

FLORIDA | Board of Pharmacy

Rules Committee

Draft Meeting Minutes

December 11, 2018

Orlando Marriott in Lake Mary

1501 International Pkwy

Lake Mary, FL 32746

Contact Hotel: 407-995-1100



Jeffrey Mesaros, PharmD, JD
Committee Chair

C. Erica White
Executive Director

Tuesday, December 11, 2018 at 10:00 AM

Call to Order - The meeting was called to order by the Committee Chair, Dr. Mesaros, at 10:02 a.m.

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

Committee Members

Jeffrey J. Mesaros, PharmD, JD - Chair
David Bisailon
Jonathan Hickman, PharmD
Jeenu Phillip, BPharm
Blanca Rivera, BPharm, MBA

Board Counsel

David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Board Staff:

C. Erica White, Executive Director
Jessica Hollingsworth, Government Analyst II

Dr. Mesaros opened the meeting by welcoming present inspectors, students, and esteemed colleagues.

1. Rule 64B16-26.351, F.A.C. – Standards for Approval of Registered Pharmacy Technician Training Programs

Discussion:

Mr. Harris provided a brief overview of why the rule was originally opened a year ago as well as updates since discussion at the last meeting. He then reviewed proposed changes to the rule, which included the following:

- Revision to subsection (1)(a) and (1)(b) to add language from the United States Department of Education and to remove the list of accredited institutions
- Revision of subsection (1)(c) to add the address for Florida Department of Education's curriculum framework for Pharmacy Technician Program information

Mr. Philip agreed with the changes and asked if board staff would have a difficult time if the list of accredited institutions were removed. Mr. Harris answered that board staff may use the database maintained by the U.S. Department of Education at ope.ed.gov.

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A motion was made by Hickman to accept the proposed changes to Rule 64B16-26.351, F.A.C. Motion passed unanimously. A motion was made by Philip to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that this rule would not likely increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

2. Rule 64B16-30.003, F.A.C. – Citations

Discussion:

Mr. Harris informed the committee that this rule was placed on the agenda in case JAPC comments were received, which did not happen. He requested for the committee to consider the following proposed additions to subsection (2)(p), (q), and (r):

- Failure to comply with pharmacist to registered pharmacist technician ratio for activities not involving sterile compounding; no injury to patient/customer
- Failure to maintain a physically separate and apart quarantine section for outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs
- Failure to remove from active stock and properly quarantine outdated prescription drugs

Dr. Mesaros suggested that the committee decide on the citations and the fine amounts separately. Mr. Philip disagreed that a quarantine section is required since a pharmacy may decide to destroy or return drugs as soon as they are removed from active stock. Based on this, he believed that the second citation is not needed. Dr. Hickman agreed that the second and third citations are redundant.

A motion was made by Philip to set the fine as \$250 for both citations. Motion passed unanimously. A motion was made by Philip to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that this rule would not likely increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

3. Rule 64B16-28.110, F.A.C. – Outdated Pharmaceuticals

Discussion:

Mr. Harris reviewed the proposed changes, which he explained would simplify the rule to contain only what statute requires. He also pointed out that changes include the transfer of responsibility from a person, such as a pharmacist or PDM, to the pharmacy. Due to this change, Mr. Harris also proposed two additional citations under Rule 64B16-30.003, F.A.C., regarding maintenance of a quarantine section and removal of outdated drugs from active stock.

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Mr. Montgomery proposed adding “beyond used date” next to expiration date for clarity. Dr. Mikhael expressed concern with placing responsibility on the pharmacy.

Edwin Bayo, Attorney, agreed with the intent of the changes but voiced concern with the language “misbranded, or adulterated” due to the possibility that pharmacies are not aware of the conditions in which drugs were produced. Ms. Rivera pointed out that adulterated prescription drugs could refer to recalls or to drugs that were not stored properly and therefore are visibly damaged. Mr. Philip clarified that misbranded drugs apply to Return to Stock vials, which could contain the wrong product or incorrect labeling.

