



AGENDA

Florida Board of Pharmacy Rules Committee Meeting August 14, 2017 – 1:00 p.m.

(immediately following Compounding Committee meeting)

Embassy Suites Fort Lauderdale * 1100 SE 17th Street
Fort Lauderdale, FL 33316 * (954)315-1326

Committee Members:

Jeffrey Mesaros, PharmD, JD – Chair
Goar Alvarez, PharmD
David Bisailon
Jeenu Philip, BPharm

Board Staff

C. Erica White, MBA, JD - Executive Director
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth – Gov. Analyst II

Board Counsel:

David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

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

1. **Posting of Licenses:**

- Rule 64B16-27.100 - Proof of licensure; Display of Current License; Pharmacist, Registered Pharmacy Intern and Registered Pharmacy Technician Identification.

2. **Institutional Pharmacies / Permits:**

- Rule 64B16-28.301 - Destruction of Controlled Substances - Institutional Class I Pharmacies (Nursing Homes)
- Rule 64B16-28.501 - Institutional Permit - Consultant Pharmacist of Record

3. **Automation:**

- Rule 64B16-28.141 - Requirements for an Automated Pharmacy System in a Community Pharmacy
- Rule 64B16-28.608 - Automated Filling Systems within a Pharmacy

4. **Drug Therapy Management:**

- Rule 64B16-27.830 Standards of Practice – Drug Therapy Management

5. **Returns by In-Patients:**

- Rule 64B16-28.118 - Unit Dose and Customized Patient Medication Package Returns by In-Patients

6. **Telehealth/Telepharmacy/Supervision:**
 - Rule 64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio
 - Rule 64B16-27.4001 Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist
 - Rule 64B16-28.109 Prescription Department; Padlock; Sign: "Prescription Department Closed"
7. **Old Business / New Business**
8. **Public Comment**
9. **Adjourn**

**SUGGESTED EDITS
AUGUST, 20017**

64B16-27.100 Proof of licensure; Display of Current License; Pharmacist, Registered Pharmacy Intern and Registered Pharmacy Technician Identification.

(1) Proof of licensure. Every pharmacist, pharmacy intern, and registered pharmacy technician must maintain proof of current licensure such that it is readily retrievable upon request by any representative of the Department or the Board or any member of the public. In addition, the registration of each registered pharmacy technician must be displayed in such manner that it is made available to the public.

(2) Identification. Every Pharmacist, Pharmacy Intern, or Registered Pharmacy Technician must be identified by means such as a clearly visible identification badge or monogrammed smock showing their name and if they are a pharmacist, pharmacy intern, or registered pharmacy technician. In addition, all registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

~~(1) The current license of each pharmacist engaged in the practice of the profession of pharmacy as defined by Section 465.003(13), F.S., in any pharmacy shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such manner that said license can be easily read by patrons of said establishment. Pharmacists employed in secondary practice sites shall present a valid wallet license as evidence of licensure upon request.~~

~~(3) No pharmacist, pharmacy intern, or registered pharmacy technician shall display, cause to be displayed or allow to be displayed, their license in any pharmacy where said pharmacist, pharmacy intern, or registered pharmacy technician is not engaged in the practice of the profession as defined in Section 465.003(13), F.S.~~

~~(3) A pharmacist and registered pharmacy intern must be clearly identified by a means such as an identification badge or monogrammed smock showing their name and if they are a pharmacist or a registered pharmacy intern.~~

~~(4) The current registration of each registered pharmacy technician shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such a manner that can be easily read by patrons of said establishment. Registered pharmacy technicians employed in a secondary practice site shall present a valid wallet registration as evidence of registration upon request. All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as a “registered pharmacy technician.” And all registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.~~

Rulemaking Authority 456.072(1)(t), 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History—Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.06, 21S-1.006, Amended 7-30-91, Formerly 21S-27.100, 61F10-27.100, Amended 1-30-96, Formerly 59X-27.100, Amended 11-18-07, 1-1-10, 10-8-15.

64B16-27.100 Display of Current License; Pharmacist, Registered Pharmacy Intern and Registered Pharmacy Technician Identification.

(1) The current license of each pharmacist engaged in the practice of the profession of pharmacy as defined by Section 465.003(13), F.S., in any pharmacy shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such manner that said license can be easily read by patrons of said establishment. Pharmacists employed in secondary practice sites shall present a valid wallet license as evidence of licensure upon request.

(2) No pharmacist shall display, cause to be displayed or allow to be displayed, their license in any pharmacy where said pharmacist is not engaged in the practice of the profession as defined in Section 465.003(13), F.S.

(3) A pharmacist and registered pharmacy intern must be clearly identified by a means such as an identification badge or monogrammed smock showing their name and if they are a pharmacist or a registered pharmacy intern.

(4) The current registration of each registered pharmacy technician shall be displayed, when applicable, in a conspicuous place in or near the prescription department, and in such a manner that can be easily read by patrons of said establishment. Registered pharmacy technicians employed in a secondary practice site shall present a valid wallet registration as evidence of registration upon request. All registered pharmacy technicians shall identify themselves as registered pharmacy technicians by wearing a type of identification badge that is clearly visible which specifically identifies the employee by name and by status as a “registered pharmacy technician.” And all registered pharmacy technicians shall state their names and verbally identify themselves as registered pharmacy technicians in the context of telephone or other forms of communication.

