

FLORIDA | Board of Pharmacy

Rules Committee

Draft Meeting Minutes

October 1-2, 2018

Embassy Suites Ft. Lauderdale

1100 SE 17th Street

Ft. Lauderdale, FL 33316

Contact Hotel: 954-315-1326



Jeffrey Mesaros, PharmD, JD
Committee Chair

C. Erica White
Executive Director

Monday, October 1, 2018 at 2:00 PM

Note: AUDIO from this meeting may can be found online: <http://floridaspharmacy.gov/>

1. Call to Order:

The meeting was called to order by the Committee Chair, Dr. Mesaros, at 2:05 p.m.

Roll Call:

Those present during the meeting included the following:

Committee Members:

Jeffrey J. Mesaros, PharmD, JD - Chair

David Bisailon

Jeenu Philip, BPharm

Blanca Rivera, BPharm, MBA

Board Counsel:

David Flynn, Assistant Attorney General

Lawrence Harris, Assistant Attorney General

Board Staff:

C. Erica White, MBA, JD Executive Director

Shay Marcelus, JD - Program Operations Administrator

2. Rules Workshop: Automation

Discussion:

Mr. Harris gave an overview on the rulemaking process and the rulemaking workshop. He discussed the various combination in which the automation systems may be utilized. He discussed how the rule do not have a clear path on how the profession will use the automation systems. He voiced his concern about the variances and waivers that have previous presented the Board. He suggested the Board has statutory authority for permits and should use the authority granted for special permits to remedy so. Wants to create a rule that world establish a new permit.

Mr. Harris suggested that the Board investigate the current procedures whereby one pharmacy may contract with another pharmacy to fill. He suggests allowing each machine to obtain a permit and have a pharmacist there via two communications to consult with the patient. The applicant will have to comply with Section 465.022, F.S., by either contractual agreements or through policies and procedures. The goal would be to ensure patient safety , in a cost effective manner, which increases access to healthcare.

Dr. Mesaros gave an overview of the history of the Board's discussions and actions surrounding automation. He suggests the Board keep in mind that there are serval rules affected by automation. He opened the discussion to the Committee and Board members.

Dr. Mikhael stated that automation will help with lower the cost of healthcare. He would like to see some increased language for the rule. Mr. Philip stated that he had concerns with the location of the automation machine. He wants clarification on how far the machine will be located from the pharmacy. He requested the committee to distinguish between a machine that dispensing as

opposed to a machine that is used as a storage unit.

Mr. Harris suggested that the Board may decide to develop several rules for different settings surrounding the use of the automation machine. The committee discussed using the special community permit to accomplish the goal of issuing a permit for each machine.

Mr. Bisailon, from a consumer perspective, believes that the Committee is on a good path with developing rules for automation. He discussed the progression of the profession and the professional effort of protecting the safety of the public.

Ms. Rivera discussed the practice of technology in other professions. She suggested the Committee look at the process that has been used in other states to gain valuable knowledge. She voiced concerns about a pharmacist being allowed to be the pharmacist of record of more than one pharmacy.

Mr. Wright discussed the Board embracing the use of technology to enhance the profession. He voiced his concerns about the new laws for surrounding controlled substances and how they will affect automation machines. He also discussed the issues that may arise with written prescriptions provided to a machine. He believes that technology will help decrease error made in the profession, but the Committee must address the common issues that may occur when dealing with technology versus an actual person.

Michael Jackson from the Florida Pharmacy Association (FPA), discussed the advancement of technology in all professions. He discussed the regulation process surrounding the practice of pharmacy in Florida. He finds issues with how a device with a permit will comply with the legal process of being served. He suggested the Board consider how an automated system can provide more services like immunizations. He questions what will happen if there is a system failure and will the Prescription Department Manager (PDM) be held responsible for such actions. He advised the Committee to consider the effects of Chapter 499, F.S., within the expansion of automated dispensing. He discussed the limitation on some pharmacies to mail medication. FPA will continue the work with the Board and looks forward to reviewing the proposed language.

