDA last inspected NECC in April 2002 and a 483 was issued to Mr. Cadden citing "sterility issues pertaining to the transfilling practices for betamethasone repository injection."[53] The report further stated that "[t]he practices that were cited on the previous FDA 483 were not in place and therefore the correction of these items was not an issue" during the current inspection.[54] The report also highlighted the fact that since April 2002, NECC's operating space approximately doubled in size and it was now "planning on marketing and selling compounded products in all 50 U.S. states per Mr. Cadden." [55]

Mr. Cadden informed the FDA inspector that he had been "telephoned by an employee from [the Rochester hospital] to notify him of the adverse reactions" and that the employee "told him the adverse reactions were due to 'administration errors' since the injections were administered intrathecally."[56] According to FDA's investigator, Mr. Cadden stated that the hospital had in fact "returned vials of the affected product to the firm and that NECC sent a sample of the returned product to its contract laboratory [ARL] for testing."[57] The test results, which were reported to the FDA investigator on August 22, 2002, came back negative for endotoxin content and microbial contamination.

On December 11, 2002, FDA NRL informed FDA NWE-DO that four out of fourteen of the vials it sampled from the lot provided by the New York District Office tested positive for bacteria. On December 12, FDA and MBP investigations returned to NECC with the test results to "determine what his intentions would be regarding the compounded product."[58] Mr. Cadden informed them that "NECC had conducted a recall of the product in August 2002,"[59] a fact that he failed to share with the investigators during the October 24 inspection. When asked about details of the recall, Mr. Cadden stated that he had "received 500-600 vials back from customers as a result of the recall. He retested one (1) of these vials for sterility and endotoxin and the results were negative."[60] The inspectors were understandably concerned that this was not a

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[52] *Id.*
[53] *Id.* at 3.
[54] *Id.* at 1.
[55] *Id.* at 3.
[56] *Id.* at 7.
[57] *Id.*
[58] *Id.* at 8.
[59] *Id.*
[60] *Id.*

representative sample and explained to Mr. Cadden that "the USP contains guidance on sample sizes in relation to lot quantities."[61]

While at the firm on December 12 and again on December 18, 2002, inspectors collected samples of methylprednisolone acetate as well as betamethasone repository injection. According to FDA's report, "[t]hese compounds were chosen because they were associated with the current and April 2002 MedWatch reports" and are "compounded by similar methods according to Mr. Cadden."[62] One FDA investigator returned to NECC on January 14 and 15, 2003. Mr. Cadden notified him that "if [he] had any other requests or questions pertaining to any of their procedures and compounding activities, [he] was to put [his] requests or questions in writing."[63] According to the investigator, Mr. Cadden brought this up when the investigator "requested the address and name of customers who received [the suspect lot of] methylprednisolone . . . [acetate] injection. . . ."[64] The investigator followed up after the inspection with a written request for the names and customers. Neither Mr. Cadden nor his lawyer chose to respond to the written request and still had not done so when, weeks later on February 10, 2003, the FDA issued NECC a 483 that detailed concerns observed during the inspections.[65]

On February 5, 2003, prior to FDA's issuance of the Form 483 to NECC, a meeting was convened with officials from FDA NWE-DO, CDER's Office of Compliance, and MBP in order to "review the inspectional history of the New England Compounding Center and develop a joint strategy for achieving safe compounding practices at the firm."[66] The immediate concern was determining how to ensure the outstanding violative betamethasone was removed from commerce. Asserting its authority under section 501(b) of the FDCA, FDA discussed its ability to seize the adulterated lot that "is still within expiry."[67] While NECC did ultimately agree to a voluntary recall, officials also discussed alternative courses of action they should consider. CDER officials "reminded everyone that in a similar situation with a South Carolina compounding pharmacy, FDA issued a press release when the firm failed to take recall action in a timely manner."[68] Based on a PowerPoint slide deck attached to an FDA memorandum describing the February 5, 2003, meeting, it is clear that FDA was discussing a fungal meningitis outbreak that had occurred a few months prior in South Carolina associated with methylprednisolone acetate compounded by a facility in Spartanburg, South Carolina, which ultimately resulted in two deaths.[69]

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[61] *Id.* Mr. Cadden informed investigators on December 18, 2002, in a related discussion about sample sizes, that he "used the recommendations of his contract laboratory (ARL)." *Id.* at 9.
[62] *Id.* at 8.
[63] *Id.* at 11.
[64] *Id.*
[65] *See id.*
[66] Memorandum from Kristina Joyce, Consumer Safety Officer, New England Dist. Office, FDA & Mark Lookabaugh, Compliance Officer, New England Dist. Office, FDA, to Central File, *February 5, 2003 Meeting with Massachusetts Board of Pharmacy/Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, at 1 (Feb. 24, 2003) [hereinafter, "Feb. 24, 2003 FDA Memorandum"].
[67] *Id.* at 2.
[68] *Id.*
[69] *See* Feb. 5, 2003 FDA Presentation, *supra* note 23, at 7-8. *See also* David Brown, *Previous Fungal Meningitis Outbreak a Decade Ago Resulted in No Oversight Changes*, WASH. POST (Nov. 5, 2012), http://www.washingtonpost.com/national/health-science/previous-fungal-meningitis-outbreak-a-decade-ago-resulted-in-no-oversight-changes/2012/11/05/8417d84e-1fa8-11e2-9cd5-b55c38388962_story.html.

At this point, "[a] discussion was held to decide if NECC should be considered a manufacturer or a compounder," which would govern how to handle the betamethasone recall, but also inform ways to address "NECC's poor compounding practices [that] would not necessarily be ultimately resolved by such an action."[70] It was decided that "current findings supported a compounding role" and that "the state would be in a better position to gain compliance or take regulatory action against NECC as necessary."[71] It is noteworthy that after closing out the inspection report by issuing the 483 and convening this meeting with State officials, FDA's primary NECC investigator and her supervisor recommended that the "firm be prohibited from manufacturing until they can demonstrate ability to make product reproducibly and dependably."[72] They further noted that if the State was "unwilling to take action, [they] recommend[ed the] firm be enjoined for GMP deficiencies."[73]

With respect to next steps, it was agreed that the State would ask Mr. Cadden "to appear before the Board of Pharmacy to answer to the current complaints."[74] MBP counsel Susan Manning discussed the fact that "Massachusetts pharmacy law states that pharmacists must act in accordance with USP recommendations" and that "this alone would imply he could be held to those standards by the state."[75] In addition, she stated that "although the state's authority does not include the ability to fine pharmacists, the state is able to take actions against a pharmacy's license, including revocation and suspension."[76] It was agreed that CDER's Office of Compliance "would work on documenting the deviations from USP standards for the state."[77] Furthermore, among other things, the State requested from FDA examples of previous consent agreements and MedWatch reports regarding adverse events from products compounded by NECC.[78]

The February 5, 2003, meeting concluded by FDA "emphasizing the potential for serious public health consequences if NECC's compounding practices, in particular those relating to sterile products, are not improved."[79] FDA acknowledged that "so long as a pharmacy's operations fall within the scope of the practice of pharmacy (as outlined in FDA's Compliance Policy Guide 460.200), FDA will generally continue to defer to state authorities for regulatory oversight. In such cases FDA will seek to engage cooperative efforts aimed at achieving regulatory compliance and ensuring the safety and quality of compounded products."[80]

On February 10, 2003, FDA issued a Form 483 to NECC and met with Mr. Cadden to review the documented observations, which included inadequate documentation to verify whether sterile drug products met set standards, a failure to maintain complaint files, and a lack

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[70] Feb. 24, 2003 FDA Memorandum, *supra* note 66, at 2.
[71] *Id.*
[72] U.S. FOOD & DRUG ADMIN., FDA ESTABLISHMENT INSPECTION REPORT OF NEW ENGLAND COMPOUNDING CENTER, at 1 (Feb. 10, 2003) [hereinafter, "FDA FEB. 10, 2003 ESTABLISHMENT INSPECTION REPORT"].
[73] *Id.*
[74] Feb. 24, 2003 FDA Memorandum, *supra* note 66, at 3.
[75] *Id.*
[76] *Id.*
[77] *Id.*
[78] *See id.*
[79] *Id.*
[80] *Id.* at 3-4.

of documentation for the reported adverse events associated with the suspect lot of methylprednisolone acetate.[81] In addition, FDA noted in the corresponding inspection report that results from the samples investigators collected from NECC "revealed that the firm has sterility and potency issues with injectable steroid suspensions (betamethasone repository USP and methylprednisolone acetate USP)."[82] During the meeting, Mr. Cadden was informed that "at this point the FDA is considering NECC a pharmacy compounder and not a drug manufacturer."[83]

On February 26, 2003, Mr. Cadden responded in writing to the 483 detailing a variety of corrective measures. He stated, "We are committed to complying with applicable laws and regulations, to ensuring high-quality care for our patients, and to upgrading our compounding procedures."[84] This letter was supplemented on May 16, 2003, detailing additional standard operating procedures that were being implemented at the facility related to compounding, as well as product and environmental testing protocols. Mr. Cadden noted "that while we are validating NECC sterile [injectable] preparation processes, we are not subject to (nor are we voluntarily subjecting ourselves to) current good manufacturing practices (cGMPs) as promulgated by FDA, since we are a compounding pharmacy, not a manufacturer."[85]

With respect to Massachusetts, the MBP did not commence any regulatory actions until well over a year later, on September 21, 2004, when the Board voted unanimously in favor of proposing a consent agreement to NECC and Mr. Cadden to resolve the aforementioned complaints received and violations observed. Then-Executive Director of the MBP, Charles Young, formally offered Mr. Cadden the consent agreement on October 4, 2004, noting in a letter "that if you choose not to enter into the Agreement, the Board will proceed to a formal hearing."[86]

According to the terms of the proposed consent agreement, NECC would have to agree that it was entered into "as a result of an adverse event complaint report investigated by the U.S. Food and Drug Administration" alleging that NECC "failed to comply with accepted standards in compounding a certain order for methylprednisolone acetate."[87] In addition, NECC would agree that this conduct "constitutes professional misconduct warranting disciplinary action by the Board" and that NECC and Mr. Cadden would be "REPRIMANDED by the Board and [NECC's] pharmacy registration and [Mr. Cadden's] pharmacist license [would be] placed on

