



**JOINT MEETING
BOARD OF PHARMACY and BOARD OF MEDICINE
FLORIDA DEPARTMENT OF HEALTH
3 p.m., April 6, 2016**

**Hilton Altamonte Springs
350 Northlake Boulevard, Altamonte Springs, Florida 32701
(407) 830-1985**

PLEASE TURN OFF ALL CELL PHONES, PAGERS AND BEEPERS DURING THE MEETING. THANK YOU.

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Donna McNulty, Senior Assistant Attorney General

WEDNESDAY, April 6, 2016 – 3 p.m.

1. Introductions
2. Opening remarks – Lucy Gee, MS, Division Director, Medical Quality Assurance
3. Controlled substances prescribing and dispensing
4. Legislation – Allison M. Dudley
 - a. HB 1241 – Ordering of Medication
 - i. Allows emergency opioid antagonist dispensing at pharmacies based on standing order
 - ii. Clarifies that nurse practitioners and physician assistants can order controlled substances for hospitals and nursing homes
 - b. HB 423 – Drug Prescription by ARNPs and PAs
 - i. Authorizes nurse practitioners and physician assistants to prescribe controlled substances
 - c. SB 964 – Prescription Drug Monitoring Program
 - i. Limits reporting requirements for certain facilities
 - ii. Expands access to the database
 - d. SB 1604 – Drugs, Devices, and Cosmetics
 - i. Amends requirement for assessing controlled substance orders
 - ii. Requires DOH create a pamphlet relating to controlled substance safety
5. Sterile compounding update – Allison M. Dudley
6. Cross-practice issues and opportunities for collaboration
7. Board member comment
8. Public comment

Participants in this public meeting should be aware that these proceedings are being recorded and that an audio file of the meeting will be posted to the boards' websites.

Roach, Emily R

From: Dudley, Allison M
Sent: Friday, March 25, 2016 3:50 PM
To: Roach, Emily R
Subject: FW: SB 7038 by Senator Aaron Bean

From: larry dalton [<mailto:hldgator1@yahoo.com>]
Sent: Monday, February 22, 2016 10:50 AM
To: Gee, Lucy <Lucy.Gee@flhealth.gov>
Cc: Michelle Byers <michellehbyers@gmail.com>
Subject: SB 7038 by Senator Aaron Bean

Lucy,

Thank you for all of your help in getting getting the Controlled Substance rules changed in the Board of Pharmacy.

We have seen a marked decrease in patient and physician complaints regarding this issue since its implementation.

Our society has been instrumental in crafting some of the language in Senator Bean's bill so to eliminate the language regarding the 5000 dose units. We have proposed eliminating this language, as it was clear in the testimony that both the distributors and the pharmacists were confused by this language.

I was wondering if you could take a look at the language and let me know what you think.

On another note, FSIPP would be honored if you would consider speaking to our society at our annual meeting which will be held in Orlando the weekend of May 20-22. I have copied our executive director on this email so she can assist you with the logistics if you can make it.

Please feel free to call me on my cell (954) 658-1429 to discuss.

Thanks in advance,

Harold L. Dalton, DO, FAAPM&R, DABPM
President, Florida Society of Interventional Pain Physicians
Assistant Clinical Professor, Nova Southeastern University College of Osteopathic Medicine
Medical Director, Florida Spine Specialists
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Fort Lauderdale, FL 33308
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64B16-27.831 Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education.

The Board of Pharmacy recognizes that it is important for the patients of the State of Florida to be able to fill valid prescriptions for controlled substances. In filling these prescriptions, the Board does not expect pharmacists to take any specific action beyond exercising sound professional judgment. Pharmacists should not fear disciplinary action from the Board or other regulatory or enforcement agencies for dispensing controlled substances for a legitimate medical purpose in the usual course of professional practice. Every patient's situation is unique and prescriptions for controlled substances shall be reviewed with each patient's unique situation in mind. Pharmacists shall attempt to work with the patient and the prescriber to assist in determining the validity of the prescription.

(1) Definitions: For purposes of this rule the following definitions shall apply:

(a) Valid Prescription. A prescription is valid when it is based on a practitioner-patient relationship and when it has been issued for a legitimate medical purpose.

(b) Invalid Prescription. A prescription is invalid if the pharmacist knows or has reason to know that the prescription was not issued for a legitimate medical purpose.

(c) Validating a Prescription. Validating a prescription means the process implemented by the pharmacist to determine that the prescription was issued for a legitimate medical purpose.

(2) General Standards for Validating a Prescription: Each prescription may require a different validation process and no singular process can fit each situation that may be presented to the pharmacist. There are circumstances that may cause a pharmacist to question the validity of a prescription for a controlled substance; however, a concern with the validity of a prescription does not mean the prescription shall not be filled. Rather, when a pharmacist is presented with a prescription for a controlled substance, the pharmacist shall attempt to determine the validity of the prescription and shall attempt to resolve any concerns about the validity of the prescription by exercising his or her independent professional judgment.

(a) When validating a prescription, neither a person nor a licensee shall interfere with the exercise of the pharmacist's independent professional judgment.

(b) When validating a prescription, the pharmacist shall ensure that all communication with the patient is not overheard by others.

(c) When validating a prescription, if at any time the pharmacist determines that in his or her professional judgment, concerns with the validity of the prescription cannot be resolved, the pharmacist shall refuse to fill or dispense the prescription.

(3) Minimum Standards Before Refusing to Fill a Prescription.

(a) Before a pharmacist can refuse to fill a prescription based solely upon a concern with the validity of the prescription, the pharmacist shall attempt to resolve those concerns and shall attempt to validate the prescription by performing the following:

1. Initiate communication with the patient or the patient's representative to acquire information relevant to the concern with the validity of the prescription;

2. Initiate communication with the prescriber or the prescriber's agent to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(b) In lieu of either subparagraph 1. or 2., but not both, the pharmacist may elect to access the Prescription Drug Monitoring Program's Database to acquire information relevant to the pharmacist's concern with the validity of the prescription.

(c) In the event that a pharmacist is unable to comply with paragraph (a) due to a refusal to cooperate with the pharmacist, the minimum standards for refusing to fill a prescription shall not be required.

(4) Duty to Report: If a pharmacist has reason to believe that a prescriber is involved in the diversion of controlled substances, the pharmacist shall report such prescriber to the Department of Health.

(5) Electronic Prescriptions: All controlled substances listed in Schedule II through V may be electronically prescribed pursuant to the provisions of Section 456.42(2), F.S. (2015), and pursuant to applicable federal law. For more information related to the federal requirements, access <http://www.deaddiversion.usdoj.gov/ecommm/index.html>.

(6) Mandatory Continuing Education: All pharmacists shall complete a Board-approved 2-hour continuing education course on the Validation of Prescriptions for Controlled Substances. The course content shall include the following:

(a) Ensuring access to controlled substances for all patients with a valid prescription;

(b) Use of the Prescription Drug Monitoring Program's Database;

(c) Assessment of prescriptions for appropriate therapeutic value;

(d) Detection of prescriptions not based on a legitimate medical purpose; and,

(e) The laws and rules related to the prescribing and dispensing of controlled substances. All licensed pharmacists shall complete the required course during the biennium ending on September 30, 2017. A 2-hour course shall be taken every biennium thereafter. The course shall count towards the mandatory 30 hours of CE required for licensure renewal. All newly licensed pharmacists must complete the required course before the end of the first biennial renewal period.

(7) Summary Record: 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 893.07(4), F.S. Such summary shall include information from which it is possible to determine the volume and identity of controlled substances being dispensed under the prescription of a specific prescriber, and the volume and identity of controlled substances being dispensed to a specific patient.

Rulemaking Authority 456.013, 465.005, 465.0155, 465.009, 465.022(12) FS. Law Implemented 456.013, 456.42, 456.43, 465.0155, 465.003, 465.009, 465.016(1)(i), (s), 465.017, 465.022(12), 893.04 FS. History—New 8-29-02, Amended 2-24-03, 11-18-07, 12-24-15.

Controlled Substances Standards Committee

December 9, 2015

Controlled Substance Standards Committee -2 pm
Residence Inn Tallahassee Universities at the Capitol

Minutes:

http://ww10.doh.state.fl.us/pub/bop/Board_Meeting_Minutes_2015/CS%20minutes%20120915_FINAL.pdf

October 5, 2015

Controlled Substance Standards Committee
Tampa Marriott Westshore

Transcript:

http://ww10.doh.state.fl.us/pub/bop/Public_Meeting_Materials/Controlled_substance_committee_october_transcript.pdf

September 21, 2015

Controlled Substance Subcommittee
Department of Health @ 10 a.m

Transcript:

http://ww10.doh.state.fl.us/pub/bop/Public_Meeting_Materials/09212015_Subcommittee_transcript.pdf

August 10, 2015

Controlled Substance Standards Committee
Double Tree by Hilton, Deerfield Beach

Transcript:

http://ww10.doh.state.fl.us/pub/bop/Board_Meeting_Minutes_2015/081015%20Controlled_Substance_Transcript.pdf

June 9, 2015

Controlled Substance Rules Committee
B Resort & Spa, Lake Buena Vista

Transcript:

http://ww10.doh.state.fl.us/pub/bop/Board_Meeting_Minutes_2015/FINAL_060915%20PHARMACY%20CONTROLLED%20SUBSTANCES%20FINAL.PDF



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State Change Could Help Patients Get Pain Medications

By DARA KAM OF THE NEWS SERVICE OF FLORIDA • OCT 8, 2015

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Reacting to pleas from desperate patients unable to get pain medications, the Florida Board of Pharmacy on Wednesday approved a rule change aimed at training pharmacists to change their mindset about prescriptions for controlled substances.

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The change switches the rule from a focus on reasons to reject prescriptions for highly addictive narcotics to an emphasis on ensuring that legitimate patients get the medications doctors have ordered.

"Instead of starting out with trying to find a reason to doubt a prescription, you start off with an assumption that everything in the prescription is good, and you work towards achieving patient access," Florida Pharmacy Association Executive Vice President Michael Jackson said after the unanimous vote Wednesday morning.

The board's action came after a series of meetings on the issue earlier this year in which members of the Controlled Substance Standards Committee heard from patients, doctors and even pharmacists frustrated by the "pharmacy crawl," where patients have traveled to up to a dozen drug stores in search of their medications. The problem has escalated statewide in the aftermath of state and federal crackdowns on "pill mills" that earned Florida a reputation as the epicenter of a prescription drug-abuse epidemic.

At least one doctor told the committee about patients with chronic pain who had committed suicide after they were unable to get prescriptions filled. Other patients complained that pharmacists had refused to fill prescriptions because they could not prove that doctors' orders were "medically necessary." Some pharmacists complained that distributors had cut back on their supplies of narcotics out of fear of scrutiny from the U.S. Drug Enforcement Administration, which has imposed heavy fines on pharmacy chains and suppliers in Florida.

"I know this is emotional," Gavin Meshad, chairman of the committee and a member of the pharmacy board who represents consumers. "People are passionate about this. I think we're doing everything in our power to try to address the problem."

The rule begins with an affirmation that "it is important for the patients of the state of Florida to be able to fill valid prescriptions for controlled substances" and spells out for pharmacists the necessary steps to ensure that the prescriptions are legitimate and that patients should have them.

The rule also includes requiring pharmacists to take a two-hour, "Validation of Prescriptions for Controlled Substances" course to educate pharmacists about ensuring access to pain medications for "all patients with a valid prescription." Pharmacists would have until 2017 to take the course.

While the regulatory change won't have any impact on the amount of drugs pharmacies are able to order from suppliers, the education requirement should help alleviate the difficulty patients are now encountering, said Board of Pharmacy Chairwoman Michele Weizer.

"If (the prescription) is a legitimate purpose and we can get in touch with the prescriber if we need to, they should find it much easier than they have in the past," she said.

The change, which still needs to go through what can be a time-consuming regulatory approval process, also won't force chain pharmacies like Walgreens and CVS to revamp corporate policies that result in some patients being blacklisted or turned down even when prescriptions are valid.

But patients can take some steps to improve chances of getting their prescriptions filled, said Jackson, whose association represents independent pharmacies.

Jackson said patients should try to find pharmacies close to their residences or workplaces and establish relationships with pharmacists. Patients should also be "open about sharing their health information" with their pharmacists, Jackson said.

"If you establish a pharmacist-patient relationship, just like a physician-patient relationship, you'll have a health care provider who's more motivated to work to resolve your problems," he said. "But screaming and yelling at pharmacists will only create doubt in the pharmacists' mind that there's something going on here that they're not sure they understand."

TAGS: [PAIN MEDS \(/TERM/PAIN-MEDS\)](#) [PAIN PILLS \(/TERM/PAIN-PILLS\)](#)

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RESOURCES > Publications & Manuals > Manuals > Pharmacist's Manual > SECTION IX-XIV

Pharmacist's Manual - SECTION IX-XIV

SECTION IX – VALID PRESCRIPTION REQUIREMENTS

To dispense controlled substances, a pharmacist must know the requirements for a valid prescription which are described in this section. A prescription is an order for medication which is dispensed to or for an ultimate user. A prescription is not an order for medication which is dispensed for immediate administration to the ultimate user (i.e., an order to dispense a drug to an inpatient for immediate administration in a hospital is not a prescription).

A prescription for a controlled substance must be dated and signed on the date when issued. The prescription must include the patient's full name and address, and the practitioner's full name, address, and DEA registration number.

The prescription must also include:

1. Drug name
2. Strength
3. Dosage form
4. Quantity prescribed
5. Directions for use
6. Number of refills authorized (if any)

A prescription must be written in ink or indelible pencil or typewritten and must be manually signed by the practitioner on the date when issued. An individual (i.e., secretary or nurse) may be designated by the practitioner to prepare prescriptions for the practitioner's signature. The practitioner is responsible for ensuring the prescription conforms to all requirements of the law and regulations, both federal and state.

Who May Issue

A prescription for a controlled substance may only be issued by a physician, dentist, podiatrist, veterinarian, mid-level practitioner, or other registered practitioner who is:

1. Authorized to prescribe controlled substances by the jurisdiction in which the practitioner is licensed to practice, and
2. Registered with DEA or exempted from registration (e.g., Public Health Service, Federal Bureau of Prisons, military practitioners), or
3. An agent or employee of a hospital or other institution acting in the normal course of business or employment under the registration of the hospital or other institution which is registered in lieu of the individual practitioner being registered, provided that additional requirements as set forth in the C.F.R. are met.

Purpose of Issue

To be valid, a prescription for a controlled substance must be issued for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. The practitioner is responsible for the proper prescribing and dispensing of controlled substances.

A prescription may not be issued in order for an individual practitioner to obtain controlled substances for supplying the individual practitioner for the purpose of general dispensing to patients.

Corresponding Responsibility

A pharmacist also needs to know there is a corresponding responsibility for the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is an invalid prescription within the meaning and intent of the CSA ([21 U.S.C. § 829](#)). The person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

A pharmacist is required to exercise sound professional judgment when making a determination about the legitimacy of a controlled substance prescription. Such a determination is made before the prescription is dispensed. The law does not require a pharmacist to dispense a prescription of doubtful, questionable, or suspicious origin. To the contrary, the pharmacist who deliberately ignores a questionable prescription when there is reason to believe it was not issued for a legitimate medical purpose may be prosecuted along with the issuing practitioner, for knowingly and intentionally distributing controlled substances. Such action is a felony offense, which may result in the loss of one's business or professional license (see *United States v. Kershman*, 555 F.2d 198 [United States Court Of Appeals, Eighth Circuit, 1977]).

Electronic Prescriptions

On March 31, 2010 the DEA published in the Federal Register an interim final rule *Electronic Prescriptions for Controlled Substances* which became effective June 1, 2010. The rule revises DEA regulations to provide practitioners with the option of writing prescriptions for controlled substances electronically. The regulations also permit pharmacies to receive, dispense, and archive these electronic prescriptions. These regulations are an addition to, not a replacement of, the existing rules.

Persons who wish to dispense controlled substances using electronic prescriptions must select software that meets the requirements of this rule. As of June 1, 2010, only those electronic pharmacy applications that comply with all of DEA's requirements as set forth in [21 C.F.R. §1311](#) may be used by DEA-registered pharmacies to electronically receive and archive controlled substances prescriptions and dispense controlled substances based on those prescriptions.



Cases Against Doctors
 Chemical Control Program
 CMEA (Combat Meth Epidemic Act)
 Controlled Substance Schedules
 DATA Waived Physicians
 Drug Disposal Information
 Drug and Chemical Information
 E-commerce Initiatives
 Federal Agencies & Related Links
 Federal Register Notices
 National Take-Back Initiative
 NFLIS
 Publications & Manuals
 Questions & Answers
 Significant Guidance Documents
 Synthetic Drugs
 Title 21 Code of Federal Regulations
 Title 21 USC Codified CSA

A registered pharmacy may process electronic prescriptions for controlled substances only if the following conditions are met:

1. The pharmacy uses a pharmacy application that meets all of the applicable requirements of **21 C.F.R. §1311**, and
2. The prescription is otherwise in conformity with the requirements of the CSA and **21 C.F.R. §1311**.

A pharmacy cannot process electronic prescriptions for controlled substances until its pharmacy application provider obtains a third party audit or certification review that determines that the application complies with DEA's requirements and the application provider provides the audit/certification report to the pharmacy. The audit report the pharmacy will receive from the pharmacy application provider will indicate if the application is capable of importing, displaying, and storing DEA-required prescription information accurately and consistently. If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display the information related to the name, address, and registration number of the practitioner, patient name and address, and prescription information (drug name, strength, quantity, directions for use), the indication of signing, and the number of refills, the pharmacy must not accept electronic prescriptions for the controlled substance.

If the third-party auditor or certification organization finds that a pharmacy application does not accurately and consistently import, store, and display **other information** required for prescriptions, the pharmacy must not accept electronic prescriptions for controlled substances that are subject to the additional information requirements. For example, until the audit or certification report indicates that the pharmacy application can import, display, and store both a hospital DEA number and the individual practitioner's extension number, the pharmacy must not accept electronic prescriptions that include only a hospital DEA registration number. The pharmacy may, however, use the application to process other controlled substance prescriptions if the audit or certification report has found that the pharmacy application meets all other requirements.

The pharmacy must determine which employees are authorized to enter information regarding the dispensing of controlled substance prescriptions and annotate or alter records of these prescriptions (to the extent such alterations are permitted under DEA regulations). The pharmacy must ensure that logical access controls in the pharmacy application are set so that only such employees are granted access to perform these functions.

When a pharmacist fills a prescription in a manner that would require, under **21 C.F.R. §1306**, the pharmacist to make notation on the prescription if the prescription were a paper prescription, the pharmacist must make the same notation electronically when filling an electronic prescription and retain the annotation electronically in the prescription record or linked files. **When a prescription is received electronically, the prescription and all required annotations must be stored electronically.**

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to the pharmacy, the pharmacist must check the pharmacy's records to ensure that the electronic version was not received and the prescription dispensed. If both prescriptions were received, the pharmacist must mark one as void.

When a pharmacist receives a paper or oral prescription that indicates that it was originally transmitted electronically to another pharmacy, the pharmacist must check with that pharmacy to determine whether the prescription was received and dispensed. If the pharmacy that received the original electronic prescription had not dispensed the prescription, that pharmacy must mark the electronic version as void or cancelled. If the pharmacy that received the original electronic prescription dispensed the prescription, the pharmacy with the paper version must not dispense the paper prescription and must mark the prescription as void.

Verification of Practitioner Registration

A pharmacist has a responsibility to ensure that a prescription has been issued by an appropriately registered or exempt practitioner (see above, *Who May Issue*). As such, it is helpful to be familiar with how a DEA registration number is constructed and to whom such registrations are issued.

Construction of Valid DEA Registration Number for Practitioners

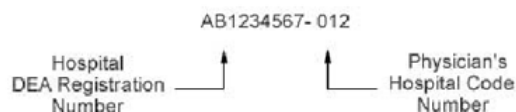
Knowing how a DEA registration number is constructed can be a useful tool for recognizing a forged prescription (see [Appendix D, Pharmacist's Guide to Prescription Fraud](#)). Prior to October 1, 1985, DEA registration numbers for physicians, dentists, veterinarians, and other practitioners started with the letter A. New registration numbers issued to practitioners after that date begin with the letter B or F. Registration numbers issued to mid-level practitioners begin with the letter M. The first letter of the registration number is almost always followed by the first letter of the registrant's last name (e.g., J for Jones or S for Smith) and then a computer generated sequence of seven numbers (such as MJ3614511).

Practitioner's Use of a Hospital's DEA Registration Number

Practitioners (e.g., intern, resident, staff physician, mid-level practitioner) who are agents or employees of a hospital or other institution, may, when acting in the usual course of business or employment, administer, dispense, or prescribe controlled substances under the registration of the hospital or other institution in which he or she is employed, in lieu of individual registration, provided that:

1. The dispensing, administering, or prescribing is in the usual course of professional practice.
2. The practitioner is authorized to do so by the state in which they practice.
3. The hospital or institution has verified that the practitioner is permitted to administer, dispense, or prescribe controlled substances within the state.
4. The practitioner acts only within the scope of employment in the hospital or institution.
5. The hospital or institution authorizes the practitioner to administer, dispense, or prescribe under its registration and assigns a specific internal code number for each practitioner.

An example of a specific internal code number is depicted below:



A current list of internal codes and the corresponding individual practitioners is to be maintained by the hospital or other institution. This list is to be available at all times to other registrants and law enforcement agencies upon request for the purpose of verifying the authority of the prescribing individual practitioner. Pharmacists should contact the hospital or other institution for verification if they have any doubts in filling such a prescription.

Exemption of Federal Government Practitioners from Registration

The requirement of registration is waived for any official of the U.S. Army, Navy, Marine Corps, Air Force, Coast Guard, Public Health Service, or Bureau of Prisons, who is authorized to administer, dispense, or prescribe, but not to procure or purchase controlled substances in the course of his or her official duties. Such officials must follow procedures set forth in **21 C.F.R. part 1306** regarding prescriptions, but must also state the branch of service or agency (e.g., "U.S. Army" or "Public Health Service") and the service identification number of the issuing official in lieu of the registration number required on prescription forms. The service identification number for a Public Health Service employee is his or her Social Security identification number.

If federal government practitioners wish to maintain a DEA registration for a private practice, which would include prescribing for private patients, these practitioners must be fully licensed to handle controlled substances by the state in which they are located.

Registration Requirements for Mid-Level Practitioners

Mid-level practitioners (MLPs) are registered and authorized by the DEA and the state in which they practice to dispense, administer, and prescribe controlled substances in the course of professional practice (see [Appendix B, Definitions](#)). Examples of MLPs include, but are not limited to, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, physician assistants, optometrists, ambulance services, animal shelters, euthanasia technicians, nursing homes, and homeopathic physicians.

MLPs may apply for an individual DEA registration granting controlled substance privileges. However, such registration is contingent upon the authority granted by the state in which they are licensed. The DEA may register MLPs whose states clearly authorize them to prescribe, dispense, and administer controlled substances in one or more schedules.

It is incumbent upon the pharmacist who fills the prescription to ensure that the MLP is prescribing within the parameters established by the state in which he/she practices. MLP authority to prescribe controlled substances varies greatly by state. Pharmacists should check with the state licensing or controlled substances authority to determine which MLP disciplines are authorized to prescribe controlled substances in the state. Pharmacists may also visit the DEA Diversion website at www.DEADiversion.usdoj.gov for a chart indicating the prescribing authority of MLPs by state (click on *Registration Support* and scroll down to **Mid-Level Practitioners Authorization by State**).

For electronic prescriptions written by mid-level practitioners, if required by State law, a supervisor's name and DEA number may be listed on the prescription, provided the prescription clearly indicates who is the supervisor and who is the prescribing practitioner.

Schedule II Controlled Substances

Schedule II controlled substances require a written prescription which must be manually signed by the practitioner or an electronic prescription that meets all DEA requirements for electronic prescriptions for controlled substances. There is no federal time limit within which a schedule II prescription must be filled after being signed by the practitioner. However, the pharmacist must determine that the prescription is still needed by the patient. While some states and many insurance carriers limit the quantity of controlled substances dispensed to a 30-day supply, there are no express federal limits with respect to the quantities of drugs dispensed via a prescription. However, the amount dispensed must be consistent with the requirement that a prescription for a controlled substance be issued only for a legitimate medical purpose by a practitioner acting in the usual course of professional practice. For a schedule II controlled substance, an oral order is only permitted in an emergency situation ([see Section X, Emergency Dispensing](#)).

Refills

The refilling of a prescription for a controlled substance listed in schedule II is prohibited (**21 U.S.C. § 829(a)**).

Issuance of Multiple Prescriptions for Schedule II Controlled Substances

The DEA has revised its regulations regarding the issuance of multiple prescriptions for schedule II controlled substances. Under the new regulation, which became effective December 19, 2007, an individual practitioner may issue multiple prescriptions authorizing the patient to receive a total of up to a 90-day supply of a schedule II controlled substance provided the following conditions are met:

1. Each prescription must be issued on a separate prescription blank.
2. Each separate prescription must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of professional practice.
3. The individual practitioner must provide written instructions on each prescription (other than the first prescription, if the prescribing practitioner intends for that prescription to be filled immediately) indicating the earliest date on which a pharmacy may fill each prescription.
4. The individual practitioner concludes that providing the patient with multiple prescriptions in this manner does not create an undue risk of diversion or abuse.
5. The issuance of multiple prescriptions is permissible under applicable state laws.
6. The individual practitioner complies fully with all other applicable requirements under the CSA and C.F.R., as well as any additional requirements under state law.

It should be noted that the implementation of this change in the regulation should not be construed as encouraging individual practitioners to issue multiple prescriptions or to see their patients only once every 90 days when prescribing schedule II controlled substances. Rather, individual practitioners must determine on their own, based on sound medical judgment, and in accordance with established medical standards, whether it is appropriate to issue multiple prescriptions and how often to see their patients when doing so.

Facsimile Prescriptions for Schedule II Controlled Substances

In order to expedite the filling of a prescription, a prescriber may transmit a schedule II prescription to the pharmacy by facsimile. The original schedule II prescription must be presented to the pharmacist and verified against the facsimile at the time the controlled substance is actually dispensed. The pharmacist must make sure the original document is properly annotated and filed with the records that are required to be kept.

Exceptions for Schedule II Facsimile Prescriptions

DEA has granted three exceptions to the facsimile prescription requirements for schedule II controlled substances. The facsimile of a schedule II prescription may serve as the original prescription as follows:

1. A practitioner prescribing a schedule II narcotic controlled substance to be compounded for the direct administration to a patient by parenteral, intravenous, intramuscular, subcutaneous or intraspinal infusion may transmit the prescription by facsimile. The pharmacy will consider the facsimile prescription a "written prescription" and no further documentation is required. All normal requirements of a legal prescription must be followed.
2. Practitioners prescribing schedule II controlled substances for residents of Long Term Care Facilities may transmit a prescription by facsimile to the dispensing pharmacy. The facsimile prescription serves as the original written prescription for the pharmacy. No further documentation is required.
3. A practitioner prescribing a schedule II narcotic controlled substance for a patient enrolled in a hospice care program certified and/or paid for by Medicare under Title XVIII or a hospice program which is licensed by the state, may transmit a prescription to the dispensing pharmacy by facsimile. The practitioner will note on the prescription that it is for a hospice patient. The facsimile serves as the original written prescription. No further documentation is required.

Schedules III-V Controlled Substances

A pharmacist may dispense directly a controlled substance listed in Schedule III, IV, or V only pursuant to either a paper prescription signed by a practitioner, a facsimile of a signed paper prescription transmitted by the practitioner or the practitioner's agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or a call-in as indicated below ([see Telephone Authorization for Schedules III-V Controlled Substances](#)).

Refills

Schedules III and IV controlled substances may be refilled if authorized on the prescription. However, the prescription may only be refilled up to five times within six months after the date of issue. After five refills or after six months, whichever occurs first, a new prescription is required.

When a prescription for any controlled substance in schedules III or IV is refilled, the following information must be entered on the back of the prescription: the dispensing pharmacist's initials, the date the prescription was refilled, and the amount of drug dispensed on the refill. If the pharmacist only initials and dates the back of the prescription, the pharmacist will be deemed to have dispensed a refill for the full face amount of the prescription.

Electronic Recordkeeping of Schedules III-IV Prescription Information

A pharmacy is permitted to use an electronic recordkeeping system for documenting refills as an alternative to the manual method for the storage and retrieval of original paper prescription orders for schedules III and IV controlled substances.

The electronic system must provide online retrieval of original prescription information for those prescriptions which are currently authorized for refill. The information must include, but is not limited to: the original prescription number; date of issuance; full name and address of the patient; the prescriber's name, address, and DEA registration number; the name, strength, dosage form and quantity of the controlled substance prescribed (and quantity dispensed if different from the quantity prescribed); and the total number of refills authorized by the prescriber.

In addition, the electronic system must provide online retrieval of the current refill history for schedules III or IV controlled substance prescriptions. This information must include, but is not limited to: the name of the controlled substance, the date of refill, the quantity dispensed, the dispensing pharmacist's identification code or name/initials for each refill, and the total number of refills dispensed to date for that prescription.

