AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

December 3, 2013

Hilton Hotel University of Florida
1714 SW 34th Street
Gainesville, FL 32607
(352) 371-3600

Committee Members:
Jeffrey J. Mesaros, PharmD, Tampa, Chair
Debra Glass, BPharm, Tallahassee
Michele Weizer, PharmD, Boca Raton

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

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

Participants in this public meeting should be aware that these proceedings are being recorded.

Tuesday, December 3, 2013 – 9:00 a.m.

1. 64B16-26.608 – Automated Filling Systems (new). Revised new language for review.
2. 64B16-28.303 – Destruction of Controlled Substances – All Permittees (Excluding Nursing Homes).
3. 64B16-28.1031 – Influenza Immunization Certification Program.
4. 64B16-28.140 – Record maintenance Systems for Community, Special-Limited Community, Special-Closed Systems, Special-Parenteral/Enteral, and Nuclear Permits.
5. 64B16-30.001 – Disciplinary Guidelines for discussion and substantive changes in response to JAPC comments.
6. 64B16-28.100(5) Pharmacy Permits – Applications and Permitting.

Tab 1. 64B16-28.608: Automated Filling Systems.

This is revised new language for a follow-up review and discussion. Some of the previous concerns and comments were:

- To include a (1)(f) defining (initial) loading
- To add subsection (3) on “Medication Loading”
- Only a pharmacist can load
- That terminology be consistent with rule 28.141 (included in this tab)
- That the rule does not release the pharmacist from responsibility for any errors
- Two years of records maintenance changed to four years
- An audit trail is maintained – see (5)(h), formerly subsection (4)
- A discussion of “reporting errors” took place and may need to be continued and/or clarified – see (6)(d), and (n), formerly in subsection (5)
- That a copy of dentistry’s adverse incident rule be provided

64B16-28.608 Automated Filling Systems within a Pharmacy (new)

(1) Definitions. The following definitions shall be applicable for purposes of this rule:

(a) "Automated filling system" means an automated system used within a pharmacy to assist in filling a prescription drug order by selecting, labeling, filling, or sealing medication for dispensing. An "automated filling system" shall not include automated devices used solely to count medication, vacuum tube drug delivery systems, or systems governed by Sections 64B16-28.606 or 64B16-28.607.

(b) "Electronic verification process" means an electronic verification, bar code verification, weight verification, radio frequency identification (RFID), or similar electronic process or system that accurately verifies medication has been properly dispensed and labeled by, or loaded into, an automated filling system.

(c) "Manufacturer Unit of Use Package" means a drug dispensed in the manufacturer's original and sealed packaging, or in the original and sealed packaging of a Repackager, without additional manipulation or preparation by the pharmacy, except for application of the pharmacy label.

(d) "Repackager" means a Repackager registered with the United States Food and Drug Administration (FDA), as defined by s. 499.003(50).

(e) "Prepacked" means any drug that has been removed from the original packaging of the manufacturer or an FDA Repackager and is placed in a container for use in an automated filling system, as referenced by s. 499.003(42).

(f) “Load” means assigning new medications for new NDC numbers to the system, which must be completed by an onsite pharmacist.

(2) Medication Stocking. Automated filling systems (hereinafter "system") may be stocked or restocked by a pharmacist, pharmacy intern, or licensed pharmacy technician under the supervision of a pharmacist, as each are defined by rule 64B16-27.1001(7).

(3) Medication Loading. System must be loaded by an onsite pharmacist.

(4) Verification. Except as provided herein, a licensed pharmacist must verify the accuracy of the final contents of any medication filled or packaged by a system, and any label affixed thereto, prior to dispensing, as defined by rule 64B16-27.1001(3).

(5) The pharmacist verification requirements of section (3) shall be deemed satisfied if:

(a) The pharmacy establishes and follows a policy and procedure manual that complies with section (6) of this rule;

(b) The system is fully automated from the time the medication is loaded into the machine until a completed, labeled and sealed prescription is produced by the system that is ready for dispensing to the patient. No manual intervention with the medication may occur after the medication is loaded into the system. For purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(c) A pharmacist must perform a prospective drug review and verify the accuracy of the prescription information used by or entered into the system for a specific patient prior to initiation of the automatic fill process.

The name, initials or identification codes(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for four (4) years after dispensing, or longer if required by applicable law;

(d) All medication Prepacked by the pharmacy must be verified by a pharmacist pursuant to rule 64B16-27.1001(3).

(e) A pharmacist verifies the correct medication, either the Manufacturer Unit of Use Package, Repacked, or Prepacked container, was properly stocked, filled and loaded in the system. Alternatively, an electronic verification process may be used to verify a Manufacturer Unit of Use Package, Repackaged, or Prepacked containers;

(f) The medication to be dispensed is selected, filled, labeled, or sealed in the prescription container by the system or dispensed by the system in a Manufacturer's Unit of Use Package, Repacked, or Prepacked container;

(g) An electronic verification process is used to verify the proper prescription label has been affixed to the correct medication, Prepackaged medication or Manufacturer Unit of Use Package for the correct patient; and

(h) An audit trail is maintained for the prescription from the beginning of the system to the dispensing from the system, and maintain for four (4) years.

(6) Policies and Procedures. Pharmacies verifying prescriptions pursuant to section (5) of this rule shall establish and follow written policies and procedures to ensure the proper, safe, and secure functioning of the system. Policies and procedures shall be reviewed annually by the pharmacist-in-charge and shall be maintained in the pharmacy's records for a minimum of four (4) years. The required annual review shall be documented in the pharmacy's records and made available upon request. At a minimum, the pharmacy shall establish and follow policies and procedures for:

(a) Maintaining the system and any accompanying electronic verification system in good working order;

(b) Ensuring accurate filling, loading, and stocking of the system;

(c) Ensuring sanitary operations of the system and preventing cross-contamination of cells, cartridges, containers, cassettes, or packages;

(d) Reporting, investigating, and addressing filling errors and system malfunctions;

(e) Testing the accuracy of the system and any accompanying electronic verification system. At a minimum, the system and electronic verification process shall be tested before the first use of the system or restarting the system and upon any modification to the system or electronic verification process that changes or alters the filling or electronic verification process;

(f) Training persons authorized to access, stock, restock, or load the system in equipment use and operations;

(g) Tracking and documenting of automated filling system errors that are not corrected prior to dispensing to the patient. Such documentation shall be maintained for four (4) years and produced to the Board upon request;

(h) Conducting routine and preventive maintenance and, if applicable, calibration;

(i) Removing expired, adulterated, misbranded or recalled drugs;

(j) Preventing unauthorized access to the system, including assigning, discontinuing or changing security access;

(k) Identifying and recording persons responsible for stocking, loading and filling the system;

(l) Ensuring compliance with state and federal law, including, all applicable labeling, storage, and security requirements;

(m) Maintaining an ongoing quality assurance program that monitors performance of the system and any electronic verification process to ensure proper and accurate functioning; and

(n) Reporting errors.

(7) Recordkeeping. Except as otherwise provided herein, records required by this rule shall be maintained in the pharmacy's records electronically or in writing for a minimum of four (4) years, or longer if required under applicable law. If the verification requirements of (4)(d) of this rule are completed by a pharmacist, the name, initials or identification code(s) of the verifying pharmacist shall be recorded in the pharmacy's records and maintained for five (5) years after dispensing. Records shall be made available for inspection and produced to the Board or the Board's authorized designee upon request.

For comparison and consistency of terms:

64B16-28.141 Requirements for an Automated Pharmacy System in a Community Pharmacy.

(1) Definitions. “Automated pharmacy system” means a mechanical system, located within or adjacent to the prescription department, that performs operations or activities, other than compounding or administration, relative to storage, packaging, dispensing, or distribution of medication, and which collects, controls, and maintains all transaction information.

(2) General Requirements. A pharmacy may use an automated pharmacy system provided that:

(a) The pharmacy develops and maintains a policy and procedure manual that includes:

1. The type or name of the system including a serial number or other identifying nomenclature.

2. A method to ensure security of the system to prevent unauthorized access. Such method may include the use of electronic passwords, biometric identification (optic scanning or fingerprint) or other coded identification.

3. A process of filling and stocking the system with drugs; an electronic or hard copy record of medication filled into the system including the product identification, lot number, and expiration date.

4. A method of identifying all the registered pharmacy interns or registered pharmacy technicians involved in the dispensing process.

5. Compliance with a Continuous Quality Improvement Program.

6. A method to ensure that patient confidentiality is maintained.

7. A process to enable the prescription department manager or designee to revoke, add, or change access at any time.

(b) The system ensures that each prescription is dispensed in compliance with the definition of dispense and the practice of the profession of pharmacy.

(c) The system shall maintain a readily retrievable electronic record to identify all pharmacists, registered pharmacy technicians, or other personnel involved in the dispensing of a prescription.

(d) The system shall provide the ability to comply with product recalls generated by the manufacturer, distributor, or pharmacy. The system shall have a process in place to isolate affected lot numbers including an intermix of drug product lot numbers.

(3) Additional Requirements for Patient Accessed Automated Pharmacy Systems. A pharmacy may use a patient accessed automated pharmacy system, provided that:

(a) Meets the requirements in subsection (2) above.

(b) The stocking or restocking of a medicinal drug shall only be completed by a Florida pharmacist, except as provided in paragraph (c) below.

(c) If the automated pharmacy system uses removable cartridges or container to store the drug, the stocking or restocking of the cartridges or containers may occur at a licensed repackaging facility and be sent to the provider pharmacy to be loaded by personnel designated by the pharmacist if:

1. A Florida pharmacist verifies the cartridge or container has been properly filled and labeled.

2. The individual cartridge or container is transported to the provider pharmacy in a secure, tamper-evident container.

3. The automated pharmacy system uses a bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the cartridge or container is accurately loaded into the automated pharmacy system.

4. The Florida pharmacist verifying the filling and labeling is responsible if the cartridge or container is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

(d) The automated pharmacy system must use at least two separate verifications, such as bar code verification, electronic verification, weight verification, radio frequency identification (RFID) or similar process to ensure that the proper medication is being dispensed from the automated system.

(e) The medication shall bear a patient specific label that complies with Rule 64B16-28.108, F.A.C.

(f) The record of transactions with the patient accessed automated pharmacy system shall be available to authorized agents of the Department of Health. The record of transactions shall include:

1. Name of the patient.
2. Name, strength, and dosage form of the drug product dispensed.
3. Quantity of drug dispensed.
4. Date and time of dispensing.
5. Name of provider pharmacy.
6. Prescription number.
7. Name of prescribing practitioner.
8. Identity of the pharmacist who approved the prescription or order.
9. Identity of the person to whom the drug was released.

