AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING
October 6, 2015
Immediately Following the Board Meeting

Tampa Marriott Westshore
1001 N. West Shore Boulevard
Tampa, Florida 33607
(813) 287-2555

Committee Members:
Jeffrey J. Mesaros, PharmD, Tampa, Chair
Jeenu Philip, BPharm
Lee Fallon, BPharm
Goar Alvarez, PharmD

Board Staff:
Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

Board Counsel:
David Flynn, Assistant Attorney General
Lynette Norr, Assistant Attorney General (Lead counsel and contact attorney for this committee meeting)

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

AGENDA

Old Business: JAPC or OFAAR communications regarding previously approved and noticed rules, and similar issues, if any.

TAB 1. Rule 64B16-28.2021 Change of Ownership.

TAB 2. Rule 64B16-28.702(6)(b)4. Modified Class II Institutional Pharmacies.

TAB 3. Rule 64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

TAB 4. Rule 64B16-28.1081 Regulation of Daily Operating Hours.

New Business: Discussion of rules to be placed on the next Rules Committee Agenda, and similar issues, if any.

TAB 1. Rule 64B16-28.2021 Change of Ownership.

NOTE: Review rule 64B16-28.2021 to ensure the rule allows efficient changes of pharmacy ownership without negatively impacting patient health and safety – specifically review stock transfer sales.

Existing Rule Language:

(1) A pharmacy permit is not transferable. Upon the sale of an existing pharmacy, a new application must be filed. In those cases where the permit is held by a corporation, the transfer of all the stock of said corporation to another person or entity does not constitute a change of ownership, provided that the initial corporation holding the permit continues to exist.

(2) A change in ownership (and issuance of a new permit number) requires that new records be started and old records closed. The process for closing a pharmacy, including the transfer of prescription files and medicinal drugs, as outlined in Rules 64B16-28.202 and 64B16-28.203, F.A.C., must be followed for the old permit. If the old permit has controlled substances, the new permit must record an “opening inventory” for DEA purposes. Both the new permit and the old permit must keep appropriate records for four (4) years for the transfer of legend drugs and controlled substances.

(3) A change in the company or person who leases the building where the permit is housed or a change in the management company which contracts with the owner of the permit for the operation of the permit does not constitute a change in ownership.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.003(11)(a), 465.018, 465.019, 465.0193, 465.0196, 465.022 FS. History–New 4-19-00, Amended 1-2-02, Formerly 64B16-28.1135, Amended 4-5-05, 7-14-14.

TAB 2. Rule 64B16-28.702(6)(b)4. Modified Class II Institutional Pharmacies.

NOTE: This minor but substantive change may have been considered previously by the Committee and the Board, but we have not been able to verify any action through our review of the minutes. Thus, it is here before you today to formally consider the proposed change.

The proposed change to subparagraph (6)(b)4. replaces a colon with a semi-colon. This changes the meaning from –

> Requiring a perpetual inventory system of all controlled substances only as required by the Pharmacy Services Committee
>
> to –
>
> Requiring a perpetual inventory of all controlled substance, period, while injectables and other medicinal drugs require a perpetual inventory system only as required by the Pharmacy Services Committee.

Proposed Change:

(6) Drugs as defined in Section 465.003(7), F.S., stocked in Modified Class II Institutional Pharmacies, Type "A" and Type "B" as provided herein, shall be those drugs generally utilized in the treatment modalities encompassed within the health care scope of the particular institutional care entity. The protocol and the policy and procedure manual for Type "A" and Type "B" Modified Class II Institutional Pharmacies shall contain definitive information as to drugs and strengths thereof to be stocked.

(b) The policy and procedure manual of facilities which are issued Type B Modified Class II Institutional Permits shall provide the following:
1. The establishment of a Pharmacy Services Committee which shall meet at least annually.
2. Provisions for the handling of the emergency box including the utilization of separate logs for recordkeeping.
3. Provisions for the secure ordering, storage and recordkeeping of all medicinal drugs at the facility.
4. Provisions for the utilization of a perpetual inventory system for all controlled substances; injectables and other medicinal drugs as required by the Pharmacy Services Committee.
5. A diagram of the facility and the security and storage of the medicinal drugs.
6. Provisions for maintaining the records of consultations for not less than four (4) years at the facility which shall be stored on-site and available for inspection by the Department of Health.

TAB 3. Rule 64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

NOTE: Review rule 64B16-28.450 and consider amendments to reflect current practice, clarify the allowance of electronic record keeping to align with other laws and rules, and to avoid duplication with section 465.0265, F.S.

Specifically review 64B16-28.450(4)(a)1. To allow an electronic record keeping alternative to indicate CENTRAL FILL or that the prescription was filled via centralized prescription filling. Specifically for non-controlled substances.

Review whether 64B16-28.450(4) or other sections have duplicate language for controlled substances vs. 21 CFR 1306. If so, consider whether that section of rule 64B16-28.450 can be deleted.