Rulemaking Authority 456.072(1)(t), 465.005, 465.0155, 465.022 FS. Law Implemented 465.022 FS. History—Amended 5-19-72, Repromulgated 12-18-74, Formerly 21S-1.06, 21S-1.006, Amended 7-30-91, Formerly 21S-27.100, 61F10-27.100, Amended 1-30-96, Formerly 59X-27.100, Amended 11-18-07, 1-1-10, 10-8-15.

Notice of Proposed Rule

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NOS.: RULE TITLES:

64B16-28.301 Destruction of Controlled Substances - Institutional Class I Pharmacies (Nursing Homes)

64B16-28.501 Institutional Permit - Consultant Pharmacist of Record

64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I Institutional or Modified II B Facilities

64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies

64B16-28.870 Special-ALF

PURPOSE AND EFFECT: The Board proposes the rule amendments to update, revise and streamline board rules relating to pharmacies serving assisted living/long term care facilities.

SUMMARY: The rules relating to pharmacies serving assisted living/long term care facilities will be updated, revised and streamlined.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.022, 465.0125 FS.

LAW IMPLEMENTED: 465.019, 465.0196, 465.0125, 465.022, 465.026 FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-28.301 Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes).

(1) No change.

(2) For each controlled substance destroyed, documentation ~~A document~~ must be completed showing the name and quantity of the drug, strength and dosage form, patient's name, prescription number and name of the institution. Destruction of the controlled substance shall be witnessed, and documentation thereof shall be ~~This documentation, at the time of destruction, shall be witnessed and~~ signed by at least two (2) of the following individuals:

a. the consultant pharmacist;

b. director of nursing;

c. and the facility administrator; or his/her designee which may include

d. a licensed physician, mid-level practitioner, nurse, or another pharmacist employed by or associated with the facility; or

e. a sworn law enforcement officer.

(3) The consultant pharmacist shall be responsible for the creation and implementation of policies and procedures to ensure that controlled substances are disposed of in accordance with applicable state and federal laws

and rules. Furthermore, the consultant pharmacist shall review all controlled substance destruction documentation monthly to ensure compliance with this rule and federal and state law.

(4) The consultant pharmacist shall ensure that non-controlled substances are returned to the provider pharmacy in compliance with Rule 64B16–28.118, F.A.C.

Rulemaking Authority 465.005, 465.022(12), FS. Law Implemented 465.022(12), 465.019, 893.07(1), (3), (5), FS. History–New 4-21-87, Formerly 21S-19.001, Amended 7-31-91, Formerly 21S-28.301, 61F10-28.301, Amended 1-30-96, Formerly 59X-28.301, Amended 7-21-09, 2-10-14,_____.

64B16-28.501 Institutional Permit - Consultant Pharmacist of Record.

(1) Each facility holding a Class I, a Class II, or a Modified Class II Institutional permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within ten (10) days of any change in the consultant pharmacist of record.

(2) The consultant pharmacist of record for a Class I, Class II, or Modified Class II, ~~or a Special ALF~~ permit shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor ~~monthly~~ the facility system for providing medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and ~~or~~ in the monthly facility inspection.

(3) A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct supplemental drug regimen review services, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

Rulemaking Specific Authority 465.005, 465.0125, 465.022 FS. Law Implemented 465.0125, 465.019, 465.022, 465.0266, FS. History–New 7-18-94, Formerly 61F10-28.501, 59X-28.501, Amended 1-2-02, 12-30-07,_____.

64B16-28.503 Transmission of Starter Dose Prescriptions for Patients in Class I ~~Institutional~~ or Modified II B Institutional Facilities.

(1) Definitions.

(a) No change.

(b) “Starter dose pharmacy” means a pharmacy that dispenses a medicinal drug pursuant to a starter dose prescription ~~for to~~ a patient in a facility served by the vendor pharmacy.

(c) “Starter dose prescription” means a prescription transmitted by a vendor pharmacy to a starter dose pharmacy for the purpose of initiating drug therapy for a patient in a facility served by the vendor pharmacy. The term “starter dose prescription” does not include prescriptions for controlled substances.

(2) A vendor pharmacy may transmit a starter dose prescription, excluding a prescription for a controlled substance, to a starter dose pharmacy if the vendor pharmacy:

(a) No change.

~~(b) Has a written contract with the starter dose pharmacy.~~

~~(b)~~(c) Has written authorization from a prescribing practitioner, directly or via facility agreement, to act as the practitioner's agent for the purpose of transmitting a starter dose prescription.

(d) through (f) re-designated (c) through (e) No change.

(3) A starter dose pharmacy may dispense a medicinal drug, excluding a controlled substance, pursuant to a starter dose prescription for a patient in a facility that holds a Class I Institutional Permit or Modified II B Permit if the starter dose pharmacy:

~~(a) Has a written contract with the vendor pharmacy.~~

~~(b) m~~Maintains a record of each starter dose prescription and.

~~(c) m~~Maintains a policy and procedure manual that references starter dose prescriptions.