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[81] *See* U.S. FOOD & DRUG ADMIN., NEW ENGLAND COMPOUNDING CENTER FORM FDA 483 (Feb. 10, 2003) [hereinafter, "FDA FEB. 10, 2003 FORM 483"].
[82] FDA FEB. 10, 2003 ESTABLISHMENT INSPECTION REPORT, *supra* note 72, at 1.
[83] FDA FEB. 10, 2003 INSPECTION REPORT, *supra* note 49, at 20.
[84] Letter from Barry Cadden, Manager, New England Compounding Center, Inc., to Daryl A. Dewoskin, Investigator, FDA & Kristina M. Joyce, Investigator, FDA (Feb. 26, 2003) [hereinafter, "Feb. 26, 2003 Cadden Letter"].
[85] Letter from Barry Cadden, Manager, New England Compounding Center, Inc., to Daryl A. Dewoskin, Investigator, FDA & Kristina M. Joyce, Investigator, FDA (May 16, 2003) [hereinafter, "May 16, 2003 Cadden Letter"].
[86] Letter from Charles R. Young, Executive Dir., Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Manager of Record, New England Compounding Ctr. (Oct. 4, 2004) (attaching proposed Consent Agreement).
[87] Proposed Consent Agreement, *In the Matter of New England Compounding Center Registration No. 2848 Barry J. Cadden, R.Ph. License No. 21239*, Docket Nos. DS-03-055, PH-03-066, at 1 (Mass. Bd. of Registration in Pharmacy, Oct. 4, 2004) [hereinafter, "MPB Proposed Consent Agreement"].

probation for a minimum three (3) year period."[88] During the probationary period, among other things, NECC and Mr. Cadden would have been required to develop and implement various policies and procedures, update the Board on a quarterly basis, and keep written reports of each adverse event reported.[89] Finally, the agreement would have required NECC and Mr. Cadden to apply in writing for termination of the probationary period, which would be granted only if all the conditions had been met.[90]

On November 11, 2004, counsel for NECC and Mr. Cadden responded to MBP's offer of the consent agreement. Similar to the company's prior responses to FDA, the letter, addressed to MBP counsel Susan Manning detailed the various corrective measures that NECC had implemented and noted that they "address –and in some instances exceed – the proposed probationary conditions."[91] After noting subsequent inspections that had been conducted "without incident," NECC's counsel stated, "While I think it is fair to say that the product of NECC's interaction with the Board . . . is a success story, such would not be the case if the resolution were to include a disciplinary sanction (including the reprimand proposed in Mr. Young's letter). The collateral consequences to many, if not all of NECC's 42 other [state] licenses, would be potentially fatal to the business. Such a catastrophe is clearly not the intended result of the Board's proposed reprimand, nor is it warranted in this case. The Board's mandate is to protect the public health safety and welfare, not to punish its licensees."[92] In conclusion, the attorney stated, "Mr. Cadden and NECC have demonstrated their commitment to remediation, and are prepared to continue to do so. In that regard, NECC and Mr. Cadden will agree to all of the probationary terms offered in Mr. Young's letter, and will further agree to bear the burden and cost of monitoring and reporting their compliance. That result could be accomplished through a non-disciplinary resolution such as a continuance (pending a period of monitoring) or a 'stayed probation.'"[93] On November 23, 2004, the MBP reviewed the "NECC response to [the] proposed Consent Agreement" and voted unanimously "to deny [the] request to revise terms."[94]

Despite the October 4, 2004, letter stating that if NECC and Mr. Cadden chose not to enter into the consent agreement, the Board would proceed to a formal hearing, there is no documentation of any such hearing having occurred. However, on January 6, 2006, NECC and Mr. Cadden did sign a consent agreement with MBP, though the terms were significantly different from those proposed by the Board in 2004. As set forth in the next section of this memorandum, NECC and the Massachusetts Board eventually agreed to only a stayed probationary period of one year.

D. 2004 Inspections and the 2006 Massachusetts Board Consent Agreement with NECC

As evidence that MBP was aware of NECC's corrective measures and disciplinary action was unwarranted, NECC's counsel pointed out in his November 11, 2004, response letter that

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[88] *Id.* at 1-2.
[89] *Id.* at 2.
[90] *Id.*
[91] Letter from Paul R. Cirel, Counsel to Barry Cadden & New England Compounding Ctr., to Susan Manning, Counsel to Mass. Bd. of Registration in Pharmacy, at 1 (Nov. 11, 2004) [hereinafter, "Nov. 11, 2004 Cirel Letter"].
[92] *Id.* at 2-3 (internal citations omitted).
[93] *Id.* at 3 (internal citations omitted).
[94] Minutes of the Meeting of the Mass. Bd. of Registration in Pharmacy, at 2 (Nov. 23, 2004).

MBP had "inspected the facility three times since last February (twice, with a representative from the FDA)."[95] However, the two inspections with FDA were not to follow up on the underlying complaints and violations covered in the proposed consent agreement, but were to investigate new allegations. Further, these inspections revealed additional violations by NECC.

On April 27, 2004, MBP had received a complaint from a Wisconsin pharmacist that raised concerns about the safety and legality of a product NECC was soliciting. According to the complaint, an NECC representative offered "a product to our plastic surgery physician that he calls extra strength triple anesthetic cream."[96] During the conversation, NECC "related to [the individual] that he would need a prescription for the product and that we could use the name of a staff member if we wanted to. He said 'other institutions have used a nurse[']s name."[97] When questioned about the legality of this approach, "He assured her it was legal. He indicated that after we received the product it was up to us how we used it and to whom it was administered."[98] Separate from this complaint, MBP received "an e-mail sent to the Board by a pharmacist practicing in Iowa. According to the complaint . . . [NECC] is advertising compounded prescription products which may constitute manufacturing since they purport to be used by multiple patients using the same prescription order."[99]

On September 21, 2004, MBP assigned an investigator to "conduct a joint/inspection with FDA . . . It is alleged that [NECC] is compound[ing] non-FDA product Trypan Blue Dye to be used as a capillary stain during cardiac procedures. This dye is not approved for this use."[100] On September 23, 2004, investigators from MBP and FDA NWE-DO visited NECC. According to a January 26, 2005, memorandum drafted by the FDA investigator, "This investigation was mainly to obtain information about the firm's compounding practices, as they relate to the compounding of Trypan blue products."[101] When investigators arrived, Mr. Cadden "acknowledged that he is the most responsible person in the firm" but also introduced them to Gregory Conigliaro who "reported that he just joined the company about eight months ago [and] that he is a Civil Engineer by profession."[102]

When FDA's investigator asked Mr. Cadden whether he had Trypan blue in stock, "He said no, because he just compounds the drug if he receives the prescriptions for certain patients."[103] However, when the FDA investigator was shown the clean room, he noticed a drawer that was identified as "Trypan Blue." He requested that Mr. Cadden open the drawer and when he did, the investigator noted that there were 189 vials of the product. After being

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[95] Nov. 11, 2004 Cirel Letter, *supra* note 91, at 2.The letter lists three inspection dates: February 20, 2004, September 23, 2004, and September 28, 2004. The letter further notes that the second and third inspections included a "representative from the FDA."
[96] E-mail from Wisconsin Dir. of Pharmacy, to James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy (Apr. 27, 2004, 11:33 AM).
[97] *Id.*
[98] *Id.*
[99] Mass. Div. of Prof'l Licensure Office of Investigations, *Request for Staff Assignment* (requested May 27, 2004).
[100] Mass. Div. of Prof'l Licensure Office of Investigations, *Request for Staff Assignment* (assigned Sept. 21, 2004).
[101] Memorandum from Investigator, New England Dist. Office, FDA, to Acting Team Leader, Div. of New Drugs & Labeling Compliance, FDA, *Inspection/Investigation of New England Compounding Center 697 Waverly Street Framingham, MA 01702*, at 1 (Jan. 26, 2005) [hereinafter, "Jan. 26, 2005 FDA Memorandum"].
[102] *Id.*
[103] *Id.* at 2.

informed that it was not an approved product and that NECC should not be compounding it, Mr. Cadden stated that he "did not know that it is not an approved product."[104] He then "told one of the employees in the laboratory to put the vials in quarantine which he told us will be eventually destroyed."[105]

FDA and MBP investigators returned to NECC on September 28, 2004. When asked about the Trypan blue, Mr. Cadden asserted that his lawyer informed him that he did not have to quarantine the product and that "there is no regulation which states that Compounding Pharmacies cannot compound FDA non-approved drugs."[106] In addition he informed the investigators that he dispensed the product the day after the last inspection and that he intends to do so "until FDA/MABP will put in writing that they cannot compound it [and] dispense it and the reason why."[107] When FDA's investigator asked Mr. Conigliaro additional questions, "he became indignant [and] he said that he does not really have the time to sit with us [and] answer all those questions."[108] Further, according to the investigator, Mr. Cadden told Mr. Conigliaro, "'Don't answer any more questions!'"[109] Prior to leaving, FDA wrote down the questions in the assignment and left them with Mr. Conigliaro. On October 1, 2004, Mr. Conigliaro responded to the questions in writing, which were shared with FDA compliance staff.[110]

On October 27, 2004, MBP's investigator sent Mr. Cadden a letter with requests for responses and additional information related to Trypan blue production and distribution, including a fill log and a copy of all prescriptions dispensed "containing more than two (2) doses per patient."[111] On November 8, 2004, Mr. Cadden responded to the letter with the requested information, along with corrective actions taken, and stated, "In summary, we regret that the invalid patient names were not discovered by our pharmacy processing staff. We have taken immediate action to insure that physicians provide, and we verify, accurate patient names in the future."[112] This response was shared with FDA's investigator. On January 19, 2005, the FDA investigator notified Mr. Cadden by phone that the district office was "closing out the inspection based on his response letter to [MBP], indicating his plan of corrective actions, which will also be forwarded to headquarters."[113]

While FDA closed out its inspection, MBP voted on November 23, 2004, to file a formal complaint based on the investigator's findings.[114] This was the same day the Board unanimously voted to deny NECC's request to revise the terms of the consent agreement that had been proposed on October 4, 2004, covering the complaints and violations associated with

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[104] *Id.*
[105] *Id.*
[106] *Id.* at 3.
[107] *Id.*
[108] *Id.*
[109] *Id.*
[110] *See id.* at 4.
[111] Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to Investigator, Mass. Div. of Health Professions Licensure Office of Investigations, at 2 (Nov. 8, 2004).
[112] *Id.*
[113] Jan. 26, 2005 FDA Memorandum, *supra* note 101, at 4.
[114] *See* MASS. DEP'T OF PUB. HEALTH, INVESTIGATION REPORT OF BARRY CADDEN, at 2 (Nov. 23, 2004) [hereinafter, "MDPH NOV. 23, 2004 INVESTIGATION REPORT"].

betamethasone repository injection and methylprednisolone acetate. It is unclear as to whether these decisions were related.