The pharmacist must verify and document that the refill data entered into the system is correct. All computer generated prescription/refill documentation must be stored in a separate file at the pharmacy and must be maintained for a period of two years from the dispensing date. To meet the C.F.R. recordkeeping requirements, the pharmacy's electronic system must comply with the following guidelines:

1. If the system provides a hard copy printout of each day's controlled substance prescription refills, each pharmacist who refilled those prescriptions must verify his/her accuracy by signing and dating the printout as he/she would sign a check or legal document.
2. The printout must be provided to each pharmacy that uses the computer system within 72 hours of the date on which the refill was dispensed. The printout must be verified and signed by each pharmacist who dispensed the refills.
3. In lieu of such a printout, the pharmacy must maintain a bound logbook or a separate file in which each pharmacist involved in the day's dispensing signs a statement, verifying that the refill information entered into the computer that day has been reviewed by him/her and is correct as shown.
4. A pharmacy's electronic system must have the capability of printing out any refill data which the pharmacy must maintain under the CSA. For example, this would include a refill-by-refill audit trail for any specified strength and dosage form of any controlled substance, by either brand or generic name or both, dispensed by the pharmacy. Such a printout must include:
 - Prescribing practitioner's name
 - Patient's name and address
 - Quantity and date dispensed on each refill
 - Name or identification code of the dispensing pharmacist
 - Original prescription number

In any electronic system employed by a user pharmacy, the central recordkeeping location must be capable of providing a printout to a requesting pharmacy of the above information within 48 hours.

1. In case a pharmacy's electronic system experiences downtime, the pharmacy must have a back-up procedure to document in writing refills of schedules III or IV controlled substances. This procedure must ensure that refills are authorized by the original prescription, that the maximum number of refills has not been exceeded, and that all required data is retained for online entry as soon as possible.

A pharmacy may use only one of the two systems described (i.e., manual or electronic) for storage and retrieval of prescription order refill information of schedules III or IV controlled substances.

Facsimile Prescriptions for Schedules III-V Controlled Substances

Prescriptions for schedules III-V controlled substances may be transmitted by facsimile from the practitioner or the practitioner's agent to the dispensing pharmacy. The facsimile is considered to be equivalent to an original prescription as long as the practitioner has manually signed the prescription.

Telephone Authorization for Schedules III-V Prescriptions

A pharmacist may dispense a controlled substance listed in schedules III, IV, or V pursuant to an oral prescription made by an individual practitioner and promptly reduced to writing by the pharmacist containing all information required for a valid prescription except for the signature of the practitioner ([see Appendix D, Pharmacist's Guide to Prescription Fraud](#)).

Transfer of Schedules III-V Prescription Information

A DEA registered pharmacy may transfer original prescription information for schedules III, IV, and V controlled substances to another DEA registered pharmacy for the purpose of refill dispensing between pharmacies, on a one time basis only. However, pharmacies electronically sharing a real-time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

Transfers are subject to the following requirements:

1. Write the word "VOID" on the face of the invalidated prescription; for electronic prescriptions, information that the prescription has been transferred must be added to the prescription record.
2. Record on the reverse of the invalidated prescription the name, address, and DEA registration number of the pharmacy to which it was transferred and the name of the pharmacist receiving the prescription information; for electronic prescriptions, such information must be added to the prescription record.
3. Record the date of the transfer and the name of the pharmacist transferring the information.

For paper prescriptions and prescriptions received orally and reduced to writing by the pharmacist, the pharmacist receiving the transferred prescription information must write the word "transfer" on the face of the transferred prescription and reduce to writing all information required to be on a prescription and include:

1. Date of issuance of original prescription.
2. Original number of refills authorized on original prescription.
3. Date of original dispensing
4. Number of valid refills remaining and date(s) and locations of previous refill(s).
5. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription information was transferred.
6. Name of pharmacist who transferred the prescription.
7. Pharmacy's name, address, DEA registration number, and prescription number from which the prescription was originally filled.

For electronic prescriptions being transferred electronically, the transferring pharmacist must provide the receiving pharmacist with the following information in addition to the original electronic prescription data:

1. The date of the original dispensing
2. The number of refills remaining and the date(s) and locations of previous refills
3. The transferring pharmacy's name, address, DEA registration number, and prescription number for each dispensing.
4. The name of the pharmacist transferring the prescription.
5. The name, address, DEA registration number, and prescription number from the pharmacy that originally filled the prescription, if different.

The pharmacist receiving a transferred electronic prescription must create an electronic record for the prescription that includes the receiving pharmacist's name and all of the information transferred with the prescription (listed above).

The original and transferred prescription(s) must be maintained for a period of two years from the date of last refill.

Pharmacies electronically accessing the same prescription record must satisfy all information requirements of a manual mode for prescription transferal.

The procedure allowing the transfer of prescription information for refill purposes is permissible only if allowable under existing State or other applicable law.

Pharmacies electronically sharing a real time, online database may transfer up to the maximum refills permitted by law and the prescriber's authorization.

Prescription Monitoring Programs

A prescription monitoring program is a state-administered data collection system used to gather prescription information. This information may be made available to state and federal investigators on a need-to-know basis.

Many states have established an electronic prescription drug monitoring program because it has proven to be an effective tool for detecting pharmaceutical diversion and for developing pharmacist and physician medical education programs. These programs heighten awareness about diversion, prescription drug abuse, drug trends, and are useful for tracking prescription medication dispensed within a state. In some states, the data can be used by pharmacists to identify potential "doctor shoppers" and those who attempt to obtain controlled substances by fraud, forgery, or deceit.

In the states that have adopted these programs, a large part of their success has been attributed to the pharmacists' participation. The DEA strongly endorses prescription monitoring programs.

SECTION X – DISPENSING REQUIREMENTS

Required Information for Prescription Labels

The pharmacist dispensing a prescription for a controlled substance listed in schedules II, III, IV, or V must affix to the package a label showing date of filling, the pharmacy name and address, the serial (prescription) number, 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. If a prescription is filled at a central fill pharmacy, the central fill pharmacy must affix to the package a label showing the retail pharmacy name and address and a unique identifier (i.e., the central fill pharmacy's DEA registration number) indicating that the prescription was filled at the central fill pharmacy.

Federal Food and Drug Administration regulations require that the label of any drug listed as a "controlled substance" in schedules II, III, or IV of the CSA must, when dispensed to or for a patient, contain the following warning: *CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.* In addition, a pharmacist who receives a prescription for a controlled substance must dispense that prescription to the patient or a member of the patient's household. To provide the controlled substance to anyone other than the patient or a member of the patient's household is distribution, not dispensing.

Schedule II Controlled Substance Prescriptions

A pharmacist may dispense a schedule II controlled substance, which is a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, only pursuant to a written prescription signed by the practitioner, except in an emergency situation as described below.

Emergency Dispensing

An "emergency prescription" in this context, is defined to mean that the immediate administration of the drug is necessary for proper treatment of the intended ultimate user, that no alternative treatment is available (including a drug which is not a schedule II controlled substance), and it is not possible for the prescribing practitioner to provide a written prescription for the drug at that time. In a bona fide emergency, a practitioner may telephone a schedule II prescription to the pharmacist who may then dispense the prescription. The prescribing practitioner must provide a written and signed prescription to the pharmacy within seven days and meet the below requirements:

1. The drug prescribed and dispensed must be limited to the amount needed to treat the patient during the emergency period. Prescribing or dispensing beyond the emergency period must be pursuant to a written prescription order.
2. The prescription order must be immediately reduced to writing by the pharmacist and must contain all information, except for the prescribing practitioner's signature.
3. If the prescribing individual practitioner is not known to the pharmacist, he/she must make a reasonable effort to determine that the oral authorization came from a registered individual practitioner, which may include a call back to the prescribing individual practitioner using his or her telephone number as listed in the telephone directory and/or other good faith efforts to insure his or her identity.
4. Within seven days after authorizing an emergency telephone prescription, the prescribing practitioner must furnish the pharmacist a written, signed prescription for the controlled substance prescribed. The prescription must have written on its face "Authorization for Emergency Dispensing" and the date of the oral order. The written prescription may be delivered to the pharmacist in person or by mail, but if delivered by mail, it must be postmarked within the seven day period. Upon receipt, the dispensing pharmacist must attach this written prescription to the oral emergency prescription which had earlier been reduced to writing by the pharmacist. By regulation, the pharmacist must notify the local DEA Diversion Field Office (Appendix K) if the prescriber fails to provide a written prescription within seven days. Failure of the pharmacist to do so will void the authority conferred on the pharmacy to dispense the controlled substance without a written prescription of a prescribing practitioner.
5. For electronic prescriptions, the pharmacist must annotate the record of the electronic prescription with the original authorization and date of the oral order.

Partial Dispensing

A prescription for a schedule II controlled substance may be partially dispensed if the pharmacist is unable to supply the full quantity of a written or emergency oral (telephone) prescription, provided the pharmacist notes the quantity supplied on the front of the written prescription, on a written record of the emergency oral prescription, or in the electronic prescription record. The remaining portion may be dispensed within 72 hours of the first partial dispensing. However, if the remaining portion is not or cannot be filled within the 72 hour period, the pharmacist must notify the prescribing practitioner. No further quantity may be supplied beyond 72 hours without a new prescription.

Partial Filling of Schedule II Prescriptions for Terminally Ill or Long Term Care Facility Patients

A prescription for a schedule II controlled substance written for a patient in a Long Term Care Facility (LTCF) or for a patient with a medical diagnosis documenting a terminal illness, may be filled in partial quantities to include individual dosage units. If there is any question whether a patient may be classified as having a terminal illness, the pharmacist must contact the practitioner prior to partially filling the prescription. Both the pharmacist and the prescribing practitioner have a corresponding responsibility to assure that the controlled substance is for a terminally ill patient.

The pharmacist must record on the prescription whether the patient is "terminally ill" or an "LTCF patient." A prescription that is partially filled and does not contain the notation "terminally ill" or "LTCF patient" must be deemed to have been filled in violation of the CSA. For each partial filling, the dispensing pharmacist must record on the back of the prescription (or on another appropriate record, uniformly maintained, and readily retrievable) the date of the partial filling, quantity dispensed, remaining quantity authorized to be dispensed, and the identification of the dispensing pharmacist. The total quantity of schedule II controlled substances dispensed in all partial fillings must not exceed the total quantity prescribed. Schedule II prescriptions for patients in an LTCF or terminally ill patients are valid for a period not to exceed 60 days from the issue date unless sooner terminated by the discontinuance of medication.

Schedules III-V Controlled Substance Prescriptions

A pharmacist may dispense a controlled substance in schedules III, IV, or V having received either a paper prescription signed by a practitioner, a facsimile of that prescription transmitted by the practitioner or their agent to the pharmacy, an electronic prescription that meets DEA's requirements for such prescriptions, or an oral prescription made by an individual practitioner. The pharmacist must promptly reduce the oral prescription to writing, including all required information except the signature of the prescribing practitioner.

Partial Dispensing

A pharmacist may partially dispense a prescription for schedules III-V controlled substances provided that each partial filling is recorded in the same manner as a refilling, the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed, and no dispensing occurs beyond six months from the date on which the prescription was issued.

Dispensing Without a Prescription

Dispensing a controlled substance without a prescription is outlined in [21 C.F.R. § 1306.26](#).

The regulation states that a controlled substance listed in schedules II, III, IV, or V which is not a prescription drug as determined under the Federal Food, Drug, and Cosmetic Act, may be dispensed by a pharmacist without a prescription to a purchaser at retail, provided that:



**KARAN OLECKNA, ETC., Appellant, v. DAYTONA DISCOUNT PHARMACY,
ETC., ET AL., Appellees.**

Case No. 5D13-3057

COURT OF APPEAL OF FLORIDA, FIFTH DISTRICT

162 So. 3d 178; 2015 Fla. App. LEXIS 1561; 40 Fla. L. Weekly D 370

February 6, 2015, Opinion Filed

PRIOR HISTORY: [**1] Appeal from the Circuit Court for Volusia County, William A. Parsons, Judge.

COUNSEL: Philip M. Burlington, of Burlington & Rockenbach, P.A., West Palm Beach, and Gregg M. Hollander of The Hollander Law Firm, P.A., Boca Raton, for Appellant.

Andrea Lozano Diederich and Bradley P. Blystone, of Marshall, Dennehey, Warner, Coleman & Goggin, Orlando, for Appellees.

JUDGES: ORFINGER, J. BERGER and LAMBERT, JJ., concur.

OPINION BY: ORFINGER

OPINION

[*179] ORFINGER, J.

This appeal arises from a final judgment dismissing with prejudice the negligence claims in Karan Oleckna's amended complaint against Daytona Discount Pharmacy, Inc. and Manish Patel, the pharmacy's owner and licensed pharmacist (collectively, "Pharmacy"). The trial court found that Pharmacy owed no actionable duty to Steven Porter under the facts alleged. We reverse.

1 Ms. Oleckna is the personal representative of the Estate of Steven Porter.

In May 2009, Steven Porter, now deceased, began treatment with Dr. Owen R. Hunt, who diagnosed him with "stress syndrome" and prescribed Xanax (Alprazolam) and Hydrocodone/Acetaminophen or Oxycodone/Acetaminophen.² It was alleged that over the next

two years, Dr. Hunt repeatedly prescribed these drugs [*180] before Mr. Porter should have depleted [**2] the preceding prescriptions. Oleckna alleged that Pharmacy filled at least thirty of these prescriptions, all written by Dr. Hunt, without question, even though the prescriptions were issued too closely in time and days before Mr. Porter should have exhausted the preceding prescription. In March 2011, Mr. Porter died due to combined drug intoxication of Alprazolam and Hydrocodone.

2 Hydrocodone is a Schedule II and III narcotic, and a controlled substance. Oxycodone is a Schedule II narcotic and controlled substance. Alprazolam is a Schedule IV controlled substance. *See § 893.03, Fla. Stat.* (2010). "A substance listed 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.'" *Hayes v. State*, 750 So. 2d 1, 4 (Fla. 1999) (quoting § 893.03(2), Fla. Stat.).

Oleckna brought negligence claims against Pharmacy,³ alleging that it owed Mr. Porter a duty to (1) use due and proper care in filling and dispensing all prescriptions; (2) exercise the level of care and skill recognized by reasonably prudent and similar pharmacy professionals; (3) not dispense or fill prescriptions that were unreasonable on their face [**3] or in light of the circumstances; (4) warn, under the circumstances; (5) comply with their own relevant policies and procedures; (6) comply with relevant statutory and regulatory provisions; and (7) not subject Mr. Porter to an unreasonable risk of harm from their foreseeable conduct. Oleckna did not

allege that Pharmacy was not properly licensed, or failed to properly compound or dispense the drugs prescribed.

3 Oleckna also brought a negligence action against Dr. Hunt, who settled his case.

Pharmacy filed a motion to dismiss, arguing that based on *McLeod v. W. S. Merrell Co., Division of Richardson-Merrell, Inc.*, 174 So. 2d 736, 737 (Fla. 1965), and our decision in *Estate of Sharp v. Omnicare, Inc.*, 879 So. 2d 34, 35 (Fla. 5th DCA 2004), there was no duty to Mr. Porter other than properly filling his valid and lawful prescriptions. The trial court granted the motion to dismiss with prejudice, reasoning:

As indicated in the Order Granting the Motion to Dismiss filed by the Defendant, Daytona Discount Pharmacy, Inc., directed to the Plaintiff's original complaint, there *appears* to be a conflict amongst the district courts as to what constitutes a viable cause of action against a prescribing pharmacist. The Plaintiff relies on *Powers v. Thobani*, 903 So. 2d 275 (Fla. 4th DCA 2005). The Defendant relies upon the *Estate of Edna Marie Sharp v. Omnicare, Inc.*, 879 So. 2d 34 (Fla. 5th DCA 2004). The 5th District case follows the Supreme Court listed standard for a cause of action set forth [**4] in *McLeod v. W.S. Merrell, Co.*, 174 So. 2d 736 (Fla. 1965). Apparently the conflict has not been recognized by the Florida Supreme Court.

In this particular case a careful reading of Count II and III, directed to the druggist and his pharmacy, have failed to allege a factual basis that would support a violation of the duty of care which has been severely limited in the *McLeod* case. As a result this court has concluded that the Plaintiff has failed to allege a recognizable cause of action against the druggist or the pharmacy in the Amended Complaint and further that there are no additional allegations that could be offered as subsequent amendments to change the outcome of this decision.

We conclude that our decision in *Estate of Sharp* is not controlling. As a result, the trial court erred in dismissing the negligence claims against Pharmacy.

The issue presented is whether Pharmacy owed a legal duty to Mr. Porter, which would support a negligence claim. This is a question of law for this Court to

determine. *Estate of Johnson ex rel. Johnson v. Badger Acquisition of Tampa LLC*, 983 So. 2d 1175, 1180 (Fla. 2d DCA 2008); *Sanderson v. Eckerd Corp.*, 780 So. 2d 930, 933 (Fla. 5th DCA 2001). "The [*181] duty element of negligence is a threshold legal question; if no legal duty exists, then no action for negligence may lie." *Jenkins v. W.L. Roberts, Inc.*, 851 So. 2d 781, 783 (Fla. 1st DCA 2003).

A pharmacy owes a customer a duty of reasonable care. Pharmacists are required to exercise that degree of [**5] care that an ordinarily prudent pharmacist would under the same or similar circumstances. Marjorie A. Shields, Annotation, *Exemplary or Punitive Damages for Pharmacist's Wrongful Conduct in Preparing or Dispensing Medical Prescription--Cases Not Under Consumer Product Safety Act*, 109 A.L.R.5th 397, § 2 (2003); see *Pittman v. Upjohn Co.*, 890 S.W.2d 425, 434 (Tenn. 1994) (stating pharmacists have duty to exercise standard of care required of pharmacy profession in same or similar communities); *Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43, 79 P.3d 922, 933 (Utah 2003) (reiterating that pharmacist has generally recognized duty to possess and exercise reasonable degree of skill, care, and knowledge that would be exercised by reasonably prudent pharmacist in same situation).

In *McLeod*, a breach of warranty case, the issue before the Florida Supreme Court was whether a pharmacy could be held strictly liable for its failure to warn a customer of the possible dangers of using the drug it dispensed in accordance with a doctor's prescription. 174 So. 2d at 738. The court rejected any imposition of strict liability and stated that a pharmacist "who sells a prescription warrants that (1) he will compound the drug prescribed; (2) *he has used due and proper care in filling the prescription (failure of which might also give rise to an action in negligence)*; (3) the proper methods were used in the compounding process; [and] (4) the drug has not been infected with some adulterating foreign substance." *Id.* at 739 (emphasis added). [**6] The *McLeod* court was not dealing with a complaint grounded in negligence, *id.* at 738, and specifically noted that a cause of action for negligence might arise when a pharmacist does not use due proper care in filling the prescription, *id.* at 739. However, the court did not say what circumstances might give rise to a negligence claim against a pharmacist.

Florida decisions since *McLeod* provide guidance. In *Dee v. Wal-Mart Stores, Inc.*, 878 So. 2d 426, 427 (Fla. 1st DCA 2004), a doctor prescribed a painkiller containing fentanyl to a patient who had had a Cesarean section. The prescription had no time limit on it. Four months after the prescription was written, the patient had it filled to treat an ankle injury. She died in her sleep as a result of toxic overexposure to fentanyl. The plaintiff alleged

that the lack of a time limit on the prescription rendered it unreasonable on its face. The prescribed painkiller was likely to be fatal if taken by a person who was not on a particular drug regimen. The plaintiff asserted that a pharmacist, viewing the date on the prescription, would reasonably have concluded that by that time, the patient was not on the proper regimen, and should have warned the patient or sought authorization from the prescribing physician before dispensing [**7] the drug. *Id.* at 427-28. The trial court dismissed the complaint, but the First District Court of Appeal reversed, finding that the allegations stated a cause of action in negligence. *Id.* at 428. Relying on *McLeod*, the *Dee* court noted that a pharmacy must use due and proper care in filling a prescription. *Id.* at 427. The court held that a pharmacy that fills a prescription that is unreasonable on its face may breach its duty of care, even if the prescription is lawful as written. *Id.*

The Fourth District Court of Appeal clarified *McLeod* further in *Powers v. Thobani*, 903 So. 2d 275 (Fla. 4th DCA 2005). [**182] In *Powers*, it was alleged that the decedent's doctor had been overprescribing narcotics to her for several months, and she eventually died of an overdose. *Id.* at 276-77. The decedent's husband sued the prescribing doctor and the two pharmacies that had filled the prescriptions. In the case of the pharmacies, he argued that they had filled every prescription without question, including numerous prescriptions so close together that the pharmacies should have been put on notice that his wife was getting too many pills within too short a period. *Id.* at 277. The trial court held that pharmacies have no duty to act in such circumstances. The Fourth District reversed, relying on *Dee* and *McLeod* [**8], and holding that those cases "confirm that factual circumstances exist under which negligence liability can be imposed on a pharmacy for failing to use due and proper care in filling prescriptions, even if the prescription is filled in accordance with the physician's instructions." *Id.* at 278. The court found that it was possible that the repeated filling of dangerous and frequently abused medications, without warning of their risks, might constitute a failure to use due and proper care. *Id.* at 279.

We agree with *Powers* and hold that a pharmacist's duty to use due and proper care in filling a prescription extends beyond simply following the prescribing physician's directions. In the instant case, accepting the allegations of the amended complaint as true, Pharmacy filled, without question, numerous prescriptions that were so close together that Pharmacy should have been put on notice that Mr. Porter was getting too many pills within too short a period--similar to the pharmacies in *Powers*. We refuse to interpret a pharmacist's duty to use "due and proper care in filling the prescription" as being satis-

fied by "robotic compliance" with the instructions of the prescribing physician. *See Arrington v. Walgreen Co.*, 664 F. Supp. 2d 1230, 1232 (M.D. Fla. 2009) (holding that, [**9] under Florida law, customer's cause of action against pharmacy arising from pharmacist's alleged failure to warn customer that prescription contained substance to which customer was allergic when filling prescription was sufficient to plead that pharmacy had duty to use proper care in filling prescription beyond simply following prescribing physician's directions).

Our decision in *Estate of Sharp* does not conflict with *Powers*. *See also Your Druggist, Inc. v. Powers*, 934 So. 2d 1182 (Fla. 2006) (where supreme court initially granted review based on certified conflict between *Estate of Sharp* and *Powers*, but later declined to exercise jurisdiction after determining, without explanation, that there was no actual conflict). In *Estate of Sharp*, the issue was whether the plaintiff sufficiently alleged a negligence claim against Omnicare, an entity providing consulting pharmacy services to the nursing home in which the decedent resided. 879 So. 2d at 36. The plaintiff alleged, among other things, that Omnicare failed to review the decedent's drug regimen and failed to detect from her records that her drug regimen was not effectively treating her medical conditions. *Id.* After reviewing the plaintiff's allegations, we concluded that Omnicare, the consultant pharmacy [**10] service provider for the nursing home, was not liable for the administration of medications that the nursing home provided to the decedent or that her physicians prescribed. We reasoned that Omnicare could not be held liable for duties that are ordinarily owed by a caretaker of the patient or the physician who has the duty to know the drug that he is prescribing and to properly monitor the patient. *See also Badger Acquisition*, 983 So. 2d 1175 (holding that consulting pharmacist did not owe legal duty to decedent that could support negligence claim because it had not increased risk to decedent as harm from [**183] pharmaceutical regime was ultimately caused by physician who prescribed medication and nursing home staff that administered medicine).

The allegations in this case are substantially different than those described in *Estate of Sharp*. Unlike here, where Pharmacy interacted directly with Mr. Porter, in *Estate of Sharp*, the consultant pharmacy had no interaction with the decedent, but instead, dealt only with the nursing home. *Accord Badger Acquisition*, 983 So. 2d at 1180-81 (explaining that under Florida law, role of consultant pharmacist is largely administrative, and is focused on record keeping, inventory, and establishing related procedures for handling medications, [**11] and qualifications to become licensed consultant pharmacist in administrative regulations also reflect ministerial role). More importantly, unlike *Estate of Sharp*, the prescrip-

tions at issue here are alleged to be unreasonable on their face because they were written in a quantity, frequency, dosage, or combination that a reasonable pharmacist would either have checked with the prescribing doctor or warned the patient.⁴ See *Bustetter v. Armor Corr. Health Servs., Inc.*, 919 F. Supp. 2d 1282, 1294 (M.D. Fla. 2013). The allegations in the present case are more similar to the scenario described in *Powers*. We conclude *Powers*, not *Estate of Sharp*, applies. Based on the foregoing, we hold that the trial court erred in dismissing the negligence claims against Pharmacy. While we cannot say whether Oleckna's claims will survive a summary judgment motion or prevail at trial, we are unwilling to hold, as a matter of law, that Pharmacy was not negligent in filling the prescriptions.

4 The Florida pharmaceutical regulatory statutes and administrative codes do not create a private cause of action against pharmacists. See *Badger Acquisition*, 983 So. 2d at 1182; *Johnson v. Walgreen Co.*, 675 So. 2d 1036, 1038 (Fla. 1st DCA 1996). However, they do describe the duties of Florida pharmacists. *Powers*, 903 So. 2d at 278. Section 465.003(6), *Florida Statutes* (2011), provides that

[a]s an element of dispensing, the pharmacist shall, prior to the actual physical transfer, [**12] 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.

See also *Fla. Admin. Code R. 64B16-27.300, 64B16-27.820*. Florida pharmacists are specifically charged with general knowledge of prescription medication and the risks presented by taking particular prescription drugs, such that they should be able to evaluate and explain the operative risks of taking a medication or series of medications. In essence, a strong policy basis already exists supporting a pharmacist's duty to warn customers of the inherent risks in filling repeated and unreasonable prescriptions with potentially fatal consequences. *Powers*, 903 So. 2d at 278.

REVERSED and REMANDED.

BERGER and LAMBERT, JJ., concur.

SPECIAL REPORT

A Proactive Response to Prescription Opioid Abuse

Robert M. Califf, M.D., Janet Woodcock, M.D., and Stephen Ostroff, M.D.

We at the Food and Drug Administration (FDA) continue to be deeply concerned about the growing epidemic of opioid abuse, addiction, and overdose — an epidemic directly related to the increasingly widespread misuse of powerful opioid pain medications. As the federal agency charged with ensuring that the drugs used by the U.S. public are both effective and safe, we are committed to working in partnership with other government agencies, health care providers, the medical products industry and, most important, patients and their families to deal proactively with this unfolding public health crisis, which has already profoundly affected individuals, families, and communities throughout our country. We will do so while also safeguarding appropriate access to vitally important pain medications for the patients who need them (Table 1).

BACKGROUND

Over the course of a given year, approximately 100 million people in the United States suffer from pain. Some 9 million to 12 million of them have chronic or persistent pain, while the remainder have short-term pain from injuries, illnesses, or medical procedures. All of them should benefit from skillful and appropriate pain management, which may include the judicious use of opioid medicines in conjunction with other methods of treatment or in circumstances in which nonaddictive therapies are insufficient to control pain.

As physicians, we have treated both the intense suffering caused by acute pain and chronic pain with all its exhausting and debilitating consequences. But we have also witnessed the devastating results of opioid misuse and abuse, such as the addiction of patients who have been prescribed opioids for pain treatment and, increasingly, diversion to people for whom the prescription was not written. Many Americans are now addicted to prescription opioids, and the number

of deaths due to prescription opioid overdose is unacceptable. This past month, our sister agency, the Centers for Disease Control and Prevention (CDC), estimated that in 2014 there were almost 19,000 overdose deaths in the United States associated with prescription opioids (Rudd R, CDC: personal communication).

Because protecting the public by ensuring the safety, efficacy, and quality of drugs is an essential part of the FDA's mission, it is appropriate to examine the agency's actions in coping with the public health crisis of opioid misuse. As FDA leaders and as physicians, we believe that these efforts must be founded on two complementary principles: that the United States must deal aggressively with opioid misuse and addiction, and at the same time, that it must protect the well-being of people experiencing the devastating effects of acute or chronic pain. It is a difficult balancing act, but we believe that the continuing escalation of the negative consequences of opioid use compels us to comprehensively review our portfolio of activities, reassess our strategy, and take aggressive actions when there is good reason to believe that doing so will make a positive difference.

We are launching this renewed effort in the context of a broad national campaign that includes a major initiative led by the Department of Health and Human Services (HHS)¹ designed to attack the problem from every angle. The number of annual opioid prescriptions written in the United States is now roughly equal to the number of adults in the population²; given these numbers, simply reinforcing opioid-related activities that are within the FDA's traditional regulatory scope will not suffice to stem the tide. Instead, we must work more closely with key federal agencies (including many within HHS), the clinical and prescriber communities, and other stakeholders to ensure that all available effective tools are brought to bear on this epidemic and that the evidence base for proper

Table 1. Responding to Prescription Opioid Abuse.

