BOARD OF PHARMACY
GENERAL BUSINESS MEETING
DRAFT MINUTES
August 25, 2021
Embassy Suites by Hilton Tampa USF Near Busch Gardens
3705 Spectrum Blvd
Tampa, FL 33612
813-903-6620

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 1:40 p.m. ET.

MEMBERS PRESENT
Jeffrey Mesaros, PharmD, JD, Chair
Jeenu Philip, BPharm,
Jonathan Hickman, PharmD
Patty Ghazvini, PharmD, BCGP

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

BOARD COUNSEL
David Flynn, Esq.
Senior Assistant Attorney General
Christopher Dierlam
Assistant Attorney General

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II. RULES DISCUSSION

a. 64B16-28.108, F.A.C., All Permits – Labels and Labeling of Medicinal Drugs

During the June 9, 2021 Rules Committee Meeting, the below language was reviewed and approved by the Committee.

64B16-28.108 All Permits – Labels and Labeling of Medicinal Drugs.
Each container of medicinal drugs dispensed shall have a label or shall be accompanied by labeling.
system.
(1) through (9) No change.
(10) The labeling affixed to compounded intravenous compounds (this does not include plain IV solutions or floor stock) shall include:
(a) Names of active ingredients;
(b) Amounts or concentrations of active ingredients;
(c) Beyond use date and time;
(d) Storage requirements (if applicable);
(e) Identification of responsible compounding personnel;
(f) Labels for batch-prepared CSPs must also include:
1. Control or lot number;
2. Auxiliary labeling (including precautions); and
3. Device-specific instructions;

(g) Labels for patient individualized intravenous preparations must also include:
1. Patient's name;
2. Location the medication is to be delivered to; and
3. Directions for use and applicable accessory and cautionary instructions.

Subsequent to the approval, the Board Office received public comments that was placed on the agenda for review.

Dale Masten, Vice-President of Regulatory Affairs, Genoa Healthcare, addressed the Committee.

Mr. Montgomery addressed the Committee and reiterated the intent of the rule was to impact the acute care setting. The suggested language that was presented during the June Committee meeting was not intended for an out-patient setting.

After discussion the Committee proposed the below changes to the rule language.

(1) through (9) No change.
(10) The labeling affixed to ~~compounded intravenous compounds~~ patient specific medications (this does not include plain IV solutions or floor stock) dispensed from an Institutional Class II, Modified Class II Type B, or Class III permit shall include:
(a) Names of active ingredients;
(b) Amounts or concentrations of active ingredients;
(c) Beyond use date and time;
(d) Storage requirements (if applicable);
(e) Identification of responsible compounding personnel and/or dispensing pharmacist;
(f) Labels for batch-prepared CSPs must also include:
1. Control or lot number;
2. Auxiliary labeling (including precautions); and
3. Device-specific instructions;
(g) Labels for ~~patient individualized intravenous preparations~~ patient specific medications must also include:
1. Patient's name;
2. Location the medication is to be delivered to; and
3. Directions for use and applicable accessory and cautionary instructions.

Motion: by Dr. Hickman to approve the proposed language as amended and present to the Full Board.
Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Dr. Hickman to find no economic impact and to find that a Statement of Estimated Regulatory Cost was not necessary, and the rule will not need legislative ratification.
Second: by Mr. Philip
Vote: Unanimous

b. 64B16-27.420, F.A.C., Pharmacy Technician – Delegable and Non-Delegable Tasks

The Board Office received a request from Sr. Director of Pharmacy Affairs for CVS Health, Lauren Paul, PharmD, MS., and proposed the Board discuss 64B16-27.420,

F.A.C., to allow technicians to transfer prescriptions verbally. The rule was placed on the Committee's agenda for review.

64B16-27.420 Pharmacy Technician – Delegable and Non-Delegable Tasks.

A pharmacy technician may only assist a pharmacist in executing or carrying out the practice of the profession of pharmacy, but shall never themselves engage in the practice of the profession of pharmacy as defined in Chapter 465, F.S. Therefore, pharmacy technicians may only perform delegable tasks as identified and defined pursuant to this rule.

(1) Delegable Tasks – Delegable tasks are those tasks that are performed pursuant to a pharmacist's direction, without the exercise of the pharmacy technician's own judgment and discretion, and which do not require the pharmacy technician to exercise the independent professional judgment that is the foundation of the practice of the profession of pharmacy.