Based on the new terms of the amended consent agreement, the complaint related to distribution of Trypan blue products without valid prescriptions was subsumed into the agreement. Despite the fact that the underlying matters were now more extensive, the amended consent agreement no longer called for a formal reprimand for professional misconduct, a three year probationary period, or a number of mandatory conditions that would have been required prior to the Board terminating the probation. The amended consent agreement included a probationary period of one year that was stayed pending satisfactory documentation related to an inspection having been conducted by Pharmacy Support, Inc. (PSI), a Board-approved evaluator, within 45 days of the effective date of the agreement. Further, NECC had to provide MBP with satisfactory documentation that PSI's recommendations were implemented and that a second inspection was conducted within six months. If such conditions were met, neither NECC's registration nor Mr. Cadden's license would be placed on probation.[115]

On January 30, 2006, PSI sent its initial audit report to Mr. Cadden and the MBP, noting that the assessment was conducted on January 17 and 18. The cover letter accompanying the report conlcuded, "Although your facility has seen significant upgrades in facility design for sterile compounding operation, there were numerous significant gaps identified during the assessment therefore, it is the opinion of the auditors that your operation needs to be upgraded and enhanced to be in substantial compliance with United States Pharmacopeia <795> or <797>."[116] The letter noted that major areas of concern included the fact that good documentation practices were inadequate; written procedures were admittedly not routinely followed; procedures were not in strict accordance with USP standards; end product testing was often performed on "stock solutions" and not the end product that is required; and validation of sterilization cycles and media fills were inadequate.[117] Numerous corrective actions were recommended, including a plan to attain compliance.

On April 7, 2006, PSI issued the final report, which concluded that "[NECC] has made significant improvements over the past several months. They have demonstrated the ability to be compliant with all state and federal regulations. The[y] have appropriate equipment, procedures, basic facility design and environmental controls."[118] However, PSI stated that, among other things, "it is the opinion of our firm that in order for NECC to be in substantial compliance . . . [a] [r]edesign of clean room 1 where sterile preparations are compounded (Floor, Ceiling, and HVAC)" must occur.[119]

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[115] *See* Consent Agreement, *In the Matter of New England Compounding Center Registration No. 2848 Barry J. Cadden, R.Ph. License No. 21239*, Docket Nos. DS-03-055, PH-03-066, DS-05-040 (Mass. Bd. of Registration in Pharmacy, Jan. 10, 2006) [hereinafter, "MPB-NECC Consent Agreement"].

[116] Letter from Vice President for Quality Operations, Pharm. Systems, Inc., to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center et al., at 2 (Jan. 30, 2006) (attaching initial audit report entitled "Observations Requiring Corrective Action").

[117] *See id.* at 1-11.

[118] PHARM. SYSTEMS, INC., FINAL REPORT: USP <795>/<797> IMPLEMENTATION – NEW ENGLAND COMPOUNDING CENTER, FRAMINGHAM, MA, at 1 (Apr. 7, 2006) [hereinafter, "PSI Final NECC Report"].

[119] *Id.*

On April 12, 2006, MBP "commend[ed] NECC on the progress to date" and requested that the firm "advise the Board in writing regarding NECC's intentions" with respect to the outstanding recommendations of PSI as well as "projected timelines for completion."[120] Mr. Cadden responded on April 19 as to how NECC would address PSI's remaining concerns. Regarding the "[r]edesign of clean room 1," Mr. Cadden stated, "It should first be noted that all sterile preparations are compounded within Class 10 Microenvironments, within 'clean room 1.' The room is not maintained as a certified clean room, nor was it ever our intent."[121] Mr. Cadden did, however, assert that the "HVAC unit in that room will be improved per PSI's suggestions. The work has been scheduled . . . and is expected to be completed by May 18, 2006."[122] On May 10, 2006, MBP requested of NECC written confirmation of HVAC work completion, along with two other items, which Mr. Cadden confirmed on May 22.[123] The next day, the Board voted to advise Mr. Cadden that NECC had satisfactorily completed the terms and conditions in the consent agreement. This decision was communicated to Mr. Cadden on June 2, 2006.[124] Apparently the MBP never shared the PSI report with the FDA.

E. FDA Warning Letter Relating to September 2004 Inspections

Based on violations of the Food, Drug, and Cosmetic Act (FDCA) either observed during FDA's joint inspections of NECC in September 2004, or otherwise brought to the agency's attention, FDA issued a Warning Letter to the company on December 4, 2006.[125] According to FDA's Regulatory Procedures Manual, "Warning Letters are issued to achieve voluntary compliance and to establish prior notice. . . . The agency position is that Warning Letters are issued only for violations of regulatory significance. Significant violations are those violations that may lead to enforcement action if not promptly and adequately corrected."[126]

The NECC Warning Letter set forth FDA's position on the agency's jurisdiction over new drugs, including compounded drugs, and its enforcement policy with respect to them. The Warning Letter referenced Compliance Policy Guide (CPG), section 460.200 ["Pharmacy Compounding"], which was issued by FDA on May 29, 2002, and several of the factors laid out in the CPG that influence FDA's enforcement policy in specific cases. The Warning Letter then

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[120] Letter from George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (Apr. 12, 2006).
[121] Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, at 1 (Apr. 19, 2006).
[122] *Id.*
[123] *See* Letter from George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (May 10, 2006) *and* Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to George A. Cayer, President, Mass. Bd. of Registration in Pharmacy (May 22, 2006).
[124] *See* Letter from George A. Cayer, President, Mass. Bd. of Registration in Pharmacy, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (June 2, 2006).
[125] *See* Warning Letter (NEW-06-07W) from Gail T. Costello, Dist. Dir., New England Dist. Office, FDA, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center (Dec. 4, 2006) [hereinafter, "FDA Warning Letter"].
[126] U.S. FOOD & DRUG ADMIN., REGULATORY PROCEDURES MANUAL, at § 4-1-1 (2011), *available at* http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176870.htm.

discussed four primary areas of NECC activity that constituted violations of the FDCA for which the agency would not exercise its enforcement discretion.[127]

First, FDA noted that NECC may be compounding copies of commercially available drug products. Specifically, FDA highlighted Trypan blue products and the fact that "on December 16, 2006, trypan blue ophthalmic solution was approved by FDA and it is commercially available."[128] In addition, according to the Warning Letter, FDA also learned that NECC "may be compounding 20% aminolevulinic acid solution," another commercially available, FDA-approved product.[129] FDA informed NECC that "FDA does not sanction the compounding of copies of FDA-approved, commercially available drugs and the agency will not exercise its enforcement discretion regarding the trypan blue and ALA products compounded by your firm."[130]

Second, FDA detailed how NECC had developed a standardized anesthetic drug product, promoted and sold it under the name "Extra Strength Triple Anesthetic Cream," and generated sales by giving physicians free samples. In addition to noting the public health risks associated with high dose local anesthetic creams, FDA stated, "These actions are not consistent with the traditional practice of pharmacy compounding, in which pharmacists extemporaneously compound reasonable quantities of drugs upon receipt of valid prescriptions from licensed practitioners to meet the unique medical needs of individual patients."[131]

Third, FDA informed Mr. Cadden that it was "in receipt of a complaint alleging that [NECC was] repackaging the approved injectable drug, Avastin, into syringes for subsequent promotion and sale to health professionals."[132] The Warning Letter explained that FDA has an established policy, articulated in the CPG, concerning the manipulation of approved sterile drug products outside the scope of FDA approval and that FDA was "especially concerned with the potential microbial contamination associated with splitting Avastin – a single-use, preservative-free, vial – into multiple doses."[133]

Finally, FDA stated that the agency had been informed that "although [NECC] advises physicians that a prescription for an individually identified patient is necessary to receive compounded drugs, [the] firm has reportedly also told physicians' offices that using a staff member's name on the prescription would suffice."[134]

FDA concluded the Warning Letter by informing Mr. Cadden that "[f]ailure to promptly correct these deviations may result in additional regulatory action without further notice, including seizure or injunction against you and your firm."[135] The agency asked to be notified in

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[127] *See* FDA Warning Letter, *supra* note 125, at 2-5.
[128] *Id.* at 2.
[129] *Id.*
[130] *Id.* at 2-3.
[131] *Id.* at 3.
[132] *Id.* at 4.
[133] *Id.*
[134] *Id.* at 5.
[135] *Id.*

writing of "any steps that you will take to correct the noted violations, including an explanation of the steps taken to prevent the recurrence of similar violations."[136]

On January 5, 2007, Mr. Cadden responded to FDA by noting at the outset that "the Warning Letter is based on an inspection of NECC that started on September 23, 2004, approximately twenty-eight months ago . . . FDA has not contacted us since concluding the inspection. Some of the letter's assertions no longer apply to NECC's operations."[137] After disputing FDA's claim to having jurisdiction over compounded drugs, Mr. Cadden stated that "NECC does not compound copies of FDA-approved commercially available drugs, introduce unapproved new drugs into interstate commerce, does not need approved [New Drug Applications] before dispensing its compounded medications, and does not process or repackage approved drugs in a manner that would subject us to FDA regulation. Nor are our compounded medications misbranded. NECC dispenses compounded medications upon the receipt of valid prescriptions."[138]

Without agreeing with the Warning Letter's assertions, Mr. Cadden informed FDA that, for business reasons, NECC stopped filling prescriptions for Trypan blue in August 2005 (sixteen months before the Warning Letter) and for 20% aminolevulinic acid solution in May 2006 (seven months before the Warning Letter).[139]

With respect to the topical anesthetic cream, Mr. Cadden asserted that NECC currently used the term "'triple anesthetic cream' . . . but only as a way to literally describe the compounded medication as a convenience to our prescribing physicians. The term is in no way trademarked or branded."[140] Further, Mr. Cadden noted, "Although we do provide a very small quantity of medications (less than ten per month) free of charge, we do so only upon receipt of a valid prescription from a licensed practitioner to meet the unique medical needs of a particular patient. . . . A valid prescription does not become unlawful just because we do not charge the physician or patient. Should the FDA believe our position on this matter is incorrect, please advise."[141]

Regarding the repackaging of Avastin, Mr. Cadden stated that it did not constitute manufacturing, that NECC only did so "upon receipt of a valid, patient-specific prescription," and that "[a]ll aspects of our sterile compounding and repacking operations were recently reviewed by an independent expert, who confirmed that NECC is in compliance with [USP standards]."[142]

Lastly, in response to FDA's assertion that NECC reportedly told physicians that the company would fill prescription written in the name of a staff member, Mr. Cadden stated, "This

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[136] *Id.*
[137] Letter from Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, to Compliance Officer, New England Dist. Office, FDA et al., at 1 (Jan. 5, 2007).
[138] *Id.* at 3.
[139] *See id.* at 3.
[140] *Id.* at 4.
[141] *Id.* at 4-5.
[142] *Id.* at 5.

allegation contradicts all of our standard operating procedures. NECC has not made such a representation to anyone, and has no idea how or why FDA arrived at this allegation."[143]

FDA did not respond to Mr. Cadden's letter until almost two years later, on October 31, 2008. In its reply, the agency "acknowledge[d] and apologize[d] for the significant delay in this correspondence."[144] Again, FDA presented an extensive summary of its authority over compounded drugs and factors the agency would consider in determining whether to exercise enforcement discretion. FDA accepted the firm's assertions with respect to the discontinued products; however, NECC's letter did not alleviate FDA's concerns regarding the manner in which the company was promoting its products and the manipulation of sterile injectables.[145]

FDA concluded by stating, "We agree that the length of intervening period was unusual. This in no way diminishes our serious concerns about your firm's operation. Your firm must promptly correct the violations noted in the December 4, 2006, Warning Letter, and establish procedures to assure that such violations do not occur. Its failure to do so may result in enforcement action including seizure of the firm's products and/or an injunction against the firm and its principals. In a future inspection, we will confirm the commitments that you made in your response. We also will verify that your firm's compounding practices are consistent with the policy articulated in the CPG, and that your firm's operation is not otherwise at odds with the conditions under which the agency exercises enforcement discretion towards pharmacy compounding."[146] This letter, which was dated October 31, 2008 and sent in follow-up to an inspection that occurred in September 2004, is the last documented correspondence between FDA and NECC until the recent outbreak.