(4) The Florida pharmacist responsible for filling, verifying, or loading the automated pharmacy system shall be responsible for her or his individual action.

(5) A prescription dispensed pursuant to the requirements of this rule shall be deemed to have been certified by the pharmacist.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.018, 465.022 FS. History–New 11-29-04, Amended 12-30-07, 1-1-10.

Additional Information from New Jersey:

STATE BOARD OF PHARMACY LAW AND PUBLIC SAFETY
Chapter 39 Last Revision Date: 8/5/2013

SUBCHAPTER 10.
AUTOMATED MEDICATION SYSTEMS

13:39-10.1 PURPOSE AND SCOPE
The rules in this subchapter establish standards applicable to all pharmacies and/or facilities that utilize automated medication systems to store, package, dispense and distribute prescriptions or medication orders.

13:39-10.2 "AUTOMATED MEDICATION SYSTEM" DEFINITION
As used in this subchapter, "automated medication system" means any process that performs operations or activities, other than compounding or administration, relative to the storage, packaging, dispensing and distribution of medications, and which collects, controls and maintains all transaction information. "Automated medication system" does not mean an automatic counting device operated pursuant to N.J.A.C. 13:39-5.9 or a mechanical drug dispensing device operated pursuant to N.J.A.C. 13:39-9.17.

13:39-10.3 AUTHORITY TO USE AUTOMATED MEDICATION SYSTEM
a) A pharmacy may use an automated medication system to fill prescriptions or medication orders provided that:

1) The pharmacist-in-charge shall be responsible for the supervision of the operation of the system, or in the case of an automated medication system utilized at a location with no on-site pharmacy, the pharmacist-in-charge of the provider pharmacy shall be responsible for the supervision of the operation of the system;
2) The pharmacy has conducted a self-inspection of the automated medication system documented on a form provided by the Board and has submitted the self-inspection to the Board;
3) The automated medication system has been tested by the pharmacy and found to dispense accurately. The pharmacy shall make the results of such testing available to the Board upon request; and
4) The pharmacy has made the automated medication system available to the Board for the purpose of inspection, whereby the Board may validate the accuracy of the selfinspection and/or of the system.

b) The pharmacist-in-charge shall be responsible for the following:

1) Reviewing and approving all policies and procedures for system operation, safety, security, accuracy and access, patient confidentiality and prevention of unauthorized access and malfunction;
2) Ensuring that medications in the automated medication system are inspected, at least once every two months, for expiration or use by date, misbranding and physical integrity, and ensuring that the automated medication system is inspected, at least once every two months, for security and accountability;
3) Assigning, discontinuing or changing personnel access to the automated medication system;
4) Ensuring that the automated medication system is stocked accurately and an accountability record is maintained in accordance with the written policies and procedures of operation; and
5) Ensuring compliance with all applicable provisions of N.J.A.C. 13:39.

13:39-10.4 WRITTEN POLICIES AND PROCEDURES OF OPERATION

a) When an automated medication system is used to fill prescriptions or medication orders, it shall be operated according to written policies and procedures of operation. The policies and procedures of operation shall:

1) Include a table of contents;

2) Include a description of all procedures of operation;

3) Set forth methods that shall ensure retention of each amendment, addition, deletion or other change to the policies and procedures of operation for at least two years after the change is made. Each such change shall be signed or initialed by the pharmacist-in-charge and shall include the date on which the pharmacist-in-charge approved the change;

4) Set forth methods that shall ensure that a pharmacist currently licensed in the transmitting jurisdiction reviews and approves the transmission of each original or new prescription or medication order to the automated medication system before the transmission is made;

5) Set forth methods to identity the quality control measures in place to ensure the accuracy of the final dispensed product;

6) Set forth methods that shall ensure that access to the records of medications and other medical information of the patients maintained by the pharmacy is limited to licensed practitioners or personnel approved to have access to the records, for the purpose of complying with N.J.A.C. 13:39-7.19;

7) Set forth methods that shall ensure that access to the automated medication system for stocking and retrieval of medications is limited to licensed practitioners or qualified pharmacy technicians, interns and externs under the supervision of a pharmacist. An accountability record, which documents all transactions relative to stocking and removing medications from the automated medication system shall be maintained; and

8) Identify the circumstances under which medications may be removed from the automated medication system by a licensed practitioner for distribution to a patient without prior order review by a pharmacist.

b) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall, at least annually, review its written policies and procedures of operation and revise them if necessary.

c) A copy of the written policies and procedures of operation adopted pursuant to this section shall be retained at the pharmacy and at the healthcare facility where the automated medication system is utilized. Upon request, the pharmacy shall provide to the Board a copy of the written policies and procedures of operation for inspection and review.

13:39-10.5 PERSONNEL TRAINING REQUIREMENTS

The pharmacist-in-charge shall be responsible for ensuring that, prior to performing any services in connection with an automated medication system, all pharmacists and pharmacy technicians, interns and externs are trained in the pharmacy's standard operating procedures with regard to automated medication systems as set forth in the written policies and procedures of operation maintained pursuant to N.J.A.C. 13:39-10.4.

13:39-10.6 WRITTEN PROGRAM FOR QUALITY ASSURANCE

a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall operate according to a written program for quality assurance of the automated medication system which:

1) Requires continuous monitoring of the automated medication system;

2) Establishes mechanisms and procedures to test the accuracy of the automated

medication system at least every six months and whenever any upgrade or change is made to the system;

3) Establishes a protocol for measuring the effectiveness of the automated medication system;

4) Requires the pharmacy to report to the Board each recurring error of the automated medication system. A "recurring error," for purposes of this section, means any specific type of inaccuracy within the automated medication system that occurs more than twice within a 14 day period; and

5) Requires the pharmacy to maintain all documentation relating to the written program for quality assurance for at least two years.

13:39-10.7 WRITTEN PLAN FOR RECOVERY

a) A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written plan for recovery from a disaster which interrupts the ability of the pharmacy to provide services. The written plan for recovery shall include:

1) Planning and preparation for a disaster;

2) Procedures for response to a disaster;

3) Procedures for the maintenance and testing of the written plan for recovery; and

4) A procedure to notify the Board, each organization which has contracted with the pharmacy, each patient of the pharmacy, and other appropriate agencies, of a disaster and the date on which the pharmacy expects to recommence the provision of service.

13:39-10.8 WRITTEN PROGRAM FOR PREVENTATIVE MAINTENANCE OF AUTOMATED MEDICATION SYSTEM

A pharmacy which uses an automated medication system to fill prescriptions or medication orders shall maintain a written program for preventative maintenance of the system.

Information Item: Florida Board of Dentistry Rule on Reporting Adverse Incidents:

64B5-14.006 Reporting Adverse Occurrences.

(1) Definitions:

(a) *Adverse occurrence* – means any mortality that occurs during or as the result of a dental procedure, or an incident that results in the temporary or permanent physical or mental injury that requires hospitalization or emergency room treatment of a dental patient that occurred during or as a direct result of the use of general anesthesia, deep sedation, conscious sedation, pediatric conscious sedation, oral sedation, minimal sedation (anxiolysis), nitrous oxide, or local anesthesia.

(b) *Supervising Dentist* – means the dentist that was directly responsible for supervising the Certified Registered Dental Hygienist (CRDH) who is authorized by proper credentials to administer local anesthesia.

(2) Dentists: Any dentist practicing in the State of Florida must notify the Board in writing by registered mail within forty-eight hours (48 hrs.) of any mortality or other adverse occurrence that occurs in the dentist's outpatient facility. A complete written report shall be filed with the Board within thirty (30) days of the mortality or other adverse occurrence. The complete written report shall, at a minimum, include the following:

(a) The name, address, and telephone number of the patient;

(b) A detailed description of the dental procedure;

(c) A detailed description of the preoperative physical condition of the patient;

(d) A detailed list of the drugs administered and the dosage administered;

(e) A detailed description of the techniques utilized in administering the drugs;

(f) A detailed description of the adverse occurrence, to include 1) the onset and type of complications and the onset and type of symptoms experienced by the patient; 2) the onset and type of treatment rendered to the patient; and 3) the onset and type of response of the patient to the treatment rendered; and

(g) A list of all witnesses and their contact information to include their address.

(3) A failure by the dentist to timely and completely comply with all the reporting requirements mandated by this rule is a basis for disciplinary action by the Board, pursuant to Section 466.028(1), F.S.

(4) Certified Registered Dental Hygienists: Any CRDH administering local anesthesia must notify the Board, in writing by registered mail within forty-eight hours (48 hrs.) of any adverse occurrence that was related to or the result of the administration of local anesthesia. A complete written report shall be filed with the Board within thirty (30) days of the mortality or other adverse occurrence. The complete written report shall, at a minimum, include the following:

(a) The name, address, and telephone number of the supervising dentist;

(b) The name, address, and telephone number of the patient;

(c) A detailed description of the dental procedure;

(d) A detailed description of the preoperative physical condition of the patient;

(e) A detailed list of the local anesthesia administered and the dosage of the local anesthesia administered;

(f) A detailed description of the techniques utilized in administering the drugs;

(g) A detailed description of any other drugs the patient had taken or was administered;

(h) A detailed description of the adverse occurrence, to include 1) the onset and type of complications and the onset and type of symptoms experienced by the patient; 2) the onset and type of treatment rendered to the patient; and 3) the onset and type of response of the patient to the treatment rendered; and

(i) A list of all witnesses and their contact information to include their address.

(5) A failure by the hygienist to timely and completely comply with all the reporting requirements mandated by this rule is a basis for disciplinary action by the Board pursuant to Section 466.028(1), F.S.

(6) Supervising Dentist:

If a Certified Registered Dental Hygienist is required to file a report under the provisions of this rule, the supervising dentist shall also file a contemporaneous report in accordance with subsection (2).

(7) The initial and complete reports required by this rule shall be mailed to: The Florida Board of Dentistry, 4052 Bald Cypress Way, Bin #C08, Tallahassee, Florida 32399-3258.

Rulemaking Authority 466.004(4), 466.017(3), (6) FS. Law Implemented 466.017(3), (5) FS. History–New 2-12-86, Amended 3-27-90, Formerly 21G-14.006, Amended 12-20-93, Formerly 61F5-14.006, Amended 8-8-96, Formerly 59Q-14.006, Amended 11-4-03, 12-25-06, 8-5-12.

TAB 2. 64B16-28.303: Destruction of Controlled Substances All Permittees (excluding Nursing Homes)

For Continued Discussion:
Below is the same language that was reviewed previously with the exception that "immediately" has been changed to "within one (1) business day."

64B16-28.303 Destruction of Controlled Substances All Permittees (excluding Institutional Class I Nursing Homes).