Issue	FDA Response
<p>Balancing individual need and societal risk. Patients require access to safe and effective pain medication, but both individuals and society must be protected from the effects of opioid misuse.</p>	<p>The FDA will consult with partners including the National Academy of Medicine to craft a framework for opioid review, approval, and monitoring that balances individual needs for pain control with the risk of addiction, as well as the broader public health consequences of opioid abuse and misuse.</p>
<p>Meeting the need for timely action. The evolving threat of opioid abuse requires a flexible interim approach while the full policy framework is in development.</p>	<p>The FDA Science Board will convene in March to advise on the role of pharmaceuticals in pain management, development of alternative pain medications, and postmarketing surveillance activities. Multiple other actions will also occur over the next several months, including an evaluation of the existing Risk Evaluation and Mitigation Strategy (REMS) requirements for extended-release/long-acting (ER/LA) opioids. An advisory committee will consider this review and offer advice regarding possible expansion of the scope and content of prescriber education and whether to expand the REMS program to include immediate-release opioids, potentially increasing the number of prescribers receiving training on pain management and safe prescribing.</p>
<p>Reviewing labeling and postmarketing surveillance requirements. Current labeling requirements include detailed instructions, and manufacturers are required to conduct postmarketing safety surveillance and research studies, but these measures may need to be reevaluated.</p>	<p>The FDA will revise postmarketing requirements, expanding the requirements for drug companies to generate postmarketing data on long-term impact of ER/LA opioid use to provide better evidence on the serious risks of misuse and abuse associated with long-term opioid use, predictors of opioid addiction, and other important issues.</p>
<p>Prioritizing abuse-deterrent formulations and overdose treatments. Abuse-deterrent opioid formulations have the potential to reduce misuse of opioid medications, and broader access to naloxone may help mitigate harm from opioid overdose.</p>	<p>The FDA will continue to support abuse-deterrent formulations and, with guidance from an advisory committee, explore and encourage development of more effective abuse-deterrent features. The FDA will also prioritize issuance of draft guidance on generic abuse-deterrent opioids and will consider ways to make naloxone more widely available, including as an over-the-counter medication. In addition, new non-abuse-deterrent formulations submitted for FDA approval will also be reviewed by an advisory committee.</p>
<p>Addressing the lack of nonopioid alternatives for pain management. Although nonopioid medications for chronic pain have recently been approved for the market, more alternatives are needed, including nonpharmacologic treatments.</p>	<p>The FDA is working closely with industry and the National Institutes of Health to develop alternative medications without the addictive properties of opioids. Nonpharmacologic approaches to pain treatment have also been identified as an urgent priority.</p>
<p>Creating clear guidelines for opioid use. The current crisis in opioid misuse and abuse will continue unless prescribing physicians have a clear understanding of appropriate use and management.</p>	<p>The FDA is supporting the CDC's guideline for prescribing opioids for chronic pain control. The FDA also supports the Surgeon General's efforts to engage the clinical community in curbing inappropriate prescribing and proactively treating opioid addiction, while reinforcing evidence-based pain management approaches that spare the use of opioids.</p>
<p>Managing pain in children. Use of opioid medications in children with severe and chronic pain conditions requires special consideration, and physicians need information that helps them prescribe such medications safely and effectively, while protecting minors who lack mature decision-making capabilities.</p>	<p>An FDA Pediatric Advisory Committee will address the use of opioid medications in children, including the development of high-quality evidence to guide treatment, and provide input on the policies for adding new pediatric opioid labeling under the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act before any new labeling is approved.</p>
<p>Developing a better evidence base. Despite ongoing efforts, the evidence base to guide the use of opioid medications, particularly in the setting of long-term use, is substantially lacking.</p>	<p>Health and Human Services agencies and the FDA program for mandated industry-funded studies are developing a coordinated plan for conducting research that will provide evidence to guide opioid use, elucidate the biologic phenomenon of pain, and consider new and alternative approaches to pain prevention and management.</p>

pain management and appropriate opioid use is optimized and translated into practice.

BALANCING INDIVIDUAL AND
SOCIETAL RISK

We will start by launching a broad reexamination of our approach, considering how best to apply existing policies to this problem, which policies need to be improved and updated, and whether new policies must be developed. Consideration of a range of risks that FDA-regulated products pose to their intended consumers and to others is important to our public health mission. In many cases, opioids can cause harm that goes beyond the risks to the person who has been prescribed the medicine, and inappropriate prescribing causes both direct and indirect harms that are difficult to track and measure but must be considered. We will therefore seek advice on how to more comprehensively take into account the risks of abuse for both patients and nonpatients when regulating these drugs.

We have asked the National Academy of Medicine (NAM) to help us develop a regulatory framework for opioid review, approval, and monitoring that balances individual need for pain control with considerations of the broader public health consequences of abuse and misuse. Assessing the long-term risks of addiction and hyperalgesia (in which the use of opioids results in excess pain rather than pain relief), as well as other toxic effects and societal harm caused by diversion and related addiction, will require extrapolation from imperfect data. The NAM brings an unbiased and highly respected perspective on these issues that can help us revise our framework.

Since this intensive review will take time, we plan to pursue other activities and decisions in the interim. The evolving nature of the threat that opioid abuse poses to our country's health demands an approach in which we constantly consider available information, seek advice, and move forward, always ready to shift our actions as new information becomes available. Specifically, at its next meeting in March, the FDA's Science Board (comprising independent experts in regulatory science) will consider a series of relevant issues, aiming to advise the FDA on the role of pharmaceuticals in pain management, development of alternative pain medications, and postmarketing surveillance activities.

REVISITING OPIOID LABELING
AND POSTMARKETING STUDY
REQUIREMENTS

We will also reexamine how opioids should be labeled more generally. Current labeling for extended-release or long-acting (ER/LA) opioids, revised in September 2013, includes strict, detailed instructions requiring descriptions of their associated risks, the need for monitoring, and the facts that opioids should be used only when other measures are insufficient, the need to continue to use opioids should be reassessed regularly, and opioids should be dispensed in limited quantities.³ In addition, manufacturers of ER/LA opioids will be required to conduct extensive postmarketing research (resulting in a total of 11 mandated studies), in order to study safety concerns that have been identified and evaluate methods to assess progress in mitigating them.

Manufacturers of ER/LA opioids are also subject to a Risk Evaluation and Mitigation Strategy (REMS)⁴ program that requires them to fund continuing medical education (CME) providers to offer, at low or no cost, CME courses on the appropriate use of these products, subject to an online FDA curriculum. More than 38,000 prescribers have taken part in these voluntary educational programs, and an evaluation of these results is under way and will be considered by an advisory committee in the spring.

But although this voluntary training remains an important public health measure, the FDA continues to support mandatory education for prescribers, as called for in the 2011 Prescription Drug Abuse Prevention Plan⁵ and reemphasized in the 2014 National Drug Control Strategy.⁶ Together with other federal agencies and the clinical community, we should strive to overcome obstacles to enacting this measure. Along with improving prescriber education, we will assess whether broader measures should be instituted for labeling and postmarketing evaluation of the entire class of opioids.

DETECTING ABUSE AND MITIGATING
HARM FROM OVERDOSE

In addition to the REMS approach to safety, the FDA has strongly supported the development and assessment of abuse-deterrent formulations

of opioids,⁷ five of which the agency has already approved. The pharmaceutical industry has shown significant interest in developing abuse-deterrent opioid formulations and the field is progressing rapidly. The availability of abuse-deterrent formulations raises questions, including how to encourage their use in place of products without abuse-deterrent features and whether to modify criteria for the review and approval of oral opioid formulations that lack abuse-deterrent features or do not offer advantages in abuse deterrence relative to currently marketed products. We will continue to support abuse-deterrent formulations and encourage development of more effective abuse-deterrent features; we are also committed to convening advisory committees to consider new versions of non-abuse-deterrent opioids. In addition, draft FDA guidance on generic abuse-deterrent opioids will review many of the key issues; making this guidance available quickly is a high priority, since the availability of less costly generic products should accelerate prescribers' uptake of abuse-deterrent formulations. However, it is important to recognize that abuse-deterrent formulations by themselves when taken orally do not prevent the development of tolerance or addiction to opioids.

We have also strongly supported the development and marketing of countermeasures that can reverse overdose, such as the opioid antagonist naloxone. Rapid advances in the development and distribution of injectable and intranasal naloxone offer an example of an effort in which broad intersectoral collaboration has saved substantial numbers of people who would otherwise have died from overdose. The recent rapid approvals of intramuscular (via auto-injector)⁸ and intranasal⁹ naloxone were important steps in improving access to this lifesaving therapy. Are there ways to expand naloxone's availability? We will continue to explore expanding availability of naloxone in the coming year, including ways to make it available over the counter.

PRIORITIZING DEVELOPMENT
OF NONOPIOID ALTERNATIVES
FOR PAIN RELIEF

We are also working closely with industry and the National Institutes of Health to develop additional alternative medications that alleviate pain but do not have the addictive properties of

opioids. Nonpharmacologic approaches to pain treatment are also an urgent priority. The FDA has approved nonopioid medications for treatment of various chronic-pain syndromes, including gabapentin (Neurontin), pregabalin (Lyrica), milnacipran (Savella), duloxetine (Cymbalta), and others, and a number of promising development programs are in the pipeline. But we need more. The FDA will use all the tools at its disposal to move these alternatives along as expeditiously as possible, while remaining mindful that all medicines have risks. For example, although nonsteroidal antiinflammatory drugs do not carry a risk of addiction, we now know that they carry increased risks of myocardial infarction, stroke, and serious gastrointestinal bleeding.

REFINING GUIDELINES FOR OPIOID
USE

A comprehensive solution to the current opioid crisis goes well beyond the FDA's remit. However, thanks to our access to rich data sources and the broader federal effort to define the issues, we are in a position to see the problems that medical practice and public health must confront and to provide guidance in addressing them. Accordingly, we are supporting the CDC's Guideline for Prescribing Opioids for Chronic Pain. The draft guideline¹⁰ received extensive public comment, and we look forward to participating in the process when the CDC finalizes it soon. We are also supporting the Surgeon General's efforts¹¹ to engage the clinical community in a concerted approach to curbing inappropriate prescribing and proactively treating opioid addiction, while reinforcing evidence-based approaches to treating pain in a manner that spares the use of opioids. Until clinicians stop prescribing opioids far in excess of clinical need, this crisis will continue unabated.

MANAGING PAIN IN CHILDREN

The care of children with debilitating pain for whom other measures do not bring comfort deserves particular consideration. Recent labeling changes for oxycodone (OxyContin) that provided evidence-based dosing information for pediatric use created substantial controversy. Children who are prescribed oxycodone or other opioids have severe conditions that include cancer, multisys-

tem trauma, and serious chronic diseases such as sickle cell anemia or have undergone multiple surgical procedures. We must care for our most vulnerable patients, but we must also do everything possible to avoid both the inappropriate prescribing of powerful opioid medications and the misuse of these prescriptions.

When Congress enacted the Pediatric Research Equity Act, it enabled the FDA to require industry to conduct studies to determine the appropriate dosing of medications in children; the Best Pharmaceuticals for Children Act provided incentives for performing these studies for products that were already approved.¹² For children whose circumstances require treatment with opioids, we will consider how best to ensure that doctors get the information they need to prescribe such medications safely and effectively, while protecting minors who lack mature decision-making capabilities.

As physicians and regulators — and as parents — we know that we must treat pain in a suffering child. But in some cases, children with serious conditions are being treated with opioids in the absence of adequate knowledge about correct indications and dosing. We must all work together to ensure that all appropriate therapeutic options for pain are available to children, but it is equally important that when opioids are used, they are prescribed and handled in an impeccably judicious manner, guided by the best and most current scientific evidence. To this end, we are convening the Pediatric Advisory Committee on two upcoming occasions in order to specifically address issues related to the use of opioid medications in children, including the development of high-quality evidence to guide treatment, pediatric labeling for opioids, and improving practice to reduce addiction, misuse, and diversion.

The committee will consider appropriate approaches for ensuring that clinicians have ready access to reliable dosing information and will recommend methods for ensuring that clinicians scrupulously follow the regulations and best practices governing the use of such medications.

DEVELOPING A BETTER EVIDENCE BASE
FOR CHRONIC PAIN TREATMENT

The FDA does its best work when high-quality scientific evidence is available to assess the risks

and benefits of intended uses of medical products. Unfortunately, the field of chronic pain treatment is strikingly deficient in such evidence. A key lesson learned during the development of the CDC guideline is that there is very little research on the long-term benefits of opioids for treating chronic pain. There is, however, growing evidence of harms associated with such use, and of the benefits of other nonopioid treatment alternatives. As with all clinical guidelines, continued research is needed to inform clinical practice. But given the severity of the crisis, the draft CDC guideline provides a highly reasonable set of recommendations for primary care providers to use in their clinical practices, allowing physicians and patients together to determine treatment plans on the basis of the best current understanding of risks and benefits.

Recognition of this problem led the FDA, several years ago, to require industry to perform a series of studies on questions that are critical for ensuring safe prescribing.⁴ For example, until recently it was believed that opioids' pain-relieving properties would not be time-dependent, but new studies have raised the question of whether opioids continue to be effective or may even increase pain in some patients after several months of use. To explore this question, 1 of the 11 postmarketing studies the FDA is requiring industry to fund is a clinical trial in which participants are randomly assigned to continue opioid therapy or to be weaned from it on a schedule over the course of 1 year of follow-up.

As policies are implemented and new evidence is generated, we will continuously assess findings and ensure that the agency's proposed strategies are evaluated in the context of new data. By implementing a coordinated effort among public and private partners, we will be able to adapt our strategies as the evidence base improves. We are committed to this renewed effort and believe that by working together we can solve the opioid crisis, while gaining ground in the national effort to prevent and control short-term and chronic pain.

Nationally, the annual number of deaths from opioid overdoses now exceeds the number of deaths caused by motor vehicle accidents.¹³ Regardless of whether we view these issues from the perspective of patients, physicians, or regulators, the status quo is clearly not acceptable. As the public health agency responsible for over-

sight of pharmaceutical safety and effectiveness, we recognize that this crisis demands solutions. We are committed to action, and we urge others to join us.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From the Food and Drug Administration, Silver Spring, MD.

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1. Department of Health and Human Services. HHS takes strong steps to address opioid-drug related overdose, death and dependence. March 26, 2015 (<http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html>).
2. Centers for Disease Control and Prevention. Vital signs: opioid painkiller prescribing. July 2014 (<http://www.cdc.gov/vitalsigns/opioid-prescribing>).
3. Food and Drug Administration. Letter to application holders: ER/LA opioid analgesic class labeling changes and postmarketing requirements (<http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM367697.pdf>).
4. Food and Drug Administration. Risk evaluation and mitigation strategy (REMS) for extended-release and long-acting opioids (<http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm163647.htm>).
5. Executive Office of the President of the United States. Epidemic: responding to America's prescription drug abuse crisis. 2011 (https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf).

6. Office of National Drug Control Policy. National Drug Control Strategy. 2014 (https://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/ndcs_2014.pdf).
7. Food and Drug Administration. Guidance for industry: abuse-deterrent opioids — evaluation and labeling. April 2015 (<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM334743.pdf>).
8. Food and Drug Administration. FDA approves new hand-held auto-injector to reverse opioid overdose. April 3, 2014 (<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm391465.htm>).
9. Food and Drug Administration. FDA moves quickly to approve easy-to-use nasal spray to treat opioid overdose. November 18, 2015 (<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm473505.htm>).
10. Federal Register Notice. Proposed 2016 guideline for prescribing opioids for chronic pain (<https://www.federalregister.gov/articles/2015/12/14/2015-31375/proposed-2016-guideline-for-prescribing-opioids-for-chronic-pain>).
11. Office of the Surgeon General. National prevention strategy — America's plan for better health and wellness. 2011 (<http://www.surgeongeneral.gov/priorities/prevention/strategy/report.pdf>).
12. Eunice Kennedy Shriver National Institute of Child Health and Human Development. About the Best Pharmaceuticals for Children Act (<http://bpca.nichd.nih.gov/about/Pages/Index.aspx>).
13. Centers for Disease Control and Prevention. Web-based Injury Statistics Query and Reporting System (WISQARS). 2014 (<http://www.cdc.gov/injury/wisqars/fatal.html>).

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1
2 An act relating to the ordering of medication;
3 amending s. 381.887, F.S.; providing that a pharmacist
4 may dispense an emergency opioid antagonist pursuant
5 to a non-patient-specific standing order for an
6 autoinjection delivery system or intranasal
7 application delivery system; amending ss. 458.347 and
8 459.022, F.S.; revising the authority of a licensed
9 physician assistant to order medication under the
10 direction of a supervisory physician for a specified
11 patient; amending s. 464.012, F.S.; authorizing an
12 advanced registered nurse practitioner to order
13 medication for administration to a specified patient;
14 providing a short title; amending s. 465.003, F.S.;
15 revising the term "prescription" to exclude an order
16 for drugs or medicinal supplies dispensed for
17 administration; amending s. 893.02, F.S.; revising the
18 term "administer" to include the term
19 "administration"; revising the definition of the term
20 "prescription"; amending s. 893.04, F.S.; conforming
21 provisions to changes made by the act; amending s.
22 893.05, F.S.; authorizing a licensed practitioner to
23 authorize a licensed physician assistant or advanced
24 registered nurse practitioner to order controlled
25 substances for a specified patient under certain
26 circumstances; reenacting ss. 400.462(26) and



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27 | 409.906(18), F.S., relating to the definition of the
28 | term "physician assistant" for purposes of the Home
29 | Health Services Act and physician assistant services
30 | under the Medicaid program, respectively, to
31 | incorporate the amendments made by the act to ss.
32 | 458.347 and 459.022, F.S., in references thereto;
33 | reenacting ss. 401.445(1) and 766.103(3), F.S.,
34 | relating to emergency examination and treatment of
35 | incapacitated persons and the Florida Medical Consent
36 | Law, respectively, to incorporate the amendments made
37 | by the act to ss. 458.347, 459.022, and 464.012, F.S.,
38 | in references thereto; reenacting ss. 409.9201(1)(a),
39 | 465.014(1), 465.1901, 499.003(43), and 831.30(1),
40 | F.S., relating to the definition of "prescription
41 | drug" for purposes of Medicaid fraud, the supervision
42 | of registered pharmacy technicians, applicability of
43 | provisions regulating the practice of orthotics or
44 | pedorthics to pharmacists, the definition of the term
45 | "prescription drug" for purposes of the Florida Drug
46 | and Cosmetic Act, and criminal penalties related to
47 | the fraudulent obtaining of medicinal drugs,
48 | respectively, to incorporate the amendment made by the
49 | act to s. 465.003, F.S., in references thereto;
50 | reenacting ss. 458.331(1)(pp), 459.015(1)(rr),
51 | 465.015(2)(c) and (3), 465.016(1)(s), 465.022(5)(j),
52 | and 465.023(1)(h), F.S., relating to grounds for



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53 | disciplinary action by the Board of Medicine or the
 54 | Board of Osteopathic Medicine, unlawful acts and
 55 | penalties related to the practice of pharmacy, grounds
 56 | for denial of a pharmacy permit or disciplinary action
 57 | against a pharmacy permittee, respectively, to
 58 | incorporate the amendments made by the act to ss.
 59 | 465.003 and 893.02, F.S., in references thereto;
 60 | reenacting ss. 112.0455(5)(i), 381.986(7)(b),
 61 | 440.102(1)(1), 499.0121(14), 768.36(1)(b),
 62 | 810.02(3)(f), 812.014(2)(c), 856.015(1)(c),
 63 | 944.47(1)(a), 951.22(1), 985.711(1)(a), 1003.57(1)(i),
 64 | and 1006.09(8), F.S., relating to the Drug-Free
 65 | Workplace Act, the compassionate use of low-THC
 66 | cannabis, drug-free workplace program requirements,
 67 | reporting of prescription drug distribution, the
 68 | definition of the term "drug" for purposes of defenses
 69 | from civil actions related to alcohol or drugs,
 70 | burglary offenses, penalties for grand theft, the
 71 | definition of the term "drug" for purposes of offenses
 72 | related to open house parties, unlawful introduction
 73 | of certain articles into correctional institutions,
 74 | county detention facilities, or juvenile detention
 75 | facilities, the definition of the term "controlled
 76 | substance" for purposes of exceptional student
 77 | instruction, and duties of school principals related
 78 | to student discipline, respectively, to incorporate



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79 | the amendment made by the act to s. 893.02, F.S., in
 80 | references thereto; reenacting s. 893.0551(3) (d) and
 81 | (e), F.S., relating to disclosure by the Department of
 82 | Health of confidential information in prescription
 83 | drug monitoring program records, to incorporate the
 84 | amendments made by the act to ss. 893.04 and 893.05,
 85 | F.S., in references thereto; providing an effective
 86 | date.

87 |
 88 | Be It Enacted by the Legislature of the State of Florida:
 89 |

90 | Section 1. Subsection (3) of section 381.887, Florida
 91 | Statutes, is amended to read:

92 | 381.887 Emergency treatment for suspected opioid
 93 | overdose.—

94 | (3) An authorized health care practitioner may prescribe
 95 | and dispense an emergency opioid antagonist to a patient or
 96 | caregiver for use in accordance with this section, and
 97 | pharmacists may dispense an emergency opioid antagonist pursuant
 98 | to such a prescription or pursuant to a non-patient-specific
 99 | standing order for an autoinjection delivery system or
 100 | intranasal application delivery system, which must be issued in
 101 | ~~the name of the patient or caregiver, which is~~ appropriately
 102 | labeled with instructions for use. Such patient or caregiver is
 103 | authorized to store and possess approved emergency opioid
 104 | antagonists and, in an emergency situation when a physician is



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105 | not immediately available, administer the emergency opioid
 106 | antagonist to a person believed in good faith to be experiencing
 107 | an opioid overdose, regardless of whether that person has a
 108 | prescription for an emergency opioid antagonist.

109 | Section 2. Paragraph (g) of subsection (4) of section
 110 | 458.347, Florida Statutes, is amended to read:

111 | 458.347 Physician assistants.—

112 | (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

113 | (g) A supervisory physician may delegate to a licensed
 114 | physician assistant the authority to, and the licensed physician
 115 | assistant acting under the direction of the supervisory
 116 | physician may, order any medication ~~medications~~ for
 117 | administration to the supervisory physician's patient ~~during his~~
 118 | ~~or her care~~ in a facility licensed under chapter 395 or part II
 119 | of chapter 400, notwithstanding any provisions in chapter 465 or
 120 | chapter 893 which may prohibit this delegation. ~~For the purpose~~
 121 | ~~of this paragraph, an order is not considered a prescription. A~~
 122 | ~~licensed physician assistant working in a facility that is~~
 123 | ~~licensed under chapter 395 may order any medication under the~~
 124 | ~~direction of the supervisory physician.~~

125 | Section 3. Paragraph (f) of subsection (4) of section
 126 | 459.022, Florida Statutes, is amended to read:

127 | 459.022 Physician assistants.—

128 | (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

129 | (f) A supervisory physician may delegate to a licensed
 130 | physician assistant the authority to, and the licensed physician



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131 assistant acting under the direction of the supervisory
132 physician may, order any medication ~~medications~~ for
133 administration to the supervisory physician's patient ~~during his~~
134 ~~or her care~~ in a facility licensed under chapter 395 or part II
135 of chapter 400, notwithstanding any provisions in chapter 465 or
136 chapter 893 which may prohibit this delegation. ~~For the purpose~~
137 ~~of this paragraph, an order is not considered a prescription. A~~
138 ~~licensed physician assistant working in a facility that is~~
139 ~~licensed under chapter 395 may order any medication under the~~
140 ~~direction of the supervisory physician.~~

141 Section 4. Paragraph (e) is added to subsection (3) of
142 section 464.012, Florida Statutes, and subsection (6) is added
143 to that section to read:

144 464.012 Certification of advanced registered nurse
145 practitioners; fees.—

146 (3) An advanced registered nurse practitioner shall
147 perform those functions authorized in this section within the
148 framework of an established protocol that is filed with the
149 board upon biennial license renewal and within 30 days after
150 entering into a supervisory relationship with a physician or
151 changes to the protocol. The board shall review the protocol to
152 ensure compliance with applicable regulatory standards for
153 protocols. The board shall refer to the department licensees
154 submitting protocols that are not compliant with the regulatory
155 standards for protocols. A practitioner currently licensed under
156 chapter 458, chapter 459, or chapter 466 shall maintain



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157 supervision for directing the specific course of medical
 158 treatment. Within the established framework, an advanced
 159 registered nurse practitioner may:

160 (e) Order any medication for administration to a patient
 161 in a facility licensed under chapter 395 or part II of chapter
 162 400, notwithstanding any provisions in chapter 465 or chapter
 163 893.

164 (6) This section shall be known as "The Barbara Lumpkin
 165 Prescribing Act."

166 Section 5. Subsections (1) and (22) of section 893.02,
 167 Florida Statutes, are amended to read:

168 893.02 Definitions.—The following words and phrases as
 169 used in this chapter shall have the following meanings, unless
 170 the context otherwise requires:

171 (1) "Administer" or "administration" means the direct
 172 application of a controlled substance, whether by injection,
 173 inhalation, ingestion, or any other means, to the body of a
 174 person or animal.

175 (22) "Prescription" ~~means and~~ includes any an order for
 176 drugs or medicinal supplies which is written, ~~signed,~~ or
 177 transmitted by any ~~word of mouth, telephone, telegram, or other~~
 178 means of communication by a ~~duly~~ licensed practitioner
 179 authorized licensed by the laws of this ~~the~~ state to prescribe
 180 such drugs or medicinal supplies, is issued in good faith and in
 181 the course of professional practice, is intended to be ~~filled,~~
 182 ~~compounded, or~~ dispensed by a another person authorized licensed



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183 by the laws of this ~~the~~ state to do so, and meets ~~meeting~~ the
 184 requirements of s. 893.04.

185 (a) The term also includes an order for drugs or medicinal
 186 supplies ~~so~~ transmitted or written by a physician, dentist,
 187 veterinarian, or other practitioner licensed to practice in a
 188 state other than Florida, but only if the pharmacist called upon
 189 to fill such an order determines, in the exercise of his or her
 190 professional judgment, that the order was issued pursuant to a
 191 valid patient-physician relationship, that it is authentic, and
 192 that the drugs or medicinal supplies ~~so~~ ordered are considered
 193 necessary for the continuation of treatment of a chronic or
 194 recurrent illness.

195 (b) ~~However,~~ If the physician writing the prescription is
 196 not known to the pharmacist, the pharmacist shall obtain proof
 197 to a reasonable certainty of the validity of the ~~said~~
 198 prescription.

199 (c) A prescription ~~order~~ for a controlled substance may
 200 ~~shall~~ not be issued on the same prescription blank with another
 201 prescription ~~order~~ for a controlled substance that ~~which~~ is
 202 named or described in a different schedule or with another, ~~nor~~
 203 ~~shall any prescription order for a controlled substance be~~
 204 ~~issued on the same prescription blank as a prescription order~~
 205 for a medicinal drug, as defined in s. 465.003(8), that is ~~which~~
 206 ~~does not fall within the definition of a controlled substance as~~
 207 ~~defined in this act.~~

208 Section 6. Paragraphs (a), (d), and (f) of subsection (2)



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209 of section 893.04, Florida Statutes, are amended to read:

210 893.04 Pharmacist and practitioner.—

211 (2) (a) A pharmacist may not dispense a controlled
 212 substance listed in Schedule II, Schedule III, or Schedule IV to
 213 any patient or patient's agent without first determining, in the
 214 exercise of her or his professional judgment, that the
 215 prescription ~~order~~ is valid. The pharmacist may dispense the
 216 controlled substance, in the exercise of her or his professional
 217 judgment, when the pharmacist or pharmacist's agent has obtained
 218 satisfactory patient information from the patient or the
 219 patient's agent.

220 (d) Each ~~written~~ prescription written ~~prescribed~~ by a
 221 practitioner in this state for a controlled substance listed in
 222 Schedule II, Schedule III, or Schedule IV must include ~~both~~ a
 223 written and a numerical notation of the quantity of the
 224 controlled substance prescribed and a notation of the date in
 225 numerical, month/day/year format, or with the abbreviated month
 226 written out, or the month written out in whole. A pharmacist
 227 may, upon verification by the prescriber, document any
 228 information required by this paragraph. If the prescriber is not
 229 available to verify a prescription, the pharmacist may dispense
 230 the controlled substance, but may insist that the person to whom
 231 the controlled substance is dispensed provide valid photographic
 232 identification. If a prescription includes a numerical notation
 233 of the quantity of the controlled substance or date, but does
 234 not include the quantity or date written out in textual format,



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235 | the pharmacist may dispense the controlled substance without
 236 | verification by the prescriber of the quantity or date if the
 237 | pharmacy previously dispensed another prescription for the
 238 | person to whom the prescription was written.

239 | (f) A pharmacist may not knowingly dispense ~~fill~~ a
 240 | prescription that has been forged for a controlled substance
 241 | listed in Schedule II, Schedule III, or Schedule IV.

242 | Section 7. Subsection (1) of section 893.05, Florida
 243 | Statutes, is amended to read:

244 | 893.05 Practitioners and persons administering controlled
 245 | substances in their absence.—

246 | (1) (a) A practitioner, in good faith and in the course of
 247 | his or her professional practice only, may prescribe,
 248 | administer, dispense, mix, or otherwise prepare a controlled
 249 | substance, or the practitioner may cause the controlled
 250 | substance ~~same~~ to be administered by a licensed nurse or an
 251 | intern practitioner under his or her direction and supervision
 252 | only.

253 | (b) Pursuant to s. 458.347(4)(g), s. 459.022(4)(f), or s.
 254 | 464.012(3), as applicable, a practitioner who supervises a
 255 | licensed physician assistant or advanced registered nurse
 256 | practitioner may authorize the licensed physician assistant or
 257 | advanced registered nurse practitioner to order controlled
 258 | substances for administration to a patient in a facility
 259 | licensed under chapter 395 or part II of chapter 400.

260 | (c) A veterinarian may ~~se~~ prescribe, administer, dispense,



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261 mix, or prepare a controlled substance for use on animals only,
 262 and may cause the controlled substance ~~it~~ to be administered by
 263 an assistant or orderly under the veterinarian's direction and
 264 supervision only.