~~(4) The contract between a vendor pharmacy and a prescribing practitioner shall:~~

~~(a) Be in writing.~~

~~(b) Identify each facility served by the vendor pharmacy for which the authorization is valid.~~

~~(c) Authorize the vendor pharmacy to transmit, as an agent of the practitioner, a starter dose prescription to a starter dose pharmacy.~~

~~(d) Be on file at the vendor pharmacy, at the facility served by the vendor pharmacy, and with the prescribing practitioner.~~

~~(e) Be available for inspection by agents of the Department of Health or the Board of Pharmacy.~~

~~(5) The contract between the vendor pharmacy and the starter dose pharmacy shall:~~

~~(a) Be in writing.~~

~~(b) Identify each facility served by the vendor pharmacy.~~

~~(c) Assign the responsibility for prospective drug use review required by Rule 64B16-27.810, F.A.C., to the vendor pharmacy.~~

~~(d) Assign the responsibility for patient counseling required by Rule 64B16-27.820, F.A.C., to the vendor pharmacy.~~

~~(e) Be referenced in the Policy and Procedure Manual of the vendor pharmacy and of the starter dose pharmacy.~~

~~(f) Be updated as necessary to identify facilities or practitioners.~~

~~(g) Be on file at the vendor pharmacy, at the starter dose pharmacy, and at the facility.~~

~~(h) Be available for inspection by authorized agents of the Department of Health and the Board of Pharmacy.~~

~~(4)(6) A record of each starter dose prescription shall be:~~

~~(a) Readily retrievable and~~

~~(b) maintained for four (4) years.~~

Rulemaking Authority 465.005, 465.019(4), 465.022 FS. Law Implemented ~~465.018~~, 465.019, 465.022(12), FS. History—New 11-29-04, Amended 7-14-14, _____.

64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies or Special Pharmacy Permits Servicing Class I, Class II, Modified Class II, and Special ALF Permitted Facilities.

(1) Definitions.

(a) “Remote Medication Order Processing” includes any of the following activities performed for a Class II Institutional Pharmacy or for Special Pharmacy Permits servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities from a remote location:

1. Receiving, interpreting, or clarifying medication orders;:-

2. Entering or transferring medication order data;:-

3. Performing prospective drug use review;:-

4. Obtaining substitution authorizations;:-

5. Interpreting and acting on clinical data;:-

6. Performing therapeutic interventions;:-

7. Providing drug information;:-

8. No change.

(b) No change.

(c) “Prospective drug use review” means an evaluation of medication orders and patient medication records for:

1. Over-utilization or under-utilization of medication;:-

2. Therapeutic duplication of medication;:-

3. Drug-disease contraindications;:-

4. Drug interactions;:-

5. Incorrect drug dosage or duration of drug treatment;:-

6. No change.

(2) General requirements.

(a) No change.

(b) A Class II Institutional pharmacy or Special Pharmacy servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities may utilize remote medication order processing if the pharmacist performing the remote medication order processing has access to sufficient patient information necessary for prospective drug use review and approval of medication orders.

(c) No change.

(d) If the pharmacist performing remote medication order processing is not an employee of the ~~Class II Institutional~~ pharmacy, the Class II Institutional pharmacy or Special Pharmacy servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities must have a written agreement or contract with the pharmacist or entity employing the pharmacist. The written agreement or contract shall:

1. Outline the services to be provided;:-

2. Delineate the responsibilities of each party including compliance with federal and state laws and regulations governing the practice of pharmacy as well as state and federal medical privacy requirements including compliance with applicable Federal HIPAA regulations;:-

3. Require that the parties adopt a policies and procedures manual;:-

4. No change.

(3) Policy and Procedures. A policy and procedures manual shall:

(a) Be accessible to each party involved in remote medication order processing;:-

(b) Be available for inspection by the Board or an authorized agent of the Department;:-

(c) Outline the responsibilities of each party involved in remote medication order processing;:-

(d) Include a current list of the name, address, telephone number, and license number of each pharmacist involved in remote medication order processing;:-

(e) Include policies and procedures for:

1. Ensuring the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations ~~Protecting the confidentiality and integrity of patient information.~~

2. Ensuring that a pharmacist performing prospective drug use review has access to appropriate drug information resources;:-

3. Ensuring that medical and nursing staff understand how to contact a pharmacist;:-

4. Maintaining records to identify the name, initials, or identification code of each person who performs a processing function for a medication order;:-

5. Complying with federal and state laws and regulations;:-

6. Operating or participating in a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolve identified problems;:-

7. No change.

(4) Records.

(a) A Class II Institutional Pharmacy or Special Pharmacy Permits servicing Class I, Class II, Modified Class II, and Special ALF permitted facilities involved in remote medication order processing shall maintain a record that identifies the name, initials, or identification code of each person who performed a processing function for every medication order. The record shall be available by medication order or by patient name.

(b) through (d) No change.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.019, 465.022, 465.026, 465.0266, FS. History—New 11-29-04, Amended 7-14-14, _____.

64B16-28.870 Special-ALF.

(1) The Special-ALF permit is an optional facility license for those Assisted Living Facilities providing a drug delivery system utilizing medicinal drugs provided in unit dose packaging.

(2) Medicinal Drugs.

(a) Medicinal drugs may not be dispensed on the premises.

(b) All medicinal drugs must be maintained in individual prescription containers for the individual patient. Medicinal drugs may not be dispensed on the premises.

(c) Medicinal drugs dispensed to the residents of a Special-ALF permit shall meet the labeling requirements of Rules 64B16-28.502 and 64B16-28.108, F.A.C.

(d) Medicinal drugs dispensed to patients of Special-ALF permits may be returned to the dispensing pharmacy's stock under the provisions of Rule 64B16-28.118, F.A.C. Dispensed controlled substances that have been discontinued shall be disposed of under the provisions of Rule 64B16-28.301, F.A.C. ~~Medicinal drugs dispensed to the residents of a Special-ALF permit shall meet the labeling requirements of Rule 64B16-28.502 and paragraph~~

64B16-28.402(1)(h), F.A.C.

(3) Consultant Pharmacist of Record.