(1) Controlled substances that cannot be retained as usable shall be securely stored in the pharmacy/prescription department of the permittee pharmacy until destroyed.

(2) Permittees are required to complete a United States Drug Enforcement Administration (D.E.A.) Form 41. This form, at the time of destruction, shall be witnessed and signed by the prescription department manager or the consultant pharmacist of record and D.E.A. agent, or a Department inspector. This method of destruction ~~does not require prior approval from D.E.A., but does~~ requires that a copy of the completed and witnessed D.E.A. Form 41 be mailed to ~~D.E.A. immediately after destruction~~ the D.E.A. office in his/her area within one (1) business day after the destruction.

(3) Another method of destruction shall be conducted by at least two persons: ~~who are either a licensed pharmacist, physician or nurse, or a sworn law enforcement officer or any combination thereof, to serve as the witnesses. A copy of the completed D.E.A. Form 41 and a letter providing the proposed date of destruction, the proposed method of destruction and the names and titles of the proposed witnesses must be received by D.E.A. at least two weeks prior to the proposed date of destruction which shall constitute a request for destruction. The drugs may not be destroyed until D.E.A. grants approval of the request for destruction. A copy of the completed and witnessed D.E.A. Form 41 shall be mailed to D.E.A. immediately after destruction.~~ One will be the prescription department manager or the consultant of record. The other will be one of the following: medical director or his/her physician designee, director of nursing or his/her licensed nurse designee, or a sworn law enforcement officer. These persons shall serve as the witnesses for the D.E.A Form 41 and the destruction. This method of destruction requires that a copy of the completed and witnessed D.E.A. Form 41 be mailed to the D.E.A.office in the permittee's area within one (1) business day after destruction.

(4) In lieu of destruction on the premises as outlined in (2) and (3) above, controlled substances may also be shipped to reverse distributors for destruction in conformity with federal guidelines.

(5) For patient specific controlled substance prescriptions in a Modified Institutional Class II B, please refer to the language in 64B16-28.301 (2).

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022, 465.018 FS. History–New 4-21-87, Formerly 21S-19.003, Amended 7-31-91, Formerly 21S-28.303, 61F10-28.303, Amended 1-30-96, Formerly 59X-28.303, Amended 2-5-07, 10-27-09, 2-1-12.

See DEA form 41 provided separately.

A Draft Board of Pharmacy proposed form may be supplied at or before the meeting.

Tab 3. 64B16-26.1031: Influenza Immunization Certification Program.

Subsection (2)(c) does not contain the title of DH Form 1997, effective 10/07, "Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking Systems)." Also, the form needs to be updated.

64B16-26.1031 Influenza Immunization Certification Program.

(1) All applications for immunization certification programs shall be made on board approved form DH-MQA 1234, "Immunization Certification Program Application", effective 04/10, which is hereby incorporated by reference. To obtain an application, contact the Board of Pharmacy at 4052 Bald Cypress Way, Bin #C04, Tallahassee, FL 32399-3254 or (850) 488-0595, or download the application from the board's website at http://www.doh.state.fl.us/mqa/pharmacy.

(2) The Board shall approve for initial certification of pharmacist administration of influenza immunizations, programs of study not less than 20 hours that include coursework covering all of the following;

(a) Mechanisms of action for vaccines, contraindications, drug interactions, and monitoring after vaccine administration;

(b) Immunization Schedules;

(c) Immunization screening questions, provision of risk/benefit information, informed consent, recordkeeping, and electronic reporting into the statewide immunization registry through enrollment application DH Form 1997, "Authorized Licensed Pharmacist User Agreement for Access to Florida SHOTS (Florida State Health Online Tracking Systems," (effective 10/07) herein incorporated by reference and may be obtained from the Board office by writing to the Board of Pharmacy, 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254 or by telephoning 1(877)888-7468;

(d) Vaccine storage and handling;

(e) Bio-Hazardous waste disposal and sterile techniques;

(f) Entering, negotiating and performing pursuant to physician oversight protocols;

(g) Community immunization resources and programs;

(h) Identifying, managing and responding to adverse incidents including but not limited to potential allergic reactions associated with vaccine administration;

(i) Procedures and policies for reporting adverse events to the Vaccine Adverse Event Reporting System (VAERS);

(j) Reimbursement procedures and vaccine coverage by federal, state and local governmental jurisdictions and private third party payors;

(k) Administration techniques;

(l) The current influenza immunization guidelines and recommendations of the United States Department of Health Centers for Disease Control and Prevention published in the Morbidity Weekly Report (MMWR) December 1, 2006, Vol. 55 No. RR-15 and updated MMWR July 13, 2007, Vol. 56, No. RR-6;

(m) Review of Section 465.189, F.S.; and

(n) Cardiopulmonary Resuscitation (CPR) training.

Successful completion of the certification program must include a successful demonstration of competency in the administration technique and a cognitive examination.

Rulemaking Authority 465.005 FS. Law Implemented 465.189 FS. History–New 3-20-08, Amended 8-30-10.

See DH Form 1997 provided separately.

Authorized Licensed Pharmacist
User Agreement
For Access to Florida SHOTS
(Florida State Health Online Tracking System)

Florida SHOTS is the centralized electronic state immunization registry for recording and tracking immunizations as authorized by s. 381.003, F.S.

Y *Completion of this agreement according to the following conditions and instructions is required for authorized access to Florida SHOTS. Pursuant to section 465.189(4), F.S., licensed pharmacists certified by the Florida Board of Pharmacy to administer influenza vaccinations to adults must report such vaccinations to the state immunization registry (Florida SHOTS). Please follow the instructions below in order to access Florida SHOTS for reporting purposes*.

TERMS OF AGREEMENT

PLEASE READ CAREFULLY. As a CONDITION for enrolling in the Florida State Health Online Tracking System, the LICENSED PHARMACIST (licensed pursuant to s. 465.007, F.S.) identified on this application for enrollment and certified to provide adult influenza virus immunizations AGREES TO:

1. Use the database to register and record immunization information for patients currently receiving immunizations under their care.
2. Enter accurate and current data in Florida SHOTS at the time of immunization administration.
3. Accept and abide by all relevant state statutes concerning medical record confidentiality and Florida SHOTS access.
4. Ensure pharmacy staff accessing Florida SHOTS, as authorized by the licensed pharmacist applicant, adheres to all laws and regulations pertaining to use and access.
5. Maintain user accounts such that only current authorized users have access to Florida SHOTS and all terminated staff are appropriately removed from access.
6. Safeguard user IDs and passwords against unauthorized use and assume responsibility for staff access to Florida SHOTS.
7. Notify Florida SHOTS personnel immediately upon revocation or suspension of license.

In addition, for all authorized users of Florida SHOTS, it is UNDERSTOOD that:

1. Authorized users may assign staff access to Florida SHOTS and are solely responsible for managing such access.
2. The authorized licensed pharmacist agrees to be solely liable and hold the Department of Health harmless for any breaches of confidentiality by the pharmacist or the pharmacist's staff.
3. Access to Florida SHOTS will be terminated immediately upon license revocation or suspension, or for breaches of confidentiality or failure to adhere to any portion of this agreement.

Complete and sign the attached form according to the following instructions:

INSTRUCTIONS:

REVIEW SECTION I AND FILL OUT SECTION II ACCORDING TO THE FOLLOWING INSTRUCTIONS:

1. Provide the pharmacy facility name, address, city, zip, phone, fax, pharmacy permit number and county where pharmacy is located.
2. Provide the information for the pharmacist applicant. The pharmacist whose name appears on this enrollment application will be responsible for granting Florida SHOTS access to other authorized pharmacy staff and will receive a user ID and password to access Florida SHOTS.
3. The pharmacist must sign the agreement in the space provided. By signing the agreement, the pharmacist agrees to ensure that staff accessing Florida SHOTS under his or her authorization will adhere to the same laws and regulations pertaining to access and maintenance of confidential information.

SECTION III – Agreement Submission - Mail or fax this form to the address or fax number indicated. If you have any questions regarding completion of the form or about Florida SHOTS, please call the telephone number provided.

Authorized Licensed Pharmacist
User Agreement
For Access to Florida SHOTS
(Florida State Health Online Tracking System)

Section I – Pharmacists *(licensed under Section 465.007, F.S.)*

./ Pursuant to section 465.189(4), F.S., pharmacists certified by the Florida Board of Pharmacy to administer influenza virus immunizations to adults must report such vaccinations to the state immunization registry (Florida SHOTS). Upon approval of this application, pharmacists will be issued a user identification and password for access to Florida SHOTS. Pharmacists may then allow their individual staff who are authorized or approved (following standard internal security procedures such as background checks conducted by the facility) to access Florida SHOTS using the pharmacist's authorization. **Pharmacists are responsible for contributing to the immunization registry as required by statute, and must ensure staff adherence to confidentiality and information security, management of system accounts (including immediate termination of accounts for staff no longer employed), and maintenance of new user identification and temporary password assignment.**

Section II – Pharmacist

Licensed Pharmacist's Name:_____
(First) (Last)

Phone:_____ Fax: (_____)_____ Email:_____

Pharmacist's License #:_____ Board Certification Number #:_____

Permitted Pharmacy Practice Location (Pursuant to s. 465.003, F.S.)

Facility Name:_____ Address:

City: _____ Zip:_____ Phone: (_____)_____ Fax: (_____)

Pharmacy Permit # _____ County:_____

Agreement - By signing below, authorized user(s) agree to abide by all terms of this agreement.

Job Title: _____ Signature:_____ Date:_____

SECTION III - Agreement Submission

Please keep a copy of this agreement for your files and mail or fax this side of the form to:

Florida Department of Health
Bureau of Immunization
4052 Bald Cypress Way
Bin # A11
Tallahassee, Florida 32399-1719

Telephone (850) 245-4342

Fax (850) 922-4195

TAB 4. 64B16-28.140: Record Maintenance Systems for Community, Special-Limited Community, Special-Closed Systems, Special-Parenteral/Enteral, and Nuclear Permits.

Subsection (1)(d) of this rule (highlighted below) cites rule 64B16-28.130, which apparently does not exist. Perhaps Rule 64B16-27.1003, with the same title, is the appropriate rule.

This matter was brought to our attention by M. Michael Jackson, BPharm.

64B16-28.140 Record Maintenance Systems for Community, Special-Limited Community, Special-Closed Systems, Special-Parenteral/Enteral, and Nuclear Permits.

(1) Requirements for records maintained in a data processing system.

(a) The pharmacy must comply with the provisions of 21 C.F.R. Section 1304.04 (a regulation of the Federal Drug Enforcement Administration), which is hereby incorporated by reference as of March 1, 1998, when such is applicable to operate such a data processing system if any controlled substances (as that term is used in Ch. 893, F.S.) are dispensed from the pharmacy.