265 (d) A certified optometrist licensed under chapter 463 may
 266 not administer or prescribe a controlled substance listed in
 267 Schedule I or Schedule II of s. 893.03.

268 Section 8. For the purpose of incorporating the amendments
 269 made by this act to sections 458.347 and 459.022, Florida
 270 Statutes, in references thereto, subsection (26) of section
 271 400.462, Florida Statutes, is reenacted to read:

272 400.462 Definitions.—As used in this part, the term:

273 (26) "Physician assistant" means a person who is a
 274 graduate of an approved program or its equivalent, or meets
 275 standards approved by the boards, and is licensed to perform
 276 medical services delegated by the supervising physician, as
 277 defined in s. 458.347 or s. 459.022.

278 Section 9. For the purpose of incorporating the amendments
 279 made by this act to sections 458.347 and 459.022, Florida
 280 Statutes, in references thereto, subsection (18) of section
 281 409.906, Florida Statutes, is reenacted to read:

282 409.906 Optional Medicaid services.—Subject to specific
 283 appropriations, the agency may make payments for services which
 284 are optional to the state under Title XIX of the Social Security
 285 Act and are furnished by Medicaid providers to recipients who
 286 are determined to be eligible on the dates on which the services



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287 were provided. Any optional service that is provided shall be
288 provided only when medically necessary and in accordance with
289 state and federal law. Optional services rendered by providers
290 in mobile units to Medicaid recipients may be restricted or
291 prohibited by the agency. Nothing in this section shall be
292 construed to prevent or limit the agency from adjusting fees,
293 reimbursement rates, lengths of stay, number of visits, or
294 number of services, or making any other adjustments necessary to
295 comply with the availability of moneys and any limitations or
296 directions provided for in the General Appropriations Act or
297 chapter 216. If necessary to safeguard the state's systems of
298 providing services to elderly and disabled persons and subject
299 to the notice and review provisions of s. 216.177, the Governor
300 may direct the Agency for Health Care Administration to amend
301 the Medicaid state plan to delete the optional Medicaid service
302 known as "Intermediate Care Facilities for the Developmentally
303 Disabled." Optional services may include:

304 (18) PHYSICIAN ASSISTANT SERVICES.—The agency may pay for
305 all services provided to a recipient by a physician assistant
306 licensed under s. 458.347 or s. 459.022. Reimbursement for such
307 services must be not less than 80 percent of the reimbursement
308 that would be paid to a physician who provided the same
309 services.

310 Section 10. For the purpose of incorporating the
311 amendments made by this act to sections 458.347, 459.022, and
312 464.012, Florida Statutes, in references thereto, subsection (1)



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313 of section 401.445, Florida Statutes, is reenacted to read:

314 401.445 Emergency examination and treatment of
315 incapacitated persons.—

316 (1) No recovery shall be allowed in any court in this
317 state against any emergency medical technician, paramedic, or
318 physician as defined in this chapter, any advanced registered
319 nurse practitioner certified under s. 464.012, or any physician
320 assistant licensed under s. 458.347 or s. 459.022, or any person
321 acting under the direct medical supervision of a physician, in
322 an action brought for examining or treating a patient without
323 his or her informed consent if:

324 (a) The patient at the time of examination or treatment is
325 intoxicated, under the influence of drugs, or otherwise
326 incapable of providing informed consent as provided in s.
327 766.103;

328 (b) The patient at the time of examination or treatment is
329 experiencing an emergency medical condition; and

330 (c) The patient would reasonably, under all the
331 surrounding circumstances, undergo such examination, treatment,
332 or procedure if he or she were advised by the emergency medical
333 technician, paramedic, physician, advanced registered nurse
334 practitioner, or physician assistant in accordance with s.
335 766.103(3).

336
337 Examination and treatment provided under this subsection shall
338 be limited to reasonable examination of the patient to determine



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339 the medical condition of the patient and treatment reasonably
 340 necessary to alleviate the emergency medical condition or to
 341 stabilize the patient.

342 Section 11. For the purpose of incorporating the
 343 amendments made by this act to sections 458.347, 459.022, and
 344 464.012, Florida Statutes, in references thereto, subsection (3)
 345 of section 766.103, Florida Statutes, is reenacted to read:

346 766.103 Florida Medical Consent Law.—

347 (3) No recovery shall be allowed in any court in this
 348 state against any physician licensed under chapter 458,
 349 osteopathic physician licensed under chapter 459, chiropractic
 350 physician licensed under chapter 460, podiatric physician
 351 licensed under chapter 461, dentist licensed under chapter 466,
 352 advanced registered nurse practitioner certified under s.
 353 464.012, or physician assistant licensed under s. 458.347 or s.
 354 459.022 in an action brought for treating, examining, or
 355 operating on a patient without his or her informed consent when:

356 (a)1. The action of the physician, osteopathic physician,
 357 chiropractic physician, podiatric physician, dentist, advanced
 358 registered nurse practitioner, or physician assistant in
 359 obtaining the consent of the patient or another person
 360 authorized to give consent for the patient was in accordance
 361 with an accepted standard of medical practice among members of
 362 the medical profession with similar training and experience in
 363 the same or similar medical community as that of the person
 364 treating, examining, or operating on the patient for whom the



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365 consent is obtained; and

366 2. A reasonable individual, from the information provided
 367 by the physician, osteopathic physician, chiropractic physician,
 368 podiatric physician, dentist, advanced registered nurse
 369 practitioner, or physician assistant, under the circumstances,
 370 would have a general understanding of the procedure, the
 371 medically acceptable alternative procedures or treatments, and
 372 the substantial risks and hazards inherent in the proposed
 373 treatment or procedures, which are recognized among other
 374 physicians, osteopathic physicians, chiropractic physicians,
 375 podiatric physicians, or dentists in the same or similar
 376 community who perform similar treatments or procedures; or

377 (b) The patient would reasonably, under all the
 378 surrounding circumstances, have undergone such treatment or
 379 procedure had he or she been advised by the physician,
 380 osteopathic physician, chiropractic physician, podiatric
 381 physician, dentist, advanced registered nurse practitioner, or
 382 physician assistant in accordance with the provisions of
 383 paragraph (a).

384 Section 12. For the purpose of incorporating the amendment
 385 made by this act to section 465.003, Florida Statutes, in a
 386 reference thereto, paragraph (a) of subsection (1) of section
 387 409.9201, Florida Statutes, is reenacted to read:

388 409.9201 Medicaid fraud.—

389 (1) As used in this section, the term:

390 (a) "Prescription drug" means any drug, including, but not



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391 limited to, finished dosage forms or active ingredients that are
 392 subject to, defined in, or described in s. 503(b) of the Federal
 393 Food, Drug, and Cosmetic Act or in s. 465.003(8), s.
 394 499.003(52), s. 499.007(13), or s. 499.82(10).

395
 396 The value of individual items of the legend drugs or goods or
 397 services involved in distinct transactions committed during a
 398 single scheme or course of conduct, whether involving a single
 399 person or several persons, may be aggregated when determining
 400 the punishment for the offense.

401 Section 13. For the purpose of incorporating the amendment
 402 made by this act to section 465.003, Florida Statutes, in a
 403 reference thereto, subsection (1) of section 465.014, Florida
 404 Statutes, is reenacted to read:

405 465.014 Pharmacy technician.—

406 (1) A person other than a licensed pharmacist or pharmacy
 407 intern may not engage in the practice of the profession of
 408 pharmacy, except that a licensed pharmacist may delegate to
 409 pharmacy technicians who are registered pursuant to this section
 410 those duties, tasks, and functions that do not fall within the
 411 purview of s. 465.003(13). All such delegated acts must be
 412 performed under the direct supervision of a licensed pharmacist
 413 who is responsible for all such acts performed by persons under
 414 his or her supervision. A registered pharmacy technician, under
 415 the supervision of a pharmacist, may initiate or receive
 416 communications with a practitioner or his or her agent, on



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417 | behalf of a patient, regarding refill authorization requests. A
418 | licensed pharmacist may not supervise more than one registered
419 | pharmacy technician unless otherwise permitted by the guidelines
420 | adopted by the board. The board shall establish guidelines to be
421 | followed by licensees or permittees in determining the
422 | circumstances under which a licensed pharmacist may supervise
423 | more than one pharmacy technician.

424 | Section 14. For the purpose of incorporating the amendment
425 | made by this act to section 465.003, Florida Statutes, in a
426 | reference thereto, section 465.1901, Florida Statutes, is
427 | reenacted to read:

428 | 465.1901 Practice of orthotics and pedorthics.—The
429 | provisions of chapter 468 relating to orthotics or pedorthics do
430 | not apply to any licensed pharmacist or to any person acting
431 | under the supervision of a licensed pharmacist. The practice of
432 | orthotics or pedorthics by a pharmacist or any of the
433 | pharmacist's employees acting under the supervision of a
434 | pharmacist shall be construed to be within the meaning of the
435 | term "practice of the profession of pharmacy" as set forth in s.
436 | 465.003(13), and shall be subject to regulation in the same
437 | manner as any other pharmacy practice. The Board of Pharmacy
438 | shall develop rules regarding the practice of orthotics and
439 | pedorthics by a pharmacist. Any pharmacist or person under the
440 | supervision of a pharmacist engaged in the practice of orthotics
441 | or pedorthics is not precluded from continuing that practice
442 | pending adoption of these rules.



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443 Section 15. For the purpose of incorporating the amendment
444 made by this act to section 465.003, Florida Statutes, in a
445 reference thereto, subsection (43) of section 499.003, Florida
446 Statutes, is reenacted to read:

447 499.003 Definitions of terms used in this part.—As used in
448 this part, the term:

449 (43) "Prescription drug" means a prescription, medicinal,
450 or legend drug, including, but not limited to, finished dosage
451 forms or active pharmaceutical ingredients subject to, defined
452 by, or described by s. 503(b) of the federal act or s.
453 465.003(8), s. 499.007(13), subsection (32), or subsection (52),
454 except that an active pharmaceutical ingredient is a
455 prescription drug only if substantially all finished dosage
456 forms in which it may be lawfully dispensed or administered in
457 this state are also prescription drugs.

458 Section 16. For the purpose of incorporating the amendment
459 made by this act to section 465.003, Florida Statutes, in a
460 reference thereto, subsection (1) of section 831.30, Florida
461 Statutes, is reenacted to read:

462 831.30 Medicinal drugs; fraud in obtaining.—Whoever:

463 (1) Falsely makes, alters, or forges any prescription, as
464 defined in s. 465.003, for a medicinal drug other than a drug
465 controlled by chapter 893;

466
467 with intent to obtain such drug commits a misdemeanor of the
468 second degree, punishable as provided in s. 775.082 or s.



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469 775.083. A second or subsequent conviction constitutes a
 470 misdemeanor of the first degree, punishable as provided in s.
 471 775.082 or s. 775.083.

472 Section 17. For the purpose of incorporating the
 473 amendments made by this act to sections 465.003 and 893.02,
 474 Florida Statutes, in references thereto, paragraph (pp) of
 475 subsection (1) of section 458.331, Florida Statutes, is
 476 reenacted to read:

477 458.331 Grounds for disciplinary action; action by the
 478 board and department.—

479 (1) The following acts constitute grounds for denial of a
 480 license or disciplinary action, as specified in s. 456.072(2):

481 (pp) Applicable to a licensee who serves as the designated
 482 physician of a pain-management clinic as defined in s. 458.3265
 483 or s. 459.0137:

484 1. Registering a pain-management clinic through
 485 misrepresentation or fraud;

486 2. Procuring, or attempting to procure, the registration
 487 of a pain-management clinic for any other person by making or
 488 causing to be made, any false representation;

489 3. Failing to comply with any requirement of chapter 499,
 490 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
 491 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
 492 the Drug Abuse Prevention and Control Act; or chapter 893, the
 493 Florida Comprehensive Drug Abuse Prevention and Control Act;

494 4. Being convicted or found guilty of, regardless of



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495 adjudication to, a felony or any other crime involving moral
 496 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
 497 the courts of this state, of any other state, or of the United
 498 States;

499 5. Being convicted of, or disciplined by a regulatory
 500 agency of the Federal Government or a regulatory agency of
 501 another state for, any offense that would constitute a violation
 502 of this chapter;

503 6. Being convicted of, or entering a plea of guilty or
 504 nolo contendere to, regardless of adjudication, a crime in any
 505 jurisdiction of the courts of this state, of any other state, or
 506 of the United States which relates to the practice of, or the
 507 ability to practice, a licensed health care profession;

508 7. Being convicted of, or entering a plea of guilty or
 509 nolo contendere to, regardless of adjudication, a crime in any
 510 jurisdiction of the courts of this state, of any other state, or
 511 of the United States which relates to health care fraud;

512 8. Dispensing any medicinal drug based upon a
 513 communication that purports to be a prescription as defined in
 514 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows
 515 or has reason to believe that the purported prescription is not
 516 based upon a valid practitioner-patient relationship; or

517 9. Failing to timely notify the board of the date of his
 518 or her termination from a pain-management clinic as required by
 519 s. 458.3265(2).

520 Section 18. For the purpose of incorporating the



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521 amendments made by this act to sections 465.003 and 893.02,
522 Florida Statutes, in references thereto, paragraph (rr) of
523 subsection (1) of section 459.015, Florida Statutes, is
524 reenacted to read:

525 459.015 Grounds for disciplinary action; action by the
526 board and department.—

527 (1) The following acts constitute grounds for denial of a
528 license or disciplinary action, as specified in s. 456.072(2):

529 (rr) Applicable to a licensee who serves as the designated
530 physician of a pain-management clinic as defined in s. 458.3265
531 or s. 459.0137:

532 1. Registering a pain-management clinic through
533 misrepresentation or fraud;

534 2. Procuring, or attempting to procure, the registration
535 of a pain-management clinic for any other person by making or
536 causing to be made, any false representation;

537 3. Failing to comply with any requirement of chapter 499,
538 the Florida Drug and Cosmetic Act; 21 U.S.C. ss. 301-392, the
539 Federal Food, Drug, and Cosmetic Act; 21 U.S.C. ss. 821 et seq.,
540 the Drug Abuse Prevention and Control Act; or chapter 893, the
541 Florida Comprehensive Drug Abuse Prevention and Control Act;

542 4. Being convicted or found guilty of, regardless of
543 adjudication to, a felony or any other crime involving moral
544 turpitude, fraud, dishonesty, or deceit in any jurisdiction of
545 the courts of this state, of any other state, or of the United
546 States;



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547 5. Being convicted of, or disciplined by a regulatory
548 agency of the Federal Government or a regulatory agency of
549 another state for, any offense that would constitute a violation
550 of this chapter;

551 6. Being convicted of, or entering a plea of guilty or
552 nolo contendere to, regardless of adjudication, a crime in any
553 jurisdiction of the courts of this state, of any other state, or
554 of the United States which relates to the practice of, or the
555 ability to practice, a licensed health care profession;

556 7. Being convicted of, or entering a plea of guilty or
557 nolo contendere to, regardless of adjudication, a crime in any
558 jurisdiction of the courts of this state, of any other state, or
559 of the United States which relates to health care fraud;

560 8. Dispensing any medicinal drug based upon a
561 communication that purports to be a prescription as defined in
562 s. 465.003(14) or s. 893.02 if the dispensing practitioner knows
563 or has reason to believe that the purported prescription is not
564 based upon a valid practitioner-patient relationship; or

565 9. Failing to timely notify the board of the date of his
566 or her termination from a pain-management clinic as required by
567 s. 459.0137(2).

568 Section 19. For the purpose of incorporating the
569 amendments made by this act to sections 465.003 and 893.02,
570 Florida Statutes, in references thereto, paragraph (c) of
571 subsection (2) and subsection (3) of section 465.015, Florida
572 Statutes, are reenacted to read:



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573 465.015 Violations and penalties.—
574 (2) It is unlawful for any person:
575 (c) To sell or dispense drugs as defined in s. 465.003(8)
576 without first being furnished with a prescription.
577 (3) It is unlawful for any pharmacist to knowingly fail to
578 report to the sheriff or other chief law enforcement agency of
579 the county where the pharmacy is located within 24 hours after
580 learning of any instance in which a person obtained or attempted
581 to obtain a controlled substance, as defined in s. 893.02, or at
582 the close of business on the next business day, whichever is
583 later, that the pharmacist knew or believed was obtained or
584 attempted to be obtained through fraudulent methods or
585 representations from the pharmacy at which the pharmacist
586 practiced pharmacy. Any pharmacist who knowingly fails to make
587 such a report within 24 hours after learning of the fraud or
588 attempted fraud or at the close of business on the next business
589 day, whichever is later, commits a misdemeanor of the first
590 degree, punishable as provided in s. 775.082 or s. 775.083. A
591 sufficient report of the fraudulent obtaining of controlled
592 substances under this subsection must contain, at a minimum, a
593 copy of the prescription used or presented and a narrative,
594 including all information available to the pharmacist concerning
595 the transaction, such as the name and telephone number of the
596 prescribing physician; the name, description, and any personal
597 identification information pertaining to the person who
598 presented the prescription; and all other material information,

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599 such as photographic or video surveillance of the transaction.

600 Section 20. For the purpose of incorporating the
601 amendments made by this act to sections 465.003 and 893.02,
602 Florida Statutes, in references thereto, paragraph (s) of
603 subsection (1) of section 465.016, Florida Statutes, is
604 reenacted to read:

605 465.016 Disciplinary actions.—

606 (1) The following acts constitute grounds for denial of a
607 license or disciplinary action, as specified in s. 456.072(2):

608 (s) Dispensing any medicinal drug based upon a
609 communication that purports to be a prescription as defined by
610 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
611 reason to believe that the purported prescription is not based
612 upon a valid practitioner-patient relationship.

613 Section 21. For the purpose of incorporating the
614 amendments made by this act to sections 465.003 and 893.02,
615 Florida Statutes, in references thereto, paragraph (j) of
616 subsection (5) of section 465.022, Florida Statutes, is
617 reenacted to read:

618 465.022 Pharmacies; general requirements; fees.—

619 (5) The department or board shall deny an application for
620 a pharmacy permit if the applicant or an affiliated person,
621 partner, officer, director, or prescription department manager
622 or consultant pharmacist of record of the applicant:

623 (j) Has dispensed any medicinal drug based upon a
624 communication that purports to be a prescription as defined by



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625 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
 626 reason to believe that the purported prescription is not based
 627 upon a valid practitioner-patient relationship that includes a
 628 documented patient evaluation, including history and a physical
 629 examination adequate to establish the diagnosis for which any
 630 drug is prescribed and any other requirement established by
 631 board rule under chapter 458, chapter 459, chapter 461, chapter
 632 463, chapter 464, or chapter 466.

633
 634 For felonies in which the defendant entered a plea of guilty or
 635 nolo contendere in an agreement with the court to enter a
 636 pretrial intervention or drug diversion program, the department
 637 shall deny the application if upon final resolution of the case
 638 the licensee has failed to successfully complete the program.

639 Section 22. For the purpose of incorporating the
 640 amendments made by this act to sections 465.003 and 893.02,
 641 Florida Statutes, in references thereto, paragraph (h) of
 642 subsection (1) of section 465.023, Florida Statutes, is
 643 reenacted to read:

644 465.023 Pharmacy permittee; disciplinary action.—

645 (1) The department or the board may revoke or suspend the
 646 permit of any pharmacy permittee, and may fine, place on
 647 probation, or otherwise discipline any pharmacy permittee if the
 648 permittee, or any affiliated person, partner, officer, director,
 649 or agent of the permittee, including a person fingerprinted
 650 under s. 465.022(3), has:



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651 (h) Dispensed any medicinal drug based upon a
652 communication that purports to be a prescription as defined by
653 s. 465.003(14) or s. 893.02 when the pharmacist knows or has
654 reason to believe that the purported prescription is not based
655 upon a valid practitioner-patient relationship that includes a
656 documented patient evaluation, including history and a physical
657 examination adequate to establish the diagnosis for which any
658 drug is prescribed and any other requirement established by
659 board rule under chapter 458, chapter 459, chapter 461, chapter
660 463, chapter 464, or chapter 466.

661 Section 23. For the purpose of incorporating the amendment
662 made by this act to section 893.02, Florida Statutes, in a
663 reference thereto, paragraph (i) of subsection (5) of section
664 112.0455, Florida Statutes, is reenacted to read:

665 112.0455 Drug-Free Workplace Act.—

666 (5) DEFINITIONS.—Except where the context otherwise
667 requires, as used in this act:

668 (i) "Prescription or nonprescription medication" means a
669 drug or medication obtained pursuant to a prescription as
670 defined by s. 893.02 or a medication that is authorized pursuant
671 to federal or state law for general distribution and use without
672 a prescription in the treatment of human diseases, ailments, or
673 injuries.

674 Section 24. For the purpose of incorporating the amendment
675 made by this act to section 893.02, Florida Statutes, in a
676 reference thereto, paragraph (b) of subsection (7) of section



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677 381.986, Florida Statutes, is reenacted to read:

678 381.986 Compassionate use of low-THC cannabis.—

679 (7) EXCEPTIONS TO OTHER LAWS.—

680 (b) Notwithstanding s. 893.13, s. 893.135, s. 893.147, or
 681 any other provision of law, but subject to the requirements of
 682 this section, an approved dispensing organization and its
 683 owners, managers, and employees may manufacture, possess, sell,
 684 deliver, distribute, dispense, and lawfully dispose of
 685 reasonable quantities, as established by department rule, of
 686 low-THC cannabis. For purposes of this subsection, the terms
 687 "manufacture," "possession," "deliver," "distribute," and
 688 "dispense" have the same meanings as provided in s. 893.02.

689 Section 25. For the purpose of incorporating the amendment
 690 made by this act to section 893.02, Florida Statutes, in a
 691 reference thereto, paragraph (1) of subsection (1) of section
 692 440.102, Florida Statutes, is reenacted to read:

693 440.102 Drug-free workplace program requirements.—The
 694 following provisions apply to a drug-free workplace program
 695 implemented pursuant to law or to rules adopted by the Agency
 696 for Health Care Administration:

697 (1) DEFINITIONS.—Except where the context otherwise
 698 requires, as used in this act:

699 (1) "Prescription or nonprescription medication" means a
 700 drug or medication obtained pursuant to a prescription as
 701 defined by s. 893.02 or a medication that is authorized pursuant
 702 to federal or state law for general distribution and use without



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703 a prescription in the treatment of human diseases, ailments, or
704 injuries.

705 Section 26. For the purpose of incorporating the amendment
706 made by this act to section 893.02, Florida Statutes, in a
707 reference thereto, subsection (14) of section 499.0121, Florida
708 Statutes, is reenacted to read:

709 499.0121 Storage and handling of prescription drugs;
710 recordkeeping.—The department shall adopt rules to implement
711 this section as necessary to protect the public health, safety,
712 and welfare. Such rules shall include, but not be limited to,
713 requirements for the storage and handling of prescription drugs
714 and for the establishment and maintenance of prescription drug
715 distribution records.

716 (14) DISTRIBUTION REPORTING.—Each prescription drug
717 wholesale distributor, out-of-state prescription drug wholesale
718 distributor, retail pharmacy drug wholesale distributor,
719 manufacturer, or repackager that engages in the wholesale
720 distribution of controlled substances as defined in s. 893.02
721 shall submit a report to the department of its receipts and
722 distributions of controlled substances listed in Schedule II,
723 Schedule III, Schedule IV, or Schedule V as provided in s.
724 893.03. Wholesale distributor facilities located within this
725 state shall report all transactions involving controlled
726 substances, and wholesale distributor facilities located outside
727 this state shall report all distributions to entities located in
728 this state. If the prescription drug wholesale distributor, out-



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729 of-state prescription drug wholesale distributor, retail
730 pharmacy drug wholesale distributor, manufacturer, or repackager
731 does not have any controlled substance distributions for the
732 month, a report shall be sent indicating that no distributions
733 occurred in the period. The report shall be submitted monthly by
734 the 20th of the next month, in the electronic format used for
735 controlled substance reporting to the Automation of Reports and
736 Consolidated Orders System division of the federal Drug
737 Enforcement Administration. Submission of electronic data must
738 be made in a secured Internet environment that allows for manual
739 or automated transmission. Upon successful transmission, an
740 acknowledgment page must be displayed to confirm receipt. The
741 report must contain the following information:

742 (a) The federal Drug Enforcement Administration
743 registration number of the wholesale distributing location.

744 (b) The federal Drug Enforcement Administration
745 registration number of the entity to which the drugs are
746 distributed or from which the drugs are received.

747 (c) The transaction code that indicates the type of
748 transaction.

749 (d) The National Drug Code identifier of the product and
750 the quantity distributed or received.

751 (e) The Drug Enforcement Administration Form 222 number or
752 Controlled Substance Ordering System Identifier on all Schedule
753 II transactions.

754 (f) The date of the transaction.



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755
756 The department must share the reported data with the Department
757 of Law Enforcement and local law enforcement agencies upon
758 request and must monitor purchasing to identify purchasing
759 levels that are inconsistent with the purchasing entity's
760 clinical needs. The Department of Law Enforcement shall
761 investigate purchases at levels that are inconsistent with the
762 purchasing entity's clinical needs to determine whether
763 violations of chapter 893 have occurred.

764 Section 27. For the purpose of incorporating the amendment
765 made by this act to section 893.02, Florida Statutes, in a
766 reference thereto, paragraph (b) of subsection (1) of section
767 768.36, Florida Statutes, is reenacted to read:

768 768.36 Alcohol or drug defense.—

769 (1) As used in this section, the term:

770 (b) "Drug" means any chemical substance set forth in s.
771 877.111 or any substance controlled under chapter 893. The term
772 does not include any drug or medication obtained pursuant to a
773 prescription as defined in s. 893.02 which was taken in
774 accordance with the prescription, or any medication that is
775 authorized under state or federal law for general distribution
776 and use without a prescription in treating human diseases,
777 ailments, or injuries and that was taken in the recommended
778 dosage.

779 Section 28. For the purpose of incorporating the amendment
780 made by this act to section 893.02, Florida Statutes, in a



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781 reference thereto, paragraph (f) of subsection (3) of section
782 810.02, Florida Statutes, is reenacted to read:

783 810.02 Burglary.—

784 (3) Burglary is a felony of the second degree, punishable
785 as provided in s. 775.082, s. 775.083, or s. 775.084, if, in the
786 course of committing the offense, the offender does not make an
787 assault or battery and is not and does not become armed with a
788 dangerous weapon or explosive, and the offender enters or
789 remains in a:

790 (f) Structure or conveyance when the offense intended to
791 be committed therein is theft of a controlled substance as
792 defined in s. 893.02. Notwithstanding any other law, separate
793 judgments and sentences for burglary with the intent to commit
794 theft of a controlled substance under this paragraph and for any
795 applicable possession of controlled substance offense under s.
796 893.13 or trafficking in controlled substance offense under s.
797 893.135 may be imposed when all such offenses involve the same
798 amount or amounts of a controlled substance.

799
800 However, if the burglary is committed within a county that is
801 subject to a state of emergency declared by the Governor under
802 chapter 252 after the declaration of emergency is made and the
803 perpetration of the burglary is facilitated by conditions
804 arising from the emergency, the burglary is a felony of the
805 first degree, punishable as provided in s. 775.082, s. 775.083,
806 or s. 775.084. As used in this subsection, the term "conditions



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807 arising from the emergency" means civil unrest, power outages,
 808 curfews, voluntary or mandatory evacuations, or a reduction in
 809 the presence of or response time for first responders or
 810 homeland security personnel. A person arrested for committing a
 811 burglary within a county that is subject to such a state of
 812 emergency may not be released until the person appears before a
 813 committing magistrate at a first appearance hearing. For
 814 purposes of sentencing under chapter 921, a felony offense that
 815 is reclassified under this subsection is ranked one level above
 816 the ranking under s. 921.0022 or s. 921.0023 of the offense
 817 committed.

818 Section 29. For the purpose of incorporating the amendment
 819 made by this act to section 893.02, Florida Statutes, in a
 820 reference thereto, paragraph (c) of subsection (2) of section
 821 812.014, Florida Statutes, is reenacted to read:

822 812.014 Theft.—

823 (2)

824 (c) It is grand theft of the third degree and a felony of
 825 the third degree, punishable as provided in s. 775.082, s.
 826 775.083, or s. 775.084, if the property stolen is:

- 827 1. Valued at \$300 or more, but less than \$5,000.
- 828 2. Valued at \$5,000 or more, but less than \$10,000.
- 829 3. Valued at \$10,000 or more, but less than \$20,000.
- 830 4. A will, codicil, or other testamentary instrument.
- 831 5. A firearm.
- 832 6. A motor vehicle, except as provided in paragraph (a).



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833 7. Any commercially farmed animal, including any animal of
834 the equine, bovine, or swine class or other grazing animal; a
835 bee colony of a registered beekeeper; and aquaculture species
836 raised at a certified aquaculture facility. If the property
837 stolen is aquaculture species raised at a certified aquaculture
838 facility, then a \$10,000 fine shall be imposed.

839 8. Any fire extinguisher.

840 9. Any amount of citrus fruit consisting of 2,000 or more
841 individual pieces of fruit.

842 10. Taken from a designated construction site identified
843 by the posting of a sign as provided for in s. 810.09(2)(d).

844 11. Any stop sign.

845 12. Anhydrous ammonia.

