

FLORIDA | Board of Pharmacy

Rules Committee

Draft Meeting Minutes

June 12, 2018

Mission Inn Resorts & Club
10400 County Road 48
Howey-in-the-Hills, FL 34737
Contact Hotel: 800-874-9053



Jeffrey Mesaros, PharmD, JD
Committee Chair

C. Erica White
Executive Director

Tuesday, June 12, 2018 at 9:00 AM

Call to Order - The meeting was called to order by the Committee Chair, Dr. Mesaros, at 9:01 a.m.

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

Committee Members:

Jeffrey Mesaros, PharmD, JD – Chair
David Bisailon
Jonathan Hickman, PharmD
Jeenu Philip, BPharm
Blanca Rivera, BPharm, MBA

Board Staff

C. Erica White, MBA, JD - Executive Director
Shay Marcelus, JD - Prog. Operations Administrator

Board Counsel:

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

1. Rule 64B16-28.141, F.A.C. - Requirements for an Automated Pharmacy System in a Community Pharmacy

Discussion:

Mr. Harris gave an overview of the past actions of the rule and the Joint Administrative Committee (JAPC) comments. A proposed response has been drafted. The estimated effective date for the rule should be in early July 2018. The floor was open for comments. Mr. Phillip commented on the JAPC letter, he asked if the term supervision would be relocated in the rule? Mr. Harris commented on the definition of supervision and the effect of having one standard definition throughout all the rules. The Committee suggested reviewing all the rules that use the term supervision and bring it before the Board at the next meeting for discussion.

2. Rule 64B16-26.351, F.A.C. – Standards for Approval of Registered Pharmacy Technician Training Programs and Review/Update of Technician Duties Research

Discussion:

An overview of the rule was given by Mr. Harris. There was a suggestion from Mr. Koch, Walmart, to create an opportunity to extend the current program offered by Walmart. There has been sample language surrounding the proposed extension of the program created by Mr. Harris. Mr. Koch made written comments which show concern about deleting the provision that required all other programs not listed in the statute to be employer based. Mr. Harris suggested the language was necessary to authorize extensions of the programs.

Michael Jackson, Florida Pharmacy Association, commented on the employer-based programs. He asked if the program director would be able to request an extension for an employee? Mr. Harris confirms the goal of the rule was to allow a program director to make the request on behalf of the employee. The goal was to give the program director the ability to use their discretion within each program. Dr. Hickman commented that the duty falls on the program director. Mrs. Rivera clarifies that the rule only applies to the employer-based programs. She asked if the employee is out for any reason, are there any exceptions? The Committee confirms there is not specific time limit on the completion requirements.

Tim Koch, Senior Director of US Ethics and Compliance for Walmart, commented on the effects of an employee not completing the program and the ability for the employees to re-enroll in a program. He requests the Board provide clarity on the employee's ability to re-enroll in a course and what process would the program director use to communicate a request for extension of a certain program to the Board. He asked, if the program would have to reapply when requesting an extension? Ms. White commented that the program would simply notify the Board office of the extension of the program.

The Committee discussed the effects refusing an employee to reenroll in a program. Ms. White suggested adding language to the rule to specifically allow an employee to reenroll into an employer-based program. Mr. Philip was not aware the Board office was not allowing reenrollment and suggested adding language. Mr. Harris suggested amending the current language to add language that would allow for an employee to reenroll into a program. Mr. Harris asked if the Committee would like to put a limit on the number of time an employee can reenroll, or should it be left up to the program director? Dr. Mikhael suggested giving the program director the power to run the program. Mr. Philip commented on the provision that limits a program to 12 months and suggested extending the time based on the new suggestion from the Board to allow for extensions.

The Committee discussed possible language changes to the rule to allow for an extension. Mr. Harris suggested adding language that allows for the extension but limits the extension to no more than six months past the length of the program. He also suggested making changes to the language to include: Employees who fail to complete an employer-based technician training programs may reenroll in a program, however, all hours completed from any previous program will not apply to the new program.

A motion was made by Dr. Hickman to allow Mr. Harris to draft the rules with the new proposed amendment and present to the Board for review. The motion was seconded by Dr. Mesaros. The motion passed unanimously.