(b) Any pharmacy using a data processing system must meet the requirements of 21 C.F.R. Section 1306.22, which is hereby incorporated by reference as of March 1, 1998.

(c) If a pharmacy's data processing system is not in compliance with this subsection, the pharmacy must maintain a manual recordkeeping system as specified in Rule 64B16-27.800, F.A.C., and Section 893.07, F.S.

(d) Original prescriptions, including prescriptions received as provided for in Rule 64B16-28.130, F.A.C., Transmission of Prescription Orders, shall be reduced to a hard copy if not received in written form. All original prescriptions shall be retained for a period of not less than two years from date of last filling. To the extent authorized by 21 C.F.R. Section 1304.04, a pharmacy may, in lieu of retaining the actual original prescriptions, use an electronic imaging recordkeeping system, provided such system is capable of capturing, storing, and reproducing the exact image of the prescription, including the reverse side of the prescription if necessary, and that such image be retained for a period of no less than two years from the date of last filling.

(e) Original prescriptions shall be maintained in a two or three file system as specified in 21 C.F.R. 1304.04(h).

(f) Requirements for back-up systems.

1. The pharmacy shall maintain a back-up copy of information stored in the data processing system using disk, tape or other electronic back-up system and update this back-up copy on a regular basis, at least weekly, to assure that data is not lost due to system failure.

2. Data processing systems shall have a workable (electronic) data retention system which can produce an audit trail of drug usage for the preceding two years as specified in Rule 64B16-27.800, F.A.C.

(g) Change or discontinuance of a data processing system.

1. Records of dispensing. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records of dispensing to the new data processing system; or

b. Purge the records of dispensing to a printout which contains the same information required on the daily printout as specified in paragraph (3)(b) of this section. The information on this hard-copy printout shall be sorted and printed by prescription number and list each dispensing for this prescription chronologically.

2. Other records. A pharmacy that changes or discontinues use of a data processing system must:

a. Transfer the records to the new data processing system; or

b. Purge the records to a printout which contains all of the information required on the original document.

3. Maintenance of purged records. Information purged from a data processing system must be maintained by the pharmacy for two years from the date of initial entry into the data processing system.

(h) Loss of Data. The prescription department manager shall report to the Board in writing any significant loss

of information from the data processing system within 10 days of discovery of the loss.

(2) All transfers of prescriptions must be strictly in accordance with the provisions of Section 465.026, F.S., and Rule 64B16-27.105, F.A.C.

(3) Records of dispensing.

(a) Each time a prescription drug order is filled or refilled, a record of such dispensing shall be entered into the data processing system.

(b) The data processing system shall have the capacity to produce a daily hard-copy printout of all original prescriptions dispensed and refilled. This hard copy printout shall contain the following information:

1. Unique identification number of the prescription;

2. Date of dispensing;

3. Patient name;

4. Prescribing practitioner's name;

5. Name and strength of the drug product actually dispensed, if generic name, the brand name or manufacturer of drug dispensed;

6. Quantity dispensed;

7. Initials or an identification code of the dispensing pharmacist; and

8. If not immediately retrievable via CRT display, the following shall also be included on the hard-copy printout:

a. Patient's address;

b. Prescribing practitioner's address;

c. Practitioner's DEA registration number, if the prescription drug order is for a controlled substance.

d. Quantity prescribed, if different from the quantity dispensed;

e. Date of issuance of the prescription drug order, if different from the date of dispensing; and

f. Total number of refills dispensed to date for that prescription drug order.

(c) The daily hard-copy printout shall be produced within 72 hours of the date on which the prescription drug orders were dispensed and shall be maintained in a separate file at the pharmacy. Records of controlled substances shall be readily retrievable from records of non-controlled substances.

(d) Each individual pharmacist who dispenses or refills a prescription drug order shall verify that the data indicated on the daily hard-copy printout is correct, by dating and signing such document in the same manner as signing a check or legal document (e.g., J.H. Smith, or John H. Smith) within seven days from the date of dispensing.

(e) In lieu of producing the printout described in paragraphs (b) and (c) of this section, the pharmacy shall maintain a log book in which each individual pharmacist using the data processing system shall sign a statement each day, attesting to the fact that the information entered into the data processing system that day has been reviewed by him or her and is correct as entered. Such log book shall be maintained at the pharmacy employing such a system for a period of two years after the date of dispensing provided, however, that the data processing system can produce the hard-copy printout on demand by an authorized agent of the Department of Health. If no printer is available on site, the hard-copy printout shall be available within 48 hours with a certification by the individual providing the printout, which states that the printout is true and correct as of the date of entry and such information has not been altered, amended or modified.

(f) The prescription department manager and the permit holder are responsible for the proper maintenance of such records and responsible that such data processing system can produce the records outlined in this section and that such system is in compliance with this subsection.

(g) Failure to provide the records set out in this section, either on site or within 48 hours for whatever reason, constitutes failure to keep and maintain records.

(h) In the event that a pharmacy which uses a data processing system experiences system downtime, the following is applicable;

1. An auxiliary procedure shall ensure that refills are authorized by the original prescription drug order and that the maximum number of refills has not been exceeded or that authorization from the prescribing practitioner has

been obtained prior to dispensing a refill; and

2. All of the appropriate data shall be retained for on-line data entry as soon as the system is available for use again.

(4) Compounding records. A written record shall be maintained for each batch/sub-batch of a compounded product under the provisions of Rule 64B16-27.700, F.A.C. This record shall include:

(a) Date of compounding.

(b) Control number for each batch/sub-batch of a compounded product. This may be the manufacture's lot number or new numbers assigned by the pharmacist. If the number is assigned by the pharmacist, the pharmacist shall also record the original manufacture's lot number and expiration dates. If the original numbers and expiration dates are not known, the pharmacy shall record the source and acquisition date of the component.

(c) A complete formula for the compounded product maintained in a readily retrievable form including methodology and necessary equipment.

(d) A signature or initials of the pharmacist or pharmacy technician performing the compounding.

(e) A signature or initials of the pharmacist responsible for supervising pharmacy technicians involved in the compounding process.

(f) The name(s) of the manufacturer(s) of the raw materials used.

(g) The quantity in units of finished products or grams of raw materials.

(h) The package size and number of units prepared.

(i) The name of the patient who received the particular compounded product.

(5) Authorization of additional refills. Practitioner authorization for additional refills of a prescription drug order shall be noted as follows:

(a) On the daily hard-copy printout; or

(b) Via the CRT display.

(6) Any other records, policy and procedure manuals, or reference materials which are not specifically required by statute or rule to be kept in a hard copy may be kept in a readily retrievable data processing system which complies with the provisions of subparagraph (1)(f)1.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.003(14), 465.022, 465.026, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.140, Amended 3-12-97, 6-4-97, Formerly 59X-28.140, Amended 10-29-97, 6-15-98, 11-11-98, 10-15-01.

Possible Rule Reference:

64B16-27.1003 Transmission of Prescription Orders.

Prescriptions may be transmitted from prescriber to dispenser in written form or by any means of communication. Prescriptions may be transmitted by facsimile systems as provided in Section 465.035, F.S., and federal law. Any direct transmission of prescriptions, including verbal, facsimile, telephonic or electronic data transmission, shall only be with the approval of the patient or patient's agent. The pharmacist receiving any such transmitted prescription shall not participate in any system that the pharmacist knows or should have reason to know restricts the patient's choice of pharmacy. The pharmacist shall take such measures necessary to ensure the validity of all prescriptions received.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 11-18-07.

End of December 3, 2013, Rules Agenda.

Tab 4 Addendum

I managed to locate a 2005 repeal of rule 64B16-28.130. This confirms that 64B16-27.1003 is the appropriate rule to cite.

64B16-28.130 Transmission of Prescription Orders.
~~Prescriptions may be transmitted from prescriber to dispenser in written form or by any means of communication. Prescriptions may be transmitted by facsimile systems as provided in Section 465.035, F.S., and federal law. Any direct transmission of prescriptions, including verbal, facsimile, telephonic, or electronic data transmission shall only be with the approval of the patient or patient's agent. The pharmacist receiving any such transmitted prescription shall not knowingly participate in any system that restricts the patient's choice of pharmacy. Pharmacists may not provide remuneration to the prescriber for any prescription referred to the dispensing pharmacy. The pharmacist shall take such measures necessary to ensure the validity of all prescriptions received.~~
Specific Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 3-16-94, Formerly 61F10-28.130, 59X-28.130, Repealed _____.

Volume 31, Number 3, January 21, 2005

Compare to:

64B16-27.1003 Transmission of Prescription Orders.
Prescriptions may be transmitted from prescriber to dispenser in written form or by any means of communication. Prescriptions may be transmitted by facsimile systems as provided in Section 465.035, F.S., and federal law. Any direct transmission of prescriptions, including verbal, facsimile, telephonic or electronic data transmission, shall only be with the approval of the patient or patient's agent. The pharmacist receiving any such transmitted prescription shall not participate in any system that the pharmacist knows or should have reason to know restricts the patient's choice of pharmacy. The pharmacist shall take such measures necessary to ensure the validity of all prescriptions received.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.022, 465.026, 893.07 FS. History–New 11-18-07.

DON GAETZ
President

WILL W. WEATHERFORD
Speaker

THE FLORIDA LEGISLATURE

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KENNETH J. PLANTE
COORDINATOR
Room 680, Pepper Building
111 W. Madison Street
Tallahassee, Florida 32399-1400
Telephone (850) 488-9110
Fax (850) 922-6934
www.japc.state.fl.us
joint.admin.procedures@leg.state.fl.us

October 2, 2013

Ms. Lynette Norr
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

Re: Department of Health: Board of Pharmacy
Rule 64B16-30.001, F.A.C.

Dear Ms. Norr:

I have reviewed proposed rule 64B16-30.001, "Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances," which was advertised in the Florida Administrative Register on September 24, 2013. I have the following comments.

Please explain whether the department has reviewed these disciplinary guidelines for compliance with the legislative intent, as required by subsection 456.079(4), Florida Statutes.

Law Implemented: It appears that sections 465.016 and 465.023, Florida Statutes, should be added as laws implemented.

64B16-30.001: It appears that each sub-sub-subparagraph in the rule text should be in capital roman numerals within parentheses, instead of lower case roman numerals.

64B16-30.001(1): It appears that the word "thereto" should be "thereunder."

64B16-30.001(2)(e)1.l.: It does not appear that the board has authority to assess administrative penalties for the acts referenced in this guideline. Subsection 465.185(2), Florida Statutes, states in part that "[t]he department shall adopt rules which assess administrative penalties for acts prohibited by subsection [465.185](1).