846 13. Any amount of a controlled substance as defined in s.
847 893.02. Notwithstanding any other law, separate judgments and
848 sentences for theft of a controlled substance under this
849 subparagraph and for any applicable possession of controlled
850 substance offense under s. 893.13 or trafficking in controlled
851 substance offense under s. 893.135 may be imposed when all such
852 offenses involve the same amount or amounts of a controlled
853 substance.

854

855 However, if the property is stolen within a county that is
856 subject to a state of emergency declared by the Governor under
857 chapter 252, the property is stolen after the declaration of
858 emergency is made, and the perpetration of the theft is



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859 facilitated by conditions arising from the emergency, the
860 offender commits a felony of the second degree, punishable as
861 provided in s. 775.082, s. 775.083, or s. 775.084, if the
862 property is valued at \$5,000 or more, but less than \$10,000, as
863 provided under subparagraph 2., or if the property is valued at
864 \$10,000 or more, but less than \$20,000, as provided under
865 subparagraph 3. As used in this paragraph, the term "conditions
866 arising from the emergency" means civil unrest, power outages,
867 curfews, voluntary or mandatory evacuations, or a reduction in
868 the presence of or the response time for first responders or
869 homeland security personnel. For purposes of sentencing under
870 chapter 921, a felony offense that is reclassified under this
871 paragraph is ranked one level above the ranking under s.
872 921.0022 or s. 921.0023 of the offense committed.

873 Section 30. For the purpose of incorporating the amendment
874 made by this act to section 893.02, Florida Statutes, in a
875 reference thereto, paragraph (c) of subsection (1) of section
876 856.015, Florida Statutes, is reenacted to read:

877 856.015 Open house parties.—

878 (1) Definitions.—As used in this section:

879 (c) "Drug" means a controlled substance, as that term is
880 defined in ss. 893.02(4) and 893.03.

881 Section 31. For the purpose of incorporating the amendment
882 made by this act to section 893.02, Florida Statutes, in a
883 reference thereto, paragraph (a) of subsection (1) of section
884 944.47, Florida Statutes, is reenacted to read:



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885 944.47 Introduction, removal, or possession of certain
886 articles unlawful; penalty.—

887 (1) (a) Except through regular channels as authorized by
888 the officer in charge of the correctional institution, it is
889 unlawful to introduce into or upon the grounds of any state
890 correctional institution, or to take or attempt to take or send
891 or attempt to send therefrom, any of the following articles
892 which are hereby declared to be contraband for the purposes of
893 this section, to wit:

894 1. Any written or recorded communication or any currency
895 or coin given or transmitted, or intended to be given or
896 transmitted, to any inmate of any state correctional
897 institution.

898 2. Any article of food or clothing given or transmitted,
899 or intended to be given or transmitted, to any inmate of any
900 state correctional institution.

901 3. Any intoxicating beverage or beverage which causes or
902 may cause an intoxicating effect.

903 4. Any controlled substance as defined in s. 893.02(4) or
904 any prescription or nonprescription drug having a hypnotic,
905 stimulating, or depressing effect.

906 5. Any firearm or weapon of any kind or any explosive
907 substance.

908 6. Any cellular telephone or other portable communication
909 device intentionally and unlawfully introduced inside the secure
910 perimeter of any state correctional institution without prior



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911 authorization or consent from the officer in charge of such
912 correctional institution. As used in this subparagraph, the term
913 "portable communication device" means any device carried, worn,
914 or stored which is designed or intended to receive or transmit
915 verbal or written messages, access or store data, or connect
916 electronically to the Internet or any other electronic device
917 and which allows communications in any form. Such devices
918 include, but are not limited to, portable two-way pagers, hand-
919 held radios, cellular telephones, Blackberry-type devices,
920 personal digital assistants or PDA's, laptop computers, or any
921 components of these devices which are intended to be used to
922 assemble such devices. The term also includes any new technology
923 that is developed for similar purposes. Excluded from this
924 definition is any device having communication capabilities which
925 has been approved or issued by the department for investigative
926 or institutional security purposes or for conducting other state
927 business.

928 Section 32. For the purpose of incorporating the amendment
929 made by this act to section 893.02, Florida Statutes, in a
930 reference thereto, subsection (1) of section 951.22, Florida
931 Statutes, is reenacted to read:

932 951.22 County detention facilities; contraband articles.-

933 (1) It is unlawful, except through regular channels as
934 duly authorized by the sheriff or officer in charge, to
935 introduce into or possess upon the grounds of any county
936 detention facility as defined in s. 951.23 or to give to or



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937 receive from any inmate of any such facility wherever said
938 inmate is located at the time or to take or to attempt to take
939 or send therefrom any of the following articles which are hereby
940 declared to be contraband for the purposes of this act, to wit:
941 Any written or recorded communication; any currency or coin; any
942 article of food or clothing; any tobacco products as defined in
943 s. 210.25(11); any cigarette as defined in s. 210.01(1); any
944 cigar; any intoxicating beverage or beverage which causes or may
945 cause an intoxicating effect; any narcotic, hypnotic, or
946 excitative drug or drug of any kind or nature, including nasal
947 inhalators, sleeping pills, barbiturates, and controlled
948 substances as defined in s. 893.02(4); any firearm or any
949 instrumentality customarily used or which is intended to be used
950 as a dangerous weapon; and any instrumentality of any nature
951 that may be or is intended to be used as an aid in effecting or
952 attempting to effect an escape from a county facility.

953 Section 33. For the purpose of incorporating the amendment
954 made by this act to section 893.02, Florida Statutes, in a
955 reference thereto, paragraph (a) of subsection (1) of section
956 985.711, Florida Statutes, is reenacted to read:

957 985.711 Introduction, removal, or possession of certain
958 articles unlawful; penalty.—

959 (1) (a) Except as authorized through program policy or
960 operating procedure or as authorized by the facility
961 superintendent, program director, or manager, a person may not
962 introduce into or upon the grounds of a juvenile detention



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963 facility or commitment program, or take or send, or attempt to
 964 take or send, from a juvenile detention facility or commitment
 965 program, any of the following articles, which are declared to be
 966 contraband under this section:

- 967 1. Any unauthorized article of food or clothing.
- 968 2. Any intoxicating beverage or any beverage that causes
 969 or may cause an intoxicating effect.
- 970 3. Any controlled substance, as defined in s. 893.02(4),
 971 or any prescription or nonprescription drug that has a hypnotic,
 972 stimulating, or depressing effect.
- 973 4. Any firearm or weapon of any kind or any explosive
 974 substance.

975 Section 34. For the purpose of incorporating the amendment
 976 made by this act to section 893.02, Florida Statutes, in a
 977 reference thereto, paragraph (i) of subsection (1) of section
 978 1003.57, Florida Statutes, is reenacted to read:

979 1003.57 Exceptional students instruction.—

980 (1)

981 (i) For purposes of paragraph (h), the term:

982 1. "Controlled substance" means a drug or other substance
 983 identified under Schedule I, Schedule II, Schedule III, Schedule
 984 IV, or Schedule V of the Controlled Substances Act, 21 U.S.C. s.
 985 812(c) and s. 893.02(4).

986 2. "Weapon" means a device, instrument, material, or
 987 substance, animate or inanimate, which is used for, or is
 988 readily capable of, causing death or serious bodily injury;



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989 | however, this definition does not include a pocketknife having a
990 | blade that is less than 2 1/2 inches in length.

991 | Section 35. For the purpose of incorporating the amendment
992 | made by this act to section 893.02, Florida Statutes, in a
993 | reference thereto, subsection (8) of section 1006.09, Florida
994 | Statutes, is reenacted to read:

995 | 1006.09 Duties of school principal relating to student
996 | discipline and school safety.—

997 | (8) The school principal shall require all school
998 | personnel to report to the principal or principal's designee any
999 | suspected unlawful use, possession, or sale by a student of any
1000 | controlled substance, as defined in s. 893.02; any counterfeit
1001 | controlled substance, as defined in s. 831.31; any alcoholic
1002 | beverage, as defined in s. 561.01(4); or model glue. School
1003 | personnel are exempt from civil liability when reporting in good
1004 | faith to the proper school authority such suspected unlawful
1005 | use, possession, or sale by a student. Only a principal or
1006 | principal's designee is authorized to contact a parent or legal
1007 | guardian of a student regarding this situation. Reports made and
1008 | verified under this subsection shall be forwarded to an
1009 | appropriate agency. The principal or principal's designee shall
1010 | timely notify the student's parent that a verified report made
1011 | under this subsection with respect to the student has been made
1012 | and forwarded.

1013 | Section 36. For the purpose of incorporating the
1014 | amendments made by this act to sections 893.04 and 893.05,



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1015 Florida Statutes, in references thereto, paragraphs (d) and (e)
1016 of subsection (3) of section 893.0551, Florida Statutes, are
1017 reenacted to read:

1018 893.0551 Public records exemption for the prescription
1019 drug monitoring program.—

1020 (3) The department shall disclose such confidential and
1021 exempt information to the following persons or entities upon
1022 request and after using a verification process to ensure the
1023 legitimacy of the request as provided in s. 893.055:

1024 (d) A health care practitioner who certifies that the
1025 information is necessary to provide medical treatment to a
1026 current patient in accordance with ss. 893.05 and 893.055.

1027 (e) A pharmacist who certifies that the requested
1028 information will be used to dispense controlled substances to a
1029 current patient in accordance with ss. 893.04 and 893.055.

1030 Section 37. This act shall take effect July 1, 2016.

U.S. Food and Drug Administration
Protecting and Promoting *Your* Health

FDA News Release

FDA moves quickly to approve easy-to-use nasal spray to treat opioid overdose

Naloxone in nasal spray form provides important new alternative for family members, first responders

For Immediate Release

November 18, 2015

Release

Today the U.S. Food and Drug Administration approved Narcan nasal spray, the first FDA-approved nasal spray version of naloxone hydrochloride, a life-saving medication that can stop or reverse the effects of an opioid overdose. Opioids are a class of drugs that include prescription medications such as oxycodone, hydrocodone, and morphine, as well as the illegal drug heroin.

Drug overdose deaths, driven largely by prescription drug overdoses, are now the leading cause of injury death in the United States – surpassing **motor vehicle crashes (<http://www-nrd.nhtsa.dot.gov/PUBS/812196.pdf>)**. In 2013, the Centers for Disease Control and Prevention **reported (<http://www.cdc.gov/drugoverdose/data/overdose.html>)** the number of drug overdose deaths had steadily increased for more than a decade. When someone overdoses on an opioid, it can be difficult to awaken the person, and breathing may become shallow or stop – leading to death if there is no medical intervention. If naloxone is administered quickly, it can counter the overdose effects, usually within two minutes.

“Combating the opioid abuse epidemic is a top priority for the FDA,” said Stephen Ostroff, M.D., acting commissioner, Food and Drug Administration. “We cannot stand by while Americans are dying. While naloxone will not solve the underlying problems of the opioid epidemic, we are speeding to review new formulations that will ultimately save lives that might otherwise be lost to drug addiction and overdose.”

Until this approval, naloxone was only approved in **[injectable forms, most commonly delivered by syringe or auto-injector \(https://www.nlm.nih.gov/medlineplus/drugin-fo/meds/a612022.html\)](https://www.nlm.nih.gov/medlineplus/drugin-fo/meds/a612022.html)**. Many first responders and primary caregivers, however, feel a nasal spray formulation of naloxone is easier to deliver, and eliminates the risk of a contaminated needle stick. As a result, there has been widespread use of unapproved naloxone kits that combine an

injectable formulation of naloxone with an atomizer that can deliver naloxone nasally. Now, people have access to an FDA-approved product for which the drug and its delivery device have met the FDA's high standards for safety, efficacy and quality.

Narcan nasal spray does not require assembly and delivers a consistent, measured dose when used as directed. This prescription product can be used on adults or children and is easily administered by anyone, even those without medical training. The drug is sprayed into one nostril while the patient is lying on his or her back, and can be repeated if necessary. However, it is important to note that it is not a substitute for immediate medical care, and the person administering Narcan nasal spray should seek further immediate medical attention on the patient's behalf.

The FDA granted **[fast-track \(http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm\)](http://www.fda.gov/ForPatients/Approvals/Fast/ucm405399.htm)** designation and **[priority review \(http://www.fda.gov/forpatients/approvals/fast/ucm405405.htm\)](http://www.fda.gov/forpatients/approvals/fast/ucm405405.htm)** for Narcan nasal spray. Fast track is a process designed to facilitate development and expedite review of drugs intended to treat serious conditions and that demonstrate the potential to address an unmet medical need. The agency's priority review program provides for an expedited review of drugs that offer a significant improvement in the safety or effectiveness of the treatment, prevention, or diagnosis of a serious condition. Narcan nasal spray is being approved in less than four months, significantly ahead of the product's prescription drug user fee goal date of January 20, 2016.

In clinical trials conducted to support the approval of Narcan nasal spray, administering the drug in one nostril delivered approximately the same levels or higher of naloxone as a single dose of an FDA-approved naloxone intramuscular injection, and achieved these levels in approximately the same time frame.

"We heard the public call for this new route of administration, and we are happy to have been able to move so quickly on a product we are confident will deliver consistently adequate levels of the medication – a critical attribute for this emergency life-saving drug," said Janet Woodcock, M.D., director of the FDA's Center for Drug Evaluation and Research.

The **[National Institute on Drug Abuse \(http://www.drugabuse.gov/\)](http://www.drugabuse.gov/)** played a critical role in the development of Narcan nasal spray as well, forming a public-private partnership by designing and conducting the clinical trials required to determine that the intranasal formulation delivered naloxone as quickly and as effectively as an injection. NIDA then worked with its private sector partners to obtain FDA approval.

"This easy-to-use intranasal formulation will no doubt save many lives," said Nora Volkow, M.D., director, National Institute on Drug Abuse at the National Institutes of Health. "While prevention is the ultimate goal, the drug's successful development illustrates how public/private scientific partnerships can play an important role in responding to a national crisis right now."

Increasing access to and the use of naloxone is part of the **[targeted strategy \(http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html\)](http://www.hhs.gov/about/news/2015/03/26/hhs-takes-strong-steps-to-address-opioid-drug-related-overdose-death-and-dependence.html)** that Health and Human Services Secretary Sylvia M. Burwell put forward in March to address the opioid epidemic and save lives. In July, addiction and advocacy groups called for expanded availability of naloxone during an **[FDA-sponsored public workshop \(http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm\)](http://www.fda.gov/Drugs/NewsEvents/ucm442236.htm)** exploring the uptake and use of the drug.

The use of Narcan nasal spray in patients who are **opioid dependent** (<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2851054/>) may result in severe opioid withdrawal characterized by body aches, diarrhea, increased heart rate (tachycardia), fever, runny nose, sneezing, goose bumps (piloerection), sweating, yawning, nausea or vomiting, nervousness, restlessness or irritability, shivering or trembling, abdominal cramps, weakness, and increased blood pressure.







Narcan nasal spray is distributed by Adapt Pharma, Inc., of Radnor, Pennsylvania.

The FDA, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products.

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Related Information
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1
2 An act relating to access to health care services;
3 amending s. 110.12315, F.S.; expanding the categories
4 of persons who may prescribe brand name drugs under
5 the prescription drug program when medically
6 necessary; amending ss. 310.071, 310.073, and 310.081,
7 F.S.; exempting controlled substances prescribed by an
8 advanced registered nurse practitioner or a physician
9 assistant from the disqualifications for certification
10 or licensure, and for continued certification or
11 licensure, as a deputy pilot or state pilot; amending
12 s. 456.072, F.S.; applying existing penalties for
13 violations relating to the prescribing or dispensing
14 of controlled substances by an advanced registered
15 nurse practitioner; amending s. 456.44, F.S.; defining
16 the term "registrant"; deleting an obsolete date;
17 requiring advanced registered nurse practitioners and
18 physician assistants who prescribe controlled
19 substances for the treatment of certain pain to make a
20 certain designation, comply with registration
21 requirements, and follow specified standards of
22 practice; providing applicability; amending ss.
23 458.3265 and 459.0137, F.S.; limiting the authority to
24 prescribe a controlled substance in a pain-management
25 clinic only to a physician licensed under ch. 458 or
26 ch. 459, F.S.; amending s. 458.347, F.S.; revising the



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27 | required continuing education requirements for a
28 | physician assistant; requiring that a specified
29 | formulary limit the prescription of certain controlled
30 | substances by physician assistants as of a specified
31 | date; amending s. 464.003, F.S.; revising the term
32 | "advanced or specialized nursing practice"; deleting
33 | the joint committee established in the definition;
34 | amending s. 464.012, F.S.; requiring the Board of
35 | Nursing to establish a committee to recommend a
36 | formulary of controlled substances that may not be
37 | prescribed, or may be prescribed only on a limited
38 | basis, by an advanced registered nurse practitioner;
39 | specifying the membership of the committee; providing
40 | parameters for the formulary; requiring that the
41 | formulary be adopted by board rule; specifying the
42 | process for amending the formulary and imposing a
43 | burden of proof; limiting the formulary's application
44 | in certain instances; requiring the board to adopt the
45 | committee's initial recommendations by a specified
46 | date; providing a short title; authorizing an advanced
47 | registered nurse practitioner to prescribe, dispense,
48 | administer, or order drugs, including certain
49 | controlled substances under certain circumstances, as
50 | of a specified date; amending s. 464.013, F.S.;
51 | revising continuing education requirements for renewal
52 | of a license or certificate; amending s. 464.018,



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53 F.S.; specifying acts that constitute grounds for
54 denial of a license or for disciplinary action against
55 an advanced registered nurse practitioner; creating s.
56 627.42392, F.S.; defining the term "health insurer";
57 requiring that certain health insurers that do not
58 already use a certain form use only a prior
59 authorization form approved by the Financial Services
60 Commission in consultation with the Agency for Health
61 Care Administration; requiring the commission in
62 consultation with the agency to adopt by rule
63 guidelines for such forms; providing that prior-
64 authorization approvals do not preclude certain
65 benefit verifications or medical reviews; amending s.
66 766.1115, F.S.; revising the definition of the term
67 "contract"; amending s. 893.02, F.S.; revising the
68 term "practitioner" to include advanced registered
69 nurse practitioners and physician assistants under the
70 Florida Comprehensive Drug Abuse Prevention and
71 Control Act if a certain requirement is met; amending
72 s. 948.03, F.S.; providing that possession of drugs or
73 narcotics prescribed by an advanced registered nurse
74 practitioner or a physician assistant does not violate
75 a prohibition relating to the possession of drugs or
76 narcotics during probation; amending ss. 458.348 and
77 459.025, F.S.; conforming provisions to changes made
78 by the act; reenacting ss. 458.331(10), 458.347(7)(g),



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79 459.015(10), 459.022(7)(f), and 465.0158(5)(b), F.S.,
 80 to incorporate the amendment made to s. 456.072, F.S.,
 81 in references thereto; reenacting ss. 456.072(1)(mm)
 82 and 466.02751, F.S., to incorporate the amendment made
 83 to s. 456.44, F.S., in references thereto; reenacting
 84 ss. 458.303, 458.3475(7)(b), 459.022(4)(e) and (9)(c),
 85 and 459.023(7)(b), F.S., to incorporate the amendment
 86 made to s. 458.347, F.S., in references thereto;
 87 reenacting s. 464.012(3)(c), F.S., to incorporate the
 88 amendment made to s. 464.003, F.S., in a reference
 89 thereto; reenacting ss. 456.041(1)(a), 458.348(1) and
 90 (2), and 459.025(1), F.S., to incorporate the
 91 amendment made to s. 464.012, F.S., in references
 92 thereto; reenacting s. 464.0205(7), F.S., to
 93 incorporate the amendment made to s. 464.013, F.S., in
 94 a reference thereto; reenacting ss. 320.0848(11),
 95 464.008(2), 464.009(5), and 464.0205(1)(b), (3), and
 96 (4)(b), F.S., to incorporate the amendment made to s.
 97 464.018, F.S., in references thereto; reenacting s.
 98 775.051, F.S., to incorporate the amendment made to s.
 99 893.02, F.S., in a reference thereto; reenacting ss.
 100 944.17(3)(a), 948.001(8), and 948.101(1)(e), F.S., to
 101 incorporate the amendment made to s. 948.03, F.S., in
 102 references thereto; providing effective dates.

103
 104 Be It Enacted by the Legislature of the State of Florida:



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Section 1. Subsection (7) of section 110.12315, Florida Statutes, is amended to read:

110.12315 Prescription drug program.—The state employees' prescription drug program is established. This program shall be administered by the Department of Management Services, according to the terms and conditions of the plan as established by the relevant provisions of the annual General Appropriations Act and implementing legislation, subject to the following conditions:

(7) The department shall establish the reimbursement schedule for prescription pharmaceuticals dispensed under the program. Reimbursement rates for a prescription pharmaceutical must be based on the cost of the generic equivalent drug if a generic equivalent exists, unless the physician, advanced registered nurse practitioner, or physician assistant prescribing the pharmaceutical clearly states on the prescription that the brand name drug is medically necessary or that the drug product is included on the formulary of drug products that may not be interchanged as provided in chapter 465, in which case reimbursement must be based on the cost of the brand name drug as specified in the reimbursement schedule adopted by the department.

Section 2. Paragraph (c) of subsection (1) of section 310.071, Florida Statutes, is amended, and subsection (3) of that section is republished, to read:

310.071 Deputy pilot certification.—



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131 (1) In addition to meeting other requirements specified in
 132 this chapter, each applicant for certification as a deputy pilot
 133 must:

134 (c) Be in good physical and mental health, as evidenced by
 135 documentary proof of having satisfactorily passed a complete
 136 physical examination administered by a licensed physician within
 137 the preceding 6 months. The board shall adopt rules to establish
 138 requirements for passing the physical examination, which rules
 139 shall establish minimum standards for the physical or mental
 140 capabilities necessary to carry out the professional duties of a
 141 certificated deputy pilot. Such standards shall include zero
 142 tolerance for any controlled substance regulated under chapter
 143 893 unless that individual is under the care of a physician, an
 144 advanced registered nurse practitioner, or a physician assistant
 145 and that controlled substance was prescribed by that physician,
 146 advanced registered nurse practitioner, or physician assistant.

147 To maintain eligibility as a certificated deputy pilot, each
 148 certificated deputy pilot must annually provide documentary
 149 proof of having satisfactorily passed a complete physical
 150 examination administered by a licensed physician. The physician
 151 must know the minimum standards and certify that the
 152 certificateholder satisfactorily meets the standards. The
 153 standards for certificateholders shall include a drug test.

154 (3) The initial certificate issued to a deputy pilot shall
 155 be valid for a period of 12 months, and at the end of this
 156 period, the certificate shall automatically expire and shall not



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157 | be renewed. During this period, the board shall thoroughly
158 | evaluate the deputy pilot's performance for suitability to
159 | continue training and shall make appropriate recommendations to
160 | the department. Upon receipt of a favorable recommendation by
161 | the board, the department shall issue a certificate to the
162 | deputy pilot, which shall be valid for a period of 2 years. The
163 | certificate may be renewed only two times, except in the case of
164 | a fully licensed pilot who is cross-licensed as a deputy pilot
165 | in another port, and provided the deputy pilot meets the
166 | requirements specified for pilots in paragraph (1)(c).

167 | Section 3. Subsection (3) of section 310.073, Florida
168 | Statutes, is amended to read:

169 | 310.073 State pilot licensing.—In addition to meeting
170 | other requirements specified in this chapter, each applicant for
171 | license as a state pilot must:

172 | (3) Be in good physical and mental health, as evidenced by
173 | documentary proof of having satisfactorily passed a complete
174 | physical examination administered by a licensed physician within
175 | the preceding 6 months. The board shall adopt rules to establish
176 | requirements for passing the physical examination, which rules
177 | shall establish minimum standards for the physical or mental
178 | capabilities necessary to carry out the professional duties of a
179 | licensed state pilot. Such standards shall include zero
180 | tolerance for any controlled substance regulated under chapter
181 | 893 unless that individual is under the care of a physician, an
182 | advanced registered nurse practitioner, or a physician assistant



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183 and that controlled substance was prescribed by that physician,
 184 advanced registered nurse practitioner, or physician assistant.
 185 To maintain eligibility as a licensed state pilot, each licensed
 186 state pilot must annually provide documentary proof of having
 187 satisfactorily passed a complete physical examination
 188 administered by a licensed physician. The physician must know
 189 the minimum standards and certify that the licensee
 190 satisfactorily meets the standards. The standards for licensees
 191 shall include a drug test.

192 Section 4. Paragraph (b) of subsection (3) of section
 193 310.081, Florida Statutes, is amended to read:

194 310.081 Department to examine and license state pilots and
 195 certificate deputy pilots; vacancies.—

196 (3) Pilots shall hold their licenses or certificates
 197 pursuant to the requirements of this chapter so long as they:

198 (b) Are in good physical and mental health as evidenced by
 199 documentary proof of having satisfactorily passed a physical
 200 examination administered by a licensed physician or physician
 201 assistant within each calendar year. The board shall adopt rules
 202 to establish requirements for passing the physical examination,
 203 which rules shall establish minimum standards for the physical
 204 or mental capabilities necessary to carry out the professional
 205 duties of a licensed state pilot or a certificated deputy pilot.
 206 Such standards shall include zero tolerance for any controlled
 207 substance regulated under chapter 893 unless that individual is
 208 under the care of a physician, an advanced registered nurse



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209 practitioner, or a physician assistant and that controlled
 210 substance was prescribed by that physician, advanced registered
 211 nurse practitioner, or physician assistant. To maintain
 212 eligibility as a certificated deputy pilot or licensed state
 213 pilot, each certificated deputy pilot or licensed state pilot
 214 must annually provide documentary proof of having satisfactorily
 215 passed a complete physical examination administered by a
 216 licensed physician. The physician must know the minimum
 217 standards and certify that the certificateholder or licensee
 218 satisfactorily meets the standards. The standards for
 219 certificateholders and for licensees shall include a drug test.

220
 221 Upon resignation or in the case of disability permanently
 222 affecting a pilot's ability to serve, the state license or
 223 certificate issued under this chapter shall be revoked by the
 224 department.

225 Section 5. Subsection (7) of section 456.072, Florida
 226 Statutes, is amended to read:

227 456.072 Grounds for discipline; penalties; enforcement.—

228 (7) Notwithstanding subsection (2), upon a finding that a
 229 physician has prescribed or dispensed a controlled substance, or
 230 caused a controlled substance to be prescribed or dispensed, in
 231 a manner that violates the standard of practice set forth in s.
 232 458.331(1)(q) or (t), s. 459.015(1)(t) or (x), s. 461.013(1)(o)
 233 or (s), or s. 466.028(1)(p) or (x), or that an advanced
 234 registered nurse practitioner has prescribed or dispensed a



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235 controlled substance, or caused a controlled substance to be
236 prescribed or dispensed, in a manner that violates the standard
237 of practice set forth in s. 464.018(1)(n) or (p)6., the
238 physician or advanced registered nurse practitioner shall be
239 suspended for a period of not less than 6 months and pay a fine
240 of not less than \$10,000 per count. Repeated violations shall
241 result in increased penalties.

242 Section 6. Section 456.44, Florida Statutes, is amended to
243 read:

244 456.44 Controlled substance prescribing.—

245 (1) DEFINITIONS.—As used in this section, the term:

246 (a) "Addiction medicine specialist" means a board-
247 certified psychiatrist with a subspecialty certification in
248 addiction medicine or who is eligible for such subspecialty
249 certification in addiction medicine, an addiction medicine
250 physician certified or eligible for certification by the
251 American Society of Addiction Medicine, or an osteopathic
252 physician who holds a certificate of added qualification in
253 Addiction Medicine through the American Osteopathic Association.

254 (b) "Adverse incident" means any incident set forth in s.
255 458.351(4)(a)-(e) or s. 459.026(4)(a)-(e).

256 (c) "Board-certified pain management physician" means a
257 physician who possesses board certification in pain medicine by
258 the American Board of Pain Medicine, board certification by the
259 American Board of Interventional Pain Physicians, or board
260 certification or subcertification in pain management or pain



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261 medicine by a specialty board recognized by the American
262 Association of Physician Specialists or the American Board of
263 Medical Specialties or an osteopathic physician who holds a
264 certificate in Pain Management by the American Osteopathic
265 Association.

266 (d) "Board eligible" means successful completion of an
267 anesthesia, physical medicine and rehabilitation, rheumatology,
268 or neurology residency program approved by the Accreditation
269 Council for Graduate Medical Education or the American
270 Osteopathic Association for a period of 6 years from successful
271 completion of such residency program.

272 (e) "Chronic nonmalignant pain" means pain unrelated to
273 cancer which persists beyond the usual course of disease or the
274 injury that is the cause of the pain or more than 90 days after
275 surgery.

276 (f) "Mental health addiction facility" means a facility
277 licensed under chapter 394 or chapter 397.

278 (g) "Registrant" means a physician, a physician assistant,
279 or an advanced registered nurse practitioner who meets the
280 requirements of subsection (2).

281 (2) REGISTRATION. ~~Effective January 1, 2012,~~ A physician
282 licensed under chapter 458, chapter 459, chapter 461, or chapter
283 466, a physician assistant licensed under chapter 458 or chapter
284 459, or an advanced registered nurse practitioner certified
285 under part I of chapter 464 who prescribes any controlled
286 substance, listed in Schedule II, Schedule III, or Schedule IV



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287 as defined in s. 893.03, for the treatment of chronic
288 nonmalignant pain, must:

289 (a) Designate himself or herself as a controlled substance
290 prescribing practitioner on his or her ~~the physician's~~
291 practitioner profile.