(2) Non-Delegable Tasks – The following tasks may not be delegated and the pharmacy technician shall not:

(a) Receive new non written prescriptions or receive any change in the medication, strength, or directions of an existing prescription;

(b) Interpret a prescription or medication order for therapeutic acceptability and appropriateness;

(c) Conduct final verification of dosage and directions;

(d) Engage in prospective drug review;

(e) Monitor prescription usage;

(f) Override clinical alerts without first notifying the pharmacist;

(g) Transfer a prescription;

(h) Prepare a copy of a prescription or read a prescription to any person for purposes of providing reference concerning treatment of the person or animal for whom the prescription was written;

(i) Engage in patient counseling;

(j) Receive therapy or blood product procedures in a permitted nuclear pharmacy, or

(k) Engage in any other act that requires the exercise of a pharmacist's professional judgment.

John Rockett, CVS Health, represented by Edwin Bayo, Esq. addressed the Committee.

Mr. Philip addressed the Committee regarding non-delegable tasks and stated that any non-clinical tasks listed in the rule could possibly be removed.

Mr. Wright addressed the Committee regarding his concerns with patient safety and would not recommend allowing a technician working remotely to complete verbal prescription orders.

Mr. Flynn addressed the Committee regarding 465.026, Florida Statutes, Filling of Certain Prescriptions, and stated the authority lies with the pharmacist. He recommended the Committee place this discussion on the October agenda to allow time to research the statutory authority for rule change.

This discussion will continue at the October Rules Committee meeting.

c. 64B16-28.100, F.A.C., Pharmacy Permits – Applications and Permitting

64B16-28.100 Pharmacy Permits – Applications and Permitting.

This rule section establishes the application and permitting requirements for pharmacies regulated under chapter 465, F.S. Any pharmacy establishment 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://floridaspharmacy.gov/resources/ 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.gov. The application must be accompanied by the appropriate fee as specified by rule 64B16-26.1022, F.A.C.

(1) All Permits:

(a) A permit is valid only for the name and, pursuant to rule 64B16-28.113, F.A.C., physical location (address) to which it is issued. The name in which the permit is issued must be the name in which the company is doing business, i.e., the name that appears on purchase and sales invoices.

1. The name in which a permit is issued may be changed upon notification to the board. To change the name in which a permit is issued the person or establishment must file with the board an original Form DH-MQA 1227 "Pharmacy Permit Name Change Form" effective December 2010, which is incorporated by reference herein, and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-02297 or on the web at http://floridaspharmacy.gov/resources/.

2. A pharmacy permit holder may request a change of practice location by completing the appropriate section(s) of the application form for the permit type.

3. Pharmacy permits are non-transferrable. However, pursuant to rule 64B16-28.2021, F.A.C., transfers of ownership interests of business entities holding a permit may be allowed. A pharmacy permit holder shall notify the Board of changes of ownership interests of business entities by completing the appropriate section(s) of the application form for the permit type.

(b) Each applicant must comply with the fingerprinting requirements in section 465.022, F.S. Electronic fingerprint information ("EFI") that has been submitted to the Florida Agency for Health Care Administration may be accessible by the Florida Department of Health for a period of sixty (60) months. If the Department is able to access EFI from AHCA, applicants will not be required to resubmit EFI for additional or new applications submitted during this time period. After sixty (60) months, new electronic fingerprint information must be submitted as part of all applications.

(c) Passing an onsite inspection (which demonstrates the applicants compliance with all applicable rules and statutes). is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the onsite inspection, the board inspector will document the applicant's compliance with all applicable rules and statutes.

(d) Pursuant to subsection 465.022(4), F.S., each applicant must attach to the application the applicant's written policies and procedures for preventing controlled substance dispensing based on fraudulent representations or invalid practitioner-patient relationships. The policy and procedure manual shall contain, at a minimum, the following:

1. Provisions to identify and guard against invalid practitioner-patient relationships.
2. Provisions to guard against filling fraudulent prescriptions for controlled substances.
3. Provisions to identify prescriptions that are communicated or transmitted legally.
4. Provisions to identify the characteristics of a forged or altered prescription.

(2) A Community Pharmacy Permit, as authorized by section 465.018, F.S., is required for every location where medicinal drugs are compounded, dispensed, stored, or sold or where prescriptions are filled or dispensed on an outpatient basis. Applicants for a community pharmacy permit must complete an application for a permit using an original Form DH-MQA 1214, "Community Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09431. Applicants for a Community Pharmacy Permit must comply with all permitting requirement found in subsection (1) of this rule and designate a prescription department manager as required by section 465.018, F.S.