(a) Each facility holding a Special-ALF permit shall designate a consultant pharmacist of record to ensure compliance with the laws and rules governing the permit. The Board office shall be notified in writing within ten (10) days of any change in the consultant pharmacist of record.

(b) The consultant pharmacist of record shall be responsible for the preparation of the Policy and Procedure Manual required by subsection 64B16-28.800(2), F.A.C. Policy and Procedure Manuals must provide for the appropriate storage conditions and security of the medicinal drugs stored at the facility.

(c) The consultant pharmacist of record shall inspect the facility and prepare a written report to be filed at the permitted facility at least monthly.

(d) The consultant pharmacist of record shall conduct Drug Regimen Reviews as required by Federal or State law, inspect the facility, and prepare a written report to be filed at the permitted facility at least monthly. In addition, the consultant pharmacist of record must monitor the facility's system for maintaining medication administration records and physician order sheets to ensure that the most current record of medications is available for the monthly drug regimen review. The consultant pharmacist of record may utilize additional consultant pharmacists to assist in this review and ~~or~~ in the monthly facility inspection.

(e) A consultant pharmacist licensed in Florida may remotely access a facility or pharmacy's electronic database from outside the facility or pharmacy to conduct supplemental drug regimen review services, subject to the pharmacy or facility establishing policies and procedures to ensure the security and privacy of confidential patient records, including compliance with applicable Federal HIPAA regulations.

Rulemaking Specific Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.016(1)(l), 465.0196 FS. History—New 2-23-98,_____.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: April 4, 2017

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: May 5, 2017

JOE NEGRON
President



Representative George R. Moraitis, Jr., Chair
Senator Kevin Rader, Vice Chair
Senator Daphne Campbell
Senator George B. Gainer
Senator Keith Perry
Representative Jason Fischer
Representative Michael Grant
Representative Sam H. Killebrew
Representative Amy Mercado
Representative Barrington A. "Barry" Russell

RICHARD CORCORAN
Speaker



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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

June 1, 2017

Mr. David Flynn
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy
Rules 64B16-28.301, .501, .503, .606, and .870, F.A.C.**

Dear Mr. Flynn:

I have reviewed the above-referenced proposed rules, which were advertised in the Florida Administrative Register on May 24, 2017. I have the following comments.

64B16-28.301(2): The first sentence of this subsection requires a description of each controlled substance that is destroyed, whereas the second sentence requires documentation of the witnessing of the destruction of the controlled substance signed by two of the persons described in paragraphs (a) through (e). Please explain whether the board requires one document or whether the separate documents describing the controlled substances and documents containing the signature(s) of the persons described in paragraphs (2)(a) through (e) are acceptable. *See* § 120.545(1)(i), Fla. Stat.

The rule appears to require documentation that the destruction was witnessed, but does not expressly state that the persons witnessing the destruction of the controlled substances must sign the documentation. If that is the board's intent, it appears the rule should be clarified. *See* § 120.545(1)(i), Fla. Stat.

Please correct the designation of the paragraphs in this rule subsection. Paragraphs a., b., c., d., and e. should be (a), (b), (c), (d), and (e). *See* Fla. Admin. Code R. 1-1.008(3)(b).

Mr. David Flynn
June 1, 2017
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64B16-28.301(2)(d): Please explain in the rule text what the board means by “associated with the facility.” *See* § 120.52(8)(d), Fla. Stat.

64B16-28.501(2): Please explain whether the inspection of the facility is part of the drug regimen review described in this subsection.

Please explain whether a comma should be inserted following “inspect the facility.” *See* proposed rule 64B16-28.870(3)(d).

64B16-28.501(3): It appears the rule text should clarify what the board means by “supplemental drug regimen review services.” Also, if supplemental drug regimen reviews are required, it appears the rule text should explain the circumstances warranting such supplemental reviews. *See* § 120.52(8)(d), Fla. Stat.

Please explain whether the supplemental drug regimen review services include inspecting the facility. If so, please explain how an inspection may be performed remotely.

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

Sincerely,



Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward Tellechea, Bureau Chief
Mr. Lawrence Harris, Assistant Attorney General

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

(1) Definitions: -

(a) “Automated pharmacy system (APS)” 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.

(b) “Establishment” means one general physical location that may extend to one or more contiguous suites, units, floors, or buildings operated and controlled exclusively by entities under common operation and control. Where multiple buildings are under common ownership, operation, and control, an intervening thoroughfare does not affect the contiguous nature of the buildings.

(c) “Pharmacist” means a pharmacist as defined by section 465.003, FS.

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

(a) The automated pharmacy system is located within the prescription department, adjacent to the prescription department, or is located on the establishment of the licensed pharmacy, and the operation of the automated pharmacy system is under the supervision of a pharmacist. An automated pharmacy system that is not located within the prescription department shall be operated as an extension of the licensed pharmacy and the automated pharmacy system shall not require an independent and separate community pharmacy permit. An automated pharmacy system that is not located within the prescription department shall have conspicuously displayed on the automated pharmacy system the name, address, contact information and the permit number of the community pharmacy that is responsible for the operation of the automated pharmacy system.

~~(b)(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.

~~(c)(b)~~ The system ensures that each prescription is dispensed in compliance with the definition of dispense as defined by section 465.003, F.S., and the practice of the profession of pharmacy. The system shall include a mechanism to ensure that the patient or an authorized agent of the patient has a means to communicate with a pharmacist responsible for dispensing the medical drug product. The means of communication may include in person, electronic, digital, or telephonic.