292 (b) Comply with the requirements of this section and
293 applicable board rules.

294 (3) STANDARDS OF PRACTICE.—The standards of practice in
295 this section do not supersede the level of care, skill, and
296 treatment recognized in general law related to health care
297 licensure.

298 (a) A complete medical history and a physical examination
299 must be conducted before beginning any treatment and must be
300 documented in the medical record. The exact components of the
301 physical examination shall be left to the judgment of the
302 registrant ~~clinician~~ who is expected to perform a physical
303 examination proportionate to the diagnosis that justifies a
304 treatment. The medical record must, at a minimum, document the
305 nature and intensity of the pain, current and past treatments
306 for pain, underlying or coexisting diseases or conditions, the
307 effect of the pain on physical and psychological function, a
308 review of previous medical records, previous diagnostic studies,
309 and history of alcohol and substance abuse. The medical record
310 shall also document the presence of one or more recognized
311 medical indications for the use of a controlled substance. Each
312 registrant must develop a written plan for assessing each



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313 patient's risk of aberrant drug-related behavior, which may
314 include patient drug testing. Registrants must assess each
315 patient's risk for aberrant drug-related behavior and monitor
316 that risk on an ongoing basis in accordance with the plan.

317 (b) Each registrant must develop a written individualized
318 treatment plan for each patient. The treatment plan shall state
319 objectives that will be used to determine treatment success,
320 such as pain relief and improved physical and psychosocial
321 function, and shall indicate if any further diagnostic
322 evaluations or other treatments are planned. After treatment
323 begins, the registrant ~~physician~~ shall adjust drug therapy to
324 the individual medical needs of each patient. Other treatment
325 modalities, including a rehabilitation program, shall be
326 considered depending on the etiology of the pain and the extent
327 to which the pain is associated with physical and psychosocial
328 impairment. The interdisciplinary nature of the treatment plan
329 shall be documented.

330 (c) The registrant ~~physician~~ shall discuss the risks and
331 benefits of the use of controlled substances, including the
332 risks of abuse and addiction, as well as physical dependence and
333 its consequences, with the patient, persons designated by the
334 patient, or the patient's surrogate or guardian if the patient
335 is incompetent. The registrant ~~physician~~ shall use a written
336 controlled substance agreement between the registrant ~~physician~~
337 and the patient outlining the patient's responsibilities,
338 including, but not limited to:



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339 | 1. Number and frequency of controlled substance
340 | prescriptions and refills.

341 | 2. Patient compliance and reasons for which drug therapy
342 | may be discontinued, such as a violation of the agreement.

343 | 3. An agreement that controlled substances for the
344 | treatment of chronic nonmalignant pain shall be prescribed by a
345 | single treating registrant ~~physician~~ unless otherwise authorized
346 | by the treating registrant ~~physician~~ and documented in the
347 | medical record.

348 | (d) The patient shall be seen by the registrant ~~physician~~
349 | at regular intervals, not to exceed 3 months, to assess the
350 | efficacy of treatment, ensure that controlled substance therapy
351 | remains indicated, evaluate the patient's progress toward
352 | treatment objectives, consider adverse drug effects, and review
353 | the etiology of the pain. Continuation or modification of
354 | therapy shall depend on the registrant's ~~physician's~~ evaluation
355 | of the patient's progress. If treatment goals are not being
356 | achieved, despite medication adjustments, the registrant
357 | ~~physician~~ shall reevaluate the appropriateness of continued
358 | treatment. The registrant ~~physician~~ shall monitor patient
359 | compliance in medication usage, related treatment plans,
360 | controlled substance agreements, and indications of substance
361 | abuse or diversion at a minimum of 3-month intervals.

362 | (e) The registrant ~~physician~~ shall refer the patient as
363 | necessary for additional evaluation and treatment in order to
364 | achieve treatment objectives. Special attention shall be given



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365 to those patients who are at risk for misusing their medications
366 and those whose living arrangements pose a risk for medication
367 misuse or diversion. The management of pain in patients with a
368 history of substance abuse or with a comorbid psychiatric
369 disorder requires extra care, monitoring, and documentation and
370 requires consultation with or referral to an addiction medicine
371 specialist or a psychiatrist.

372 (f) A registrant ~~physician registered under this section~~
373 must maintain accurate, current, and complete records that are
374 accessible and readily available for review and comply with the
375 requirements of this section, the applicable practice act, and
376 applicable board rules. The medical records must include, but
377 are not limited to:

- 378 1. The complete medical history and a physical
379 examination, including history of drug abuse or dependence.
- 380 2. Diagnostic, therapeutic, and laboratory results.
- 381 3. Evaluations and consultations.
- 382 4. Treatment objectives.
- 383 5. Discussion of risks and benefits.
- 384 6. Treatments.
- 385 7. Medications, including date, type, dosage, and quantity
386 prescribed.
- 387 8. Instructions and agreements.
- 388 9. Periodic reviews.
- 389 10. Results of any drug testing.
- 390 11. A photocopy of the patient's government-issued photo



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391 identification.

392 12. If a written prescription for a controlled substance
393 is given to the patient, a duplicate of the prescription.

394 13. The registrant's ~~physician's~~ full name presented in a
395 legible manner.

396 (g) A registrant shall immediately refer patients with
397 signs or symptoms of substance abuse ~~shall be immediately~~
398 ~~referred~~ to a board-certified pain management physician, an
399 addiction medicine specialist, or a mental health addiction
400 facility as it pertains to drug abuse or addiction unless the
401 registrant is a physician who is board-certified or board-
402 eligible in pain management. Throughout the period of time
403 before receiving the consultant's report, a prescribing
404 registrant ~~physician~~ shall clearly and completely document
405 medical justification for continued treatment with controlled
406 substances and those steps taken to ensure medically appropriate
407 use of controlled substances by the patient. Upon receipt of the
408 consultant's written report, the prescribing registrant
409 ~~physician~~ shall incorporate the consultant's recommendations for
410 continuing, modifying, or discontinuing controlled substance
411 therapy. The resulting changes in treatment shall be
412 specifically documented in the patient's medical record.
413 Evidence or behavioral indications of diversion shall be
414 followed by discontinuation of controlled substance therapy, and
415 the patient shall be discharged, and all results of testing and
416 actions taken by the registrant ~~physician~~ shall be documented in



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417 the patient's medical record.

418

419 This subsection does not apply to a board-eligible or board-
420 certified anesthesiologist, physiatrist, rheumatologist, or
421 neurologist, or to a board-certified physician who has surgical
422 privileges at a hospital or ambulatory surgery center and
423 primarily provides surgical services. This subsection does not
424 apply to a board-eligible or board-certified medical specialist
425 who has also completed a fellowship in pain medicine approved by
426 the Accreditation Council for Graduate Medical Education or the
427 American Osteopathic Association, or who is board eligible or
428 board certified in pain medicine by the American Board of Pain
429 Medicine, the American Board of Interventional Pain Physicians,
430 the American Association of Physician Specialists, or a board
431 approved by the American Board of Medical Specialties or the
432 American Osteopathic Association and performs interventional
433 pain procedures of the type routinely billed using surgical
434 codes. This subsection does not apply to a registrant ~~physician~~
435 who prescribes medically necessary controlled substances for a
436 patient during an inpatient stay in a hospital licensed under
437 chapter 395.

438 Section 7. Paragraph (b) of subsection (2) of section
439 458.3265, Florida Statutes, is amended to read:

440 458.3265 Pain-management clinics.—

441 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
442 apply to any physician who provides professional services in a



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443 pain-management clinic that is required to be registered in
 444 subsection (1).

445 (b) ~~Only a person may not dispense any medication on the~~
 446 ~~premises of a registered pain-management clinic unless he or she~~
 447 ~~is~~ a physician licensed under this chapter or chapter 459 may
 448 dispense medication or prescribe a controlled substance
 449 regulated under chapter 893 on the premises of a registered
 450 pain-management clinic.

451 Section 8. Paragraph (b) of subsection (2) of section
 452 459.0137, Florida Statutes, is amended to read:

453 459.0137 Pain-management clinics.—

454 (2) PHYSICIAN RESPONSIBILITIES.—These responsibilities
 455 apply to any osteopathic physician who provides professional
 456 services in a pain-management clinic that is required to be
 457 registered in subsection (1).

458 (b) ~~Only a person may not dispense any medication on the~~
 459 ~~premises of a registered pain-management clinic unless he or she~~
 460 ~~is~~ a physician licensed under this chapter or chapter 458 may
 461 dispense medication or prescribe a controlled substance
 462 regulated under chapter 893 on the premises of a registered
 463 pain-management clinic.

464 Section 9. Paragraph (e) of subsection (4) of section
 465 458.347, Florida Statutes, is amended, and paragraph (c) of
 466 subsection (9) of that section is republished, to read:

467 458.347 Physician assistants.—

468 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—



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469 (e) A supervisory physician may delegate to a fully
470 licensed physician assistant the authority to prescribe or
471 dispense any medication used in the supervisory physician's
472 practice unless such medication is listed on the formulary
473 created pursuant to paragraph (f). A fully licensed physician
474 assistant may only prescribe or dispense such medication under
475 the following circumstances:

476 1. A physician assistant must clearly identify to the
477 patient that he or she is a physician assistant. Furthermore,
478 the physician assistant must inform the patient that the patient
479 has the right to see the physician prior to any prescription
480 being prescribed or dispensed by the physician assistant.

481 2. The supervisory physician must notify the department of
482 his or her intent to delegate, on a department-approved form,
483 before delegating such authority and notify the department of
484 any change in prescriptive privileges of the physician
485 assistant. Authority to dispense may be delegated only by a
486 supervising physician who is registered as a dispensing
487 practitioner in compliance with s. 465.0276.

488 3. The physician assistant must file with the department a
489 signed affidavit that he or she has completed a minimum of 10
490 continuing medical education hours in the specialty practice in
491 which the physician assistant has prescriptive privileges with
492 each licensure renewal application. Three of the 10 hours must
493 consist of a continuing education course on the safe and
494 effective prescribing of controlled substance medications which



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495 is offered by a statewide professional association of physicians
496 in this state accredited to provide educational activities
497 designated for the American Medical Association Physician's
498 Recognition Award Category 1 credit or designated by the
499 American Academy of Physician Assistants as a Category 1 credit.

500 4. The department may issue a prescriber number to the
501 physician assistant granting authority for the prescribing of
502 medicinal drugs authorized within this paragraph upon completion
503 of the foregoing requirements. The physician assistant shall not
504 be required to independently register pursuant to s. 465.0276.

505 5. The prescription must be written in a form that
506 complies with chapter 499 and must contain, in addition to the
507 supervisory physician's name, address, and telephone number, the
508 physician assistant's prescriber number. Unless it is a drug or
509 drug sample dispensed by the physician assistant, the
510 prescription must be filled in a pharmacy permitted under
511 chapter 465 and must be dispensed in that pharmacy by a
512 pharmacist licensed under chapter 465. The appearance of the
513 prescriber number creates a presumption that the physician
514 assistant is authorized to prescribe the medicinal drug and the
515 prescription is valid.

516 6. The physician assistant must note the prescription or
517 dispensing of medication in the appropriate medical record.

518 (9) COUNCIL ON PHYSICIAN ASSISTANTS.—The Council on
519 Physician Assistants is created within the department.

520 (c) The council shall:



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521 1. Recommend to the department the licensure of physician
522 assistants.

523 2. Develop all rules regulating the use of physician
524 assistants by physicians under this chapter and chapter 459,
525 except for rules relating to the formulary developed under
526 paragraph (4)(f). The council shall also develop rules to ensure
527 that the continuity of supervision is maintained in each
528 practice setting. The boards shall consider adopting a proposed
529 rule developed by the council at the regularly scheduled meeting
530 immediately following the submission of the proposed rule by the
531 council. A proposed rule submitted by the council may not be
532 adopted by either board unless both boards have accepted and
533 approved the identical language contained in the proposed rule.
534 The language of all proposed rules submitted by the council must
535 be approved by both boards pursuant to each respective board's
536 guidelines and standards regarding the adoption of proposed
537 rules. If either board rejects the council's proposed rule, that
538 board must specify its objection to the council with
539 particularity and include any recommendations it may have for
540 the modification of the proposed rule.

541 3. Make recommendations to the boards regarding all
542 matters relating to physician assistants.

543 4. Address concerns and problems of practicing physician
544 assistants in order to improve safety in the clinical practices
545 of licensed physician assistants.

546 Section 10. Effective January 1, 2017, paragraph (f) of



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547 subsection (4) of section 458.347, Florida Statutes, is amended
548 to read:

549 458.347 Physician assistants.—

550 (4) PERFORMANCE OF PHYSICIAN ASSISTANTS.—

551 (f)1. The council shall establish a formulary of medicinal
552 drugs that a fully licensed physician assistant having
553 prescribing authority under this section or s. 459.022 may not
554 prescribe. The formulary must include ~~controlled substances as~~
555 ~~defined in chapter 893,~~ general anesthetics, and radiographic
556 contrast materials, and must limit the prescription of Schedule
557 II controlled substances as listed in s. 893.03 to a 7-day
558 supply. The formulary must also restrict the prescribing of
559 psychiatric mental health controlled substances for children
560 younger than 18 years of age.

561 2. In establishing the formulary, the council shall
562 consult with a pharmacist licensed under chapter 465, but not
563 licensed under this chapter or chapter 459, who shall be
564 selected by the State Surgeon General.

565 3. Only the council shall add to, delete from, or modify
566 the formulary. Any person who requests an addition, a deletion,
567 or a modification of a medicinal drug listed on such formulary
568 has the burden of proof to show cause why such addition,
569 deletion, or modification should be made.

570 4. The boards shall adopt the formulary required by this
571 paragraph, and each addition, deletion, or modification to the
572 formulary, by rule. Notwithstanding any provision of chapter 120



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573 to the contrary, the formulary rule shall be effective 60 days
574 after the date it is filed with the Secretary of State. Upon
575 adoption of the formulary, the department shall mail a copy of
576 such formulary to each fully licensed physician assistant having
577 prescribing authority under this section or s. 459.022, and to
578 each pharmacy licensed by the state. The boards shall establish,
579 by rule, a fee not to exceed \$200 to fund the provisions of this
580 paragraph and paragraph (e).

581 Section 11. Subsection (2) of section 464.003, Florida
582 Statutes, is amended to read:

583 464.003 Definitions.—As used in this part, the term:

584 (2) "Advanced or specialized nursing practice" means, in
585 addition to the practice of professional nursing, the
586 performance of advanced-level nursing acts approved by the board
587 which, by virtue of postbasic specialized education, training,
588 and experience, are appropriately performed by an advanced
589 registered nurse practitioner. Within the context of advanced or
590 specialized nursing practice, the advanced registered nurse
591 practitioner may perform acts of nursing diagnosis and nursing
592 treatment of alterations of the health status. The advanced
593 registered nurse practitioner may also perform acts of medical
594 diagnosis and treatment, prescription, and operation as
595 authorized within the framework of an established supervisory
596 protocol ~~which are identified and approved by a joint committee~~
597 ~~composed of three members appointed by the Board of Nursing, two~~
598 ~~of whom must be advanced registered nurse practitioners; three~~



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599 | ~~members appointed by the Board of Medicine, two of whom must~~
600 | ~~have had work experience with advanced registered nurse~~
601 | ~~practitioners; and the State Surgeon General or the State~~
602 | ~~Surgeon General's designee. Each committee member appointed by a~~
603 | ~~board shall be appointed to a term of 4 years unless a shorter~~
604 | ~~term is required to establish or maintain staggered terms. The~~
605 | ~~Board of Nursing shall adopt rules authorizing the performance~~
606 | ~~of any such acts approved by the joint committee. Unless~~
607 | ~~otherwise specified by the joint committee, such acts must be~~
608 | ~~performed under the general supervision of a practitioner~~
609 | ~~licensed under chapter 458, chapter 459, or chapter 466 within~~
610 | ~~the framework of standing protocols which identify the medical~~
611 | ~~acts to be performed and the conditions for their performance.~~
612 | The department may, by rule, require that a copy of the protocol
613 | be filed with the department along with the notice required by
614 | s. 458.348.

615 | Section 12. Section 464.012, Florida Statutes, is amended
616 | to read:

617 | 464.012 Certification of advanced registered nurse
618 | practitioners; fees; controlled substance prescribing.—

619 | (1) Any nurse desiring to be certified as an advanced
620 | registered nurse practitioner shall apply to the department and
621 | submit proof that he or she holds a current license to practice
622 | professional nursing and that he or she meets one or more of the
623 | following requirements as determined by the board:

624 | (a) Satisfactory completion of a formal postbasic



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625 educational program of at least one academic year, the primary
626 purpose of which is to prepare nurses for advanced or
627 specialized practice.

628 (b) Certification by an appropriate specialty board. Such
629 certification shall be required for initial state certification
630 and any recertification as a registered nurse anesthetist or
631 nurse midwife. The board may by rule provide for provisional
632 state certification of graduate nurse anesthetists and nurse
633 midwives for a period of time determined to be appropriate for
634 preparing for and passing the national certification
635 examination.

636 (c) Graduation from a program leading to a master's degree
637 in a nursing clinical specialty area with preparation in
638 specialized practitioner skills. For applicants graduating on or
639 after October 1, 1998, graduation from a master's degree program
640 shall be required for initial certification as a nurse
641 practitioner under paragraph (4) (c). For applicants graduating
642 on or after October 1, 2001, graduation from a master's degree
643 program shall be required for initial certification as a
644 registered nurse anesthetist under paragraph (4) (a).

645 (2) The board shall provide by rule the appropriate
646 requirements for advanced registered nurse practitioners in the
647 categories of certified registered nurse anesthetist, certified
648 nurse midwife, and nurse practitioner.

649 (3) An advanced registered nurse practitioner shall
650 perform those functions authorized in this section within the



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651 framework of an established protocol that is filed with the
652 board upon biennial license renewal and within 30 days after
653 entering into a supervisory relationship with a physician or
654 changes to the protocol. The board shall review the protocol to
655 ensure compliance with applicable regulatory standards for
656 protocols. The board shall refer to the department licensees
657 submitting protocols that are not compliant with the regulatory
658 standards for protocols. A practitioner currently licensed under
659 chapter 458, chapter 459, or chapter 466 shall maintain
660 supervision for directing the specific course of medical
661 treatment. Within the established framework, an advanced
662 registered nurse practitioner may:

- 663 (a) Monitor and alter drug therapies.
664 (b) Initiate appropriate therapies for certain conditions.
665 (c) Perform additional functions as may be determined by
666 rule in accordance with s. 464.003(2).
667 (d) Order diagnostic tests and physical and occupational
668 therapy.

669 (4) In addition to the general functions specified in
670 subsection (3), an advanced registered nurse practitioner may
671 perform the following acts within his or her specialty:

- 672 (a) The certified registered nurse anesthetist may, to the
673 extent authorized by established protocol approved by the
674 medical staff of the facility in which the anesthetic service is
675 performed, perform any or all of the following:

- 676 1. Determine the health status of the patient as it



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677 | relates to the risk factors and to the anesthetic management of
678 | the patient through the performance of the general functions.

679 | 2. Based on history, physical assessment, and supplemental
680 | laboratory results, determine, with the consent of the
681 | responsible physician, the appropriate type of anesthesia within
682 | the framework of the protocol.

683 | 3. Order under the protocol preanesthetic medication.

684 | 4. Perform under the protocol procedures commonly used to
685 | render the patient insensible to pain during the performance of
686 | surgical, obstetrical, therapeutic, or diagnostic clinical
687 | procedures. These procedures include ordering and administering
688 | regional, spinal, and general anesthesia; inhalation agents and
689 | techniques; intravenous agents and techniques; and techniques of
690 | hypnosis.

691 | 5. Order or perform monitoring procedures indicated as
692 | pertinent to the anesthetic health care management of the
693 | patient.

694 | 6. Support life functions during anesthesia health care,
695 | including induction and intubation procedures, the use of
696 | appropriate mechanical supportive devices, and the management of
697 | fluid, electrolyte, and blood component balances.

698 | 7. Recognize and take appropriate corrective action for
699 | abnormal patient responses to anesthesia, adjunctive medication,
700 | or other forms of therapy.

701 | 8. Recognize and treat a cardiac arrhythmia while the
702 | patient is under anesthetic care.



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703 9. Participate in management of the patient while in the
 704 postanesthesia recovery area, including ordering the
 705 administration of fluids and drugs.

706 10. Place special peripheral and central venous and
 707 arterial lines for blood sampling and monitoring as appropriate.

708 (b) The certified nurse midwife may, to the extent
 709 authorized by an established protocol which has been approved by
 710 the medical staff of the health care facility in which the
 711 midwifery services are performed, or approved by the nurse
 712 midwife's physician backup when the delivery is performed in a
 713 patient's home, perform any or all of the following:

- 714 1. Perform superficial minor surgical procedures.
- 715 2. Manage the patient during labor and delivery to include
- 716 amniotomy, episiotomy, and repair.
- 717 3. Order, initiate, and perform appropriate anesthetic
- 718 procedures.
- 719 4. Perform postpartum examination.
- 720 5. Order appropriate medications.
- 721 6. Provide family-planning services and well-woman care.
- 722 7. Manage the medical care of the normal obstetrical
- 723 patient and the initial care of a newborn patient.

724 (c) The nurse practitioner may perform any or all of the
 725 following acts within the framework of established protocol:

- 726 1. Manage selected medical problems.
- 727 2. Order physical and occupational therapy.
- 728 3. Initiate, monitor, or alter therapies for certain



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729 uncomplicated acute illnesses.

730 4. Monitor and manage patients with stable chronic
731 diseases.

732 5. Establish behavioral problems and diagnosis and make
733 treatment recommendations.

734 (5) The board shall certify, and the department shall
735 issue a certificate to, any nurse meeting the qualifications in
736 this section. The board shall establish an application fee not
737 to exceed \$100 and a biennial renewal fee not to exceed \$50. The
738 board is authorized to adopt such other rules as are necessary
739 to implement the provisions of this section.

740 (6) (a) The board shall establish a committee to recommend
741 a formulary of controlled substances that an advanced registered
742 nurse practitioner may not prescribe or may prescribe only for
743 specific uses or in limited quantities. The committee must
744 consist of three advanced registered nurse practitioners
745 licensed under this section, recommended by the board; three
746 physicians licensed under chapter 458 or chapter 459 who have
747 work experience with advanced registered nurse practitioners,
748 recommended by the Board of Medicine; and a pharmacist licensed
749 under chapter 465 who is a doctor of pharmacy, recommended by
750 the Board of Pharmacy. The committee may recommend an evidence-
751 based formulary applicable to all advanced registered nurse
752 practitioners which is limited by specialty certification, is
753 limited to approved uses of controlled substances, or is subject
754 to other similar restrictions the committee finds are necessary



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755 to protect the health, safety, and welfare of the public. The
756 formulary must restrict the prescribing of psychiatric mental
757 health controlled substances for children younger than 18 years
758 of age to advanced registered nurse practitioners who also are
759 psychiatric nurses as defined in s. 394.455. The formulary must
760 also limit the prescribing of Schedule II controlled substances
761 as listed in s. 893.03 to a 7-day supply, except that such
762 restriction does not apply to controlled substances that are
763 psychiatric medications prescribed by psychiatric nurses as
764 defined in s. 394.455.

765 (b) The board shall adopt by rule the recommended
766 formulary and any revision to the formulary which it finds is
767 supported by evidence-based clinical findings presented by the
768 Board of Medicine, the Board of Osteopathic Medicine, or the
769 Board of Dentistry.

770 (c) The formulary required under this subsection does not
771 apply to a controlled substance that is dispensed for
772 administration pursuant to an order, including an order for
773 medication authorized by subparagraph (4)(a)3., subparagraph
774 (4)(a)4., or subparagraph (4)(a)9.

775 (d) The board shall adopt the committee's initial
776 recommendation no later than October 31, 2016.

777 (7) This section shall be known as "The Barbara Lumpkin
778 Prescribing Act."

779 Section 13. Effective January 1, 2017, subsection (3) of
780 section 464.012, Florida Statutes, as amended by this act, is



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781 amended to read:

782 464.012 Certification of advanced registered nurse
783 practitioners; fees; controlled substance prescribing.—

784 (3) An advanced registered nurse practitioner shall
785 perform those functions authorized in this section within the
786 framework of an established protocol that is filed with the
787 board upon biennial license renewal and within 30 days after
788 entering into a supervisory relationship with a physician or
789 changes to the protocol. The board shall review the protocol to
790 ensure compliance with applicable regulatory standards for
791 protocols. The board shall refer to the department licensees
792 submitting protocols that are not compliant with the regulatory
793 standards for protocols. A practitioner currently licensed under
794 chapter 458, chapter 459, or chapter 466 shall maintain
795 supervision for directing the specific course of medical
796 treatment. Within the established framework, an advanced
797 registered nurse practitioner may:

798 (a) Prescribe, dispense, administer, or order any drug;
799 however, an advanced registered nurse practitioner may prescribe
800 or dispense a controlled substance as defined in s. 893.03 only
801 if the advanced registered nurse practitioner has graduated from
802 a program leading to a master's or doctoral degree in a clinical
803 nursing specialty area with training in specialized practitioner
804 skills ~~Monitor and alter drug therapies.~~

805 (b) Initiate appropriate therapies for certain conditions.

806 (c) Perform additional functions as may be determined by



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807 rule in accordance with s. 464.003(2).

808 (d) Order diagnostic tests and physical and occupational
809 therapy.

810 Section 14. Subsection (3) of section 464.013, Florida
811 Statutes, is amended to read:

812 464.013 Renewal of license or certificate.—

813 (3) The board shall by rule prescribe up to 30 hours of
814 continuing education biennially as a condition for renewal of a
815 license or certificate.

816 (a) A nurse who is certified by a health care specialty
817 program accredited by the National Commission for Certifying
818 Agencies or the Accreditation Board for Specialty Nursing
819 Certification is exempt from continuing education requirements.
820 The criteria for programs must ~~shall~~ be approved by the board.

821 (b) Notwithstanding the exemption in paragraph (a), as
822 part of the maximum 30 hours of continuing education hours
823 required under this subsection, advanced registered nurse
824 practitioners certified under s. 464.012 must complete at least
825 3 hours of continuing education on the safe and effective
826 prescription of controlled substances. Such continuing education
827 courses must be offered by a statewide professional association
828 of physicians in this state accredited to provide educational
829 activities designated for the American Medical Association
830 Physician's Recognition Award Category 1 credit, the American
831 Nurses Credentialing Center, the American Association of Nurse
832 Anesthetists, or the American Association of Nurse Practitioners



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833 | and may be offered in a distance learning format.

834 | Section 15. Paragraph (p) is added to subsection (1) of
835 | section 464.018, Florida Statutes, and subsection (2) of that
836 | section is republished, to read:

837 | 464.018 Disciplinary actions.—

838 | (1) The following acts constitute grounds for denial of a
839 | license or disciplinary action, as specified in s. 456.072(2):

840 | (p) For an advanced registered nurse practitioner:

841 | 1. Presigning blank prescription forms.

842 | 2. Prescribing for office use any medicinal drug appearing
843 | on Schedule II in chapter 893.

844 | 3. Prescribing, ordering, dispensing, administering,
845 | supplying, selling, or giving a drug that is an amphetamine, a
846 | sympathomimetic amine drug, or a compound designated in s.
847 | 893.03(2) as a Schedule II controlled substance, to or for any
848 | person except for:

849 | a. The treatment of narcolepsy; hyperkinesis; behavioral
850 | syndrome in children characterized by the developmentally
851 | inappropriate symptoms of moderate to severe distractibility,
852 | short attention span, hyperactivity, emotional lability, and
853 | impulsivity; or drug-induced brain dysfunction.

854 | b. The differential diagnostic psychiatric evaluation of
855 | depression or the treatment of depression shown to be refractory
856 | to other therapeutic modalities.

857 | c. The clinical investigation of the effects of such drugs
858 | or compounds when an investigative protocol is submitted to,



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859 reviewed by, and approved by the department before such
860 investigation is begun.

861 4. Prescribing, ordering, dispensing, administering,
862 supplying, selling, or giving growth hormones, testosterone or
863 its analogs, human chorionic gonadotropin (HCG), or other
864 hormones for the purpose of muscle building or to enhance
865 athletic performance. As used in this subparagraph, the term
866 "muscle building" does not include the treatment of injured
867 muscle. A prescription written for the drug products identified
868 in this subparagraph may be dispensed by a pharmacist with the
869 presumption that the prescription is for legitimate medical use.

870 5. Promoting or advertising on any prescription form a
871 community pharmacy unless the form also states: "This
872 prescription may be filled at any pharmacy of your choice."

873 6. Prescribing, dispensing, administering, mixing, or
874 otherwise preparing a legend drug, including a controlled
875 substance, other than in the course of his or her professional
876 practice. For the purposes of this subparagraph, it is legally
877 presumed that prescribing, dispensing, administering, mixing, or
878 otherwise preparing legend drugs, including all controlled
879 substances, inappropriately or in excessive or inappropriate
880 quantities is not in the best interest of the patient and is not
881 in the course of the advanced registered nurse practitioner's
882 professional practice, without regard to his or her intent.

