

FLORIDA | BOARD OF PHARMACY

Rules Committee

Draft Meeting Minutes

January 12, 2018
Telephone Conference
1:00 P.M.



Jeffrey Mesaros, PharmD, JD
Committee Chair

C. Erica White
Executive Director

Friday, January 12, 2018 at 1:00 P.M.

Call to Order - The meeting was called to order by the Committee Chair, Dr. Mesaros, at 1:00 p.m.

Roll Call - Those present during the meeting included the following:

Board Members

Jeffrey J. Mesaros, PharmD, JD, Chair
Jeenu Philip, BPharm, Vice-Chair
David Bisailon
Jonathan Hickman, PharmD
Blanca R. Rivera, RPh, CPh, MPharm, MBA

Attorneys

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Board Staff:

C. Erica White, Executive Director
Irene Lake, Program Operations Administrator

Mr. Harris provided a brief overview and history of the proposed updates and revisions to Rule 64B16-28.100 F.A.C., which have not been updated since 2013. In the process of reviewing the rule changes, it was determined that changes were also needed for the Prescription Department Manager (PDM) and Consultant of Record (COR) rules and forms.

Recommended changes would include moving language from 28.100 related to PDMs and CORs into their respective rules to ensure all information was consolidated in one place and to parallel the COR rules with the PDM rules. A proposed change to the PDM and COR forms is to make it optional for the out-going individual to notify the Board that they are being removed as the designated PDM or COR for the pharmacy.

Substantive changes have been made, but minor changes may still be needed for the forms. For example, all applications should include a check box asking if the applicant is under investigation or prosecution for a crime in any jurisdiction.

The updated forms need to be in use as soon as possible. Mr. Harris encouraged the Board to consider voting the rules and incorporated forms out. JAPC comments are anticipated. If the Board votes to adopt the changes in February, Mr. Harris asks that they authorize him to make any technical changes without having to come back to the Board. Substantive changes would come back to the Board.

Dr. Mesaros commented that the changes are consistent with aligning with applications and avoiding duplication across rules. Dr. Mesaros entertained a motion to February. Motion made by Mr. Bisailon to move to February. Motion passes.

1. **Rule 64B16-27.450, F.A.C.** – Prescription Department Managers
Mr. Bisailon asked for clarification on the notification timeline in (b) for internet pharmacies.
Mr. Harris responded that the timelines are statutory requirements. Ms. Rivera asked if a PDM

was allowed to be less than a full-time employee. Mr. Harris responded that he was not aware of a statute or rule that required a PDM to be a full-time employee. There is a restriction that a PDM cannot be a PDM for more than one pharmacy, unless approved by the Board.

Motion made by Mr. Philip to approve edits as out-lined understanding there may be minor edits by February. Motion passes.

2. **Rule 64B16-28.501, F.A.C.** – Institutional Permit – Consultant Pharmacist of Record
Mr. Harris stated that the changes are more substantive and attempted to parallel the PDM rule. The PDM rule includes the responsibilities of the PDM. He asked if the Board wanted to add responsibilities of the COR.

Ms. Rivera asked if it was mandatory to find a replacement within 10 days when the COR is terminated immediately. Mr. Flynn responded that there must be a COR at all times. Mr. Harris added that he has seen where pharmacies have hired PDMs through temporary staffing agencies, but was not sure if the same could be done with CORs.

Motion made by Mr. Bisailon to approve edits. Motion passes.

3. **Rule 64B16-28.100 F.A.C.** – Pharmacy Permits – Applications and Permitting
Discussions encompassed in introduction and within individual permits.

4. **Rule 64B16-28.100, F.A.C., and Amendments to Pharmacy Permit Applications:**

- Community Pharmacy Permit – DH MQA 1214 – Changes recommended to reflect consistency under the Licensure Process section of each application describing timeframe the permit is issued. Motion made by Mr. Philip to approve edits as out-lined with the understanding there may be minor edits for February. Motion passes. Mr. Harris advised he will review each application to ensure consistency.
- Institutional Pharmacy Permit – DH MQA 1215 - Motion made by Mr. Bisailon to approve edits as out-lined with the understanding there may be minor edits for February. Motion passes.
- Nuclear Pharmacy Permit – DH MQA 1218 – Motion made by Mr. Bisailon to approve edits as out-lined with the understanding there may be minor edits for February. Motion passes.
- Special Pharmacy Permit – DH MQA 1220 - Motion made by Mr. Philip to approve edits as out-lined with the understanding there may be minor edits for February. Motion passes.
- Special Sterile Compounding Pharmacy Permit – DH MQA 1270 – Mr. Flynn will be working with Mr. Montgomery on this application. He anticipates minor stylistic and verbal changes, but substance should not be changing. Motion made by Mr. Bisailon to approve edits as out-lined with the understanding there may be minor edits for February. Motion passes.
- Internet Pharmacy Permit – DH MQA 1216 – Mr. Philip pointed out that the application incorrectly includes the language regarding the existence of a delay with Community Pharmacy permits. Motion made by Mr. Philip to approve edits as out-lined with the understanding there may be minor edits for February. Motion passes.

Motion made by Dr. Mesaros to move forward to the February meeting. Motion passes.

- Change in Prescription Department Manager - DH-PH10
The outgoing PDM license number and date is not required for Board staff to process incoming PDM update. Clarify language on form regarding the Transaction Control

Number for fingerprints and add to language to rule. Ms. White to research how applicant can obtain the TCN number. Website provides information on how to obtain TCN. Link can be incorporated in form.

- Change in Consultant Pharmacist of Record - DH-MQA 1184

Motion made by Mr. Bisailon to move forward to the February meeting. Motion passes.

5. **Old Business / New Business**

None

6. **Public Comment**

None

7. **Adjourn**

Motion made by Mr. Philip to adjourn. Motion passes.

DRAFT