BOARD OF PHARMACY
RULES COMMITTEE MEETING
DRAFT MINUTES
December 16, 2020
1:00 p.m. ET
Call In Number: (888) 585-9008
Conference Code: 599-196-982(#)

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

I. CALL TO ORDER/ROLL CALL

Dr. Mesaros called the Rules Committee meeting to order at 1:00 p.m. ET.

MEMBERS PRESENT
Jeffrey Mesaros, PharmD, JD, Chair
Jeenu Philip, BPharm,
David Wright, BPharm

ABSENT MEMBERS
Jonathan Hickman, PharmD

STAFF PRESENT
Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL
Christopher Dierlam, Esq.
Assistant Attorney General

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II. RULES DISCUSSION

a. HB 59 Automated Pharmacy Systems
    i. 64B16-28.141, F.A.C., Requirements for use if an Automated Pharmacy System by a Community Pharmacy

Mr. Dierlam provided an overview of HB 59 and 465.0253, F.S.

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

(1) Definitions:

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

(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 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.

(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, 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 pharmacist verifies the cartridge, container or unit of use packages have been properly filled and labeled.

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

4. The pharmacist verifying the filling and labeling retains responsibility if the cartridge, 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 pharmacist responsible for filling, verifying, 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.

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, 7-5-18.

Mr. Wright addressed the Committee regarding his concerns for the security of the Automated Pharmacy Systems.

Mr. Philip addressed the Committee and indicated that the bill is prescriptive and outlines the requirements. He stated he would be in favor of repealing the current rule language.

Michael Jackson, Executive Vice President of the Florida Pharmacy Association, addressed the Committee regarding the existing rule in place and stated that it was his understanding the bill was passed with the intent rule would remain in effect. He inquired with the Committee regarding the qualifying agents responsible for stocking the automated pharmacy systems.

Cynthia Henderson addressed the Committee regarding her involvement with the bill during the legislative process. She indicated it was also her understanding that rules should remain in effect to assure the security of the systems and would be opposed to repealing the current rule language.

Mr. Wright addressed the Committee regarding labeling requirements.

Gary Dalon addressed the Committee regarding the requirement of real time patient counseling.

Mr. Philip addressed Mr. Dalon's concern and stated the counseling of patients is addressed in additional rules in 64B16 F.A.C. which applies throughout the practice act.

Mr. Wright suggested we continue this discussion at the next Committee Meeting.

Dr. Mesaros will work with Board Counsel with the preparation of materials for the next Committee Meeting.

b. HB 19 International Export Pharmacy Permit

Ms. Sapp provided an overview of HB19 and an update of Rule 64B-12.001 Financial Responsibility Requirements for International Export Pharmacy Permittees.

This legislation was passed last year and establishes two prescription drug importation programs: The Canadian Drug Importation Program under the Agency for Health Care Administration and the International Drug Importation Program under the Department of Business and Professional Regulation. Implementation of this legislation was contingent upon federal authorization and The US Department of Health and Human Services has finalized their rules so the Department of Business and Professional Regulation, in collaboration with the Department of Health, is working on their proposal to operate a pilot program for importing prescription drugs into the state.

This information was provided as an update to the current implementation status.

c. 64B16-28.830, F.A.C., Special – Closed System Pharmacy

During the June 4, 2020 Meeting the Board granted a Petition for Variance or Waiver of Rule 64B16-28.830, F.A.C., for nine months to allow Guardian Pharmacy's seven special closed system pharmacy locations to dispense prescription drugs to their employees and immediate relatives.

The Board requested for this rule to be placed on the Rules Committee Agenda for further discussion and possible amendments.

Proposed rule language was been provided for the Committees review.

64B16-28.830 Special – Closed System Pharmacy.

(1) A Special – Closed System Pharmacy permit is a type of special pharmacy as provided for by section 465.0196, F.S., which dispenses medicinal drugs, utilizing closed delivery systems, to facilities where prescriptions are individually prepared for the ultimate consumer, including nursing homes, jails, ALF's (Adult Congregate Living Facilities), ICF-IIDs (Intermediate Care Facilities – Developmentally Delayed, also known as ICF – Individuals with Intellectual Disabilities), or other custodial care facilities when defined by AHCA rules and which the Board may approve.

(2) A special – closed system pharmacy permittee shall maintain a policy and procedure manual including drug procurement, storage, handling, compounding, dispensing, record keeping and disposition, as well as procedures for preventing the dispensing of controlled substances based upon fraudulent prescriptions.

(3) A special – closed system pharmacy permittee shall provide twenty-four-hour emergency and on-call service.

(4) A special – closed system pharmacy permittee may dispense parenteral and enteral medications as provided by rule.

(5) A special – closed system pharmacy permittee may dispense medicinal drugs to their employees, pharmacy staff and their dependents.

(5~~6~~) A special – closed system pharmacy permittee shall be under the supervision of a prescription department manager who is responsible for maintaining all drug records, providing security of the prescription department and following other rules as relate to the practice of pharmacy. The prescription department manager of a closed system pharmacy shall not be the prescription department manager of any other pharmacy permit except when the permit is within the premises of a community pharmacy permit.

(7~~6~~) The utilization of registered pharmacy interns and registered pharmacy technicians is as provided by rules 64B16-26.400, 64B16-27.4001, 64B16-27.410, and 64B16-27.420, F.A.C.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.0196, 465.022 FS. History–New 7-31-91, Amended 10-1-92, Formerly 21S-28.830, 61F10-28.830, 59X-28.830, Amended 1-1-10, 5-8-18.

Martin Dix, Esq. addressed the Committee.

Mr. Wright addressed the Committee regarding the addition of medical model home to the language.

Dr. Mesaros will work with Board Counsel on finalizing rule language.

Dr. Mesaros opened the floor for public comment.

No public comments received.

Motion: by Mr. Wright to approve the amended proposed language to be presented to the Full Board.
Second: by Mr. Philip
Vote: Unanimous

III. ADJOURNMENT

There being no further business the meeting adjourned at 2:20 p.m. ET.