(3) An Institutional Pharmacy Permit, as authorized by section 465.019, F.S., is required for any location in any health care institution where medicinal drugs are compounded, dispensed, stored or sold. Applicants for an Institutional Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1215, "Institutional Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09432. Applicants for an Institutional Pharmacy Permit must comply with all permitting requirements found in subsection (1) of this rule and designate a consultant pharmacist of record as required by section 465.019, F.S.

(4) A Nuclear Pharmacy Permit, as authorized by section 465.0193, F.S., is required for every location where radioactive drugs and chemicals within the classification of medicinal drugs are compounded, dispensed, stored, or sold. Applicants for a Nuclear Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1218, "Nuclear Pharmacy Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09433. Applicants for a Nuclear Pharmacy Permit must comply with all permitting requirements found in subsection (1), of this rule and designate a nuclear pharmacist as the prescription department manager as required by subsection 64B16-28.901(1), F.A.C.

(5) A Special Pharmacy Permits as authorized by section 465.0196, F.S., is required for any location where medicinal drugs are compounded, dispensed, stored, or sold and which is 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," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09434.

(a) Applicants for a Special Pharmacy Permit must comply with all permitting requirement found in subsection (1) of this rule; and designate a prescription department manager or consultant pharmacist of record as required by section 465.0196, F.S.

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

1. A Special Limited Community Permit is required for any 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. A Special Parenteral and Enteral Permit is required for any pharmacy which provides 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. A Special Closed System Pharmacy Permit is required for any pharmacy not open to the public and where prescriptions are individually prepared for dispensing utilizing closed delivery systems, for ultimate consumers in health care institutions including nursing homes, jails, Assisted Living Facilities (ALFs), Intermediate Care Facilities for the Developmentally Delayed (ICF-IID) 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. A Special Pharmacy – End Stage Renal Disease (ESRD) Permit is required for any 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. A Special Pharmacy – Parenteral/Enteral Extended Scope Permit is required for any pharmacy which compounds patient specific parenteral/enteral preparations in conjunction with institutional pharmacy permits, as provided in rule 64B16-28.560, F.A.C.

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) An Internet Pharmacy Permit, as authorized by section 465.0197, F.S., is required for any location not otherwise licensed or issued a permit under this chapter, within or outside this state that uses the Internet to communicate with or obtain information from consumers and uses the information to fill or refill prescriptions or to dispense, distribute, or otherwise engage in the practice of pharmacy in this state. Applicants for an Internet Pharmacy permit must complete an application for a permit using an original Form DH-MQA 1216, "Internet Pharmacy Permit Application and Information" which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09435 Rev 01/18. Applicants for an Internet Pharmacy Permit must comply with all permitting requirements found in subsection (1) of this rule and designate a prescription department manager or consultant pharmacist of record as required by section 465.0197, F.S.

(7) Special Sterile Compounding Permit: Except those pharmacies which already hold an active stand-alone Special Parenteral/Enteral or Special Parenteral/Enteral Extended Scope Compounding permit, or a Modified Class II-B pharmacy that meets the requirements of subsection 64B16-28.802(6), F.A.C., any pharmacy, including an outsourcing facility, engaged in sterile compounding must obtain a special sterile compounding permit by filing an application on form DH-MQA 1270, "Special Sterile Compounding Permit Application and Information," Rev 01/18, which is incorporated by reference herein and is available at http://www.flrules.org/Gateway/reference.asp?No=Ref-09436.
Applicants for a Special Sterile Compounding Permit must comply with all permitting requirements in subsection (1) of this rule and designate a prescription department manager or consultant pharmacist of record.

Mr. Flynn addressed the Committee regarding clarification of what defines a passing inspection.

After discussion the Committee proposed the below changes to the rule language.

(1) All Permits:
(a) through (b) No change.
(c) ~~Passing an onsite inspection is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address. At the time of the onsite inspection, the board inspector will document the applicant's compliance with all applicable rules and statutes.~~ An onsite inspection demonstrating full compliance with all applicable rules and statutes is a prerequisite to issuance of a new permit, whether based on an initial application, change of ownership, or change of address.
(d) No change.
(2) through (7). No Change.

Motion: by Dr. Hickman to approve the proposed language as amended and present to the Full Board.
Second: by Dr. Ghazvini
Vote: Unanimous

Motion: by Dr. Hickman to find no economic impact and to find that a Statement of Estimated Regulatory Cost was not necessary, that the rule will not need legislative ratification and to find that no part of this rule or a violation of this rule should be designated as a minor violation.
Second: by Mr. Philip
Vote: Unanimous

III. ADJOURNMENT

There being no further business the meeting adjourned at 3:15 p.m. ET.