Review whether to amend 64B16-28.450(4) to allow any or all pharmacies involved in the centralized prescription filling process to be on the label in order to avoid patient confusion while ensuring the rule contains appropriate safeguards that the pharmacies involved in the process are available to the patient as required by section 465.0265 F.S.

Existing Rule Language:

64B16-28.450 Centralized Prescription Filling, Delivering and Returning.

(1) As used herein:
(a) The term “originating pharmacy” means a pharmacy wherein the prescription which will be filled by the central fill pharmacy is initially presented; and
(b) The term “central fill pharmacy” means a pharmacy which performs centralized prescription filling, delivering, and returning for one or more originating pharmacies.
(2) Pharmacies acting as the central fill pharmacy must:
(a) Be authorized to dispense medications under the provisions of Chapter 465, F.S., and the rules promulgated thereto, and
(b) Have the same owner as the originating pharmacy or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.
(3) All central fill and originating pharmacies engaged in centralized prescription filling shall create and keep current a Policy and Procedure Manual which shall:
(a) Be maintained at the locations of the central fill and originating pharmacies;
(b) Include the information required by paragraphs 465.0265(2)(a)-(f), F.S.;
(c) Designate the types of medications that may and may not be filled by the central fill pharmacy;
(d) Set forth procedures for communicating orders from the originating pharmacy to the central fill pharmacy;

(e) Set forth procedures for securely transporting the filled prescriptions from the central fill pharmacy to the originating pharmacy; and
(f) Designate the specific services provided and the duties and responsibilities of the central fill and originating pharmacies.
(4) The central fill and originating pharmacy shall each be identified on the prescription container label. The originating pharmacy shall be identified with pharmacy name and address. The central fill pharmacy may be identified by a code available at the originating pharmacy. Prescription and labeling requirements for pharmacies participating in central prescription filling, delivering and returning:
(a) Prescriptions may be transmitted electronically from an originating pharmacy to a central fill pharmacy including via facsimile. The originating pharmacy transmitting the prescription information must:
1. Write the word “central fill” on the face of the original prescription and record the name, address, and DEA registration number if a controlled substance of the originating pharmacy to which the prescription has been transmitted and the name of the originating pharmacy’s pharmacist transmitting the prescription, and the date of transmittal;
2. Ensure all the information required to be on a prescription pursuant to Sections 456.0392 and 893.04, F.S., is transmitted to the central fill pharmacy either on the face of the prescription or in the electronic transmission of information;
3. Indicate in the information transmitted the number of refills already dispensed and the number of refills remaining;
4. Maintain the original prescription for a period of four (4) years from the date the prescription was last filled.
5. Keep a record of receipt of the filled prescription, including the date of receipt, the method of delivery (private, common or contract carrier) and the name of the originating pharmacy’s employee accepting delivery.
(b) The central fill pharmacy receiving the transmitted prescription must:
1. Keep a copy of the prescription if sent via facsimile, or an electronic record of all the information transmitted by the originating pharmacy, including the name, address, and DEA registration number, if a controlled substance, of the originating pharmacy transmitting the prescription;
2. Keep a record of the date of receipt of the transmitted prescription, the name of the licensed pharmacist filling the prescription, and dates of filling or refilling of the prescription;
3. Keep a record of the date the filled prescription was delivered to the originating pharmacy and the method of delivery (private, common or contract carrier).
4. A central fill pharmacy’s pharmacist filling a written or emergency oral prescription for a controlled substance listed in Schedule II shall affix to the package a label showing the date of filling, the originating pharmacy’s name and address, a unique identifier (e.g., the central fill pharmacy’s DEA registration number) indicating the prescription was filled at the central fill pharmacy, the serial number of the prescription, the name of the patient, the name of the prescribing practitioner, and directions for use and cautionary statements, if any, contained in such prescription or required by law.
(5) Delivery of medications. All deliveries of medications from the central fill pharmacy to the originating pharmacy or to the ultimate consumer must be made in a timely manner.