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

~~(e)(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) ~~The requirements in subsection (2) above are met. Meets the requirements in subsection (2) above.~~

(b) Except as provided in paragraph (d) below, the stocking or restocking of a medicinal drug shall only be completed by the following:

1. a ~~Florida~~ pharmacist;

2. a pharmacy intern under the direct and immediate personal supervision of a pharmacist; or

3. a registered pharmacy technician under the direct supervision of a pharmacist, ~~except as provided in paragraph (c) below.~~

(c) Access to the Automated Pharmacy System in the absence of a pharmacist for purposes of servicing and maintenance by non-pharmacy licensed personnel shall be permitted provided that the system is capable of tracking individual access and preventing unauthorized access, and the system employs user based access or other technology that will prevent access to areas of the dispensing cabinet where drugs are stored. If the system does not employ such technology, access to the system for servicing and maintenance is permitted only under the direct supervision of a pharmacist.

~~(d)~~ If the automated pharmacy system uses removable cartridges or containers to store the drug or uses unit of use packages, the stocking or restocking of the cartridges, ~~or containers or unit of use packages~~ may occur at a licensed repackaging facility and may 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 or unit of use packages~~ have ~~has~~ been properly filled and labeled.

2. The individual cartridge, ~~or container or unit of use package~~ 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 or unit of use package~~ is accurately loaded into the automated pharmacy system.

4. The ~~Florida~~ pharmacist verifying the filling and labeling retains is responsibility-responsible if the cartridge, ~~or container or unit of use package~~ is stocked or restocked incorrectly by the personnel designated to load the cartridges or containers.

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

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

~~(g)~~ 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 or supervising~~ 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.

Notice of Proposed Rule

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.: RULE TITLE:

64B16-28.608 Automated Filling Systems within a Pharmacy

PURPOSE AND EFFECT: The Board proposes the rule amendment to clarify definitions and update the rule.

SUMMARY: The rule will be updated and definitions will be clarified.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.0155, FS.

LAW IMPLEMENTED: 465.003(17), 465.0155, FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-28.608 Automated Filling Systems within a Pharmacy.

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

(a) No change.

(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 prepared for dispensing by ~~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) through (e) No change.

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

(2) The system drug identifier database shall be maintained by a pharmacist and shall not be delegated.

~~(3)(2) No change.~~

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

(4) No change.

(5) The pharmacist verification requirements of subsection (4) shall be deemed satisfied if:

(a) No change.

(b) The system is fully automated from the time the medication is stocked ~~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 stocked ~~loaded~~ into the system. For

purposes of this section, manual intervention shall not include preparing a finished prescription for mailing, delivery, or storage;

(c) through (d) No change.

(e) A pharmacist verifies the correct medication, either the Manufacturer Unit of Use Package, Repacked, or Prepacked container, was properly stocked, filled and ~~stocked loaded~~ in the system. Alternatively, an electronic verification process may be used to verify a ~~M~~anufacturer ~~U~~nit of ~~U~~se ~~P~~ackage, 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 ~~M~~anufacturer's ~~U~~nit of ~~U~~se ~~P~~ackage, 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 ~~M~~anufacturer ~~U~~nit of ~~U~~se ~~P~~ackage, for the correct patient; and

(h) No change.

(6) The pharmacist verification requirements of subsection (4) shall be deemed satisfied for a system that is not fully automated when all or part of the system is used for Manufacturer Unit of Use Packages if:

(a) The system utilizes an Electronic Verification Process to verify that the correct drug matches the correct prescription label;

(b) The Electronic Verification Process activities are undertaken by a pharmacist, pharmacy intern, or registered pharmacy technician under the supervision of a pharmacist, as each are defined by subsection 64B16-27.1001(7), F.A.C. and consistent with Section 64B16-27.4001, F.A.C.

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

~~(7)(6)~~ Policies and Procedures. Pharmacies verifying prescriptions pursuant to subsections ~~(5)~~ or (6) 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 prescription department manager or consultant pharmacist of record 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 ~~process system~~ in good working order;

(b) Ensuring the integrity of the drug identity database and identification of persons responsible for database entries

~~(b)(c)~~ Ensuring accurate filling, ~~loading, and~~ stocking, and verification of the system, as applicable;

~~(d)(e)~~ No change.

~~(e)(d)~~ Testing the accuracy of the system and any accompanying electronic verification ~~process 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)(e)~~ Training persons authorized to access, stock, restock, or ~~utilize load~~ the system in equipment use and operations, as applicable;

~~(g)(f)~~ through ~~(i)(h)~~ No change.

~~(j)(i)~~ Identifying and recording persons responsible for stocking, ~~loading~~ and filling the system;

~~(k)(j)~~ through ~~(l)(k)~~ No change.

~~(8)(7)~~ No change.

Rulemaking Authority 465.005, 465.0155 FS. Law Implemented 465.003(17), 465.0155 FS. History—New 3-24-14, ___.

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 6, 2017

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: November 16, 2016

JOE NEGRON
President



Representative George R. Moraitis, Jr., Chair
Senator Kevin Rader, Vice Chair
Senator Daphne Campbell
Senator George B. Gainer
Senator Keith Perry
Representative Jason Fischer
Representative Michael Grant
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Representative Amy Mercado
Representative Barrington A. "Barry" Russell

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THE FLORIDA LEGISLATURE
**JOINT ADMINISTRATIVE
PROCEDURES COMMITTEE**

July 14, 2017

Mr. David Flynn
Assistant Attorney General
Department of Legal Affairs
PL-01, The Capitol
Tallahassee, Florida 32399-1050

**Re: Department of Health: Board of Pharmacy
Rule 64B16-28.608, F.A.C.**

Dear Mr. Flynn:

I have reviewed the above-referenced proposed rule, which was advertised in the Florida Administrative Register on July 11, 2017. I have the following comments.