F. Recent Colorado Complaints Related to NECC and Corresponding Actions

With respect to additional correspondence between NECC and State authorities, the next interaction between the parties was a satisfactory MBP inspection conducted on May 24, 2011, in connection with the renovation and expansion of NECC's Framingham facility. This was the last inspection of NECC's facility prior to the meningitis outbreak.

On July 26, 2012, however, an inspector for the Colorado Board of Pharmacy notified MBP Director James Coffey that NECC had violated the terms of a Cease and Desist Order the State had issued the company on April 15, 2011, based on NECC's distribution of "a stock compounded prescription drug . . . to a prescription drug outlet in the State of Colorado."[147] Mr. Coffey was informed that, during the course of a routine hospital pharmacy inspection in Colorado on July 17, 2012, the inspector observed a number of invoices and products from NECC. After this conversation, on July 26, 2012, the Colorado inspector emailed Mr. Coffey a copy of "the Special Report submitted to the Chief Inspector for the Pharmacy Board in

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[143] *Id.* at 6.
[144] Letter from Compliance Officer, New England Dist. Office, FDA, to Barry J. Cadden, Dir. of Pharmacy, New England Compounding Center, at 1 (Oct. 31, 2008).
[145] *See id.* at 2-4.
[146] *Id.* at 4.
[147] *See* Cease and Desist Order, *In the Matter of the Unauthorized and Unlawful Distribution of Prescription Drugs and/or Compounded Prescription Drugs in Colorado by New England Compounding Center, Inc.*, Case No. 2011-3973 (Colo. State Bd. of Pharmacy, Apr. 15, 2011).

Colorado concerning the receipt of non-patient specific compounded products into Colorado."[148] The inspector asked Mr. Coffey for "any information that the Massachusetts Board could provide concerning if this practice is allowed under Massachusetts pharmacy law."[149] Mr. Coffey responded on July 27, "The Massachusetts Board of Pharmacy will respond as soon as possible following a thorough review and analysis of the same."[150] Mr. Coffey then forwarded his correspondence with the Colorado inspector, along with the report, to MBP counsel Susan Manning and others in the MDPH, including several past NECC inspectors.[151]

Included in the Colorado report is email correspondence from May 2011 between FDA's Denver and New England District Offices relating to NECC's "illegal distribution of compounded drugs to hospitals in the Denver metropolitan area."[152] Several FDA employees were on this email chain, including at least one NWE-DO compliance officer involved in past NECC actions. Based on the Committee's investigation, it appears that FDA did not contact the MBP about the Colorado Board's concerns in May 2011 or any time thereafter, as Mr. Coffey was first informed by the Colorado inspector on July 26, 2012.

MDPH officials informed Committee staff that they first became aware of this complaint from Colorado while reviewing responsive documents pursuant to the Committee's investigation. On November 6, 2012, Dr. Lauren Smith, MDPH Interim Commissioner, issued a statement that Mr. Coffey had been terminated and Susan Manning had been placed on administrative leave. According to Dr. Smith, "The director of the Board is responsible for ordering investigations. Mr. Coffey failed to order an investigation or take any other action on the Colorado complaint. It is incomprehensible that Mr. Coffey and Ms. Manning did not act on the Colorado complaint given NECC's past, and their responsibility to investigate complaints. Following the outbreak, staff also failed to disclose the existence of Colorado's complaint to leadership at DPH."[153] Dr. Smith stated that "[t]here is no evidence at this time that staff informed Board [of Pharmacy] members about the Colorado issues. We continue to interview all Board members as part of our investigation into their handling of this situation and will not hesitate to make further changes and personnel actions if we deem them to be necessary."[154] However, it has come to the Committee's attention that as of November 8, 2012, the current President of the Board has yet to be interviewed.

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[148] E-mail from Pharmacy Inspector, Colo. State Bd. of Pharmacy, to James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy (July 26, 2012, 3:06 PM).
[149] *Id.*
[150] E-mail from James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy, to Pharmacy Inspector, Colo. State Bd. of Pharmacy (July 27, 2012, 7:33 AM).
[151] *See* E-mail from James D. Coffey, Dir., Mass. Bd. of Registration in Pharmacy, to Susan Manning, Counsel to Mass. Bd. of Registration in Pharmacy et al. (July 27, 2012, 7:34 AM) (forwarding Colorado "Special Report").
[152] E-mail from Senior Case Review Expert, Denver Dist. Office, FDA, to Supervising Consumer Safety Officer, New England Dist. Office, FDA et al. (May 10, 2011, 4:19 PM).
[153] Press Release, Mass. Dep't of Pub. Health, Statement of Interim Commissioner Dr. Lauren Smith on NECC Investigation (Nov. 7, 2012), *available at* http://www.mass.gov/eohhs/docs/dph/quality/boards/pharmacy/121107-statement-from-lauren-smith.pdf.
[154] *Id.*

IV. ISSUES

The following issues will be explored at the hearing:

- Both State and Federal inspectors documented a number of deficiencies and violations at NECC since as early as 2002, many of which are similar to those at issue in the ongoing meningitis investigation. Were the FDA's and the Massachusetts Board of Pharmacy's enforcement actions appropriate?

- Why didn't FDA pursue any enforcement actions against the NECC despite having emphasized in 2003 the potential for serious public health consequences if the company's compounding practices, in particular those relating to sterile products, were not improved?

- Prior to this outbreak, the Massachusetts Board of Pharmacy had investigated at least twelve separate complaints relating to NECC and its management. While many of these complaints covered NECC's sales and marketing tactics, several were associated with serious adverse events and uncovered deficiencies with NECC's compounding operations. How was NECC able to maintain its pharmacy license despite repeated violations?

- What did State and Federal authorities do to confirm that sufficient corrective measures were taken after these inspections? How did they communicate with each other to ensure such responses were adequate to protect the public health?

V. STAFF CONTACTS

If you have any questions regarding this hearing, please contact Karen Christian or John Stone with the Subcommittee on Oversight and Investigations at (202) 225-2927.

MASSACHUSETTS BOARD OF REGISTRATION IN PHARMACY

Sterile Compounding Pharmacy Information Sheet

Massachusetts pharmacies that are licensed by the Massachusetts Board of Registration in Pharmacy (Board) and engage in the compounding of sterile products that have completed and submitted a Sterile Compounding Pharmacy Attestation of Compliance are required to **complete this Information Sheet and return it with the requested documents to the Board by 12 Noon on Friday, November 9, 2012.**

FAILURE of any Massachusetts pharmacy that performs sterile compounding to complete and return this Information Sheet and other requested information to the Board by 12 Noon on Friday, NOVEMBER 9, 2012 will be a ground for discipline of the pharmacy license by the Board as a violation of 247 CMR 10.03(q).

Please direct any questions regarding this request to pharmacy.admin@massmail.state.ma.us

Name of Massachusetts Pharmacy _____
Street Address _____
City/Town _____ Zip Code _____
Tel. No. _____ Fax No. _____

Name of Manager of Record _____ Lic. No. PH_____
Signature_____ Date_____
E-mail _____

1. Hours of operation: Weekdays: _____ Weekends: _____
2. Staffing:

   Total No. Pharmacy Staff: Pharmacists: _____ Technicians: _____ Interns:_____

   No. staff preparing sterile products: Pharmacists:_____ Technicians:_____ Interns: _____
3. Job descriptions for individuals involved with compounding of sterile products (attach)
4. Competency training documents (attach)
5. Size of and number of clean rooms: _____
6. Number of laminar flow hoods: _____
7. List all non-sterile active pharmaceutical ingredients (API) used for sterile compounding: _____
   _____
   _____
8. Describe methods of sterilizing (e.g., filtration, autoclave): _____
   _____
9. Describe process of environmental sampling: _____
   _____
10. Describe process to determine Beyond-Use-Dating (BUD): _____
    _____
11. List of sterile products compounded (attach)

12. List of customers (attach)

I, _____ (Print Name) ATTEST, under the pains and penalties of perjury, to the truthfulness of the information provided herein.

Signature: _____ Date:_____

Please direct any questions regarding this Pharmacy Information Sheet to pharmacy.admin@massmail.state.ma.us

Please FAX (617 973 0980) OR SCAN (pharmacy.admin@massmail.state.ma.us) a completed and signed Information Sheet and other requested information to the Massachusetts Board of Registration Pharmacy BY 12 NOON ON FRIDAY, NOVEMBER 9, 2012. Please mail an original signed form AND requested information to the Board at the address below:

Board of Registration in Pharmacy
ATTN: Sterile Compounding Pharmacy Information Sheet
239 Causeway Street, 5th floor
Boston, MA 02114

Florida Pharmacy Association
Supporting Florida Pharmacy Since 1887

November 13, 2012

Mr. Mark Whitten
Executive Director
Florida Board of Pharmacy
4052 Bald cypress Way, C-04
Tallahassee, Florida 32399

Re: Pharmacists' Commitment to Patient Safety and Compounding Quality

Dear Mr. Whitten:

As a state organization representing pharmacy practitioners in all settings, we offer our deepest sympathy and condolences to patients and families affected by the fungal meningitis outbreak due to contaminated injectable products. The pharmacy profession is dedicated to ensuring patient safety and access to quality medications that meet patients' needs. Based on our understanding of this tragedy, the entity involved was not engaged in traditional compounding practices specific to particular patients or in-office use by a physician that is integral to all aspects of pharmacy practice, but was possibly engaged in unregulated, unlicensed drug manufacturing.