3. Rule 64B16-30.001, F.A.C. - Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances

Discussion:

The disciplinary guidelines have two major changes. First, the matrix for the violation. Mr. Harris has made some suggestion for the Committee to change some of the violations. Secondly, Mr. Harris is suggesting two new violations: 1. Failure to request photo or other verification of identity prior to dispensing a controlled substance. 2. Failure to inform customer of less expensive drug when cost sharing obligation of the customer exceeds the retail price. Due to the new violation, the Committee will have to come up with a new penalty guideline.

Mr. Jackson, commented on the failure to request photo or other verification of identity prior to dispensing a controlled substance. Mr. Harris comments that the pharmacist must check the identification and the rule and violation would only apply when a pharmacist dispenses the drug and there is no documentation that the identity was verified. Mr. Jackson comments on the new elements of the information that must be provided to the PDMP. He asked if any field of the required information in the PDMP may be left blank? Mr. Philip commented on the conflict that may arise with leaving a required field blank. Mr. Harris believed that the program will be fixed on the PDMP side.

Mr. Bayo commented on the violation associated with a failure to request identification. Mr. Harris clarifies that the first violation must be a citation. The second offense will be a disciplinary offense. He suggested the Board to keep that in mind when developing the disciplinary guidelines. The Committee discussed possible changes to the disciplinary guidelines regarding the learning curve of the new rules. Mr. Bayo asked the Committee to clarify whether the violation will be against the pharmacist or the pharmacy. Mrs. Rivera shows concerns about

the way the Board is handling the violation in relation to other boards. Dr. Mikhael comments that the Board has always considered mitigating factors when determining a violation. The Committee discussed the circumstances that could lead to a one-year suspension and the possible effects on the pharmacist and the pharmacy. Mr. Harris makes the Committee aware that most of the penalties are the same as those in the current rules now.

Mr. Wright comments on the one -year suspension in relation to a violation for not informing the patient of the option of a lower prescription price in subsection (r). Dr. Mesaros comments on the learning curve that will happen based on the new rule in subsection (q) and the penalties that with a possible violation. Dr. Mikael comments on the possibility of providing education on the rules.

Mr. Jackson comments on the calls the FPA receives in references to HB21 from both physicians and pharmacist. He discussed the concerns his office receives from the profession. He continues with the concerns of the profession based on the requirement to write acute pain on the prescription and how the pharmacist can cure a failure of the physician to follow the rule. Ms. White suggested that the rules for each board may remedy the issue. She is currently tracking the language of the rule. Dr. Hickman comments on the difference in informing the patient the prescription is incomplete and a pharmacist refusing to fill a prescription. The Committee discussed the options for the pharmacist to inform different boards of a physician's failure to follow the new rule.

Brian Kahn commented on the requirement of informing the patient of the lesser alternative of a prescription. He has concerns on the variation of the prices of prescriptions and the ability to consistently implement the rule despite the financial burden it may have. Mr. Bayo commented on the violations under Chapter 499. He suggested the violation are on the harsher side and suggested revising the one-year suspension. Mr. Ron Salem, commented on the electronic submission and how it effects the requirements of the rule. He recommends the Committee take the hospice facilities in to consideration when developing rules. Mr. Bob Parrado asked the Committee to consider the faculties who handle ALS patient when developing the rules.

Dr. Mesaros asked Mr. Harris to advise the Committee on the development of the rules based of the comments before the Committee. Mr. Harris discussed the penalties of a first offense. The Committee discussed the penalties guidelines for a license issued in error by the Board. The Committee discussed options of voluntary relinquishment and revocation. Mr. Bayo commented on the administrative law process that takes place when a license is issued in error.

The Committee discussed changing the language in the rule. Also, the Committee discussed lowering the fines from one thousand dollars. Mr. Harris comments that the legislative has made it clear that they take such violations very serious. He also suggested lowering the fine range may hinder Prosecution Services Unit in negotiating settlement agreements. Dr. Mesaros suggested changing the fine and revisiting the fine after a year to allow for the learning curve. The Committee discussed possible fine amounts for a citation and the fine amounts under the disciplinary guidelines. The Committee discussed lowering the fines. There was discussion of lowering the fine to \$500.