64B16-28.608: It appears that section 465.022(1) should be added as rulemaking authority and as a law implemented.

64B16-28.608(2): Please explain what the board means by "system drug identifier database." It appears that term should be defined in subsection (1). *See* §§ 120.54(2)(b), .545(1)(i), Fla. Stat.

Also, it is unclear whether that term is intended to be synonymous with "drug identity database" used in paragraph (7)(b).

64B16-28.608(5)(e): Please explain why this rule paragraph refers to being properly "stocked" twice.

64B16-28.608(6)(b): It appears the end of this paragraph should end with a semi-colon instead of a period. Also, it appears it would be helpful to include the word "and."

64B16-28.608(7)(b): Please explain what the board means by "drug identity database." *See* comments to 64B16-28.608(2).

It appears that this rule paragraph should end with a semi-colon.

Mr. David Flynn

July 14, 2017

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Also, there are two paragraphs numbered as (7)(b). Please correct the second (7)(b) to be (7)(c).

64B16-28.608(7)(j): Please remove the comma following the word “stocking” and preceding “and filling.”

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

Sincerely,

A handwritten signature in blue ink that reads "Marjorie C. Holladay". The signature is written in a cursive style.

Marjorie C. Holladay
Chief Attorney

cc: Mr. Edward Tellechea, Bureau Chief
Mr. Lawrence Harris, Assistant Attorney General

MCH:SA WORD/MARJORIE/64B16_28.608LS071417_163380

64B16-27.830 Standards of Practice - Drug Therapy Management.

(1) “Prescriber Care Plan” means an individualized assessment of a patient and orders for specific drugs, laboratory tests, and other pharmaceutical services intended to be dispensed or executed by a pharmacist. The Prescriber Care Plan shall be written by a physician licensed pursuant to Chapter 458, 459, 461, or 466, F.S., or similar statutory provision in another jurisdiction, and may be transmitted by any means of communication. The Prescriber Care Plan shall specify the conditions under which a pharmacist shall order laboratory tests, interpret laboratory values ordered for a patient, execute drug therapy orders for a patient, and notify the physician.

(2) “Drug Therapy Management” means any act or service by a pharmacist in compliance with orders in a Prescriber Care Plan.

(3) A pharmacist may provide Drug Therapy Management services for a patient, incidental to the dispensing of medicinal drugs or as a part of consulting concerning therapeutic values of medicinal drugs or as part of managing and monitoring the patient’s drug therapy. A pharmacist who provides Drug Therapy Management services for a patient shall comply with orders in a Prescriber Care Plan, insofar as they specify:

(a) Drug therapy to be initially dispensed to the patient by the pharmacist; or

(b) Laboratory values or tests to be ordered, monitored and interpreted by the pharmacist; or

(c) The conditions under which the duly licensed practitioner authorizes the execution of subsequent orders concerning the drug therapy for the patient; or

(d) The conditions under which the pharmacist shall contact or notify the physician.

(4) A pharmacist who provides Drug Therapy Management services shall do so only under the auspices of a pharmacy permit that provides the following:

(a) A transferable patient care record that includes:

1. A Prescriber Care Plan that includes a section noted as “orders” from a duly licensed physician for each patient for whom a pharmacist provides Drug Therapy Management services;

2. Progress notes; and

(b) A pharmaceutical care area that is private, distinct, and partitioned from any area in which activities other than patient care activities occur, and in which the pharmacist and patient may sit down during the provision of Drug Therapy Management services; and

(c) A continuous quality improvement program that includes standards and procedures to identify, evaluate, and constantly improve Drug Therapy Management services provided by a pharmacist.

Specific Authority 465.005, 465.0155 FS. Law Implemented 465.003(13), 465.0155, 465.022(1)(b) FS. History—New 4-4-00.

Notice of Proposed Rule

DEPARTMENT OF HEALTH

Board of Pharmacy

RULE NO.: RULE TITLE:

64B16-28.118 Unit Dose and Customized Patient Medication Package Returns by In-patients

PURPOSE AND EFFECT: The Board proposes the rule amendment to clarify definitions.

SUMMARY: Definitions will be clarified.

SUMMARY OF STATEMENT OF ESTIMATED REGULATORY COSTS AND LEGISLATIVE RATIFICATION:

The Agency has determined that this will not have an adverse impact on small business or likely increase directly or indirectly regulatory costs in excess of \$200,000 in the aggregate within one year after the implementation of the rule. A SERC has not been prepared by the Agency.

The Agency has determined that the proposed rule is not expected to require legislative ratification based on the statement of estimated regulatory costs or if no SERC is required, the information expressly relied upon and described herein: During discussion of the economic impact of this rule at its Board meeting, the Board, based upon the expertise and experience of its members, determined that a Statement of Estimated Regulatory Costs (SERC) was not necessary and that the rule will not require ratification by the Legislature. No person or interested party submitted additional information regarding the economic impact at that time.

Any person who wishes to provide information regarding a statement of estimated regulatory costs, or provide a proposal for a lower cost regulatory alternative must do so in writing within 21 days of this notice.

RULEMAKING AUTHORITY: 465.005, 465.022 FS.