Pharmacists compound medications in response to a prescription from a physician or other legally-authorized prescriber to meet patient-specific needs. Under Florida law, patients may receive compounded medications when they have a need for a customized medication, when a drug shortage or product discontinuation occurs, when the needed strength or dosage form is not available from a manufacturer, or when an allergen-free version of a medication is needed. Pharmacists provide these compounded products to patients under a patient-specific prescription or for in-office use by a prescribing practitioner. Pharmacists also compound prescriptions for veterinary needs.

It is not uncommon for a patient who needs a particular medication yet is unable to swallow a solid oral dosage form due to the insertion of a nasogastric tube. In these cases and many others similar to this there is a need for a compounded form of the medication prescribed. Pharmacists can prepare a liquid version of that drug to allow for insertion into the tube. This is considered basic compounding.

We believe that patients must continue to have access to high quality compounded medications that are not commercially available from a manufacturer. Pharmacists working in all practice settings such as hospitals and health systems, community pharmacies, long-term care and assisted-living settings, and even our nation's uniformed services must work to meet defined quality standards and to comply with state boards of pharmacy regulations in pharmacy sterile and nonsterile compounding

practices. Importantly, all practice settings and health professionals providing sterile compounding should follow defined quality standards. Many of these standards can be found published on the Pharmacy Compounding Accreditation Board (PCAB) web site. Pharmacies may also be held to accreditation and certification requirements when compounding sterile products to further assure quality and compliance. The Florida Pharmacy Association at its August 2006 Executive Committee supports the voluntary participation of Florida providers to become accredited with PCAB.

The Florida Pharmacy Association as well as our national pharmacy organizations and our colleague state pharmacy associations throughout the country are committed to working with Congress; state legislatures; state boards of pharmacy regulating the practice of pharmacy; and the Department of Business and Professional Regulation and the United States Food and Drug Administration (FDA), which regulates pharmaceutical manufacturers and distributors, on compounding issues. In addition, we will collaborate with physicians, other prescribers, and other key stakeholders to prevent further tragedy.

Florida has one of the most comprehensive regulatory structures governing the practice of pharmacy in our country. Florida's rules on sterile compounding clearly prohibit the activities leading to the New England tragedy and the Florida Board of Pharmacy holds the legal authority to take appropriate action to suspend or revoke the non-resident pharmacy permit of NECC. The Florida Pharmacy Association believes Florida should hold nonresident pharmacies, such as NECC, to the stringent compliance standards established under current Florida compounding law for all Florida-permitted pharmacies. The Florida Pharmacy Association further urges the Board to consider recommending legislative changes that would require non-resident pharmacy permit holders to have a Florida licensed pharmacist manager acting in nonresident pharmacies as is required by a number of other states, particular if such out-of-state pharmacy is dispensing compounded medications into our State. The pedigree laws that apply to in-state permitted pharmacies must more clearly apply to non-resident pharmacy permit holders. If a non-resident pharmacy permit holder, such as NECC, is engaged in the manufacturing of drugs, the Board of Pharmacy must have the clear authority and the resources to take action against such non-resident pharmacy's permit and the Department of Business and Regulation must be clearly authorized to require a full prescription drug pedigree or any medications dispensed in this state, regardless of where the dispensing pharmacy is located.

Finally, the FPA recommends that the Department of Health invest in resources to train our state's inspection team on the complexities of compounding services. We understand that resources of the Department are strained with the state struggling to balance its budget. Practitioner licensing fees that have in recent years been diverted from Medical Quality Assurance trust funds must be restored and used to address enforcement, compliance and quality issues. The lack of enforcement in the Northeast has shown us that adequate enforcement resources are essential to patient safety.

We are prepared to be a resource for policymakers and stakeholders to work toward identification of a clear delineation between drug manufacturing and traditional pharmacy compounding, to ensure that state pharmacy boards, DBPR and the FDA have the resources necessary for effective enforcement in areas within their jurisdiction,

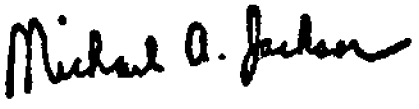
and to find an appropriate, balanced approach to assure public safety and continued access to compounded medications.

The Florida Pharmacy Association is the oldest and largest organization representing the profession of pharmacy in Florida. The members include pharmacists with expertise in community, institutional, long term care, consulting, managed care, nuclear, compounding, infusion therapy, academic and governmental service. The Association has networked with over 30 local invited and affiliated pharmacy organizations with outreach to most Florida licensed pharmacists. The FPA has advocated for and implemented a number of quality improvement and pharmacist patient care initiatives in this state and has served the profession since 1887.

Florida Pharmacy Association is the professional society representing Florida pharmacists, united to improve public health and patient care, enhance professional development and advocate for the interest of the profession. The Association is organized to preserve and advance the practice of pharmacy and to serve the professional needs of all pharmacists, pharmacy students, and pharmacy technicians.

We thank you for this opportunity to allow us to comment on this issue and on behalf of the leadership and members of the FPA, I am available for any questions that you may have.

With kindest regards,



Michael A. Jackson, BPharm
Executive Vice President and CEO

Cc: FPA Board of Directors

United States Senate
HEALTH, EDUCATION, LABOR, AND PENSIONS COMMITTEE

The New England Compounding Center and the Meningitis Outbreak of 2012: A Failure to Address Risk to the Public Health

Committee Staff Report

November 15, 2012

On September 26, 2012, as a result of the rapid work of the Tennessee Department of Public Health and the Centers for Disease Control and Prevention (CDCP), an outbreak of an unusual strain of fungal meningitis was identified. Preservative free methylprednisolone acetate (MPA), administered via spinal injection, was quickly identified as a likely source of the infections. The MPA was traced back to a compounding pharmacy in Framingham Massachusetts, the New England Compounding Pharmacy Inc., doing business as the New England Compounding Center (NECC). The Food and Drug Administration (FDA) subsequently determined that three separate lots of MPA, totaling over 17,000 doses produced by NECC between May 21, 2012 and August 10, 2012, were contaminated with the *exserohilum rostratum* fungus.[i]

To date, NECC's failure to produce a sterile and safe product has led to more than 30 deaths and over 450 serious illnesses requiring treatment with high risk anti-fungal medications. The efforts of the CDCP and the Tennessee Department of Public Health allowed public health officials in 23 states to rapidly track and begin monitoring the approximately 14,000 possible recipients of the contaminated drug. But thousands of people around the country continue to wait and see whether they will develop meningitis, joint infections, spinal abscesses, or arachnoiditis. Those treated will face the risk of kidney and liver damage from the powerful anti-fungal drugs.

While the quick work of the public health community has led to early identification and treatment of many cases of meningitis, and reduced the fatalities resulting from the administration of the contaminated MPA, the Committee's investigation demonstrates that this crisis should have, and could have, been avoided entirely.

Since its creation in 1998, inspections of NECC by state, federal, and independent investigators have identified and documented profound deficiencies in the company's production of sterile drugs. The company has also been cited on multiple occasions for improper use of prescription blanks to solicit orders and failure to comply with state regulations requiring patient-specific prescriptions for compounded drugs.

Moreover, the same drug at issue in the current outbreak, NECC-produced MPA, had previously been a suspected cause of at least two cases with bacterial meningitis-like symptoms. These reports triggered an FDA inspection of the facility ten years prior to the current outbreak, in August 2002.

While the FDA sampling of NECC-produced MPA proved sterile at the time, other MPA samples were found to contain bacteria.[ii] As an FDA employee stated in a power point presentation to the Massachusetts Board of Registration in Pharmacy (Board) at the time, "Sterilization techniques and aseptic practices continue to raise questions, despite no positive (nonsterile) results from latest samples. Absence of evidence is not evidence of absence."[1]

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[i] Testing of the third lot is ongoing.

[ii] An outbreak of fungal meningitis caused by MPA compounded by a South Carolina pharmacy also occurred in mid-2002.

Four years later in 2006, an independent evaluator reported to NECC manager and co-owner Barry Cadden that major areas of concern included "inadequate and incomplete documentation," that "end product testing is often performed on 'stock solutions' and not the end product that is required," "process controls including validation of sterilization cycles and media fills are inadequate," and "in many cases the procedures are not in strict accordance with USP 795/797" as required by Massachusetts state law.[2]

In view of these repeated concerns with regard to the ability of NECC to safely produce compound drugs, it is difficult to understand why definitive action was never taken to either revoke its license or, at a minimum, closely monitor the company's operations. Instead, the company was allowed to grow and expand operations, ultimately holding licenses to ship drugs to at least 45 states. The same owners were subsequently permitted to open the far larger Ameridose, which supplied compounded drugs to hospitals around the country. Also, that company now has been found to lack adequate procedures to ensure that the compounds produced are safe, uniform or sterile.

This report is based on information obtained in the course of the Committee's investigation. It is intended to recount the known history of NECC, its related companies and their interactions with federal and state regulators as of November 15, 2012 to better understand the events leading to the current public health crisis.

The New England Compounding Company

NECC was created in 1998 by the Conigliaro family. Three Conigliaro siblings and their spouses own the company: Douglas and Carla Conigliaro; Barry Cadden and Lisa Conigliaro Cadden; and Gregory Conigliaro. Ownership and management of the company have remained essentially unchanged since 1998. Pharmacists Barry Cadden and Lisa Conigliaro Cadden own 25 percent of the company, Carla Conigliaro owns 65 percent, and Gregory Conigliaro owns 10 percent. Gregory Conigliaro also owns a neighboring recycling business. Barry Cadden was in charge of operations and significant amounts of the actual compounding at NECC during the entire period of operations. The three siblings and spouses also own Ameridose and Alaunus, two companies created in 2006, in similar proportions.

NECC was granted a special pharmacy license by the Board in June 1998. That license allowed the company to produce compounded pharmaceutical products without operating a full-service pharmacy, but still subject to the state requirement that the company to have an individual patient prescription for each dose compounded. Massachusetts also adopted United States Pharmacopeia Standard <797>, which sets forth standards for compounding pharmacies including requirements for clean facilities, specific training for operators, and air quality evaluations.[3]

The first enforcement action against NECC began just 10 months after issuance of the license. In April of 1999, the Board filed a complaint against NECC for including blank prescriptions in solicitations to practitioners, a practice that violated state law. Six months later, in November of 1999, the Board resolved the complaint by issuing a warning to NECC in a private non-disciplinary advisory letter.[4]

In June 2001, the Idaho Board of Pharmacy complained to the Massachusetts Board that NECC was, among other things, including unapproved prescription forms in its solicitations to Idaho practitioners. Documents are unclear regarding whether the Board took formal action on this complaint. In fact, as detailed below, it appears that the Board has a dysfunctional system for logging incoming complaints and evaluating whether a complaint warrants assignment to an inspector.[5] Documents received by the Committee make clear, however, that NECC was investigated or warned for prescription-related concerns on at least 5 other occasions in the following 10 years.