Ms. Rivera suggested having the FPA members participate in the development of the proposed language to better serve the public and the profession. Dr. Mikhael discussed the issues of overregulating the professional judgment of the pharmacist. He thinks the result must be one that makes the profession better when regulating the profession. Mr. Wright discussed the Board considering the overall cost of healthcare not just the cost of dispensing the medications alone. He suggested the cost factor not be the driving factor when making the decisions to enhance the profession. Mr. Flynn clarified that the discussion of cost also relates to the cost of rulemaking.

Mr. Ed Rickert, pharmacist and attorney, discussed the importance of the issue to providing healthcare to the patient. He agrees with Dr. Mikhael that whatever rule developed is better than what we currently have. He discussed issues of accountability and how other states have addressed the issue. He discussed how other states treat the machine as an extension of the pharmacy and not an individual entity. He continued to address the issues discussed about the type of medication the machine can dispense. He discussed the need for opioids in the profession and that should be considered the patient's ability to get access to all prescription medication when developing the rules. He suggested the Committee consider allowing companies to have access to the automation system to benefit their employees and not restrict them to only healthcare facilities.

The Committee discussed the issue of storing the medication and the possible option to regulate the process storage.

Meeting recessed at 3:20 p.m. Meeting reconvened at 3:35 p.m.

Richard Palumbo, discussed the issue of security with the automated system. He recommended the Board consider placing the remote automated system in multiple locations. He suggested there may be other companies that may need access to such systems and the Board should be careful in limiting the access to the systems to only healthcare facilities. Mr. Wright discussed what factors the Board should consider in expanding the accessibility to the automated systems to the public.

Mr. Harris clarified that he recommends that someone will be tasked with servicing each machine. The servicer is likely not going to be the applicant for the permit but rather the hospital or pharmacy. The relationship with the permit owner and servicer will be contractual. He believes it important to understand that this will be a special permit that will allow the establishment. He discussed the process that should be in place to inspect the machine. Mr. Harris believes most of the issues discussed will be the responsibility of the applicant to show the Board the proper procedures are in place to maintain compliance with the rule associated with the permit. He discussed the possible issues in having a PDM over more than one machine and what the Board should consider in developing rules regarding the responsibilities of the PDM.

Mr. Flynn informed the Committee there are currently rules relating to automated systems. The committee discussed what process will be in place for inspecting the machine.

Dr. Mikhael discussed having an extension of the original location of the community permit instead of issuing a new permit. Mr. Harris does not think the Board has the authority to grant an extension of an existing permit. He suggested creating a new special permit and require all applicant to comply with all the requirements to obtain the permit.

Motion to adjourn the Rules Workshop was made by Dr. Mesaros, and the Motion was seconded by Ms. Rivera. Motion passed unanimously.

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

Discussion: Joint Administrative Procedures Committee (JAPC) Letter

Mr. Harris told the Committee that there were a couple of difference pieces. The Committee proposed rule changes, and in response, there were some Joint Administrative Procedures Committee (JAPC) Comments. Staff attorney for JAPC had one comment, which was that that the language in the proposed rule, did not match the language in the application instructions for training programs provided by a branch of the federal armed services.

Mr. Harris offered the proposed language to change the rule text, which would be: "Pharmacy technician training programs provided by a branch of the federal armed services using a curriculum developed on or before April 1, 2018." Motion to accept the change and proposed language made by Ms. Rivera. Motion seconded by Mr. Basillion. Motion passed unanimously.

Mr. Harris asked the Committee to vote on whether the Notice of Change would have an adverse impact on small business, result in increased costs in excess \$200,000 within one year, increase

costs in excess of \$1,000,000 within five (5) years of the change being implemented, or whether a violation of any part of this rule could be remedied through the issuance of a Notice of Non-Compliance as a Minor Violation. Mr. Bisailon made a Motion that this Notice of Change would not, and the Motion was seconded by Ms. Rivera. Motion carried.