LAW IMPLEMENTED: 465.016(1)(l) FS.

IF REQUESTED WITHIN 21 DAYS OF THE DATE OF THIS NOTICE, A HEARING WILL BE SCHEDULED AND ANNOUNCED IN THE FAR.

THE PERSON TO BE CONTACTED REGARDING THE PROPOSED RULE IS: C. Erica White, Executive Director, Board of Pharmacy, 4052 Bald Cypress Way, Bin C04, Tallahassee, Florida 32399-3254.

THE FULL TEXT OF THE PROPOSED RULE IS:

64B16-28.118 Unit Dose and Customized Patient Medication Package Returns ~~by In-patients.~~

~~No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions:~~

~~(1) Definitions. As used herein:~~

~~(a) A "unit dose system" means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this Rule, a product in an unopened, sealed, manufacture's container is deemed to be a unit dose package.~~

~~(b) A "customized patient medication package" means a system wherein all USP approved multi-dose units are physically connected (also referred to as a "container"). The use of customized patient medication packages must comply with the provisions of subsection 64B16-28.108(5), F.A.C.~~

~~(c) A "closed drug delivery system" is a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient.~~

~~(d) For purposes of this rule, "facility" shall mean any health care institution operating with a Class I, Class II, Modified Class II, or Special ALF permit.~~

~~(2) No pharmacist shall place into the stock of any pharmacy permittee any part of any prescription, compounded or dispensed, which is returned by a patient except under the following conditions:~~

~~(1) through (2) re-designated (a) through (b) No change.~~

~~(3) A "unit dose system" to which this rule applies means a system wherein all individually sealed unit doses are physically connected as a unit. For purpose of this section, a product in an unopened, sealed, manufacture's container is deemed to be a unit dose package.~~

~~(4) A "customized patient medication package" to which this rule applies means a system wherein all USP~~

~~approved multi-dose units are physically connected and are referred to as a container. The use of customized patient medication packages must comply with the provisions of subsection 64B16-28.108(5), F.A.C.~~

~~(5) A “closed drug delivery system” to which this rule applies is a system in which the actual control of the unit dose or customized patient medication package is maintained by the facility rather than by the individual patient.~~

~~(3)(6) All pharmacies utilizing unit dose or customized patient medication packages shall address specific policies and procedures regarding their preparation and use in the pharmacy’s ~~their~~ Policy and Procedures Manual. Rulemaking Specific Authority 465.005, 465.022 FS. Law Implemented 465.016(1)(l), 465.019, FS. History–New 11-10-80, Formerly 21S-1.36, 21S-1.036, Amended 7-31-91, Formerly 21S-28.118, 61F10-28.118, 59X-28.118, Amended 9-23-99, 7-1-02,_____.~~

NAME OF PERSON ORIGINATING PROPOSED RULE: Board of Pharmacy

NAME OF AGENCY HEAD WHO APPROVED THE PROPOSED RULE: Board of Pharmacy

DATE PROPOSED RULE APPROVED BY AGENCY HEAD: June 6, 2017

DATE NOTICE OF PROPOSED RULE DEVELOPMENT PUBLISHED IN FAR: July 11, 2017

64B16-27.410 Registered Pharmacy Technician to Pharmacist Ratio.

(1) General Conditions. When the pharmacist delegates tasks to a registered pharmacy technician, such delegation must enhance the ability of the pharmacist to practice pharmacy to serve the patient population. A pharmacist shall not supervise more than one (1) registered pharmacy technician nor shall a pharmacy allow a supervision ratio of more than one (1) registered pharmacy technician to one (1) pharmacist (1:1), unless specifically authorized to do so pursuant to the provisions of this rule.

(2) Required Documentation. Regardless of the technician ratio, every pharmacy, pharmacist, Prescription Department Manager (PDM) and Consultant Pharmacist (CP) that employs or utilizes registered pharmacy technicians must comply with the following conditions:

(a) Establish and maintain a written Policy and Procedures Manual regarding the number of registered pharmacy technician positions and their utilization that includes the specific scope of delegable tasks of the technicians, job descriptions, and task protocols. The Policy and Procedures Manual or Manuals must include policies and the procedures for implementing the policies for each category enumerated below:

1. Supervision by a pharmacist;
2. Minimum qualifications of the registered pharmacy technician as established by statute and rule;
3. In-service education or on-going training and demonstration of competency specific to the practice site and job function;
4. General duties and responsibilities of the registered pharmacy technicians;
5. All functions related to prescription processing;
6. All functions related to prescription legend drug and controlled substance ordering and inventory control, including procedures for documentation and recordkeeping;
7. All functions related to retrieval of prescription files, patient files, patient profile information and other records pertaining to the practice of pharmacy;
8. All delegable tasks and non-delegable tasks as enumerated in Rule 64B16-27.420, F.A.C.;
9. Confidentiality and privacy laws and rules;
10. Prescription refill and renewal authorization;
11. Registered pharmacy technician functions related to automated pharmacy systems; and
12. Continuous Quality Improvement Program.

(b) Establish and maintain documentation that is signed by the registered pharmacy technician acknowledging the technician has reviewed the Policy and Procedures Manual(s). Compliance with this paragraph must be achieved by April 7, 2015, or within ninety (90) days from the date the registered pharmacy technician is hired.