Ms. Rivera stated that more responsibility needs to be placed on the pharmacy. Mr. Philip informed the board that during the last NABP conference, a discussion ensued regarding elimination of the PDM, which would affect this rule. He proposed discussing it during the full board meeting. Discussion ensued regarding whether the pharmacy or persons within the pharmacy should be held responsible.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, thanked Mr. Harris for his work on the proposed rule changes. He expressed concern over the effects of the proposed citations on inspections, particularly cases in which a pharmacy is inspected during cleanup and an outdated drug is found that has not yet been removed. Multiple board members agreed with Mr. Jackson’s concerns.

Robert Difiore, Pharmaceutical Program Manager with Investigative Services, clarified that inspectors are trained to regulate the rules. He explained that they must notate anything found on their inspection forms. Mr. Wright asked whether inspectors would have to issue a citation if the rule were updated. Mr. Difiore answered that citations are not mandatory, but notations are. He also suggested that the board choose the number of notations an investigator must find to issue the related citation.

Further discussion ensued regarding whether responsibility should fall on the pharmacy. Ms. Rivera proposed changing the second sentence of Rule 64B16-28.110, F.A.C. to the following:

“Accordingly, all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and pharmaceuticals shall be removed or quarantined from active stock.”

Mr. Harris clarified the new proposed language to Rule 64B16-28.110, F.A.C., which was the following:

“Under no circumstances may prescription drugs, pharmaceuticals, or devices which bear upon the container an expiration or beyond used date which has been reached be sold or dispensed to the public. Accordingly, all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs and pharmaceuticals shall be removed or quarantined from active stock.”

A motion made by Hickman to accept the proposed changes to Rule 64B16-28.110, F.A.C. Motion passed unanimously. A motion was made by Rivera to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Rivera to acknowledge that this rule would not likely

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increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Rivera to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

4. Rule 64B16-27.410, F.A.C. – Registered Pharmacy Technician to Pharmacist Ratio

Discussion:

Due to no JAPC comments, this rule was not discussed.

5. Rule 64B16-26.400, F.A.C. – Pharmacy Interns; Registration; Employment

Discussion:

Mr. Harris reminded the board of their discussion at the last meeting on amending the rule to place obligation of notifying the board on the intern and on schools when interns no longer qualify for their license. He voiced concern with the difficulty of placing burden on the school in rule. Mr. Philip agreed and suggested asking the schools instead of changing the rule.

Dr. Hickman requested clarification on the outcome for interns who graduate or receive a pharmacist license. Mr. Flynn clarified that interns who have graduated may keep their license and Ms. White added that when an intern receives their pharmacist license, the board office expires their intern license.

Mr. Flynn suggested that since there is no rule-making authority to obligate schools, the board office could create an outreach program to build a relationship and promote consistent reporting. Mr. Montgomery stated that some companies have agreements with schools in which the company is notified when an intern drops out of their program. Ms. Rivera clarified that this does not occur for all interns. Mr. Harris suggested that obligating the intern in rule will likely cause schools to start making their students aware of this rule or cause schools to provide regular updates to the board office. Dr. Mikhael pointed out that pharmacies would likely be diligent in ensuring their interns are still enrolled in school if given the responsibility. Ms. Rivera disagreed that burden should be placed on pharmacies since they rely on the department for an intern's license status.

A motion was made by Philip to open Rule 64B16-26.400, F.A.C. for development and to direct board staff to contact schools on an annual basis to promote consistent reporting. Motion passed unanimously.

6. Discussion of Annual Regulatory Plan

Discussion:

Mr. Harris provided a brief overview of the annual regulatory plan. He informed the committee that during session, any legislation passed must take priority over the board's agenda. Mr. Flynn added that counsel may not be aware of all factors/impacts regarding updates to automation rules and requested that stakeholders and board staff collaborate to keep them abreast, so they may move forward successfully.

Mr. Philip asked whether Rule 64B16-27.630, F.A.C. should be updated before February's

meeting in preparation for an updated CDC schedule. Dr. Mesaros agreed.

7. Old Business / New Business

None

8. Public Comment

None

9. Adjournment

The meeting adjourned at 12:04 p.m.

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