64B16-30.001(2)(e)2.a.(ii)[sic]: It appears that the word "altered" should be "adulterated." *See* § 499.005(3), Fla. Stat.

64B16-30.001(2)(h): It appears that the citation to paragraph 465.016(1)(i), Florida Statutes, should be to paragraph 465.016(1)(j).

64B16-30.001(2)(h)1.: Please explain why a knowing violation does not impose the mandatory $10,000 fine as a minimum fine pursuant to paragraph 456.072(2)(d), Florida Statutes. *See* § 120.52(8)(c), Fla. Stat.

64B16-30.001(2)(u)1.: Please explain why this violation does not impose the mandatory $10,000 fine pursuant to paragraph 456.072(2)(d), Florida Statutes. *See* § 120.52(8)(c), Fla. Stat.

64B16-30.001(2)(u)4.: Please explain why this violation cites paragraph 456.072(1)(a), Florida Statutes.

64B16-30.001(2)(u)11.: Please explain why this violation does not impose the mandatory $10,000 fine pursuant to paragraph 456.072(2)(d), Florida Statutes. *See* § 120.52(8)(c), Fla. Stat.

64B16-30.001(3): Please provide statutory authority for stating in the rule text that "[t]he board shall be entitled to deviate from the above-mentioned guidelines upon a showing of aggravating or mitigating circumstances by clear and convincing evidence presented to the board prior to the imposition of a final penalty." *See* § 120.57(1)(j), Fla. Stat. ("Findings of fact shall be based upon a preponderance of the evidence, except in penal or licensure disciplinary proceedings or except as otherwise provided by statute, and shall be based exclusively on the evidence of record and on matters officially recognized.")

Please explain why the rule text states, "The fact that an Administrative Law Judge of the Division of Administrative Hearings may or may not have been aware of the below-mentioned aggravating or mitigating circumstances prior to a recommendation of penalty in a Recommended Order shall not obviate the duty of the board to consider aggravating and mitigating circumstances brought to its attention prior to the issuance of a Final Order." This appears to be contrary to the provisions of subsection 456.079(5), Florida Statutes, which requires an administrative law judge, in recommending

penalties, to folow the penalty gudelines established by the board and state in writing the mitigating or aggravating cicumstances upon which the recommended penalty is based. *See* § 120.52(8)(c), Fla. Stat.

As always, please let me know if you have any questions. Otherwise, I look forward to your response.

Sincerely,

Marjorie C. Holladay
Chief Attorney

MCH:SA WORD/MARJORIE/64B16_30.001LS100213_154735

Rules Committee Addendum December 3, 2013

TAB 5. Rule 64B16-30.001 Disciplinary Guidelines – Substantive Changes Noted by JAPC:

Proposed changes are highlighted and include 64B16-30.001:

1. (1): the word "thereto" is changed to "thereunder"
2. (2)(e)2.a.(ii): the word "altered" is changed to "adulterated"
3. (2)(h): the citation to paragraph 465.016(1)(i) is changed to 465.016(j)
4. (2)(h)1.: a mandatory $10,000 fine is imposed for a knowing violation
5. (2)(u)1.: a mandatory $10,000 fine is imposed
6. (2)(u)4.: this violation is changed to cite paragraph (1)(e) instead of (1)(a)
7. (2)(u)11.: a mandatory $10,000 fine is imposed

Additional technical changes will be made at the time of adoption.

Rule Text as noticed for development (a substantial rewrite) showing substantive changes requested by JAPC:

Rule 64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances.
(1) The board sets forth below a range of disciplinary guidelines from which disciplinary penalties will be imposed upon licensees guilty of violating Chapter 465 or Section 828.055, F.S. The purpose of the disciplinary guidelines is to give notice to licensees of the range of penalties which will normally be imposed upon violations of particular provisions of Chapter 465 or Section 828.055, F.S. The term license means any permit, registration, certificate, or license, including a provisional license, issued by the Department. Penalty ranges are shown as minimum and maximum guidelines as well as for first time single count violations and for multiple or repeated violations of the same provision of Chapter 465, F.S., or the rules promulgated thereunder ~~thereto~~. If an actual range of penalties is not provided, the listed penalty shall be the guideline penalty for the violation(s) unless aggravating or mitigating factors are shown. All penalties at the upper range of the sanctions set forth in the guidelines, e.g., suspension, revocation, etc., include lesser penalties, e.g., fine, continuing education, probation, or reprimand, which may be included in the final penalty at the board's discretion. Probation may be subject to conditions, including restriction from practice in certain settings, restricting the licensee to working only under designated conditions or in certain settings, requiring continuing or remedial education, or any other restriction found to be necessary for the protection of the public health, safety, and welfare. In addition to any other discipline imposed under these guidelines, the board shall assess costs relating to the investigation and prosecution of the case.
(2) The following disciplinary guidelines shall be followed by the board in imposing disciplinary penalties upon licensees and permittees for violation of the below mentioned statutes and rules. For the purposes of this rule, the descriptions of the violations are abbreviated and the full statute or rule cited should be consulted to determine the prohibited conduct.

	PENALTY RANGE	
VIOLATION	MINIMUM, INCLUDING FIRST TIME OR SINGLE COUNT VIOLATIONS	MAXIMUM, INCLUDING MULTIPLE OR REPEATED VIOLATIONS OF THE SAME PROVISION
(a) Obtaining a license or permit by misrepresentation, fraud, or error (Section 465.016(1)(a), F.S.) (Section 465.023(1)(a), F.S.)		
1. By negligent misrepresentation on original application or renewal	$1,000 fine and 12 hour Laws and Rules course or MPJE and 3 hour ethics	$5,000 fine and one (1) year suspension, to Revocation

	course	
2. By fraudulent misrepresentation on original application or renewal	$10,000 fine for each count and Revocation	$10,000 fine for each count and Revocation
3. By error of the Department or Board on original application or renewal	Revocation	Revocation
(b) Procuring or attempting to procure a license or permit for another person by false representation. (Section 465.016(1)(b), F.S.) (Section 465.023(1)(b), F.S.)	$10,000 fine for each count and Revocation	$10,000 fine for each count and Revocation
(c) Permitting any unlicensed persons, including owner or operator of pharmacy, to practice pharmacy. (Section 465.016(1)(c), F.S.)	$2,500 fine and 12 hour Laws & Rules course or Multistate Pharmacy Jurisprudence Exam (MPJE)	$5,000 to $10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
(d) Being unfit or incompetent to practice pharmacy by reason of habitual intoxication, medicinal drug abuse, or physical or mental condition that threatens public safety. (Section 465.016(1)(d), (m), F.S.)	$250 fine, indefinite suspension with PRN review and board appearance	Revocation
(e) Violating laws governing the practice of pharmacy. (Section 465.016(1)(e), F.S.) (Section 465.023(1)(c), F.S.)		
1. Chapter 465, F.S.:		
a. Failure to supervise registered pharmacy technician. (Section 465.014, F.S.)	$250 fine and one (1) year probation and 12 hour Laws and Rules course or MPJE	$1000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
b. Operating a pharmacy that is not registered. (Section 465.015(1)(a), F.S.)	$500 fine per month to maximum of $5,000 (penalty will require permittee to renew permit or cease practice)	$10,000 fine (penalty will require permittee to renew permit or cease practice), to Revocation
c. Operating a pharmacy where an unlicensed, unregistered, or unsupervised person practices pharmacy. (Section 465.015(1)(b), F.S.)	$5,000 fine and one (1) year probation	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation

d. Making a false or fraudulent statement to the board. (Section 465.015(2)(a), F.S.)	$10,000 fine	$10,000 fine and Revocation
e. Practicing pharmacy as an inactive licensee. (Section 465.015(2)(b), F.S.)	Fine based on length of time in practice while inactive; $500 fine per month	$10,000 fine and two (2) years suspension, to Revocation
f. Selling or dispensing drugs without a prescription. (Section 465.015(2)(c), F.S.)		
(i) Non-scheduled legend drugs.	$1,500 fine	$5,000 fine and one (1) year probation, to Revocation
(ii) Scheduled (controlled substances) legend drugs.	$5,000 fine and (1) year probation	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
g. Selling samples or complimentary drugs. (Section 465.015(2)(d), F.S.)		
(i) Non-scheduled legend drugs.	$1,500 fine and (1) year probation	$5,000 fine and one (1) year probation, to Revocation
(ii) Scheduled (controlled substances) legend drugs.	$5,000 fine and one (1) year probation	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
h. Failure to notify the board of, or failure to have, a prescription department manager or a supervising, a responsible, or a consultant pharmacist. (Sections 465.018, .019, .0193, .0196, or .0197, F.S. and 465.022(10), (11), F.S.)		
(i) Failure to notify. (Section 465.018, F.S.)	Fine based on length of time prior to notifying board. $500 per month	$7,500 maximum (penalty requires notification or ceasing practice)
(ii) Failure to have prescription department manager or a supervising, a responsible, or a consultant pharmacist of record.	Fine based on length of time practicing without designated pharmacist, $750 fine per month and one (1) year probation	$2,000 fine per month, to Revocation
i. Failure to comply with substitution of legend drug requirements.	$500 fine and 12 hour Laws & Rules course or MPJE	$2,500 fine, 12 hour Laws & Rules course or MPJE, and