(c) Establish and maintain documentation that demonstrates the registered pharmacy technician has received training in the established job description, delegable tasks, task protocols, and policy and procedures in the specific pharmacy setting where the delegable tasks will be performed. Documentation shall consist of one of the following items:

1. Certification by the supervising licensee;
2. Certification by an instructor, trainer, or other similar person;
3. Training attendance logs or completion certificates, accompanied by an outline of the materials addressed; or
4. Exam or written questionnaires.

(3) The Policy and Procedures Manual(s) required by paragraph (2)(a) must be maintained on-site where the pharmacy technician will perform the delegable tasks and must be available during a Department inspection or at the request of the Board of Pharmacy. However, any and all documentation required by paragraphs (2)(b) and (c) must be maintained and must be provided to the Board of Pharmacy or a Department inspector within 72 hours of a request.

(4) Three to One (3:1) Ratio: Any pharmacy or any pharmacist engaged in sterile compounding shall not exceed a ratio of up to three (3) registered pharmacy technicians to one (1) pharmacist (3:1).

(5) Four to One (4:1) Ratio: Any pharmacy or any pharmacist may allow a supervision ratio of up to four (4) registered pharmacy technicians to one (1) pharmacist (4:1), as long as the pharmacist or pharmacy is not engaged in sterile compounding.

(6) Six to One (6:1) Ratio:

(a) Non-dispensing pharmacies. Any pharmacy which does not dispense medicinal drugs, and the pharmacist(s) employed by such pharmacy, may allow a supervision ratio of up to six (6) registered pharmacy technicians to one (1) pharmacist (6:1), as long as the pharmacy or pharmacist is not involved in sterile compounding.

(b) Dispensing pharmacies. A pharmacy which dispenses medicinal drugs may utilize a six to one (6:1) ratio in any physically separate area of the pharmacy from which medicinal drugs are not dispensed. A “physically separate area” is a part of the pharmacy which is separated by a permanent wall or other barrier which restricts access between the two areas.

Rulemaking Authority 465.005, 456.069(1), 465.014, 465.017, 465.022 FS. Law Implemented 465.014, 465.022 FS. History—New 2-14-77, Amended 3-31-81, Formerly 21S-4.02, Amended 8-31-87, Formerly 21S-4.002, Amended 9-9-92, Formerly 21S-27.410, 61F10-27.410, Amended 1-30-96, Formerly 59X-27.410, Amended 2-23-98, 10-15-01, 1-1-10, 1-7-15, 7-6-15.

64B16-27.4001 Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist.

(1) Delegation: A pharmacist shall not delegate more tasks than he or she can personally supervise and ensure compliance with this rule. A pharmacist may delegate those non-discretionary delegable tasks enumerated in Rule 64B16-27.420, F.A.C., to the following types of pharmacy technicians:

(a) Registered Pharmacy Technicians (RPT): are those technicians who are duly registered with the board pursuant to Section 465.014(2), F.S.;

(b) Pharmacy Technicians in Training (PTT): are those technicians who are receiving practical (non-didactic) training in delegable tasks as part of employer-based or non-employer based board-approved pharmacy technician training programs who are not required to be duly registered with the board as pharmacy technicians.

(2) Supervision: Delegated tasks must be performed under the direct supervision of a pharmacist and pursuant to the following definitions and requirements:

(a) Direct Supervision: means supervision by a pharmacist who is on the premises at all times the delegated tasks are being performed; who is aware of delegated tasks being performed; and who is readily available to provide personal assistance, direction and approval throughout the time the delegated tasks are being performed.

(b) Use of Technology: A pharmacist, as an adjunct to assist in the direct supervision of the pharmacy technician, may employ technological means to communicate with or observe the pharmacy technician. A pharmacist shall make certain all applicable state and federal laws, including, but not limited to confidentiality, are fully observed when employing technological means of communication and observation.

Rulemaking Authority 465.005, 465.0155, 465.022 FS. Law Implemented 465.014 FS. History—New 12-31-14.

64B16-28.109 Prescription Department; Padlock; Sign: “Prescription Department Closed.”

(1) The prescription department of any community pharmacy permittee shall be considered closed whenever the establishment is open and a pharmacist is not present and on duty. A sign with bold letters not less than two (2) inches in width and height, shall be displayed in a prominent place in the prescription department so that it may easily be read by patrons of that establishment. The sign shall contain the following language: “Prescription Department Closed.”

(2) The term “not present and on duty” shall not be construed to prevent a pharmacist from exiting the prescription department for the purpose of consulting or responding to inquiries or providing assistance to patients or customers, attending to personal hygiene needs, taking a meal break pursuant to Rule 64B16-27.1001, F.A.C., or performing any other function for which the pharmacist is responsible, provided that such activities are conducted in a manner consistent with the pharmacist’s responsibility to provide pharmacy services.

(3) At all times when the prescription department is closed, either because of the absence of a pharmacist or for any other reason, it shall be separated from the remainder of the establishment by partition or other means of enclosure, thereby preventing access to the prescription department by persons not licensed in Florida to practice the profession of pharmacy.

(4) The partition or other means of enclosure shall be securely locked or padlocked and only a pharmacist shall have the means to gain access to the prescription department.

(5) Whenever the prescription department of any community pharmacy establishment is closed, no person other than a pharmacist shall enter, be permitted to enter or remain in the prescription department.

Specific Authority 465.005, 465.022 FS. Law Implemented 465.022 FS. History—Amended 8-20-63, 5-19-72, Repromulgated 12-18-74, Amended 5-6-80, Formerly 21S-1.14, 21S-1.014, Amended 7-31-91, Formerly 21S-28.109, 61F10-28.109, 59X-28.109, Amended 6-15-98, 4-10-05.