883 7. Prescribing, dispensing, or administering a medicinal
884 drug appearing on any schedule set forth in chapter 893 to



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885 himself or herself, except a drug prescribed, dispensed, or
886 administered to the advanced registered nurse practitioner by
887 another practitioner authorized to prescribe, dispense, or
888 administer medicinal drugs.

889 8. Prescribing, ordering, dispensing, administering,
890 supplying, selling, or giving amygdalin (laetrile) to any
891 person.

892 9. Dispensing a substance designated in s. 893.03(2) or
893 (3) as a substance controlled in Schedule II or Schedule III,
894 respectively, in violation of s. 465.0276.

895 10. Promoting or advertising through any communication
896 medium the use, sale, or dispensing of a substance designated in
897 s. 893.03 as a controlled substance.

898 (2) The board may enter an order denying licensure or
899 imposing any of the penalties in s. 456.072(2) against any
900 applicant for licensure or licensee who is found guilty of
901 violating any provision of subsection (1) of this section or who
902 is found guilty of violating any provision of s. 456.072(1).

903 Section 16. Section 627.42392, Florida Statutes, is
904 created to read:

905 627.42392 Prior authorization.—

906 (1) As used in this section, the term "health insurer"
907 means an authorized insurer offering health insurance as defined
908 in s. 624.603, a managed care plan as defined in s. 409.962(9),
909 or a health maintenance organization as defined in s.
910 641.19(12).



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911 (2) Notwithstanding any other provision of law, in order
912 to establish uniformity in the submission of prior authorization
913 forms on or after January 1, 2017, a health insurer, or a
914 pharmacy benefits manager on behalf of the health insurer, which
915 does not use an electronic prior authorization form for its
916 contracted providers shall use only the prior authorization form
917 that has been approved by the Financial Services Commission in
918 consultation with the Agency for Health Care Administration to
919 obtain a prior authorization for a medical procedure, course of
920 treatment, or prescription drug benefit. Such form may not
921 exceed two pages in length, excluding any instructions or
922 guiding documentation.

923 (3) The Financial Services Commission in consultation with
924 the Agency for Health Care Administration shall adopt by rule
925 guidelines for all prior authorization forms which ensure the
926 general uniformity of such forms.

927 (4) Electronic prior-authorization approvals do not
928 preclude benefit verification or medical review by the insurer
929 under either the medical or pharmacy benefits.

930 Section 17. Paragraph (a) of subsection (3) of section
931 766.1115, Florida Statutes, is amended to read:

932 766.1115 Health care providers; creation of agency
933 relationship with governmental contractors.—

934 (3) DEFINITIONS.—As used in this section, the term:

935 (a) "Contract" means an agreement executed in compliance
936 with this section between a health care provider and a



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937 governmental contractor for volunteer, uncompensated services
938 which allows the health care provider to deliver health care
939 services to low-income recipients as an agent of the
940 governmental contractor. ~~The contract must be for volunteer,~~
941 ~~uncompensated services, except as provided in paragraph (4)(g).~~
942 For services to qualify as volunteer, uncompensated services
943 under this section, the health care provider, or any employee or
944 agent of the health care provider, must receive no compensation
945 from the governmental contractor for any services provided under
946 the contract and must not bill or accept compensation from the
947 recipient, or a public or private third-party payor, for the
948 specific services provided to the low-income recipients covered
949 by the contract, except as provided in paragraph (4)(g). A free
950 clinic as described in subparagraph (d)14. may receive a
951 legislative appropriation, a grant through a legislative
952 appropriation, or a grant from a governmental entity or
953 nonprofit corporation to support the delivery of contracted
954 services by volunteer health care providers, including the
955 employment of health care providers to supplement, coordinate,
956 or support the delivery of such services. The appropriation or
957 grant for the free clinic does not constitute compensation under
958 this paragraph from the governmental contractor for services
959 provided under the contract, nor does receipt or use of the
960 appropriation or grant constitute the acceptance of compensation
961 under this paragraph for the specific services provided to the
962 low-income recipients covered by the contract.



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963 Section 18. Subsection (21) of section 893.02, Florida
 964 Statutes, is amended to read:

965 893.02 Definitions.—The following words and phrases as
 966 used in this chapter shall have the following meanings, unless
 967 the context otherwise requires:

968 (21) "Practitioner" means a physician licensed under
 969 ~~pursuant to~~ chapter 458, a dentist licensed under ~~pursuant to~~
 970 chapter 466, a veterinarian licensed under ~~pursuant to~~ chapter
 971 474, an osteopathic physician licensed under ~~pursuant to~~ chapter
 972 459, an advanced registered nurse practitioner certified under
 973 chapter 464, a naturopath licensed under ~~pursuant to~~ chapter
 974 462, a certified optometrist licensed under ~~pursuant to~~ chapter
 975 463, ~~or~~ a podiatric physician licensed under ~~pursuant to~~ chapter
 976 461, or a physician assistant licensed under chapter 458 or
 977 chapter 459, provided such practitioner holds a valid federal
 978 controlled substance registry number.

979 Section 19. Paragraph (n) of subsection (1) of section
 980 948.03, Florida Statutes, is amended to read:

981 948.03 Terms and conditions of probation.—

982 (1) The court shall determine the terms and conditions of
 983 probation. Conditions specified in this section do not require
 984 oral pronouncement at the time of sentencing and may be
 985 considered standard conditions of probation. These conditions
 986 may include among them the following, that the probationer or
 987 offender in community control shall:

988 (n) Be prohibited from using intoxicants to excess or



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989 | possessing any drugs or narcotics unless prescribed by a
 990 | physician, an advanced registered nurse practitioner, or a
 991 | physician assistant. The probationer or community controllee may
 992 | ~~shall~~ not knowingly visit places where intoxicants, drugs, or
 993 | other dangerous substances are unlawfully sold, dispensed, or
 994 | used.

995 | Section 20. Paragraph (a) of subsection (1) and subsection
 996 | (2) of section 458.348, Florida Statutes, are amended to read:
 997 | 458.348 Formal supervisory relationships, standing orders,
 998 | and established protocols; notice; standards.—

999 | (1) NOTICE.—

1000 | (a) When a physician enters into a formal supervisory
 1001 | relationship or standing orders with an emergency medical
 1002 | technician or paramedic licensed pursuant to s. 401.27, which
 1003 | relationship or orders contemplate the performance of medical
 1004 | acts, or when a physician enters into an established protocol
 1005 | with an advanced registered nurse practitioner, which protocol
 1006 | contemplates the performance of medical ~~acts identified and~~
 1007 | ~~approved by the joint committee pursuant to s. 464.003(2) or~~
 1008 | acts set forth in s. 464.012(3) and (4), the physician shall
 1009 | submit notice to the board. The notice shall contain a statement
 1010 | in substantially the following form:

1011 |
 1012 | I, ...(name and professional license number of
 1013 | physician)..., of ...(address of physician)... have hereby
 1014 | entered into a formal supervisory relationship, standing orders,



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1015 or an established protocol with ...(number of persons)...
 1016 emergency medical technician(s), ...(number of persons)...
 1017 paramedic(s), or ...(number of persons)... advanced registered
 1018 nurse practitioner(s).

1020 (2) ESTABLISHMENT OF STANDARDS BY JOINT COMMITTEE.—The
 1021 joint committee ~~created under s. 464.003(2)~~ shall determine
 1022 minimum standards for the content of established protocols
 1023 pursuant to which an advanced registered nurse practitioner may
 1024 perform medical acts ~~identified and approved by the joint~~
 1025 ~~committee pursuant to s. 464.003(2)~~ or acts set forth in s.
 1026 464.012(3) and (4) and shall determine minimum standards for
 1027 supervision of such acts by the physician, unless the joint
 1028 committee determines that any act set forth in s. 464.012(3) or
 1029 (4) is not a medical act. Such standards shall be based on risk
 1030 to the patient and acceptable standards of medical care and
 1031 shall take into account the special problems of medically
 1032 underserved areas. The standards developed by the joint
 1033 committee shall be adopted as rules by the Board of Nursing and
 1034 the Board of Medicine for purposes of carrying out their
 1035 responsibilities pursuant to part I of chapter 464 and this
 1036 chapter, respectively, but neither board shall have disciplinary
 1037 powers over the licensees of the other board.

1038 Section 21. Paragraph (a) of subsection (1) of section
 1039 459.025, Florida Statutes, is amended to read:

1040 459.025 Formal supervisory relationships, standing orders,



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1041 and established protocols; notice; standards.—

1042 (1) NOTICE.—

1043 (a) When an osteopathic physician enters into a formal
 1044 supervisory relationship or standing orders with an emergency
 1045 medical technician or paramedic licensed pursuant to s. 401.27,
 1046 which relationship or orders contemplate the performance of
 1047 medical acts, or when an osteopathic physician enters into an
 1048 established protocol with an advanced registered nurse
 1049 practitioner, which protocol contemplates the performance of
 1050 medical acts ~~identified and approved by the joint committee~~
 1051 ~~pursuant to s. 464.003(2)~~ or acts set forth in s. 464.012(3) and
 1052 (4), the osteopathic physician shall submit notice to the board.
 1053 The notice must contain a statement in substantially the
 1054 following form:

1055
 1056 I, ...(name and professional license number of osteopathic
 1057 physician)..., of ...(address of osteopathic physician)... have
 1058 hereby entered into a formal supervisory relationship, standing
 1059 orders, or an established protocol with ...(number of
 1060 persons)... emergency medical technician(s), ...(number of
 1061 persons)... paramedic(s), or ...(number of persons)... advanced
 1062 registered nurse practitioner(s).

1063 Section 22. Subsection (10) of s. 458.331, paragraph (g)
 1064 of subsection (7) of s. 458.347, subsection (10) of s. 459.015,
 1065 paragraph (f) of subsection (7) of s. 459.022, and paragraph (b)
 1066 of subsection (5) of s. 465.0158, Florida Statutes, are



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1067 reenacted for the purpose of incorporating the amendment made by
 1068 this act to s. 456.072, Florida Statutes, in references thereto.

1069 Section 23. Paragraph (mm) of subsection (1) of s. 456.072
 1070 and s. 466.02751, Florida Statutes, are reenacted for the
 1071 purpose of incorporating the amendment made by this act to s.
 1072 456.44, Florida Statutes, in references thereto.

1073 Section 24. Section 458.303, paragraph (b) of subsection
 1074 (7) of s. 458.3475, paragraph (e) of subsection (4) and
 1075 paragraph (c) of subsection (9) of s. 459.022, and paragraph (b)
 1076 of subsection (7) of s. 459.023, Florida Statutes, are reenacted
 1077 for the purpose of incorporating the amendment made by this act
 1078 to s. 458.347, Florida Statutes, in references thereto.

1079 Section 25. Paragraph (c) of subsection (3) of s. 464.012,
 1080 Florida Statutes, is reenacted for the purpose of incorporating
 1081 the amendment made by this act to s. 464.003, Florida Statutes,
 1082 in a reference thereto.

1083 Section 26. Paragraph (a) of subsection (1) of s. 456.041,
 1084 subsections (1) and (2) of s. 458.348, and subsection (1) of s.
 1085 459.025, Florida Statutes, are reenacted for the purpose of
 1086 incorporating the amendment made by this act to s. 464.012,
 1087 Florida Statutes, in references thereto.

1088 Section 27. Subsection (7) of s. 464.0205, Florida
 1089 Statutes, is reenacted for the purpose of incorporating the
 1090 amendment made by this act to s. 464.013, Florida Statutes, in a
 1091 reference thereto.

1092 Section 28. Subsection (11) of s. 320.0848, subsection (2)



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1093 of s. 464.008, subsection (5) of s. 464.009, and paragraph (b)
 1094 of subsection (1), subsection (3), and paragraph (b) of
 1095 subsection (4) of s. 464.0205, Florida Statutes, are reenacted
 1096 for the purpose of incorporating the amendment made by this act
 1097 to s. 464.018, Florida Statutes, in references thereto.

1098 Section 29. Section 775.051, Florida Statutes, is
 1099 reenacted for the purpose of incorporating the amendment made by
 1100 this act to s. 893.02, Florida Statutes, in a reference thereto.

1101 Section 30. Paragraph (a) of subsection (3) of s. 944.17,
 1102 subsection (8) of s. 948.001, and paragraph (e) of subsection
 1103 (1) of s. 948.101, Florida Statutes, are reenacted for the
 1104 purpose of incorporating the amendment made by this act to s.
 1105 948.03, Florida Statutes, in references thereto.

1106 Section 31. Except as otherwise expressly provided in this
 1107 act, this act shall take effect upon becoming a law.
 1108

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1
2 An act relating to the prescription drug monitoring
3 program; amending s. 893.055, F.S.; providing that
4 certain acts of dispensing controlled substances in
5 specified facilities are not required to be reported
6 to the prescription drug monitoring program;
7 authorizing the designee of a pharmacy, prescriber, or
8 dispenser to have access to a patient's record in the
9 prescription drug monitoring program's database for a
10 specified purpose; authorizing an impaired
11 practitioner consultant to access an impaired
12 practitioner program participant's or referral's
13 record in the prescription drug monitoring program's
14 database; amending s. 893.0551, F.S.; authorizing the
15 designee of a health care practitioner, pharmacist,
16 pharmacy, prescriber, or dispenser or an impaired
17 practitioner consultant to receive certain information
18 from the prescription drug monitoring program;
19 providing an effective date.
20

21 Be It Enacted by the Legislature of the State of Florida:
22

23 Section 1. Paragraph (g) is added to subsection (5) of
24 section 893.055, Florida Statutes, and paragraphs (b) and (c) of
25 subsection (7) and subsection (12) of that section are amended,
26 to read:

27 893.055 Prescription drug monitoring program.—

28 (5) When the following acts of dispensing or administering
29 occur, the following are exempt from reporting under this

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30 section for that specific act of dispensing or administration:

31 (g) A rehabilitative hospital, assisted living facility, or
32 nursing home dispensing a certain dosage of a controlled
33 substance, as needed, to a patient as ordered by the patient's
34 treating physician.

35 (7)

36 (b) A pharmacy, prescriber, or dispenser, or the designee
37 of a pharmacy, prescriber, or dispenser, shall have access to
38 information in the prescription drug monitoring program's
39 database which relates to a patient of that pharmacy,
40 prescriber, or dispenser in a manner established by the
41 department as needed for the purpose of reviewing the patient's
42 controlled substance prescription history. Other access to the
43 program's database shall be limited to the program's manager and
44 to the designated program and support staff, who may act only at
45 the direction of the program manager or, in the absence of the
46 program manager, as authorized. Access by the program manager or
47 such designated staff is for prescription drug program
48 management only or for management of the program's database and
49 its system in support of the requirements of this section and in
50 furtherance of the prescription drug monitoring program.

51 Confidential and exempt information in the database shall be
52 released only as provided in paragraph (c) and s. 893.0551. The
53 program manager, designated program and support staff who act at
54 the direction of or in the absence of the program manager, and
55 any individual who has similar access regarding the management
56 of the database from the prescription drug monitoring program
57 shall submit fingerprints to the department for background
58 screening. The department shall follow the procedure established

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59 by the Department of Law Enforcement to request a statewide
60 criminal history record check and to request that the Department
61 of Law Enforcement forward the fingerprints to the Federal
62 Bureau of Investigation for a national criminal history record
63 check.

64 (c) The following entities are ~~shall~~ not be allowed direct
65 access to information in the prescription drug monitoring
66 program database but may request from the program manager and,
67 when authorized by the program manager, the program manager's
68 program and support staff, information that is confidential and
69 exempt under s. 893.0551. Before ~~Prior to~~ release, a ~~the~~ request
70 by the following entities shall be verified as authentic and
71 authorized with the requesting organization by the program
72 manager, the program manager's program and support staff, or as
73 determined in rules by the department as being authentic and as
74 having been authorized by the requesting entity:

75 1. The department or its relevant health care regulatory
76 boards responsible for the licensure, regulation, or discipline
77 of practitioners, pharmacists, or other persons who are
78 authorized to prescribe, administer, or dispense controlled
79 substances and who are involved in a specific controlled
80 substance investigation involving a designated person for one or
81 more prescribed controlled substances.

82 2. The Attorney General for Medicaid fraud cases involving
83 prescribed controlled substances.

84 3. A law enforcement agency during active investigations of
85 ~~regarding~~ potential criminal activity, fraud, or theft regarding
86 prescribed controlled substances.

87 4. A patient or the legal guardian or designated health

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88 care surrogate of an incapacitated patient as described in s.
89 893.0551 who, for the purpose of verifying the accuracy of the
90 database information, submits a written and notarized request
91 that includes the patient's full name, address, and date of
92 birth, and includes the same information if the legal guardian
93 or health care surrogate submits the request. The request shall
94 be validated by the department to verify the identity of the
95 patient and the legal guardian or health care surrogate, if the
96 patient's legal guardian or health care surrogate is the
97 requestor. Such verification is also required for any request to
98 change a patient's prescription history or other information
99 related to his or her information in the electronic database.

100 5. An impaired practitioner consultant who is retained by
101 the department under s. 456.076 for the purpose of reviewing the
102 database information of an impaired practitioner program
103 participant or a referral who has agreed to be evaluated or
104 monitored through the program and who has separately agreed in
105 writing to the consultant's access to and review of such
106 information.

107
108 Information in the database for the electronic prescription drug
109 monitoring system is not discoverable or admissible in any civil
110 or administrative action, except in an investigation and
111 disciplinary proceeding by the department or the appropriate
112 regulatory board.

113 (12) A prescriber or dispenser, or his or her designee, may
114 have access to the information under this section which relates
115 to a patient of that prescriber or dispenser as needed for the
116 purpose of reviewing the patient's controlled drug prescription

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117 history. A prescriber or dispenser acting in good faith is
118 immune from any civil, criminal, or administrative liability
119 that might otherwise be incurred or imposed for receiving or
120 using information from the prescription drug monitoring program.
121 This subsection does not create a private cause of action, and a
122 person may not recover damages against a prescriber or dispenser
123 authorized to access information under this subsection for
124 accessing or failing to access such information.

125 Section 2. Paragraphs (d), (e), and (g) of subsection (3)
126 of section 893.0551, Florida Statutes, are amended, paragraph
127 (h) is added to subsection (3) of that section, and subsections
128 (6) and (7) of that section are republished, to read:

129 893.0551 Public records exemption for the prescription drug
130 monitoring program.—

131 (3) The department shall disclose such confidential and
132 exempt information to the following persons or entities upon
133 request and after using a verification process to ensure the
134 legitimacy of the request as provided in s. 893.055:

135 (d) A health care practitioner, or his or her designee, who
136 certifies that the information is necessary to provide medical
137 treatment to a current patient in accordance with ss. 893.05 and
138 893.055.

139 (e) A pharmacist, or his or her designee, who certifies
140 that the requested information will be used to dispense
141 controlled substances to a current patient in accordance with
142 ss. 893.04 and 893.055.

143 (g) The patient's pharmacy, prescriber, or dispenser, or
144 the designee of the pharmacy, prescriber, or dispenser, who
145 certifies that the information is necessary to provide medical

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146 treatment to his or her current patient in accordance with s.
147 893.055.

148 (h) An impaired practitioner consultant who has been
149 authorized in writing by a participant in, or by a referral to,
150 the impaired practitioner program to access and review
151 information as provided in s. 893.055(7)(c)5.

152 (6) An agency or person who obtains any confidential and
153 exempt information pursuant to this section must maintain the
154 confidential and exempt status of that information and may not
155 disclose such information unless authorized by law. Information
156 shared with a state attorney pursuant to paragraph (3)(a) or
157 paragraph (3)(c) may be released only in response to a discovery
158 demand if such information is directly related to the criminal
159 case for which the information was requested. Unrelated
160 information may be released only upon an order of a court of
161 competent jurisdiction.

162 (7) A person who willfully and knowingly violates this
163 section commits a felony of the third degree, punishable as
164 provided in s. 775.082, s. 775.083, or s. 775.084.

165 Section 3. This act shall take effect July 1, 2016.

Note--Relevant portions are highlighted in yellow.

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1
2 An act relating to drugs, devices, and cosmetics;
3 amending s. 385.211, F.S.; authorizing a certain type
4 of specialty hospital to conduct research on
5 cannabidiol and low-THC cannabis if contracted with
6 the Department of Health to perform such research;
7 amending s. 499.003, F.S.; providing, revising, and
8 deleting definitions for purposes of the Florida Drug
9 and Cosmetic Act; requiring rulemaking; specifying a
10 default rule until the Department of Business and
11 Professional Regulation adopts a rule; amending s.
12 499.005, F.S.; revising prohibited acts related to the
13 distribution of prescription drugs; conforming a
14 cross-reference; amending s. 499.0051, F.S.;
15 prohibiting the distribution of prescription drugs
16 without delivering a transaction history, transaction
17 information, and transaction statement; providing
18 penalties; deleting provisions and revising
19 terminology related to pedigree papers, to conform to
20 changes made by the act; amending s. 499.006, F.S.;
21 conforming provisions; amending s. 499.01, F.S.;
22 requiring nonresident prescription drug repackagers to
23 obtain an operating permit; authorizing a manufacturer
24 to engage in the wholesale distribution of
25 prescription drugs; providing for the issuance of
26 virtual prescription drug manufacturer permits and
27 virtual nonresident prescription drug manufacturer
28 permits to certain persons; providing exceptions from
29 certain virtual manufacturer requirements; requiring a

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30 nonresident prescription drug repackager permit for
31 certain persons; deleting surety bond requirements for
32 prescription drug wholesale distributors; requiring
33 that certain persons obtain an out-of-state
34 prescription drug wholesale distributor permit;
35 providing that a restricted prescription drug
36 distributor permit is not required for distributions
37 between certain pharmacies; requiring the Department
38 of Business and Professional Regulation to establish
39 by rule when such distribution constitutes regular and
40 systematic supplying of a prescription drug; requiring
41 certain third party logistic providers to be licensed;
42 requiring research and development labeling on certain
43 prescription drug active pharmaceutical ingredient
44 packaging; requiring certain manufacturers to create
45 and maintain certain records; requiring certain
46 prescription drug distributors to provide certain
47 information to health care entities for which they
48 repackage prescription drugs; requiring the department
49 to adopt rules concerning repackaged prescription drug
50 safety and integrity; amending s. 499.012, F.S.;

51 providing for issuance of a prescription drug
52 manufacturer permit or retail pharmacy drug wholesale
53 distributor permit when an applicant at the same
54 address is a licensed nuclear pharmacy or community
55 pharmacy; providing for the expiration of deficient
56 permit applications; requiring trade secret
57 information submitted by an applicant to be maintained
58 as a trade secret; authorizing the quadrennial renewal

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59 of permits; providing for calculation of fees for such
60 permit renewals; revising procedures and application
61 requirements for permit renewals; providing for late
62 renewal fees; allowing a permittee who submits a
63 renewal application to continue operations; removing
64 certain application requirements for renewal of a
65 permit; requiring bonds or other surety of a specified
66 amount; requiring proof of inspection of
67 establishments used in wholesale distribution;
68 authorizing the Department of Business and
69 Professional Regulation to contract for the collection
70 of electronic fingerprints under certain
71 circumstances; providing information that may be
72 submitted in lieu of certain application requirements
73 for specified permits and certifications; removing
74 provisions relating to annual renewal and expiration
75 of permits; conforming cross-references; amending s.
76 499.01201, F.S.; conforming provisions; amending s.
77 499.0121, F.S.; revising prescription drug
78 recordkeeping requirements; specifying recordkeeping
79 requirements for manufacturers and repackagers of
80 medical devices, over-the-counter drugs, and
81 cosmetics; increasing the quantity of unit doses of a
82 controlled substance that may be ordered in any given
83 month by a customer without triggering a requirement
84 that a wholesale distributor perform a reasonableness
85 assessment; conforming provisions; amending s.
86 499.015, F.S.; providing for the expiration, renewal,
87 and issuance of certain drug, device, and cosmetic

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88 product registrations; providing for product
89 registration fees; amending ss. 499.03, 499.05, and
90 499.051, F.S.; conforming provisions to changes made
91 by the act; amending s. 499.82, F.S.; revising the
92 definition of "wholesale distribution" for purposes of
93 medical gas requirements; amending s. 499.83, F.S.;
94 authorizing licensed hospices to obtain on behalf of,
95 and sell medical oxygen to, their patients without
96 obtaining a medical oxygen retail establishment permit
97 in certain circumstances; specifying recordkeeping
98 requirements; amending s. 499.89, F.S.; conforming
99 provisions; repealing s. 499.01212, F.S., relating to
100 pedigree papers; amending ss. 409.9201, 499.067,
101 794.075, and 921.0022, F.S.; conforming cross-
102 references; creating s. 893.30, F.S.; creating the
103 "Victoria Siegel Controlled Substances Safety
104 Education and Awareness Act"; requiring the Department
105 of Health to develop an educational pamphlet relating
106 to certain controlled substance issues; requiring the
107 department to encourage health care providers to
108 disseminate certain educational information; requiring
109 the department to encourage consumers to discuss
110 controlled substance risks with certain health care
111 providers; requiring the State Surgeon General to
112 provide certain educational resources on the
113 department's website; requiring the department to fund
114 controlled substance safety education and awareness
115 with certain grants; encouraging the department to
116 collaborate with other entities to create a systematic

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117 approach to increasing public awareness regarding
118 controlled substance safety; providing an effective
119 date.

120

121 Be It Enacted by the Legislature of the State of Florida:

122

123 Section 1. Subsection (2) of section 385.211, Florida
124 Statutes, is amended to read:

125 385.211 Refractory and intractable epilepsy treatment and
126 research at recognized medical centers.—

127 (2) Notwithstanding chapter 893, medical centers recognized
128 pursuant to s. 381.925, or an academic medical research
129 institution legally affiliated with a licensed children's
130 specialty hospital as defined in s. 395.002(28) that contracts
131 with the Department of Health, may conduct research on
132 cannabidiol and low-THC cannabis. This research may include, but
133 is not limited to, the agricultural development, production,
134 clinical research, and use of liquid medical derivatives of
135 cannabidiol and low-THC cannabis for the treatment for
136 refractory or intractable epilepsy. The authority for recognized
137 medical centers to conduct this research is derived from 21
138 C.F.R. parts 312 and 316. Current state or privately obtained
139 research funds may be used to support the activities described
140 in this section.

141 Section 2. Section 499.003, Florida Statutes, is amended to
142 read:

143 499.003 Definitions of terms used in this part.—As used in
144 this part, the term:

145 (1) "Active pharmaceutical ingredient" includes any

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2553 amended, and departmental rules.

2554 (15) DUE DILIGENCE OF PURCHASERS.—

2555 (b) A wholesale distributor must take reasonable measures
2556 to identify its customers, understand the normal and expected
2557 transactions conducted by those customers, and identify those
2558 transactions that are suspicious in nature. A wholesale
2559 distributor must establish internal policies and procedures for
2560 identifying suspicious orders and preventing suspicious
2561 transactions. A wholesale distributor must assess orders for
2562 more ~~greater~~ than 7,500 ~~5,000~~ unit doses of any one controlled
2563 substance in any one month to determine whether the purchase is
2564 reasonable. In making such assessments, a wholesale distributor
2565 may consider the purchasing entity's clinical business needs,
2566 location, and population served, in addition to other factors
2567 established in the distributor's policies and procedures. A
2568 wholesale distributor must report to the department any
2569 regulated transaction involving an extraordinary quantity of a
2570 listed chemical, an uncommon method of payment or delivery, or
2571 any other circumstance that the regulated person believes may
2572 indicate that the listed chemical will be used in violation of
2573 the law. The wholesale distributor shall maintain records that
2574 document the report submitted to the department in compliance
2575 with this paragraph.

2576 Section 10. Subsection (4) of section 499.015, Florida
2577 Statutes, is amended to read:

2578 499.015 Registration of drugs, devices, and cosmetics;
2579 issuance of certificates of free sale.—

2580 (4) Unless a registration is renewed, it expires 2 years
2581 after the last day of the month in which it was issued. Any

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2962

812.135 (2) (a) 1st,PBL Home-invasion robbery
with firearm or other
deadly weapon.

2963

876.32 1st Treason against the
state.

2964

2965 Section ~~22. Section 893.30, Florida Statutes, is created to~~
2966 ~~read:~~

2967 ~~893.30 Controlled substance safety education and~~
2968 ~~awareness.-~~

2969 ~~(1) This section may be cited as the "Victoria Siegel~~
2970 ~~Controlled Substance Safety Education and Awareness Act."~~

2971 ~~(2) The department shall develop a written pamphlet~~
2972 ~~relating to controlled substances which includes educational~~
2973 ~~information about the following:~~

2974 ~~(a) Precautions regarding the use of pain management~~
2975 ~~prescriptions.~~

2976 ~~(b) The potential for misuse and abuse of controlled~~
2977 ~~substances by adults and children.~~

2978 ~~(c) The risk of controlled substance dependency and~~
2979 ~~addiction.~~

2980 ~~(d) The proper storage and disposal of controlled~~
2981 ~~substances.~~

2982 ~~(e) Controlled substance addiction support and treatment~~
2983 ~~resources.~~

2984 ~~(f) Telephone helplines and website links that provide~~
2985 ~~counseling and emergency assistance for individuals dealing with~~

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2986 substance abuse.

2987 (3) The department shall encourage health care providers,
2988 including, but not limited to, hospitals, county health
2989 departments, physicians, and nurses, to disseminate and display
2990 information about controlled substance safety, including, but
2991 not limited to, the pamphlet created pursuant to subsection (2).