(Sections 465.025(2), (3), (4), F.S.)		one (1) year probation
j. Failure to follow negative formulary requirements. (Section 465.025(6), F.S.) (Rule 64B16-27.500, F.A.C.)	$1,000 fine and 12 hour Laws & Rules course or MPJE	$2,500 fine, 12 hour Laws & Rules course or MPJE, and one (1) year probation
k. Failure to follow emergency prescription requirements. (Section 465.0275, F.S.)	$500 fine	$1,000 fine and one (1) year probation
l. Engage in prohibited rebate scheme. (Section 465.185, F.S.)	$1,500 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine, 12 hour Laws & Rules course or MPJE, and one (1) year probation, to Revocation
m. Failure to comply with pharmacist dispensing requirements. (Section 465.186, F.S.)		
(i) Failure to follow procedure, but dispense drug appearing on formulary. (Section 465.186(3), F.S.) (Rule 64B16-27.210, F.A.C.)	$500 fine	$1000 fine and one (1) year probation to suspension of right to dispense
(ii) Dispensing drug not on the formulary. (Section 465.186(2), F.S.) (Rules 64B16-27.220, .230, F.A.C.)	$1,500 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year probation to $10,000 fine and Revocation
n. Failure to timely report fraudulent obtaining or attempted obtaining of controlled substances from a pharmacy. (Section 465.015(3), F.S.)		
(i) Failure to timely report	$500 fine	$1,000 fine and one (1) year probation
(ii) Failure to report	$1,000 fine and one (1) year probation	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
o. Violation of facsimile prescription requirements (Section 465.035, F.S.)	$500 fine	$1,000 fine and one (1) year probation
p. Violation of requirements for administration of vaccines and		

epinephrine autoinjection. (Section 465.189, F.S.) (Section 465.009(6)(a), F.S.)		
(i) Failure to enter into a written protocol.	$2,500 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year probation
(ii) Failure to maintain proper insurance.	$500 fine and suspension until insured	$1,000 fine, suspension until insured, followed by one (1) year probation
(iii) Failure to maintain and make available patient records.	$500 fine	$1,000 fine and one (1) year probation
(iv) Uncertified administration of vaccine.	$5,000 fine and suspension until certified	$7,500 fine and suspension until certified, followed by one (1) year probation, to Revocation
(v) Failure to submit copy of protocol or written agreement to the board.	$500 fine	$1,000 fine and one (1) year probation
2. Chapter 499, F.S.:		
a. Adulteration or misbranding of a drug. (Section 499.005(2), (3), F.S.) (Section 499.006, F.S.) (Section 499.007, F.S.)		
(i) Adulteration of a drug. (Section 499.005(2) F.S.) (Section 499.006, F.S.)	$1000 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
(ii) Receipt or delivery of any drug that is adulterated ~~altered~~ or misbranded. (Section 499.005 (3), F.S.)	$1000 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year probation, to Revocation
(iii) Incomplete or inaccurate labeling. (Section 499.007, F.S.) (Rule 64B16-28.108, F.A.C.	$250 fine and 12 hour Laws & Rules course or MPJE	$2,500 fine and one (1) year probation
(iv) Fraudulent misbranding of legend drugs. (Section 499.007, F.S.)	$10,000 fine and one (1) year suspension followed by one (1) year probation	$10,000 fine and two (2) years suspension followed by two (2) years probation, to Revocation
b. Failure to obtain a permit or	$500 fine per month to	$10,000 fine (penalty will

registration, or operating without a valid permit when it is required. (Section 499.005(22), F.S.	maximum of $5,000 (penalty will require permittee to renew permit or cease practice)	require permittee to renew permit or cease practice), to Revocation
c. Prescription drug pedigree violations. (Section 499.005(28), F.S.) (Section 499.0051, F.S.)	$500 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year probation, to Revocation
d. Recordkeeping requirement. (Section 499.0121, F.S.) (Section 499.005(18), (19), F.S.)	$500 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year probation, to Revocation
e. Storage of drugs. (Section 499.0121, F.S.)	$500 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year probation, to Revocation
3. Chapter 893, F.S. (Controlled Substances):		
a. Filling a written or oral prescription for controlled substances that does not meet the requirements of Chapter 893.F.S. (Section 893.04(1)(a), (b), (c), F.S.)	$1,500 fine	$5,000 fine and one (1) year probation, to Revocation
b. Failing to retain prescription records for two (2) years. (Section 893.04(1)(d), F.S.)	$1,000 fine	$5,000 fine and one (1) year probation, to Revocation
c. Failing to appropriately label. (Section 893.04(1)(e), F.S.) d. Dispensing a Schedule II drug inappropriately with a non-written prescription. (Section 893.04(1)(f), F.S.)	$250 fine and 12 hour Laws & Rules course or MPJE $5,000 fine and one (1) year probation	$2,500 fine and (1) year probation $10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
e. Inappropriate refilling of Schedule III, IV, or V drugs. (Section 893.04(1)(g), F.S.) (Section 893.04(2)(e), F.S.)	$1,750 fine and one (1) year probation	$5,000 fine and one (1) year suspension
f. Receiving controlled substances without an appropriate order form. (Section 893.06(1), F.S.)	$2,500 fine	$5,000 fine and one (1) year probation, to Revocation
g. Possession of controlled substances outside the regular course of business, occupation, profession, employment, or duty. (Section 893.06(2), F.S.)	$2,500 fine and one (1) year probation	$5,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation

h. Failure to take a biennial inventory. (Section 893.07(1)(a), (2), (3), (4), (5), F.S.)	$1,000 fine	$2,500 fine and one (1) year probation
i. Failure to maintain a complete and accurate record of controlled substances. (Section 893.07(1)(b), (2), (3), (4), (5), F.S.)	$1,000 fine and one (1) year probation	$5,000 fine and two (2) years probation, to Revocation
j. Dispensing Schedule V controlled substances in other than good faith. (Section 893.08(3)(b), F.S.)	$5,000 fine and one (1) year probation	$10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
k. Inappropriate selling of Schedule V controlled substance. (Section 893.08(3)(c), F.S.)	$1,500 fine and one (1) year probation	$5,000 fine and one (1) year suspension
l. Unlawful possession of controlled substance. (Section 893.13, F.S.)	$5,000 fine and two (2) years probation	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
4. Violation of Federal Drug Abuse Act 21 U.S.C. 821 et seq. (Manufacture, Distribution, and Dispensing of Controlled Substances)	$500 fine and one (1) year probation	$2,000 fine up to $10,000 and one (1) year suspension followed by two (2) years probation, to Revocation
5. Violation of Food and Drug Act 21 U.S.C. 301 – 392.	$2,500 fine and one (1) year suspension	$7,500 fine and two (2) years suspension followed by two (2) years probation, to Revocation
(f) Criminal conviction related to Pharmacy. (Section 465.016(1)(f), F.S.) (Section 465.023(1)(d)		
1. Misdemeanor.	$1,000 fine	$5,000 fine, one (1) year probation, to Revocation
2. Felony.	$5,000 fine and one (1) year suspension followed by two (2) years probation	$10,000 fine and two (2) years suspension followed by three (3) years probation, to Revocation
(g) Using in the compounding of a prescription, or furnishing upon prescription, an ingredient or article different in any manner from the ingredient or article prescribed,	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication

except as authorized in Section 465.019(6), F.S. or Section 465.025, F.S., (Section 465.016(1)(g), F.S.); or, compounding, dispensing or distributing legend drugs outside professional practice of pharmacy. (Section 465.016(1)(i), F.S.)	errors of no less than eight (8) hours	errors of no less than eight (8) hours, and two (2) years probation, to Revocation
(h) Filing a false report or failing to file a report required by law. (Section 465.016(1)(j)~~(i)~~, F.S.)		
1. Knowing violation.	$10,000 ~~$2,000~~ fine and one (1) year probation	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
2. Negligent violation.	Reprimand	One (1) year probation and $1,000 fine
(i) Failure to make prescription price information available. (Section 465.016(1)(k), F.S.)	$250 fine and 12 hour Laws & Rules course or MPJE	$1,000 fine and one (1) year probation
(j) Improperly placing returned drugs into the stock of a pharmacy. (Section 465.016(1)(l), F.S.)	$1,500 fine	$3,000 fine and one (1) year probation
(k) Violating a rule or order of the Board or Department. (Section 465.016(1)(n), F.S.)		
1. Rules of Board of Pharmacy.		
a. Rules 64B16-28.101 to 64B16-28.1035, F.A.C. Rule 64B16-27.100, F.A.C. Rule 64B16-28.109, F.A.C. Rule 64B16-27.103, F.A.C. Rule 64B16-27.104, F.A.C. Rule 64B16-26.400, F.A.C. Rule 64B16-26.2032 F.A.C. Rule 64B16-28.1081, F.A.C. Rule 64B16-27.105, F.A.C. Rule 64B16-27.211, F.A.C. Rule 64B16-28.113, F.A.C. Rule 64B16-28.2021, F.A.C. Rule 64B16-28.603, F.A.C.	$500 fine and 12 hour Laws & Rules course or MPJE	One (1) year probation and $2,000 fine
b. Sink and running water, sufficient space, refrigeration, sanitation, equipment.	Suspension until compliance	$2,000 fine and Revocation

(Rule 64B16-28.102, F.A.C.)		
c. Knowingly purchase, sell, possess, or distribute counterfeit drugs. (Rule 64B16-27.101, F.A.C.)	$5,000 fine, one (1) year suspension followed by one (1) year probation to Revocation	$10,000 fine and Revocation
d. Failure to remove outdated pharmaceuticals, or dispensing of same. (Rule 64B16-28.110, F.A.C.)	$500 fine for possession, $1,000 fine for dispensing	$2,500 - $5,000 fine and two (2) years probation, to Revocation
e. Violation of destruction of controlled substances. (Rules 64B16-28.301, and .303 F.A.C.)	$500 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and two (2) years probation, to Revocation
f. Serving as consultant pharmacist without being licensed as a consultant pharmacist. (Rule 64B16-26.300, F.A.C.)	$500 per month up to $5,000 fine (fine based upon the length of time the person is serving as a consultant without being licensed as a consultant pharmacist)	$7,500 fine and one (1) year suspension followed by two (2) years probation, to Revocation
g. Violation of requirements for records maintained in a data processing system. (Rule 64B16-28.140, F.A.C.)	$1,000 fine and 12 hour Laws & Rules course or MPJE plus 8 hours CE course in record keeping	$5,000 fine and two (2) years probation, to Revocation
h. Failure to properly store legend drugs. (Rule 64B16-28.120, F.A.C.)	$1,000 fine and 12 hour Laws & Rules course or MPJE	$5,000 fine and one (1) year probation, to Revocation
i. Practicing nuclear pharmacy without being licensed as a nuclear pharmacist. (Rule 64B16-26.303, F.A.C.)	$500 per month up to $5,000 fine (fine based upon the length of time the person is practicing without being licensed as a nuclear pharmacist)	$10,000 fine and one (1) year suspension, to Revocation
j. Failure to follow technical requirements for nuclear pharmacy. (Rules 64B16-28.901 and .902, F.A.C.)	One (1) year probation and $1,000 fine, to $2,500 fine and six (6) months suspension followed by one (1) year probation	$5,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
k. Failure to properly transfer prescription files and medicinal drugs when closing pharmacy. (Rules 64B16-28.202 and .203, F.A.C.)	Revocation	Revocation

l. Failure to complete the required continuing education during the biennial licensure period. (Rule 64B16-26.103, F.A.C.)		
(i) Failure to complete less than ten (10) hours.	$500 fine and suspension until completed	$1,500 fine and suspension until completed
(ii) Failure to complete ten (10) or more hours.	$1,000 fine. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.	$2,500 fine and suspension until deficiency and penalty units are completed. In addition, licensees shall take two (2) additional hours of continuing education for each of the continuing education deficiencies. Said hours shall not count for continuing education renewal requirements for the next biennium.
m. Failure to retain continuing education records. (Rule 64B16-26.603, F.A.C.)	$250 fine	$1,500 fine and suspension of license until undocumented courses are completed and documentation is submitted to the Department.
n. Failure to practice in accordance with established practice standards. (Rules 64B16-27.1001 and .104, F.A.C.)		
(i) Pharmacist	$500 to $1,000 fine and 12 hour Laws & Rules course or MPJE to one (1) year probation	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
(ii) Pharmacy Intern	$250 to $500 fine and 12 hour Laws & Rules course or MPJE	$1000 to $5,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
(iii) Permittee	$500 to $1,000 fine and 12 hour Laws & Rules course or MPJE to one (1) year probation	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
o. Failure to have or maintain current policies and procedures for automated pharmacy system or central fill pharmacy. (Rules 64B16-28.141 and.450,	$500 to $1000 fine and 12 hour Laws & Rules course or MPJE	$2,500 to $5,000 fine and suspension of license/permit until current policies and procedures are in place, to Revocation