Adverse Events

To the Committee's knowledge, the first time the safety of NECC's products was called into question was in early 2002. In March 2002, a prescribing doctor reported to the FDA that as many as five patients became ill following an epidural injection of NECC-produced betamethasone repositories.[6] He reported the illnesses to the FDA, alerted NECC about the issue, and returned unused doses to NECC without taking samples.[7] However, when the FDA arrived to inspect NECC on April 9, 2002, there were no records for the drugs in question.[8]

The FDA, joined for part of the inspection by the Board, spent three days inspecting NECC's facilities. When searching NECC's database, the FDA found a "date made" entry for the lot-number of drugs cited in the report but noted that "no associated records could be retrieved."[9] The FDA inspection report recounts that Barry Cadden asserted that the lot had never been produced but could provide no documentation that the lot had been cancelled.[10] Additionally, although the FDA contacted the physician making the report and confirmed he had returned the unused portion to NECC, FDA inspectors could find no record of the return.[11]

In the course of the inspection, FDA inspectors were told by Barry Cadden that approximately 4 lots of product produced between March and April 2002 had tested positive for endotoxin and were awaiting disposal.[12] FDA inspectors documented that NECC had sampled betamethasone repositories immediately after sterilization in the autoclave, and then left the product for up to 7 to 10 days before placing it in individual vials.[13] FDA inspectors reported an additional 8 areas of concern including a lack of procedures to ensure the operation of the autoclave, use of expired products, and inaccurate beyond use (i.e. expiration) dating.[14, iii]

In August of 2002, another series of adverse events were reported to the FDA.[15] These reports indicated that at least 2 patients were hospitalized for meningitis-like symptoms, and that the suspected sources of the infections were epidural injections of NECC-produced MPA, the same drug at issue in the current outbreak.[16]

The FDA, joined for part of the inspection by the Board, returned to NECC for a series of six days of inspections between October 2002 and February 2003. At that time Barry Cadden indicated to FDA inspectors that NECC was in the process of drastically expanding its operations. Since the FDA's prior inspection, NECC had doubled its square footage and hired

[iii] Two days after the inspections, on April 18, 2002, the Nevada Board of Pharmacy submitted a complaint to the Board, alleging that NECC was selling non-FDA approved products in the state. It is unclear if the Board took any action as a result of this complaint.

additional staff. Further, NECC's manager stated his intent to expand sales to all 50 states, up from the 13 states in which it was then licensed.[17]

FDA tested unused vials of the MPA collected from the location of the adverse event report, and found that 5 of the 16 vials were contaminated with bacteria. The FDA also tested other vials obtained during inspections of NECC and found problems with super potent MPA and sub-potent betamethasone repositories.[18] Investigators again documented the use of procedures insufficient to ensure safe compounding. Those concerns included a "lack of documentation to verify that the autoclave itself is maintained and calibrated to perform its intended function," as well as a concern regarding a lack of safe procedures to ensure that "the transfer of bulk drug product and equipment from the autoclave... to another room ... is not introducing contamination into the finished product."[19] The FDA's inspectors concluded, "Sample results revealed that the firm has sterility and potency issues with injectable steroid suspensions (betamethasone repository USP and methylprednisolone acetate USP)."[20]

In April 2002, prior to these inspections, the United States Supreme Court in *Thompson v. Western States Medical Center* ruled that section 503A of the Food Drug and Cosmetics Act included an impermissible restriction on commercial speech. The Supreme Court did not address provisions that clarified FDA's authority to regulate certain compound pharmacies, which the lower court held was not severable from the unconstitutional commercial speech restrictions. While NECC would likely have been subject to FDA regulation pursuant to section 503A of the Food Drug and Cosmetics Act, FDA's authority with regard to NECC under 503A was unclear after *Western States*, although FDA's general authority against unapproved new drugs, misbranded, or adulterated product was not in dispute. Despite the ambiguity regarding 503A, in May 2002 the FDA issued guidance which reasserted its authority to inspect compounding pharmacies and provided a non-exhaustive list of factors that the agency would consider in determining whether to take enforcement action when the scope and nature of a pharmacy's activities raise the kind of concerns ordinarily associated with drug manufacturing.

In this case, FDA took the position that the Board was better situated to take action against NECC. An FDA memo documenting a February 5, 2003, meeting between the FDA and the staff of the Board states that "a discussion was held to determine if NECC should be considered a manufacturer or a compounder" and that "current findings supported a compounding role."[21] The memo concludes:

> Mr. Elder [from FDA] concluded the meeting by summarizing the discussions and *emphasizing the potential for serious public health consequences if NECC's compounding practices, in particular those relating to specific sterile products are not improved*. The point was made that so long as a pharmacy's operations fall within the scope of the practice of pharmacy...FDA will generally defer to state authorities for regulatory oversight. In such cases FDA will seek to engage cooperative efforts aimed at achieving regulatory compliance and ensuring the safety and quality of compounded products.[22]

The FDA then officially stated in the NECC Inspection Report issued February 10, 2003, "[R]eferral to Massachusetts State Board of Pharmacy. Recommend firm be prohibited from manufacturing until they can demonstrate ability to make product reproducibly and dependably.

If state is unwilling to take action, recommend firm be enjoined for [Good Manufacturing Practices] deficiencies."[23]

Despite the formal recommendation that the state take action, it is unclear whether the Board took any additional action for the next year.[iv] It also does not appear that FDA conducted any follow-up to verify whether Massachusetts' response was sufficient to protect public health and safety.

Finally, on February 20, 2004, the Board staff conducted a compliance inspection and noted that NECC had taken corrective actions for the safety concerns identified in 2002 and 2003.[24] Nonetheless, the Board's staff recommended a public reprimand of NECC for its prior misconduct.[25]

On September 21, 2004, more than two years after the first reported cases of meningitis and other adverse events, and apparently acting on the staff recommendation, the Board voted to seek a public censure and probation for NECC's misconduct leading to the infections.[26,v] As was the Board's custom, they sent a consent decree to NECC that, if agreed to, would impose the relevant discipline and monitoring requirements for a three-year period.[27] The Board's staff transmitted its proposed consent decree to NECC on October 4, 2004.[28]

NECC did not agree to the proposed consent decree. NECC wrote to the Board asking it to instead consider non-public disciplinary action, to better protect NECC's business interest.[29] Counsel for NECC wrote: "once disclosed, the reprimand will surely result in inquiries/investigations in [other] jurisdictions. Regardless of the derivative actions taken, the attendant legal and administrative costs will be devastating."[30] The Board voted in November of 2004 to decline NECC's request for modifications to the consent decree.[31] Following that action by the Board, Committee interviews with Board staff suggest that the consent decree was referred for formal action to prosecuting attorneys within the Massachusetts Department of Public Health.[32]

For over a year, the record shows no formal order was filed and no hearing was held. Instead, it appears that attorneys for the Department of Public Health negotiated a modified consent agreement approved by the Board with an effective date of January 10, 2006.[33] The revised consent decree required that NECC submit to two inspections over a six-month period by a third-party evaluator, as well as a series of written assurances that recommended improvements had been made, in exchange for a suspended period of non-public probation.[34] The agreement

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[iv] FDA's investigation report also notes that Mr. Cadden, the manager of NECC, was serving on a committee for the state of Massachusetts, created to revise state regulations controlling compounding pharmacies. (FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., February 10, 2003.) The committee's work, however, became moot after the release of USP 797, which then was adopted by Massachusetts. 247 CMR 9.01(3)

[v] Between the Board staff report recommending censure and the Board vote to issue the consent decree, pharmacist Sophia Pasedis was appointed to the eleven-member Board. Ms. Pasedis appears to have been an employee of NECC in some capacity at the time of her appointment, and thus recused herself from the Board consideration of the consent decree. Ms. Pasedis is currently a manager of the Conigliaros' other drug company, Ameridose.

was referred to as "non-disciplinary" and was "not reported to the National Association of State Boards of Pharmacy or other outside report agencies[.]"[35]

Thus, almost four years after the two series of adverse events, including hospitalizations, likely caused by MPA, and three years after the FDA had stressed "the potential for serious public health consequences if NECC's compounding practices, in particular those relating to specific sterile products are not improved,"[36] the Board merely required NECC to hire an outside monitor, and made no mention of suspension or revocation of NECC's license.

PSI Monitoring

Pursuant to the revised consent decree, a third-party auditor, Pharmacy Support, Inc. (PSI) was selected to evaluate NECC's compliance with United States Pharmacopeia Standard 797, which the Board had recently adopted as the governing standard for Massachusetts.[37] PSI inspected NECC in January 2006 and noted multiple concerns, including sterility concerns. Among them, PSI noted a range of fundamental problems, including:

- NECC had "no requirements for donning proper attire or hand washing" when compounding medicines;
- "Mixing instructions are not specific and do not always indicate time and temperature;"
- "No quality control procedures are defined;"
- "Non-sterile 70% IPA is used to sanitize;"
- "Beard covers not worn;"
- "Hairnets and beard covers were not worn properly;"
- "Environmental monitoring procedures are inadequate;"
- "Calibrations are not performed properly;"
- "Floors in the unclassified/hybrid buffer area have not been sanitized in 3 months of use;"
- "[Beyond use dates] assigned incorrectly;"
- "There are no written procedures for receipt, storage, and accountability of controlled substances;"
- "[Standard Operating Procedures] are inadequate or not followed;"
- "Complaint forms were not available for some complaints logged in the complaint log;"
- "Most sections of complaint forms are not complete;"
- "Lot numbers are not assigned appropriately;"
- "4 out of 8 gloves observed had holes while CSP was compounded;" and
- Dry heat "sterilization equipment has not been verified."[38]

NECC took significant corrective measures, including replacing deficient equipment, conducting several training sessions for staff, and adopting a wide range of new standard operating procedures.[39] PSI submitted a final report on April 7, 2006, stating that NECC was largely compliant with pharmaceutical standards.[40,vi] In April and May, the Board received two

[vi] Six days later, at the end of an 8-week jury trial and three-year indictment, both PSI's CEO and Chief Compliance Officer were criminally convicted on 19 counts including fraud, mail fraud, and a violation of the Food and Drug Control Act. *US v. Caputo*, No. 03 CR 0126 (N.D. Ill. Oct 16, 2003). It is unclear how PSI was selected as the Massachusetts Board of Pharmacy has been unable to identify or produce documents discussing the selection of PSI in detail. Documents do show that PSI submitted a proposal to

more cursory letters from NECC assuring compliance with its remaining open issues.[41] On June 2, 2006, the Board informed NECC that it had fulfilled the requirements of its consent decree and that it considered the matter closed.[42]

