

*MEETING MINUTES*

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

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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.**

Tuesday, October 6, 2015 – Immediately following Full Board meeting

Dr. Mesaros called the meeting to order at 9:11 am.

All members were present.

Ms. Norr stated two letters from JAPC have been received with comments regarding Rule 64B16-26.1031 and 64B16-26.1032. Ms. Norr then asked the committee to address the comments.

Some issue's brought up in the JAPC letters were the incorporation of various documents that were referenced during the last committee meeting on DH 1997 and DH-MQA 1125.

JAPC has recommended the specific documents be incorporated into the rule; the SHOTS form, adult immunization schedule and the travel recommendation list.

Ms. Dudley said the SHOTS form is a DOH rule and should not be referenced in the Board of Pharmacy rule. She said references to SHOTS should be removed from the application. Board staff will add a link to SHOTS information on the Board website, [FloridasPharmacy.gov](http://FloridasPharmacy.gov).

Ms. Norr stated she decided not to incorporate the CDC schedule in the rule. She then stated there is no available pdf form of the adult travel immunizations, only a website.

Dr. Weizer stated the 2016 Online Yellow Book is a very effective website to use when looking for travel recommendation list. Mr. Philip stated the Yellow Book has a list of just travel vaccines under appendix B.

[CDC.gov/travel/yellowbook](http://CDC.gov/travel/yellowbook)

<http://wwwnc.cdc.gov/travel/yellowbook/2016/appendices/appendix-b-travel-vaccine-summary-table>

Motion: by Dr. Mesaros, to write back to JAPC and advise we are not going to incorporate the CDC guidelines by reference because it's in the statute.

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

Dr. Weizer stated we have been dealing with the change of ownership issue for years. Pharmacies sell 100 percent of stock and keep the corporation open through Sunbiz (Florida Department of State Division of Corporations) therefore the Board office is not notified of the change. Dr. Weizer stated this is an opportunity to create a new application process.

Ms. Norr asked the committee to 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 and propose new language.

Mr. Flynn stated with the new process the new owner needed to be fingerprinted.

Dr. Weizer's solution to the committee was to create a stock transfer permit application for any transfer of 5 percent or more. We would require an inspection to be done within 90 days. The permit number would not change and the application would serve as notification to the Board.

After further discussion the committee asked Ms. Norr to work on rule language for notification.

During Wednesday morning committee reports Dr. Mesaros stated Rule 64B16-28.2021, Change of Ownership has been tabled until the December Board meeting.

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

Ms. Norr stated a 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. Therefore, 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 substances, period, while injectables and other medicinal drugs require a perpetual inventory system only as required by the Pharmacy Services Committee.

Ms. Norr proposed Rule 64B16-28.702(6)(b)(4), Modified Class II Institutional Pharmacies be broken down into two parts therefore creating a new #4,#5, #6 and adding a #7.

Motion: by Dr. Weizer, to accept proposed edits. Motion carried.

Motion: by Dr. Weizer, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Fallon, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Break 10:55-11:21

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

Ms. Norr asked the committee to 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. and to 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. She then asked the committee 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 and also to 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.

Tim Koch with Wal-Mart suggested the language in (4)(a) mirrors CFR 1306.27. He stated it might be best to break up the recordkeeping requirements and call out the following for NON-CONTROLLED substances and then refer to 1306.27 for how to handle controlled substances. The reason being, that if (when) DEA updates the rules for controlled substances, you don't have to open up the rule and change the language again.

The changes he requested for non-controlled substances are as follows:

- \* (4)(a)1. Electronically record in the pharmacy recordkeeping (operating) system or document on the face of the original prescription that the prescription has been filled at a central fill pharmacy[added for those pharmacies without a means for recording electronically] ....
- \* (4)(a)5. Keep an electronic or paper record of receipt...

Mr. Flynn stated we do not want to limit ourselves in what changes we make. Dr. Mesaros stated we are trying to clean up the rule for the practitioners and align with record keeping requirements; we do not want to create unnecessary restrictions.

Dr. Mesaros read the proposed language changes to Rule 64B16-28.450, Centralized Prescription Filling, Delivering and Returning and stated the change should coincide with any Federal requirements.

The existing rule language is:

(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;

The proposed language change to 28.450(4)(a)(1) would be:

(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. **Electronically record in the pharmacy record keeping system or document on the face of the original prescription that the prescription has been filled at a central fill pharmacy. If a controlled substance, [w]**rite 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;

Motion: by Dr. Alvarez, to accept proposed edits. Motion carried.

Motion: by Mr. Philip, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Fallon, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

There was discussion regarding patients being confused with multiple pharmacies being listed on the prescription label.

Dr. Mesaros stated he would confer with Lynette Norr to come up with clarification for the December Rules committee meeting.

Lunch Break 12:17-1:47

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

Ms. Norr asked the committee to 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.

The current rule language is as follows:

**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.

After discussion, the committee requested Ms. Norr draft the proposed language and bring to full board.

Motion: by Dr. Fallon, to move to full board for discussion. Motion carried.

Ms. Norr presented the following proposed language during Wednesday's board meeting.

Proposed language is as follows:

**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 post a sign in block letters not less than one inch in height stating the hours the prescription department is open each day. The sign 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.**

Motion: by Mr. Philip, that there is not an adverse economic impact on small business and that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Dr. Weizer stated the holiday section has been deleted but does not think that was the intention. She then stated the proposed edit didn't delineate the holidays, so now we just required people to work holidays.

Dr. Mesaros stated Rule 64B16-28.1081, Regulation of Daily Operating Hours, will be tabled until December Board meeting.

Motion: by Dr. Fallon, to table Rule 64B16-28.1081 until December Board meeting. Motion carried.

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

Ms. Dudley requested the pharmacy technician training rule be placed on an upcoming rules committee agenda.

Dr. Alvarez suggested discussion around physician dispensing. Dr. Mesaros suggested we discuss during normal board comment and then see if the rule needs to be addressed. He then recommended Dr. Alvarez speak to Mr. Flynn and considering placing it on the December agenda.

Ms. Glass requested discussion regarding intern licenses that do not expire. Ms. Dudley did not think we had the power to create a rule and suggested Ms. Glass confer with Mr. Flynn.

Dr. Mikhael suggested discussion regarding how many hours a Prescription Department Manager must spend in a pharmacy.

Motion: by Dr. Fallon, to ADJOURN at 2:54 pm. Motion carried.