2992 (4) The department shall encourage consumers to discuss the
2993 risks of controlled substance use with their health care
2994 providers.

2995 (5) The State Surgeon General shall make publicly
2996 available, by posting on the department's website, the pamphlet
2997 created pursuant to subsection (2) and additional resources as
2998 appropriate.

2999 (6) The department shall fund the promotion of controlled
3000 substance safety education and awareness under this section
3001 through grants from private or federal sources.

3002 (7) The department is encouraged to collaborate with other
3003 agencies, organizations, and institutions to create a systematic
3004 approach to increasing public awareness regarding controlled
3005 substance safety.

3006 Section 23. This act shall take effect July 1, 2016.

Regulation through education: Florida's actions to ensure a quality and consistent sterile compounded drug supply

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Abstract

In October 2012, a sterile compounding pharmacy in Framingham, Massachusetts, New England Compounding Center (NECC), shipped compounded injectables contaminated with fungal meningitis that sickened and killed hundreds of patients around the country. In Florida 25 patients were infected, 7 died. Florida faced one of the greatest public health threats in recent years. The Florida Department of Health (department) and Florida Board of Pharmacy (board) took immediate action to identify and establish safeguards within the existing statutory authority and, with the action of the Florida Legislature, long-term solutions to ensure a safe compounded drug supply entering and exiting the state. This article will review the events leading to sweeping changes in Florida's regulatory environment through administrative rule promulgation and legislation; development of documented processes for future sterile compounded drug recalls; and the department's innovative regulatory response with licensed sterile compounding pharmacies-a shift in focus from discipline for practice infractions to education on process standards that focus on quality and consistency.

Key words: Sterile compounding; non-sterile compounding; USP 797; non-resident pharmacy; outsourcing facility

Introduction

In October 2012 an outbreak of fungal meningitis was reported in the United States. The Centers for Disease Control and Prevention traced the outbreak to fungal contamination in 3 lots of methylprednisolone acetate used for spinal steroid injections. The medication was compounded and shipped by New England Compounding Center (NECC) in Framingham, Massachusetts. The contaminated drugs were distributed to facilities in 20 states. The outbreak killed 64 people and sickened over 750. In Florida, 25 patients were infected, 7 died. At the time, NECC was licensed in Florida as a non-resident

pharmacy and subject to the state's limited regulatory authority. On October 25, 2012, the Department obtained a disciplinary voluntary relinquishment from NECC stipulating that the pharmacy may never re-apply for a permit in Florida.

In December 2014, 14 owners or former employees were charged by federal prosecutors with a variety of criminal violations. In May 2015 a federal bankruptcy judge approved a plan that will give victims access to a \$200 million compensation fund. Fourteen former employees of the New England Compounding Center, including its founders and majority shareholders face federal racketeering charges in what authorities say is the largest criminal case every brought over contaminated medicine.¹

State Regulatory Environment in 2012

In the fall of 2012, any pharmacy permittee, except animal shelters, assisted living facilities or nursing homes, and excluding nuclear pharmaceuticals, could perform compounding. A special parenteral/enteral permit allowed the compounding of sterile products without some of the additional mandates required of a community pharmacy permit (e.g. the mandate to be open 40 hours a week). A special parenteral/enteral permit was not required, however, to perform sterile compounding. In November 2012 there were 285 special parenteral/enteral pharmacy permittees in Florida. A total of 7,879 Florida licensed pharmacies were authorized to compound in that same month.

The Board rules allowed compounding of drugs or devices in anticipation of prescriptions for drugs that were not commercially available. Additionally, the rules allowed compounding from bulk, commercially available drugs, based on a patient-specific prescription and allowed compounding for office use, defined to mean the administration of a compounded drug to a patient by a health care practitioner in a treatment setting. Pharmacies were allowed to prepare multiple doses of a drug without patient-specific prescriptions and to provide those drugs to doctors' offices and clinics based on regularly observed prescribing patterns. At the time, according to the International Academy of Compounding Pharmacists², 42 states allowed office use compounding in some form. Six states specifically prohibited this type of compounding, and two states were silent.

Sterile compounding, in board rule, was classified as high risk, medium risk, low risk and immediate use. High-Risk Level Compounding Sterile Preparations (CSPs) were defined as products compounded under conditions set forth in rule and included products compounded using non-sterile ingredients that are incorporated into sterile parenteral administration products. Key requirements set in board rule included a laminar flow hood in a clean room or a barrier isolator and no sink or drain in the clean room. Sterility testing was required if high risk compounding of batches larger than 25 units was performed and if sterile compounded preparations were stored longer than specified in board rule. All compounding personnel were required to demonstrate competency by preparing a commercially available sterile fluid culture media in which media-filled vials were incubated at 23-35 degrees Celsius for 14 days. Failure was defined as visible turbidity in the medium on or before 14 days.

In the fall of 2012, pharmacies in Florida were inspected by 18 department employees, five of whom were licensed pharmacists. The frequency of inspections was established

in board rule. New pharmacies were inspected twice during their first year; the frequency of other pharmacy inspections was based on prior inspection history or disciplinary action taken by the board, but no less than every other year. Non-resident pharmacies were inspected by the regulatory body in the state in which they were physically located, according to the standards in that state. No proof of inspection was required for license renewal. The board had no authority to inspect non-resident pharmacies and disciplinary action could not commence until 6 months following an infraction to allow the state in which the pharmacy was located to take action.

In-state pharmacies that performed sterile compounding were inspected according to specifications in board rule that included a review of sterility documentation for high risk level sterile preparations compounded in batches greater than 25 units or if stored longer than authorized by rule, performance of a visual check of the compounding area, a review of policies and procedures, verification that there were no sinks or drains in the clean room, and verification of adequate supplies and equipment. Department inspectors did not test air quality of clean rooms and laminar flow hoods or the sterility of compounded products and although they checked for documentation of certification of clean rooms and laminar flow hoods that had been performed by an outside entity hired by the pharmacy, the board had no requirements of the outside entity adopted by rule.

Violations identified during an inspection were handled in one of two ways: 1) the pharmacy was given an opportunity to correct minor violations (e.g. outdated policies and procedures) and provide proof of correction by mail; or 2) for more serious violations, a complaint was opened for investigation and possible emergency action based upon an immediate and serious risk to the public health and safety. Of six pharmacies under an emergency suspension order in November 2012, two were related to compounding violations. Rejuvi Pharmaceuticals was issued an emergency suspension order on October 24, 2012 for not being clean and safe for sterile compounding. People's Choice Pharmacy was issued an emergency suspension order on November 6, 2012 for a complete disregard for quality assurance in high-risk sterile compounding and the use of unlicensed personnel for high-risk sterile compounding making the pharmacy unsafe and putting the public at risk.

In the almost 4 year period from January 1, 2009 through November 30, 2012, the Board took disciplinary action related to the practice of compounding against two pharmacists and three pharmacies.

Department of Health and Board of Pharmacy Response

Within 24 hours of learning of the contaminated products shipped by NECC, the department instituted a modified incident command system to manage outreach to patients, facilities, and health care providers and to coordinate inter-agency response, including physical inspections. The department's office of the general counsel managed the legal response including issuance of subpoenas and obtaining a licensure relinquishment from NECC that stipulated the company would never apply for a permit in Florida in the future. As the emergency team stood down, the structure was retained in the department's bureau for regulatory enforcement and today the staff monitors daily the FDA website and email alert system for all voluntary drug recalls. The recall and outreach process resulted in development of documented procedures for future recall

activities. It also included the development of standardized outreach communication scripts; creation of a standardized *Affidavit of Compliance of Non-Shipment to Florida*³, standardized data collection methods; and a detailed process map.

All voluntary recalls are investigated to determine if the pharmacy is permitted in Florida, and if any products were shipped to Florida locations. A documented process is followed that involves telephonic communication with the pharmacy if permitted; a request for shipping records to Florida locations (by subpoena, if necessary); and outreach to facilities, practitioners, and/or patients, if warranted. Furthermore, upon receipt of a FDA recall involving a licensed Florida pharmacy or any pharmacy that may have engaged in the unlicensed practice of pharmacy in Florida, a complaint is opened immediately and its investigation given priority.

The department outreach⁴ commenced on Friday, October 5, 2012 and continued 7 days a week until outreach to 257 facilities was completed on October 22, 2012. Completed outreach was defined as documented contact via phone, on-site visit to hand serve a notice, or return receipt for certified mail when first two attempts were unsuccessful.

In an article published by the New England Journal of Medicine, "Regulating Compounding Pharmacies after NECC", November 8, 2012, the author states,

"Some observers have chastised the FDA for not acting sooner against NECC, given the agency's authority to block illegal drug manufacturing. But this critique ignores the complex regulatory history. FDA authority over compounding has never been straight-forward, and though the agency can react once a problem is obvious, it's unclear how it should proactively gather information on potential violations before a crisis erupts. The thousands of U.S. compounding pharmacies are not registered with the FDA; they are not subject to federal recordkeeping and reporting rules for drug manufacturers....Without information about the actual conditions in compounding pharmacies, regulators cannot act to address violations."⁵

This description of the federal landscape closely mirrored the state of Florida's regulatory landscape with sterile compounding. Limited regulation yielded little information and regulatory knowledge about sterile compounding conditions, quantities, or processing standards. In October 2012, to gather critical information to guide policy and direct needed change, the board sent a voluntary compounding survey to 7,747 pharmacies; the response rate was less than 10%. Stronger measures were enacted.

On November 15, 2012, the board published a notice of emergency rule, "Immediate Notification of Compounding Status and Inspections". In citing the specific reasons for finding an immediate danger to the public health, safety or welfare, the notice stated, in part:

"For the protection of the citizens' health, welfare and safety from continued proliferation of unsanitary or contamination compounding environments and distribution of contaminated products into this state, the board is in immediate need of comprehensive data: the specific compounding activities taking place at all permitted pharmacies and non-resident pharmacies. The rule is specifically designed to target, though inspection reporting requirements of non-resident pharmacies, to identify

and minimize the immediate threat of contaminated procures. The rule is also critical for identifying the high risk compounding activities in Florida pharmacies, so the department and board can prioritize inspections to minimize the immediate health and safety risks associated with unsanitary and unsterile compounding facilities in Florida.”⁶

The emergency rule took effect on Monday, November 26, 2012 and a mandatory, web-based survey response was required of all licensed pharmacy permit holders, including non-residents, with a deadline for response of December 11, 2012. Failure to timely complete the survey constituted grounds for disciplinary action.⁷

The survey provided information critical to the board and the department to form legislative, rule and policy changes. With a response rate of 92%, we learned that 946 (12%) pharmacies were performing sterile compounding of which, 32% (301) were non-resident pharmacies. Extensive information was also compiled about the types of sterile products compounded, bulk and/or in bulk for office use; and shipments to other states (of the 307 who shipped sterile compounded products to other states, only 57 were physically located in Florida).

Since the emergency rule adoption in 2012, the board has engaged in extensive rulemaking to ensure that all Florida pharmacies engaging in sterile compounding are permitted and inspected based upon more stringent standards. On September 23, 2013, the Board created through rule, a new Special Sterile Compounding Permit.⁸ The rule required all pharmacies engaged in sterile compounding to obtain the permit on or before March 21, 2014.

On June 22, 2014, the board amended its rule on the Definition of Compounding, 64B16-27.700, F.A.C.⁹, to make it clear that any pharmacy engaging in office use compounding of sterile products intended for human use, must be in full compliance with 21 U.S.C. § 353b, including being federally registered as an outsourcing facility.¹⁰ The rule change adopted and incorporated 21 U.S.C. § 353b (eff. Nov. 27, 2013) by reference.

The Board also adopted significant changes to its rule, Standards of Practice for Compounding Sterile Preparations, 64B16-27.797, F.A.C.¹¹, which went into effect on October 1, 2014. Most significantly, the amended rule requires all sterile compounding to be performed in accordance with the minimum practice and quality standards of the following chapters of the United States Pharmacopeia (USP):

- (a) Chapter 797, Pharmaceutical Compounding-Sterile Preparations¹²
- (c) Chapter 71, Sterility Tests
- (d) Chapter 85, Bacterial Endotoxins Test
- (e) Chapter 731, Loss on Drying

Legislative action

In fall 2013, Florida legislators and their staff analysts and counsels included the department in a series of meetings during which enhanced sterile compounding enforcement tools were identified, and legislative guardrails regulating compounding

pharmacies were crafted. Committee Substitute for House bill 7077¹³ was passed in 2014 and enacted sweeping reforms especially related to non-resident pharmacies intending to ship sterile compounded products into Florida. The legislation also addressed some significant regulatory gaps and, for the first time, compounding and outsourcing facilities were defined in statute. Compounding is defined as combining, mixing, or altering the ingredients of one or more drugs or products to create another drug or product. An outsourcing facility is defined as a single physical location registered as an outsourcing facility under the federal Drug Quality and Security Act, at which sterile compounding of a drug or product is conducted.

A non-resident sterile compounding permit is required of all non-resident pharmacies intending to ship to Florida. Registration requires proof of registration as an outsourcing facility or state licensure; an attestation that any sterile compounded product shipped or otherwise introduced into this state will meet or exceed Florida laws and rules governing sterile compounding; and any sterile compounded product shipped or otherwise introduced has not been, and will not be, compounded in violation of laws and rules governing sterile compounding where the application is located. (Note: NECC was in violation of Massachusetts state law which prohibited bulk sterile compounding.) An applicant must also show proof of an inspection within the previous 6 months by the regulatory or licensing agency that shows compliance with Florida standards. The department and the board were further granted authority to sanction a permittee for conduct that **could** cause harm and to conduct onsite inspections or contract with an entity approved by the board for non-resident applicants and permittees, the cost of which is directly billed to the applicant or permittee. As of the date of this article, the board has approved two third-party inspectors: National Association of Boards of Pharmacy and the Accreditation Commission for Health Care.¹⁴

Regulatory changes, rule or legislative, are routinely communicated by the board to licensees and permittees through the board website, through association newsletters, and by news release. To minimize the likelihood of another NECC-type event, the department chose to additionally provide face-to-face training to educate pharmacists on the specific set of process standards that concentrate on the quality and consistency of medications that are produced and against which department inspections will be conducted.

Regulation through Education

Before beginning the more stringent inspections, to ensure pharmacy inspectors could inspect to the new standards required with the board's adoption of USP 797 standards, in April 2013, Florida's senior pharmacists completed a three-day sterile compounding "boot camp" training offered by CriticalPoint. CriticalPoint's Sterile Compounding Boot Camp "indoctrinates learners to current sterile compounding best practices through presentation of theoretical and practical information presented in e-learning, classroom and realistic workplace simulations. Classes are taught in a state-of-the-art facility designed for cleanroom and pharmacy practice demonstrations, covering all aspects of USP 797 while using a hands-on training methodology. Attendees completing this program gain an understanding of how to develop and implement an operation that meets or exceeds USP 797 standards." Since the training, senior pharmacists have completed monthly consultation calls, discussing such topics as how to conduct a

detailed record review and a thorough observation of compounding practices and environment and how to ensure sterility testing is being conducted.

Although well prepared to begin conducting sterile compounding inspections using USP 797 standards, department leaders decided to first instruct sterile compounding pharmacies on the new quality assurance and consistency standards adopted in board rule and reflected in the newly revised inspection forms, before formal inspections commenced. Teaching to pass an inspection, unlike teaching to pass an exam, meant pharmacists and their technicians didn't learn correct answers; they learned proper standards and techniques that would ensure, most importantly, a safe sterile compounded drug supply, and secondarily, a compliant inspection.

To reach the broadest audience, the department mailed invitations to its first training in October 2014 to all sterile compounding pharmacy permit holders, resident and non-resident. The cost was free and 5 hours of continuing education credit were offered. 301 in-state and out-of-state attendees gave resoundingly positive feedback.

Using mobile inspection devices prepopulated with 134 inspection items¹⁵ linked to the department's licensure database, inspectors began conducting inspections that fall and tracked the most common deficiencies they discovered. Some of the most common deficiencies identified were:

- Quality control
- Hazardous Drugs
- Personnel Cleansing
- Facility Design and Certification
- Immediate Use of High Risk
- On-Site Sterility Testing
- Verification
- Dispensing Distribution
- Radiopharmaceuticals

These formed the core curriculum for the follow-up training in the fall of 2015. Attendance exceeded expectations, with 506 in-state and out-of-state pharmacists and staff participating. The 2016 training will reiterate training on standards for quality and consistency that have been deficient in the past two years, but more specifically focus on upcoming changes to USP 797 standards expected in 2017.

Results

Rule changes adopted by the Florida Board of Pharmacy and statutory changes enacted by the Florida Legislature have had some impact on the number of resident and non-resident permitted sterile compounding pharmacies. Before the board established a special sterile compounding permit and adopted USP 797 standards by rule, according to its mandatory survey results, Florida had 645 in-state sterile compounding pharmacies and 301 non-resident sterile compounding pharmacies. After the board rule went into effect and the Legislature enacted changes to requirements for non-resident sterile compounding pharmacies, Florida today has 157 non-resident and 460 in-state sterile compounding pharmacies, a 48% and 29% reduction, respectively.

Since the implementation of a modified incident command structure immediately following the NECC contamination, used when the department becomes aware of an FDA voluntary recall of compounded drugs, the Department has been able to improve its recall response from several weeks to one day. This improvement was reflected recently during a recall of the Prescription Drug Center on April 7, 2015, when the entire recall response was completed in 24 hours and 215 customers were contacted. As of January 2015 there have been 23 FDA recalls requiring action (18 non-resident, 5 in-state). As a result of the recalls, 3 agreed to voluntarily restrict their practice and not ship sterile compounded drugs into Florida; 2 have entered into disciplinary relinquishments and 7 have closed their doors. The enforcement staff have completed approximately 1,100 calls.

Because the Legislature granted the department greater enforcement authority, especially related to non-resident pharmacies, an actual case scenario provides compelling evidence of its effectiveness. In fall of 2014, a Florida non-resident sterile compounding pharmacy located in Texas was listed on the FDA's website with serious inspection deficiencies and a voluntary recall was requested for all of their sterile compounded products. The pharmacy declined. The day Florida learned of the inspection deficiencies, staff called the pharmacy and requested them to sign a voluntary agreement to immediately cease shipping to Florida and to recall all products already shipped to Florida. They declined, citing **no evidence of patient harm**. The department immediately commenced drafting an emergency suspension order based upon a clear and immediate threat to the public safety (the new law gave authority to take emergency action for a **threat** of patient harm); an injunction in circuit court prohibiting them from shipping into Florida; a voluntary agreement to stop shipping and recall all products shipped to Florida; and scheduled Florida inspectors to conduct an onsite inspection. When notified of their options, the pharmacy conducted a nationwide recall the same day.

The goal of the Department is to ensure a safe drug supply in Florida, and while enforcement remains a priority, emphasis today is on educating pharmacies on safe sterile compounding standards; not to discipline or threaten discipline for each inspection deficiency. Regulation through education has demonstrated its success in a variety of results. While deficiencies are still identified, increased outreach and education have led to less serious deficiencies that can be solved with a corrective action plan. From October 1, 2014 to October 20, 2015, inspectors have observed a 23.6 percent reduction in deficiencies in the following areas: on-site sterility testing, endotoxin testing, facility design and certification, quality and control, personnel cleansing, garbing and competency evaluation, and policies and procedures. This has led to a reduction of disciplinary cases as well. During the first quarter of fiscal year 2014-2015, the department had 14 disciplinary cases compared to 8 cases in the first quarter of fiscal year 2015-2016. This marks a 43% reduction in formal investigations related to sterile compounding. The department has also established a performance target to achieve by 2016: 95% of sterile compounding pharmacies will pass a first-time inspection with no serious deficiencies. Today we are at 83%.

And one final example, the last in-state Florida registered sterile compounding pharmacy that had to issue a voluntary recall was Lowlite Investments Inc., doing business as Olympia Pharmacy, on May 29, 2013.

Conclusion

A public health threat such as that posed by the distribution of contaminated sterile compounded products by New England Compounding Center required a swift and collaborative response to create short and long-term solutions in Florida. Without impacting the supply of needed sterile compounded products, Florida achieved a safer sterile compounded drug supply through rigorous standards and inspections. Regulation through education has demonstrated its importance in achieving quality and consistency in sterile compounded products through improved inspection results.

References{in process}

- ¹ Cbsnews.com, (2015). *Arrests in compounding pharmacy meningitis outbreak*. Retrieved 6 November 2015, from <http://www.cbsnews.com/news/arrests-in-compounding-pharmacy-meningitis-outbreak/>
- ² Iacprx.org, (2015). *IACP Law Library - International Academy of Compounding Pharmacists*. Retrieved 6 November 2015, from <http://www.iacprx.org/?227>
- ³ *Affidavit of Compliance of Non-Shipment to Florida*
- ⁴ Florida Department of Health, *DOH/MQA OUTREACH TO FACILITIES SHIPPED NECC PRODUCTS*, Tallahassee, FL (2012). Retrieved 6 November 2015, from <http://floridaspharmacy.gov/pdfs/compound-timeline.pdf>
- ⁵ Utterson, K. (2012). *Regulating Compounding Pharmacies after NECC*. *New England Journal Of Medicine*, 367(21), 1969-1972. <http://dx.doi.org/10.1056/nejmp1212667>
- ⁶ Flrules.org, (2015). *64B16ER12-1: Immediate Notification of Compounding Status and Inspections - Florida Administrative Rules, Law, Code, Register - FAC, FAR, eRulemaking*. Retrieved 6 November 2015, from <https://www.flrules.org/gateway/ruleNo.asp?id=64B16ER12-1>
- ⁷ Florida Department of Health, *Florida Board of Pharmacy Compounding Survey Report*. Tallahassee, FL. (2013). Retrieved 6 November 2015, from <http://floridaspharmacy.gov/Forms/info-compounding-survey-report.pdf>
- ⁸ Fla. Admin. Code R. 64B16-28.100 (2013).
- ⁹ Fla. Admin. Code R. 64B16-27.700 (2014).
- ¹⁰ (2015). Retrieved 6 November 2015, from Civic Impulse. (2015). H.R. 3204 — 113th Congress: Drug Quality and Security Act. Retrieved from <https://www.govtrack.us/congress/bills>
- ¹¹ Fla. Admin. Code R. 64B16-27.797 (2014).
- ¹² Pharmacopeia.cn, (2015). *General Chapters: PHARMACEUTICAL COMPOUNDING-STERILE PREPARATIONS*. Retrieved 6 November 2015, from http://www.pharmacopeia.cn/v29240/usp29nf24s0_c797_viewall.html
- ¹³ Act effective Oct. 1, 2014, ch. 2014 Fla. Laws 148
- ¹⁴ Achc.org, (2015). *ACHC | Home Health Accreditation | Hospice Accreditation | DMEPOS Accreditation | Pharmacy and PCAB Accreditation | Private Duty Accreditation | Sleep Accreditation | Behavioral Health Accreditation | CMS Deeming Authority*. Retrieved 6 November 2015, from <http://www.achc.org/>
- ¹⁵ Florida Department of Health, *State of Florida, Department of Health, Investigative Services, Sterile Compounding*, Tallahassee, FL (2014). Retrieved 6 November 2015, from <http://www.floridahealth.gov/licensing-and-regulation/enforcement/inspection-program/documents/sterile-cmpd-form.pdf>

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- **[Reporting Unlawful Sales of Medical Products on the Internet](/Safety/ReportaProblem/ucm059315.htm)**
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- **[MedWatchLearn](http://www.accessdata.fda.gov/scripts/MedWatchLearn/)**
- **[Voluntary Adverse Event Reporting Contact Information](/Safety/MedWatch/HowToReport/ucm337471.htm)**

[More in Reporting Serious Problems to FDA](/Safety/MedWatch/HowToReport/default.htm)

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Compounding and the FDA: Questions and Answers

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- [Is combining two or more drugs considered compounding? \(http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#combine\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#combine)
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- [Does the Drug Quality and Security Act \(DQSA\) cover the compounding of animal drugs?](#)

1. What is “compounding”?

In general, compounding is a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient.

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2. Is combining two or more drugs considered compounding?

Yes, compounding includes the combining of two or more drugs.

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3. Why do some patients need compounded drugs?

Sometimes, the health needs of a patient cannot be met by an FDA-approved medication. For example:

- if a patient has an allergy and needs a medication to be made without a certain dye; or
- if an elderly patient or a child can't swallow a pill and needs a medicine in a liquid form that is not otherwise available.

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4. Are compounded drugs approved by the FDA?

Compounded drugs are not FDA-approved. This means that FDA does not verify the safety, or effectiveness of compounded drugs. Consumers and health professionals rely on the drug approval process to ensure that drugs are safe and effective and made in accordance with Federal quality standards. Compounded drugs also lack an FDA finding of manufacturing quality before such drugs are marketed.

Generally, state boards of pharmacy will continue to have primary responsibility for the day-to-day oversight of state-licensed pharmacies that compound drugs in accordance with the conditions of **[section 503A of the FDCA \(http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/US-CODE-2010-title21-chap9-subchapV-partA-sec353a.pdf\)](http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/US-CODE-2010-title21-chap9-subchapV-partA-sec353a.pdf)**, although FDA retains some authority over their operations. However, outsourcing facilities that register under section 503B are regulated by FDA and must comply with CGMP requirements and will be inspected by FDA according to a risk-based schedule.

5. What are the risks associated with compounded drugs?

There can be health risks associated with compounded drugs that do not meet federal quality standards. Compounded drugs made using poor quality practices may be sub- or super-potent, contaminated, or otherwise adulterated. Additional health risks include the possibility that patients will use ineffective compounded drugs instead of FDA-approved drugs that have been shown to be safe and effective.

6. Who regulates and inspects facilities that compound drugs?

Generally, state boards of pharmacy will continue to have primary responsibility for the day-to-day oversight of state-licensed pharmacies that compound drugs in accordance with the conditions of [section 503A of the FDCA \(http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/US-CODE-2010-title21-chap9-subchapV-partA-sec353a.pdf\)](http://www.gpo.gov/fdsys/pkg/USCODE-2010-title21/pdf/US-CODE-2010-title21-chap9-subchapV-partA-sec353a.pdf), although FDA retains some authority over their operations. For example, the adulteration or misbranding of drugs compounded under section 503A, or false or misleading statements in the labeling or advertising of such drugs, may result in violations of Federal law. Firms that register with FDA as “outsourcing facilities” under section 503B will be regulated by FDA and inspected by FDA according to a risk-based schedule. [\[Back to top \(http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#top\)\]](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm339764.htm#top)

7. What is FDA doing to implement the new law?

Please see FDA implementation of the [Compounding Quality Act \(/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm\)](http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/ucm375804.htm).

8. What is an outsourcing facility?

The Drug Quality and Security Act, signed into law on November 27, 2013, creates a new section 503B in the FDCA. Under section 503B, a compounder can become an “outsourcing facility.” The law defines an “outsourcing facility” as a facility at one geographic location or address that is engaged in the compounding of sterile drugs; has elected to register as an outsourcing facility; and complies with all of the requirements of section 503B.

An outsourcing facility can qualify for exemptions from the FDA approval requirements and the requirement to label products with adequate directions for use, but not the exemption from current good manufacturing practice (CGMP) requirements. Outsourcing facilities:

- must comply with CGMP requirements;
- will be inspected by FDA according to a risk-based schedule; and
- must meet certain other conditions, such as reporting adverse events and providing FDA with certain information about the products they compound.

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9. How does an outsourcing facility register with FDA?

FDA has issued draft guidance on registering and reporting for those entities that intend to register as outsourcing facilities.

They should register using FDA’s electronic drug registration system or by sending an email to FDA’s drug registration and listing staff with the required registration information. FDA will provide assistance to outsourcing facilities that need assistance with the electronic registration system.

FDA is also providing an interim process that registered outsourcers may use to provide information about the products that they make under the reporting provisions of the new law.

In the future, FDA plans to make necessary modifications to its electronic listing system to accommodate the information outsourcing facilities must provide. The interim provisions provide an Excel spreadsheet format that an outsourcing facility may use to provide the necessary information.

10. What happens to compounders who conduct outsourcing operations but do not register with FDA?

If a compounder does not register with FDA as an outsourcing facility, it will not qualify for the section 503B exemption from the FDA approval requirements and the requirement to label products with adequate directions for use. If that compounder also fails to satisfy the conditions for the section 503A exemption, it will be subject to all of the requirements of the FDCA that are applicable to drugs made by conventional manufacturers, including the new drug approval, adequate directions for use, and CGMP requirements.

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11. How will FDA deal with compounders that do not register as outsourcers but fail to comply with the requirements of section 503A of the FDCA?

If a compounded drug does not qualify for the exemptions under either section 503A or 503B of the FDCA, it would be subject to all of the requirements of the FDCA that are applicable to drugs made by conventional manufacturers, including the new drug approval, adequate directions for use, and CGMP requirements.

FDA issued a draft guidance that describes FDA's intention with regard to the provisions of section 503A that require rulemaking or other action to implement. This draft guidance also describes the provisions of the law that are applicable to compounded drugs that do not qualify for the exemptions described above, and the other provisions of the FDCA applicable to compounded drugs regardless of whether they qualify for the exemptions under section 503A.

12. Does the Drug Quality and Security Act (DQSA) cover the compounding of animal drugs?

No, the DQSA does not cover animal compounding. For questions about animal drug compounding, contact FDA's Center for Veterinary Medicine at **AskCVM@fda.hhs.gov** (mailto:**AskCVM@fda.hhs.gov**).

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