(a) A community central fill pharmacy may deliver medications for an originating pharmacy to the ultimate consumer or the consumer's agent under the following additional conditions:
1. The pharmacies are under the same ownership or have a written contract specifying the services to be provided by each pharmacy, including delivery services to the ultimate consumer or the consumer's agent.
2. The pharmacies shall have a pharmacist available 40 hours a week, either in person or via two-way communication technology, such as a telephone, to provide patient counseling.
3. The pharmacies shall include a toll-free number that allows the patient to reach a pharmacist for the purposes of patient counseling.
4. The central fill pharmacy shall only deliver via carrier to the ultimate consumer or the consumer's agent those medications which could have been delivered via carrier by the originating pharmacy.
5. The central fill pharmacy shall not deliver to the ultimate consumer or consumer's agent substances listed as controlled substances under Chapter 893, F.S.
(b) The delivery of a filled prescription by a community central fill pharmacy to the ultimate consumer or the consumer's agent pursuant to a contract with an originating pharmacy shall not be considered dispensing within the definition set forth in Section 465.003(6), F.S.
(c) A Class II institutional central fill pharmacy may only deliver medications to the originating pharmacy.
(6) Each pharmacist that performs a specific function within the processing of a central fill prescription shall be responsible for any errors or omissions committed by that pharmacist during the performance of that specific function.
(7) A community pharmacy which acts as the central fill pharmacy and which notifies the Board that its pharmacy practice is limited only to such practice shall be exempt from the following rules:
(a) Rule 64B16-28.1035, F.A.C., Patient Consultation Area;
(b) The signage requirement of subsection 64B16-28.109(1), F.A.C.; and
(c) Rule 64B16-28.1081, F.A.C., Regulation of Daily Operating Hours.

Rulemaking Authority 465.005, 465.0155, 465.0265 FS. Law Implemented 465.003(16), 465.019, 465.022, 465.0265 FS. History–New 9-23-03, Amended 7-27-04, 4-28-08, 2-5-14, 8-27-15.

Law Implemented:

465.0265 Centralized prescription filling.—
(1) A pharmacy licensed under this chapter may perform centralized prescription filling for another pharmacy, provided that the pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy, the responsibilities of each pharmacy, and the manner in which the pharmacies will comply with federal and state laws, rules, and regulations.
(2) Each pharmacy performing or contracting for the performance of centralized prescription filling pursuant to this section must maintain a policy and procedures

manual, which shall be made available to the board or its agent upon request. The policy and procedures manual shall include the following information:
(a) A description of how each pharmacy will comply with federal and state laws, rules, and regulations.
(b) The procedure for maintaining appropriate records to identify the pharmacist responsible for dispensing the prescription and counseling the patient.
(c) The procedure for tracking the prescription during each stage of the filling and dispensing process.
(d) The procedure for identifying on the prescription label all pharmacies involved in filling and dispensing the prescription.
(e) The policy and procedure for providing adequate security to protect the confidentiality and integrity of patient information.
(f) The procedure to be used by the pharmacy in implementing and operating a quality assurance program designed to objectively and systematically monitor, evaluate, and improve the quality and appropriateness of patient care.
(3) The filling, delivery, and return of a prescription by one pharmacy for another pursuant to this section shall not be construed as the filling of a transferred prescription as described in s. 465.026 or as a wholesale distribution as defined in s. 499.003.
(4) The board shall adopt rules pursuant to ss. 120.536(1) and 120.54 necessary to implement this section.
History.—s. 2, ch. 2002-182; s. 40, ch. 2008-207; s. 38, ch. 2010-161; s. 34, ch. 2014-89.

TAB 4. Rule 64B16-28.1081 Regulation of Daily Operating Hours.

NOTE: Review rule 64B16-28.1081 to determine the current benefit to patients' safety and/or health to requiring a pharmacy to be open a minimum of 40 hours per week and whether the rule needs additional safeguards to ensure patient access when a pharmacy is open less than 40 hours per week.

Existing Rule Language:

64B16-28.1081 Regulation of Daily Operating Hours.
Any person who receives a community pharmacy permit pursuant to Section 465.018, F.S., and commences to operate such an establishment shall keep the prescription department of the establishment open for a minimum of forty (40) hours per week. The Board hereby approves exceptions to the requirements noted above and permits closing of the prescription department for the following holidays: New Year's Day, Memorial Day, Fourth of July (Independence Day), Labor Day, Veterans' Day, Thanksgiving, Christmas and any bona fide religious holiday provided that notice of such closing is given in a sign as set forth herein. A sign in block letters not less than one inch in height stating the hours the prescription department is open each day shall be displayed either at the main entrance of the establishment or at or near the place where prescriptions are dispensed in a prominent place that is in clear and unobstructed view. The prescription department manager may petition the Board in writing to operate the prescription department for less than forty (40) hours per week, but no less than twenty (20) hours per week. Prior to approving reduced hours, the Board may require the prescription department manager to appear before the Board to explain in detail the services that will be performed. Any pharmacy open less than 40 hours shall have a policy and procedure that provides a mechanism for access to a pharmacist during the time the pharmacy is not open for the remainder of the forty hour week. Any pharmacy that is not open 40 hours a week, must post the days and hours that the pharmacy is open and the information for after-hours access. Any pharmacy open less than 40 hours shall also have a policy and procedure for transferring a prescription pursuant to Rule 64B16-27.105, F.A.C., or receiving an emergency dose pursuant to Section 465.0275, F.S. during the time the pharmacy is open less than 40 hours.

Rulemaking Authority 465.005, 465.022 FS. Law Implemented 465.022(1) FS. History–New 4-10-05, Amended 2-1-12.