A motion was made by Mr. Phillip to amend paragraph (m) and (n), strike the one-year suspension and add a \$250 fine plus 12 hours of law and rules or MPJE up to one year of probation. Mr. Montgomery voiced his concerns on the fines associated with a violation of the confidentiality rule. Mr. Bayo suggested adding option for 1-year probation to all fines. Mr. Phillip asked if the Board would still could revoke a license on a first offense for very egregious offenses. Mr. Harris confirms the option will still be available to the Board. The Committee

discussed options available for a knowing violation versus a negligent violation. Dr. Mikael suggested adding language for a knowing and negligent violation for subsection (m) but keep the same penalty range. The Committee discussed the severity of the fine when the pharmacist has a willing disregard for the law.

Mr. Phillip moved to strike the one-year suspension for a first-time offense on subsection (g). He agrees with Mr. Bayo recommendation to allow an option for a 1-year probation instead of 1-year suspension for all current offenses. Dr. Mikael suggested keeping the language of up to a 1-year suspension for certain circumstances. The Committee discussed the requirement to be certified before allowed to administer a vaccine after a violation of administering a vaccine without the proper certification. The Committee discussed the \$5000 fine associated with the violation and the possibility of suspension versus probation.

The proposed changes are:

1. In Rule 64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances paragraph (m) and (n), strike the one-year suspension and add a \$250 fine plus 12 hours of law and rules or MPJE up to one-year probation. 2.
2. In Rule 64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances, in subsection (o), there will be a negligent failure portion and an intentional failure portion of the rule. The violation will be copied here from page 7, paragraph (h), subsection (1) and (2).
3. All violations in Rule 64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances with a one-year suspension as a violation will be changed to one-year probation for the first violation.
4. In Rule 64B16-30.001 Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances, in subsection (p), the fine will be \$5,000 and suspension of the immunization certification up to one year.

Motion to by Mr. Philips to accept the changes. Motion was seconded by Mr. Bisailon. The motion passed unanimously.

4. Rule 64B16-30.002, F.A.C. - Minor Violations

Discussion:

No action needed on this item.

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

Discussion:

Mr. Harris gives an overview of the changes of the rule. He asked the Committee for the statutory fine associated with a violation. The Committee discussed the fines and issue that may arise from lower the fine. Dr. Hickman suggested a fine \$125. Mr. Bisailon commented that the fine should deter individuals from committing the offense and the Board has been pushing for the enforcement of the use of the PDMP and this is the tool to accomplish the goal. Mr. Dix commented that the first 3 rule changes are geared toward opioids and would give rise to the justification of a different fine. The Committee discussed possible fines.

A motion was made by Mrs. Rivera to make Rule 64B16-30.003, F.A.C. Citations subsection L-O \$100. Motion seconded by Dr. Hickman. Motion passed unanimously.

6. Overview of Draft Rule 64B16-28.750, F.A.C. - Class III Institutional Pharmacies

Discussion:

Mr. Harris gave an overview of the new permit. Ms. White gave an overview of the process the Board office will use to issue the new license. The permit will stay the same but the class III modifier will be applied to the original permit. The Committee discussed the possibility of having FAQs for the new application.

Motion to accept the Draft Rule 64B16-28.750, F.A.C. Class III Institutional Pharmacies, the application, and all the amendments made by Dr. Hickman. The motion was seconded by Mr. Bisailon. Motion passed unanimously. Motion to approve subcommittee meeting made by Dr. Hickman. The motion was seconded by Mr. Bisailon. Motion passed unanimously.

7. Amendments to Current Rules to Implement

Discussion:

Motion to accept the Draft Rule 64B16-28.750, F.A.C. Class III Institutional Pharmacies, the application, and all the amendments made by Dr. Hickman. The motion was seconded by Mr. Bisailon. Motion passed unanimously.

8. Old Business / New Business

9. Public Comment

10. Adjournment

Motion to adjourn was made by Mr. Bisailon. The motion was seconded by Mr. Phillip.

The meeting adjourned at 12:37 p.m.