Additional NECC Complaints

At the time the Board acted to send the initial consent decree to NECC, it also acted to resolve three additional complaints against NECC in September 2004.[43] Despite ongoing investigations relating to serious adverse events, the Board issued three *non-disciplinary* private advisory letters to NECC resolving complaints submitted during the prior two years from practitioners in South Dakota, Texas, and Wisconsin.[44] While the advisory letters fail to spell out the specifics of the complaints, and the original complaints have not been reviewed by the Committee to date, it appears that NECC may have been soliciting bulk orders rather than patient-specific prescriptions, conduct that NECC was initially reprimanded for in 1999. A Board inspection report from around that time specifically notes that NECC "continues to reduce to writing orders on bulk purchase order forms and not on the approved prescription blanks. An issue previously addressed with Mr. Cadden."[45]

Additionally, in April 2004, five months before issuance of the advisory letters, the Board received a new complaint from a practitioner regarding the safety of NECC compounded triple anesthetic cream. The complaint states "My second concern is that [redacted] related to the purchasing technician that he would need a prescription for the product and that we could use the name of a staff member if we wanted to. He said 'other' institutions have used a nurses name....He assured her that it was legal. He indicated that after we received the product it was up to us how we used it and whom it was administered to."[46] It appears that this complaint triggered a Board inspection on November 2004. When questioned about the use of false names, Cadden responded "a review of the same documentation provided to you does show what would appear to be incorrect or repetitive names being provided by several of our prescribing physicians."[47] Yet the Board staff again recommended issuance of yet another non-disciplinary advisory letter dismissing this complaint.

On November 7, 2012, Department of Public Health officials informed the Committee that a July 2012 complaint against NECC, from the Colorado Board, for producing drugs in the absence of a patient-specific prescription had been discovered in the email of the Board's Executive Director. The complaint, which was received while the contaminated lots of MPA were still being produced by NECC, provided clear photographic evidence that NECC was shipping products in the absence of patient-specific prescriptions.[48] Further, Colorado had issued a cease and desist order to NECC in 2011 regarding this practice.[49] Board staff never acted on the July 2012 complaint, and it is unclear that the Board itself was aware of the complaint.[vii]

While Massachusetts state law requires that a compounding pharmacy possess a patient-specific prescription before preparing a compound drug, it appears that NECC has been

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the Massachusetts Board and the prosecutor negotiating the consent agreement provided contact information to NECC's counsel.

[vii] The Board also informed the Committee that it had terminated the Executive Director and placed the Board's Counsel on administrative leave as a result of this discovery.

consistently preparing and shipping batch products either in the absence of a prescription or to false prescription recipients since 1998. No regulatory entity appears to have undertaken a serious investigation of this ongoing practice, and the Board instead routinely dismissed and/or failed to act upon these repeated complaints.

Additional FDA Action

Two days after the Board finally voted to issue the consent decree in September 2004, the FDA and the Board returned to NECC, this time pursuant to a complaint regarding the company's improper production of an injectable dye used in ophthalmic procedures, Trypan Blue.[50] After Barry Cadden initially denied that any Trypan Blue was in stock, FDA inspectors located 189 vials of the product. Trypan Blue is commercially available and should not be compounded.[51]

This inspection led to the issuance of a December 4, 2006 FDA Warning Letter to NECC. The Warning Letter details issues including: the sale of compounded drugs without a patient-specific prescription; compounding copies of commercially-available drugs; selling misbranded compounding drugs; and compounding standardized non-approved drugs, with associated public health risks, on a large scale. It specifically notes that NECC "has reportedly told physicians' offices that using a staff member name on a prescription would suffice."[52]

While the FDA Warning Letter seeks corrective action within 15 days and threatens that failure to correct could result in further regulatory action including seizure or injunction, it does not appear that any further action was contemplated or that any efforts to ensure that corrective action were sought by the agency. Moreover, FDA chose to issue this Warning Letter without having learned from the Board what, if any, disciplinary actions had been taken in response to the inspections from October 2002-February 2003.[53] In January 2007 NECC responded to the Warning Letter, and in October 2008 the FDA re-asserted its authority to take "enforcement action, including seizure of the firm's products and/or an injunction against the firm and its principals" if violations noted in the Warning Letter were not corrected. The FDA also stated that "[i]n a future inspection, we will ... verify that your firm's compounding practices are consistent with the policy articulated in the [Compliance Policy Guidelines.]"[54] This response came two years from the date of FDA's initial Warning Letter and four years from the date of the relevant inspection. FDA took no further action until the recent outbreak.

Further, a May 2011 email exchange shows that FDA staff, including the signatory to the October 2008 letter re-asserting FDA inspection authority, received a copy of a Colorado Cease and Desist Order issued to NECC in 2011 as the result of distribution of non-patient specific compounded drugs to hospitals in the Denver area. FDA staff apparently did not share the Cease and Desist order with the Massachusetts Board, or suggest that the Colorado Board do so until Colorado inspectors again discovered NECC stock compound drugs in another Colorado hospital in July 2012.[55]

Inspection Findings Subsequent to the Outbreak

Unfortunately the long history of concerns was borne out in inspections by FDA and the Board following the 2012 fungal meningitis outbreak. The Massachusetts Board began a series

of inspections of NECC on September 26, 2012. The Board and/or the FDA continued inspecting NECC from that date until October 26, 2012. The findings demonstrate a basic lack of compliance with USP <797> or with safe compounding as evidenced most clearly by the fact that "[v]isible black particulate matter was seen in several recalled sealed vials of Methylprednisolone Acetate."[56] Perhaps most critically, the FDA inspection found that NECC's environmental monitoring system documented 61 instances between January and August 2012 when either bacteria or mold was detected in concentrations exceeding action-level thresholds.[57]

The inspection reports found that while sterility testing conducted on the contaminated lots did not reveal unacceptably high levels of endotoxins, the sample provided was insufficient relative to the batch size. In fact when FDA sampled 50 vials of returned MPA it determined all fifty were contaminated with microbial growth despite the fact that sterility tests on one sample from the same lot in August 2012 has proven clear.[58] The FDA and Board inspections unsurprisingly again document a basic lack of procedure to ensure sterile products were being compounded safely including:

- Inspectors observed "greenish yellow discoloration" lining one of two autoclaves used to sterilize various components and equipment;[59]

- Inspectors observed "yellow residue lining the rear return of Weigh Station 2 Hood and greenish residue lining the rear return of Weigh Station 3 Hood...used to weigh active ingredients and other raw materials;" [60]

- "Residual powder was visually observed within the [powder] hood during inspection;"

- "[Tacky] mats, which are used to trap dirt, dust, and other potential contaminants from shoes prior to clean room entry...were visibly soiled with assorted debris;"[61] and

- "A leaking boiler adjacent to the requisite clean room created an environment susceptible to contaminant growth."[62]

The inspections also documented a continued disregard for the requirements of a patient-specific prescription for each compounded product. The state's preliminary investigation report noted: "NECC distributed large batches of compounded sterile products directly to facilities apparently for general use rather than requiring a prescription for an individual patient."

Ameridose

One month after the terms of NECC's 2006 consent decree were deemed satisfied, the Board approved a license for a new company, Ameridose, owned by the Conigliaro family.[63, viii] Massachusetts Board Member Sophia Pasedis has been a manager of record for the company.[64] According to media reports, Douglas Conigliaro, although not listed as an owner or manager, plays a significant role at Ameridose.[65]

[viii] The ownership distribution is essentially the same with Carla Conigliaro owning 65 percent, Barry and Lisa Cadden owning 25 percent and Gregory Conigliaro owning 10 percent. (11-9-12 HELP Committee staff interview with NECC attorneys.)

Ameridose is also a sterile compounding company, but because it produces batch drugs for hospitals rather than patient-specific prescriptions, it is registered as a manufacturer with the FDA as well as with the Massachusetts Board.[66] The company does not manufacture any FDA approved product but rather is exclusively a large-scale compounder.

Until the outbreak, Ameridose contracted with Novation, the largest group purchasing organization in the country. Thus, Ameridose products were available to Novation's 3,000 hospital members as well as 22,000 other providers and facilities. Despite the history of problems with NECC and the joint ownership of the two companies, neither the licensure of Ameridose nor the large scale of its operations appears to have raised any concerns amongst the Board or the Board staff. Documents suggest that Ameridose was subject to routine pre-announced inspections by the Board in 2008 and 2011.[67]

However, the FDA had serious concerns with Ameridose. The FDA inspected the company in 2008 and found serious problems with the company's operations. Despite the large scale of Ameridose's operations even in 2008, investigators documented that products were shipped immediately without waiting for the results of sterility testing, that testing for potency and dose uniformity is not routinely performed and procedures were insufficient, and that the company was generally not in compliance with the requirements of USP 797 as required by Massachusetts law. As an example, management could not locate test results for 3 of 17 active ingredients inspected. Results of sampling tests taken at the August 2008 inspection returned a finding of superpotent Oxytocin, resulting in a recall of the product and an additional inspection in September 2008.[68] FDA staff placed Ameridose on the work plan for high risk facilities and recommended that a warning letter be issued to the company although no such letter was actually issued.[69]

While Ameridose was also the subject of at least 9 reports to the FDA of adverse events, faulty products, or medication errors, it is unclear that any of these triggered an inspection or investigation.[70] Following NECC's identification as the source of the fungal meningitis, the Board secured a temporary stop of Ameridose operations, though the company continues to hold a valid license. After the FDA began inspections on October 31, 2012, Ameridose issued a voluntary recall of all products.[71]

On November 12, 2012, the FDA issued a preliminary inspection report for Ameridose, finding startlingly similar problems to those they found NECC. Although the FDA has not reported any findings of contaminated drugs from Ameridose, the agency's preliminary findings "raised concerns about a lack of sterility assurance for products produced at and distributed by this facility."[72]

The FDA's inspection found that, like at NECC, there were clear problems with ensuring that drugs were sterile, or that doses were uniform. The FDA found that batches of drug product were not tested to ensure sterility, and that procedures were not established, written, or followed to prevent microbiological contamination of sterile drug products. What procedures were available did not include adequate validation of sterilization. The report also notes that the company failed to write or follow procedures detailing other aspects of their business.[73]

Moreover, the FDA found that testing of Ameridose's product did not include appropriate laboratory determination of conformance to the identity and strength of each active ingredient. And there were no written procedures for production and process controls to assure that the drug products had the identity, strength, quality and purity they purported to possess.[74]

Additionally, the FDA found that the buildings were not in good repair, that equipment and utensils were not cleaned, maintained, and sanitized at appropriate intervals to prevent contamination. The company further lacked suitable procedures to facilitate cleaning and maintenance, lacked equipment for adequate control over air pressure, and were infested with vermin.[75]

Conclusion

Given the history of NECC, the fact that the company produced and shipped a contaminated product that has led to 32 deaths and 461 infections to date is not a surprise. The surprise is that they were allowed to continue to engage in drug compounding for over a decade with this record.