F.A.C.)		
p. Failure to have or maintain standards for an institutional pharmacy. (Rules 64B16-28.602, .6021, .605, .606, .702, F.A.C.)	$500 fine and 12 hour Laws & Rules course or MJPE	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation
q. Failure to have or maintain standards for a special pharmacy. (Rules 64B16-28.800, .810, .820, .840, .850, .860, .870, F.A.C.)	$500 fine and 12 hour Laws & Rules course or MJPE	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation
r. Failure to maintain standards for animal control shelters. (Rule Chapter 64B16-29, F.A.C.)	$500 fine and 12 hour Laws & Rules course or MJPE	$2,500 to $5,000 fine and suspension of license until policies and procedures are in place, to Revocation
s. Failure to comply with Board's rule on patient counseling. (Rules 64B16-27.800, .810, .820, F.A.C.)	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation
t. Standards of practice for compounding CSPs. (Rules 64B16-27.700 and .797, F.A.C.)		
(i) No harm	$500 fine, 12 hour Laws & Rules course, and course governing sterile compounds, to $2,000 fine and one (1) year probation	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
(ii) Harm	$2,000 fine, one (1) year probation, and 12 hour Laws & Rules course, to Revocation	Revocation
2. Violation of orders of the Board or Department.	$2,500 fine and one (1) year probation, to suspension until compliance with order	$5,000 fine and one (1) year probation, to suspension until compliance with order, to Revocation
(l) License disciplined by another jurisdiction for an offense that would constitute a violation of this chapter. (Section 465.016(1)(h), F.S.) (Section 465.023(1)(e), F.S.)	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes	Same penalty as imposed in other jurisdiction or as closely as possible to penalties set forth in Florida Statutes to $10,000 fine and

		Revocation
(m) Failing to report to the Department any Chapter 458 or 459 licensee violation. (Section 465.016(1)(o), F.S.)	$500 fine and 12 hour Laws & Rules course or MJPE	$1,500 fine and 12 hour Laws & Rules course or MJPE
(n) Abandoning or allowing permit to become null and void after notice of disciplinary proceedings. (Section 465.018(3), F.S.)	Revocation	Revocation
(o) Failing to notify the Board of commencement or cessation of practice due to discipline in another jurisdiction. (Section 465.016(1)(p), F.S.)	$500 fine and 12 hour Laws & Rules course or MJPE	$2,000 fine and two (2) years probation
(p) Using or releasing patient records improperly. (Section 465.016(1)(q), F.S.)	$1,000 fine and 12 hour Laws & Rules course or MJPE	$2,500 fine and one (1) year probation
(q) Knowingly, or with reason to believe, dispensing based on purported prescription where patient-prescriber relationship is invalid. (Section 465.016(1)(s), F.S.) (Section 465.023(1)(h), F.S.)		
(i) Reason to believe	$2,000 fine, 12 hour Laws & Rules course or MJPE, and one (1) year probation	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
(ii) Knowingly	Revocation	Revocation
(r) Committing an error or omission during prescription drug processing. (Section 465.016(1)(t), F.S.)	$250 fine without ingestion or harm, to $500 with ingestion, and complete approved CE course in the prevention of medication errors of no less than eight (8) hours	$500 fine without ingestion or harm, to $1,000 with ingestion, complete approved CE course in the prevention of medication errors of no less than eight (8) hours, and two (2) years probation, to Revocation
(s) Guilty of a felony involving moral turpitude. (Section 465.023(1)(d), F.S.)	$1,000 fine and 12 hour Laws & Rules course or MJPE	$5,000 fine and one (1) year probation, to Revocation
(t) Guilty of a crime related to health care fraud. (Section 465.023(1)(g), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license

(u) Violating 456.072, F.S. (Section 465.016(1)(r), F.S.)		
1. Making misleading, deceptive, or fraudulent representation in or related to the practice of the licensee's profession. (Section 456.072(1)(a), F.S.)	$10,000 ~~$1,500~~ fine and one (1) year probation	Revocation and a fine of $10,000
2. Intentionally violating any rule adopted by the Board or the Department. (Section 456.072(1)(b), F.S.)	$2,500 fine and two (2) years probation	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
3. Being convicted or found guilty of, or entering a plea of guilty or nolo contendere to, regardless of adjudication, a crime in any jurisdiction which relates to the practice of, or the ability to practice, a licensee's profession. (Section 456.072(1)(c), F.S.)		
a. Misdemeanor	$1,000 fine and suspension until compliant	$2,500 fine and suspension until compliant, followed by one (1) year probation, to Revocation
b. Felony	$3,000 fine and one (1) year probation	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
4. Failing to comply with the educational course requirements for human immunodeficiency virus and acquired immune deficiency syndrome, or medical errors. (Section 456.072(1)(e)~~(a)~~, F.S.) (Rules 64B16-26.103(1)(c), (4)(e), F.A.C.)	$500 fine	$1,000 fine
5. Having a license or the authority to practice the regulated profession revoked, suspended, or otherwise acted against, including the denial of licensure, by the licensing authority of any jurisdiction, including its agencies or subdivisions, for a violation that would constitute a violation under Florida law. The licensing authority's acceptance of a relinquishment of licensure,	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation	Same penalty as imposed in other jurisdiction or as closely as possible to penalties for similar violation, to $10,000 fine and Revocation

stipulation, consent order, or other settlement, offered in response to or in anticipation of the filing of charges against the license, shall be construed as action against the license. (Section 456.072(1)(f), F.S.)		
6. Having been found liable in a civil proceeding for knowingly filing a false report or complaint with the Department against another licensee. (Section 456.072(1)(g), F.S.)	$3,000 fine	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
7. Attempting to obtain, obtaining, or renewing a license to practice a profession by bribery, by fraudulent misrepresentation, or through an error of the Department or the Board. (Section 456.072(1)(h), F.S.)	$10,000 fine and Revocation or denial of license application	$10,000 fine and Revocation or denial of license application
8. Except as provided in Section 465.016, F.S., failing to report to the Department any person who the licensee knows is in violation of this part, the chapter regulating the alleged violator, or the rules of the Department or the Board. (Section 456.072(1)(i), F.S.)	$500 fine and 12 hour Laws & Rules course or MJPE	$1,500 fine and 12 hours Laws & Rules or MJPE, to one (1) year suspension or Revocation
9. Aiding, assisting, procuring, employing, or advising any unlicensed person or entity to practice a profession contrary to this part, the chapter regulating the profession, or the rules of the Department or the Board. (Section 456.072(1)(j), F.S.)	$2,000 fine and 12 hour Laws & Rules course or MJPE, to one (1) year probation	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
10. Failing to perform any statutory or legal obligation placed upon a licensee, including failure to repay student loans or perform scholarship service obligations. (Section 456.072(1)(k), F.S.)		
a. Generally	$2,000 fine	$2,500 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
b. Student loans or scholarship service	The minimum disciplinary action imposed shall be a suspension of the license until new payment terms are	Suspension of the license until new payment terms are agreed upon or the scholarship obligation is

	agreed upon or the scholarship obligation is resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount	resumed, followed by probation for the duration of the student loan or remaining scholarship obligation period, and a fine equal to 10 percent of the defaulted loan amount, to Revocation with a minimum total fine of $10,000
11. Making or filing a report which the licensee knows to be false, intentionally or negligently failing to file a report or record required by state or federal law, or willfully impeding or obstructing another person to do so. Such reports or records shall include only those that are signed in the capacity of a licensee. (Section 456.072(1)(l), F.S.)	~~$2,500 fine and two (2) years probation~~	~~$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation~~
a. Knowingly filing a false report or willful obstruction	$10,000 fine and two (2) years probation	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
b. Negligently failing to file a report or record	$2,500 fine	$5,000 fine and one (1) year probation, to Revocation
12. Making deceptive, untrue, or fraudulent representations in or related to the practice of a profession or employing a trick or a scheme in or related to the practice of a profession. (Section 456.072(1)(m), F.S.)	$10,000 fine and two (2) years probation	$10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
13. Exercising influence on the patient or client for the purpose of financial gain of the licensee or a third party. (Section 456.072(1)(n), F.S.)	$3,000 fine and two (2) years probation	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
14. Practicing or offering to practice beyond the scope permitted by law or accepting and performing professional responsibilities the licensee knows, or has reason to know, the licensee is not competent to perform. (Section 456.072(1)(o), F.S.)	$2,000 fine and two (2) years probation	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation

15. Delegating or contracting for the performance of professional responsibilities by a person when the licensee delegating or contracting for performance of such responsibilities knows, or has reason to know, such person is not qualified by training, experience, and authorization when required to perform them. (Section 456.072(1)(p), F.S.)	$2,000 fine and two (2) years probation	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
16. Violating any provision of Chapter 456, the applicable professional practice act, a rule of the Department or the Board, or a lawful order of the Department or the Board, or failing to comply with a lawfully issued subpoena of the Department. (Section 456.072(1)(dd), F.S.) (Section 456.072(1)(q), F.S.)	$1,000 fine and 12 hour Laws & Rules course or MPJE, to one (1) year probation	$5,000 to $10,000 fine and one (1) year suspension followed by one (1) year probation, to Revocation
17. Improperly interfering with an investigation or inspection authorized by statute, or with any disciplinary proceeding. (Section 456.072(1)(r), F.S.)	$2,500 fine and two (2) years probation	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
18. Engaging or attempting to engage in sexual misconduct as defined and prohibited in s. 456.063(1). (Section 456.072(1)(v), F.S.)	$10,000 fine and Revocation	$10,000 fine and Revocation
19. Being unable to practice with reasonable skill and safety by reason of illness or use of alcohol, drugs, narcotics, chemicals, or as a result of any mental or physical condition (board has authority to issue order to compel examination). (Section 456.072(1)(z), F.S.)	$500 fine, suspension until safe to practice with reasonable skill and safety, and appearance before the board	$2,500 fine and Revocation
20. Failing to report to the Board, or the Department if there is no Board, in writing within 30 days after the licensee has been convicted or found guilty of, or entered a plea of nolo contendere to, regardless of adjudication, a crime in any jurisdiction. (Section 456.072(1)(x), F.S.)	$1,000 fine	$5,000 to $10,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
21. Testing positive for any drug, as defined in s. 112.0455, F.S., on any	$500 fine, suspension until safe to practice with	$2,500 fine and Revocation

confirmed preemployment or employer ordered drug screening when the practitioner does not have a lawful prescription and legitimate medical reason for using such drug. (Section 456.072(1)(aa), F.S.)	reasonable skill and safety and appearance before the board	
22. Being terminated from, or failing to successfully complete, an impaired practitioners treatment program. (Section 456.072(1)(hh), F.S.)	Suspension until successful completion or receipt of written confirmation of compliance with ongoing treatment and a fine of up to $1,000	Revocation
23. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, under 18 U.S.C. s. 669, ss. 285-287, s. 371, s. 1001, s. 1035, s. 1341, s. 1343, s. 1347, s. 1349, or s. 1518, or 42 U.S.C. ss. 1320a-7b, relating to the Medicaid program. (Section 456.072(1)(ii), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license
24. Failing to remit the sum owed to the state for overpayment from the Medicaid program pursuant to a final order, judgment, or settlement. (Section 456.072(1)(jj), F.S.)	$500 to $5,000 fine and one (1) year probation	$2,500 to $5,000 fine and suspension until amount owed is remitted, followed by two (2) years probation, to Revocation
25. Being terminated from the state Medicaid program pursuant to s. 409.913, any other state Medicaid program, or the federal Medicare program, as a result of fraud and abuse unless eligibility to participate in the program from which the practitioner was terminated has been restored. (Section 456.072(1)(kk), F.S.)	$10,000 fine and one (1) year probation, to one (1) year suspension followed by one (1) year probation	$10,000 fine and two (2) years suspension followed by two (2) years probation, to Revocation
26. Being convicted of, or entering a plea of guilty or nolo contendere to, any misdemeanor or felony, regardless of adjudication, a crime in any jurisdiction which relates to health care fraud. (Section 456.072(1)(ll), F.S.)	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license	Revocation and a fine of $10,000, or in the case of application for licensure, denial of license
(v) Violation of Section 828.055, F.S. by a permitted county or municipal animal control agency or humane society		

1. Using drugs for animal euthanasia for an improper use. (Section 828.055(3)(a), F.S.)	Reprimand and a fine of $250	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation
2. Failing to take reasonable precautions against misuse, theft, loss, or diversion. (Section 828.055(3)(b), F.S.)	Reprimand and a fine of $250	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation
3. Failing to detect or to report a significant loss, theft, or inventory shortage of drugs. (Section 828.055(3)(c), F.S.)	Reprimand, $500 fine, and one (1) year probation	$1,000 fine and one (1) year suspension followed by two (2) years probation, to Revocation
4. Failing to follow the rules of the Board regarding proper storage and handling of drugs. (Section 828.055(3)(d), F.S.)	Reprimand and a fine of $250	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation
5. Violating any provision of Section 828.055, Chapter 465, Chapter 499, F.S., or any rule adopted under those chapters. (Section 828.055(3)(e), F.S.)	Reprimand and a fine of $250	$500 fine and one (1) year suspension followed by one (1) year probation, to Revocation

(3) The board shall be entitled to deviate from the above-mentioned guidelines upon a showing of aggravating or mitigating circumstances by clear and convincing evidence presented to the board prior to the imposition of a final penalty. The fact that an Administrative Law Judge of the Division of Administrative Hearings may or may not have been aware of the below-mentioned aggravating or mitigating circumstances prior to a recommendation of penalty in a Recommended Order shall not obviate the duty of the board to consider aggravating and mitigating circumstances brought to its attention prior to the issuance of a Final Order.

(a) Aggravating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the enhancement of a penalty beyond the maximum level of discipline in the guidelines shall include but not be limited to the following:

1. History of previous violations of the practice act and the rules promulgated thereto.

2. In the case of negligent acts, the magnitude and scope of the damage or potential damage inflicted upon the patient or the general public by the licensee's misfeasance.

3. Evidence of violation of professional practice acts in other jurisdictions wherein the licensee has been disciplined by the appropriate regulatory authority.

4. Harm occurred.

(b) Mitigating circumstances; circumstances which may justify deviating from the above set forth disciplinary guidelines and cause the lessening of a penalty beyond the minimum level of discipline in the guidelines shall include but not be limited to the following:

1. In cases of negligent acts, the minor nature of the damage or potential damage to the patient's or the public's health, safety, and welfare resulting from the licensee's misfeasance.

2. Lack of previous disciplinary history in this or any other jurisdiction wherein the licensee practices his profession.

3. Restitution of any monetary damage suffered by the patient.

4. The licensee's professional standing among his peers.

5. Steps already taken by the licensee to insure the non-occurrence of similar violations in the future, including continuing education.

6. The degree of financial hardship incurred by a licensee as a result of the imposition of fines or the suspension

of his practice.

(4) All fines imposed by the Board shall be paid within a period of ninety (90) days from the date of the final order entered by the Board. This time limitation may be modified by the Board for good cause shown in order to prevent undue hardship.

Rulemaking Authority 456.072, 456.079, 465.005 FS. Law Implemented 456.072, 456.079 FS. History–New 3-1-87, Amended 5-11-88, Formerly 21S-17.001, 21S-30.001, 61F10-30.001, Amended 6-26-95, 1-30-96, Formerly 59X-30.001, Amended 12-3-97, 11-15-98, 5-3-00, 1-2-02, 11-29-06, 9-26-12, 2-14-13,_____.

AGENDA ADDENDUM
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING
December 3, 2013
Hilton Hotel University of Florida
1714 SW 34th Street
Gainesville, FL 32607
(352) 371-3600

Added to the Rules Committee Agenda as TAB 6 is the following rule:

6. Rule 64B16-28.100(5) Pharmacy Permits – Applications and Permitting.

TAB 6: Rule 64B16-28.100(5) Pharmacy Permits – Applications and Permitting.

Because the Board is amending rule 64B16-28.810 "Special Pharmacy – Limited Community Permit," the rule and the application form incorporated within rule 64B16-28.100(5) also need to be updated to include the changes to rule 64B28.810.

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This section addresses the application and permitting requirements of business establishments regulated under Chapter 465, F.S. Any establishment that is required to have a permit shall apply to the board for the appropriate permit on forms indicated in this rule. Applications and forms referenced in this section may be accessed or downloaded from the web at http://www.doh.state.fl.us/mqa/pharmacy or may be obtained by contacting the Board the Board of Pharmacy, at 4052 Bald Cypress Way, Bin #C04, Tallahassee, Florida 32399-3254, or (850) 488-0595. Inquiries regarding the status of the application or license verification may be obtained at http://www.FLHealthsource.com. The application must be accompanied with a $250 initial permit fee, payable to the Board.

(1)-(4) No Change

(5) Special Pharmacy Permits as authorized in Section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which are not a community pharmacy, institutional pharmacy, nuclear pharmacy or internet pharmacy. Applicants for a Special-Limited Community, Special – Parenteral and Enteral, Special – Closed System Pharmacy, Special – End Stage Renal Disease (ESRD), Special – Parenteral/Enteral Extended Scope, and Special – Assisted Living Facility (ALF) permits must complete an application for a permit using an original Form DH-MQA 1220, "Special Pharmacy Permit Application and Information," effective ~~August 2012~~ _____, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02303.

(a) Applicants for a Special Pharmacy Permit must:

1. Comply with all permitting requirement found in subsection (1) of this rule; and

2. Designate a prescription department manager or consultant pharmacist of record as required by Section 465.0196, F.S.;

(b) The permittee and the newly designated prescription department manager shall notify the board within 10 days of any change in the prescription department manager using an original Form DH-MQA PH10, "Prescription Department Manager Change," effective December 2010.

(c) The Board shall be notified in writing within 10 days of any change in the consultant pharmacist of record using an original Form DH-MQA 1184, "Change of Consultant Pharmacist of Record," effective December 2010.

(d) The Board recognized the following types of Special Pharmacy permits:

1. Special Limited Community Permit may be obtained by an Institutional Class II Pharmacy that dispenses medicinal drugs to employees, medical staff, emergency room patients, and other patients on continuation of a course of therapy.

2. Special Parenteral and Enteral Permit is required to provide parenteral (IV), enteral, and cytotoxic pharmacy services to outpatients. The applicant must be compliant with the Standard for Compounding Sterile Preparations found in Rule 64B16-27.797, F.A.C. Special – Parenteral and Enteral Pharmacy Permits may stand-alone or be used in conjunction with a Community Pharmacy or Special – Closed System Pharmacy Permit. The permittee must provide 24-hour telephone accessibility.

3. Special Closed System Pharmacy Permit is not open to the public and prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, ALF's, Intermediate Care Facility/Mentally Retarded (ICF-MR's) or other custodial care facilities when defined by AHCA rules which the Board may approve. This permit may not provide medications to in-patients in a hospital.

4. Special Pharmacy – End Stage Renal Disease (ESRD) Permit is a type of special pharmacy which is limited in scope of pharmacy practice to the provision of dialysis products and supplies to persons with chronic kidney failure for self-administration at the person's home or specified address.

5. Special Pharmacy – Parenteral/Enteral Extended Scope Permit is required for pharmacies to compound patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, provided requirements set forth herein are satisfied.

6. Special – Assisted Living Facility (ALF) Permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(6)-(7) No Change

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 456.013, 456.025(3), 465.018, 465.019, 465.0193, 465.0196, 465.0197, 465.022 FS. History–New 2-21-13.

Proposed changes to page 1 of Form DH-MQA 1220:

1 Special- Limited Community Pharmacy Permit currently reads:

1. **Special- Limited Community Pharmacy Permit** are only available to Institutional Class II permittees as an additional permit to allow the Institutional Class II permit to provide medications to employees, medical staff and up to a three-day supply of medication to patients being discharged under certain conditions.

Proposed Changes:

1. **Special- Limited Community Pharmacy Permit** are only available to Institutional Class II permittees as an additional permit to allow the Institutional Class II permit to provide medications to employees, medical staff, ~~and~~ up to a three-day supply of medication to patients being discharged under certain conditions, and to discharged patients of the hospital who are under a continuation of a course of therapy using multi-dose medicinal drugs when the requirements in rule 64B16-28.810(4) are met.