Both federal and state regulators were well aware that NECC and its owners posed a risk to the public health. Both had documented that the company routinely flouted requirements that it compound products only when a patient specific prescription was received, compounded unapproved and commercially available products, potentially destroyed documents and samples relevant to adverse events, and most critically, repeatedly failed to demonstrate that the company could safely compound sterile products. There were a number of authorities and mechanisms for both federal and state regulators to address this issue, but bureaucratic inertia appears to be what allowed a bad actor to repeatedly risk public health.

The Committee will continue its investigation to determine how this tragic failure of oversight occurred, and how it can best be prevented in the future.

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[1] FDA Internal Memorandum, February 24, 2003, re: *February 5, 2003 Meeting with Massachusetts Board of Pharmacy / Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, p. 10 of Attachment 1.

[2] Letter from Pharmacy Support, Inc., to New England Compounding Center, January 30, 2006, and enclosure: *Compounding Sterile and Non Sterile Preparations Observations and Recommendations Final Report.*

[3] 247 CMR 9.01(3).

[4] Committee staff interview with Board inspectors 11/9/12.

[5] Senate HELP Committee staff interviews of Massachusetts Department of Public Health staff, October and November, 2012.

[6] FDA *Investigative Report,* re: FACTS 298826, New England Compounding Pharmacy Inc. EI 4/9, 4/10, 4/16/02; FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., April 16, 2002.

[7] FDA *Investigative Report,* re: FACTS 298826, New England Compounding Pharmacy Inc. EI 4/9, 4/10, 4/16/02.

[8] Id.

[9] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., April 16, 2002, p. 4.

[10] Id. at 4.
[11] Id. at 4.
[12] Id. at 7.
[13] Id. at 7.
[14] Id. at 8.
[15] FDA *Establishment Inspection Report and Continuation Sheet,* re: FACTS 332851, New England Compounding Pharmacy Inc., EI Start: 10/24/02, EI End: 2/10/03; FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., February 10, 2003, p. 5.
[16] FDA *Establishment Inspection Report and Continuation Sheet,* re: FACTS 332851, New England Compounding Pharmacy Inc., EI Start: 10/24/02, EI End: 2/10/03, pp. 4-5.
[17] Id.
[18] Id.
[19] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, R. Ph, Owner and Director of Pharmacy, New England Compounding Pharmacy, Inc., February 10, 2003, p. 1.
[20] Id. at 2.
[21] FDA Internal Memorandum, February 24, 2003, re: *February 5, 2003 Meeting with Massachusetts Board of Pharmacy / Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, p. 2.
[22] Id. at 3-4.
[23] FDA *Establishment Inspection Report,* re: FACTS 332851, New England Compounding Pharmacy Inc., EI Start: 10/24/02, EI End: 2/10/03, p. 1.
[24] Massachusetts Department of Public Health – Division of Health Professions Licensure, *Investigation Report*, Re: New England Compounding Center, DS 03 055, and Barry Cadden, PH 03 066, March 4, 2004, p. 9.
[25] Id. at 9.
[26] Massachusetts Board of Registration in Pharmacy, *Pharmacy Board Meeting Minutes: Tuesday, September 21, 2004,* p. 9.
[27] Letter from the Massachusetts Board of Registration in Pharmacy to New England Compounding Center, re: *Docket Number DS-03-055/PH-03-066/ New England Compounding Center (Permit #2848) and Barry Cadden, R.Ph., License No. 21239,* October 4, 2004; Massachusetts Board of Registration in Pharmacy, *Consent Agreement* re: *Docket No. DS-03-055, PH-03-066.*
[28] Id.
[29] Letter from Paul Cirel, counsel for New England Compounding Center, to Board of Registration in Pharmacy, re: *Docket Number DS-03-055/PH-03-066/ New England Compounding Center (Permit #2848) and Barry Cadden, R.Ph., License No. 21239,* November 11, 2004.
[30] Id. at 4.
[31] Massachusetts Board of Registration in Pharmacy, *Pharmacy Board Meeting Minutes: Tuesday, November 23, 2004*, p2.
[32] Senate HELP Committee staff interviews of Massachusetts Department of Public Health staff, October and November, 2012.
[33] Massachusetts Board of Registration in Pharmacy, *Consent Agreement* re: *Docket No. DS-03-055, PH-03-066, DS-05-040,* January 10, 2006.
[34] Id.
[35] Id. at 1.
[36] FDA Internal Memorandum, February 24, 2003, re: *February 5, 2003 Meeting with Massachusetts Board of Pharmacy / Division of Professional Licensure (239 Causeway Street, Boston, MA 02114)*, p. 2.
[37] Letter from Pharmacy Support, Inc., to New England Compounding Center, January 30, 2006, and enclosure: *Compounding Sterile and Non Sterile Preparations Observations and Recommendations Final Report.*
[38] Id.

[39] Pharmacy Support, Inc., *Final Report USP <795>/<797> Implementation New England Compounding Center Framingham, Ma,* April 7, 2006.
[40] Id.
[41] Letters between Board and NECC, April 12, 2006, April 19, 2006, May 10, 2006, and May 22, 2006.
[42] Letter from MA Board to NECC, June 2, 2006.
[43] Massachusetts Board of Registration in Pharmacy, *Pharmacy Board Meeting Minutes: Tuesday, September 21, 2004.*
[44] Letter from the Massachusetts Board of Registration in Pharmacy to New England Compounding Center, re: *In the matter of DS-03-038 and PH-03-042 – New England Compounding Center (Permit #2848),* September 30, 2004; Massachusetts Board of Registration in Pharmacy, *Advisory Letter* re: *Docket No. DS-03-036, PH-03-042,* September 30, 2004; Letter from the Massachusetts Board of Registration in Pharmacy to New England Compounding Center, re: *In the matter of DS-03-060 and PH-03-070 – New England Compounding Center (Permit #2848),* September 30, 2004; Massachusetts Board of Registration in Pharmacy, *Advisory Letter* re: *Docket No. DS-03-060, PH-03-070,* September 30, 2004; Massachusetts Board of Registration in Pharmacy, *Advisory Letter* re: *Docket No. DS-04-062, PH-04-161,* September 30, 2004.
[45] Massachusetts Department of Public Health – Division of Health Professions Licensure, *Investigation Report*, Re: New England Compounding Center, DS 03 055, and Barry Cadden, PH 03 066, March 4, 2004 at 7.
[46] Email from [redacted] to Massachusetts Board of Registration in Pharmacy, re: *New England Compounding Center Activity in the State of Wisconsin*, April 27, 2004.
[47] Massachusetts Department of Public Health – Division of Health Professions Licensure, *Investigation Report*, Re: New England Compounding Center, DS 05 040, reviewed by Board Members on November 23, 2004.
[48] E-mail from Colorado Department of Regulatory Agencies to Massachusetts Board of Registration in Pharmacy, re: *New England Compounding Center,* July 26, 2012; Colorado State Board of Pharmacy, *Special Report*, re: *New Egland Compounding Pharmacy, Inc. (WHO 7832),* July 20, 2012.
[49] Id.
[50] FDA Internal Memorandum, Re: *Inspection/Investigation of New England Compounding Center,* January 26, 2005.
[51] Id. at 2.
[52] FDA Warning Letter to NECC, Dec 4, 2006.
[53] FDA Internal Memorandum, Re: *Inspection/Investigation of New England Compounding Center,* January 26, 2005 at 4.
[54] Letter from FDA to NECC, Oct 31, 2008.
[55] E-mails between Colorado Board of Pharmacy and FDA, May 10, 2011 and July 16, 2012; Colorado State Board of Pharmacy, Special Report, re: New England Compounding Pharmacy, Inc. (WHO 7832), July 20, 2012.
[56] Massachusetts Board of Registration in Pharmacy Report, *NECC Preliminary Investigation Findings*, October 23, 2012, at 4.
[57] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, Owner, New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center, October 26, 2012.
[58] FDA *Inspectional Observations*, Form FDA483, issued to Barry Cadden, Owner, New England Compounding Pharmacy, Inc., d/b/a/ New England Compounding Center, October 26, 2012.
[59] Massachusetts Board of Registration in Pharmacy Report, *NECC Preliminary Investigation Findings*, October 23, 2012 at 1.
[60] Id. at 7.
[61] Massachusetts Board of Registration in Pharmacy Report, *NECC Preliminary Investigation Findings*, October 23, 2012 at 4.
[62] Id. at 5.

[63] Ameridose, LLC, *Application for a New Store – 50 Fountain Street*, 2006.
[64] Id.
[65] Abby Goodnough *et. al.*, "Spotlight Put on Founders of Drug Firm in Outbreak," *New York Times,* October 24, 2012, http://www.nytimes.com/2012/10/25/health/with-meningitis-outbreak-a-spotlight-on-family-behind-compounding-pharmacy.html?pagewanted=all (accessed November 14, 2012).
[66] *See, e.g.* FDA *Establishment Inspection Report, Ameridose, LLC*, January 16, 2008, p. 1; Ameridose, LLC, *Application for a New Store – 50 Fountain Street*, 2006.
[67] The Commonwealth of Massachusetts, Division of Health Professions Licensure, *Inspection Report*, 11/19/08; The Commonwealth of Massachusetts, Division of Health Professions Licensure, *Inspection Report*, 11/7/11.
[68] FDA *Establishment Inspection Report, Ameridose, LLC*, EI Start: 09/17/2008, EI End: 09/18/2008.
[69] FDA *Establishment Inspection Report, Ameridose, LLC*, August 22, 2008, p. 1.
[70] FDA, *FAERS search results for suspect drugs labeled as Ameridose, New England Compounding Center or Alaunus, Reports initially received by FDA from 1/1/02 to 9/25/12*, provided to Committee on November 8, 2012; *See also,* Letter from Wiley Rein, LLP to Massachusetts Board of Registration in Pharmacy, re: *Complaint Against Ameridose LLC for Unlawful Manufacturing and Distribution of Pre-Mixed Nicardipine Injection Products,* June 30, 2010 (the resulting investigation was administratively closed).
[71] FDA Press release: *FDA reports voluntary recall of all Ameridose drug products,* October 31, 2012, http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm326361.htm, (accessed November 14, 2012).
[72] Id.
[73] FDA *Inspectional Observations*, Form FDA483, issued to Gary Conigliaro, Vice President and General Manager, Ameridose, LLC, November 9, 2012.
[74] Id.
[75] Id.