Discussion: Comments to Proposed Rule Changes

Mr. Harris stated that the Board received written comments on the proposed changes to the rule, which must be considered before the Board may proceed. Jessica Langley, Executive Director of Education for the National Health Career Association, made comments on the proposed rule relating to Pharmacy Technician Training Programs, and also discussed the benefits to the profession for having a pathway for certification for technicians.

Ms. Langley recommended the inclusion of career and tech ed programs which are approved by the Department of Education in the list of approved Pharmacy Technician Training Programs (typically high school programs). The Committee discussed the proposed rule and the list of approved training programs. Discussion took place on possibly reducing the list of the approved training programs. Mrs. Langley, believes that the list is every extensive and does not follow the standards set by other states.

Mr. Wright is in support of having the high school students in profession. His concern is the age of the students. Mr. Flynn clarifies that an applicant must be 17 years of age to be registered as a pharmacy technician. Mrs. Rivera discussed the age requirements under the DEA permit and how they differ from the rules in Florida.

Ms. Langley discussed the possible issue that may affect the profession in expanding to allow individuals to enter the profession. She informs the Committee that 74% of the technicians are currently certified. Ed Bayo, attorney, discussed the requirement that all program must be certified and what issues may arise with employer-based programs and the new mandate. Mr. Harris clarifies that by requiring programs to now be certified may create a cost impact. Ed Bayo, discussed the similarity of the of the certification within pharmacy and those present in the Board of Nursing.

Ms. White discussed what issued the Board staff may face when approving the programs without a list of the national certifying entities.

The Committee discussed possible language change to make the rule more concise. Mr. Harris requested to develop proposed language and bring the proposed language back to the Board for review and/ or approval. Committee approved the request.

Tim Koch, commented on the language in Section (1) of the rule and the affect it may have on the profession. He suggested the language as suggested would allow any program can become an approved training program without any standard that must be followed. Mr. Philip informed the Committee that some states have decided to use the national certification.

Ed Bayo, discussed the similarity of the of the certification within pharmacy and those present in the Board of Nursing.

Motion to recess the Committee meeting was made by Dr. Mesaros. Motion was seconded by Ms. Rivera. Motion passed unanimously. Meeting recessed at 5:31 p.m.

Tuesday, October 2, 2018 at 9:00 a.m.

The meeting reconvened at 9:00 a.m. on Tuesday, October 2, 2018.

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

The Committee discussed proposed amendments to the rule, which were required by the passage of HB 21. The rule amendments did receive some substantial comments from JAPC.

Discussion: JAPC Letter and draft response

- First issue is regarding fraudulent conduct regarding reinstating the statutory fine of \$10,000 Mr. Harris request that the Committee look at the proposed language regarding the range of penalties. Mr. Harris stated that his “job” is to ensure that the range of penalties is “meaningful”. Mr. Harris requested the Committee to vote on the proposed fine amounts. Motion to file a Notice of Change in order to approve the correction fine amounts changes to the rule was made by Mr. Bisallion, and was seconded by Ms. Rivera.

Mr. Harris asked the Committee to vote on whether the Notice of Change would have an adverse impact on small business, result in increased costs in excess \$200,000 within one year, increase costs in excess of \$1,000,000 within five (5) years of the change being implemented, or whether a violation of any part of this rule could be remedied through the issuance of a Notice of Non-Compliance as a Minor Violation. Mr. Bisailion made a Motion that this Notice of Change would not, and the Motion was seconded by Ms. Rivera. Motion carried.

Mr. Harris asked the Committee to vote on the question of whether a violation of any part of

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

Discussion: Mr. Harris gave an overview of the 3:1 pharmacy technician ratio only applies to sterile compounding operations. The proposed language attempts to capture this clarification. The proposed language regarding 3:1 ratio does not apply to other areas of the pharmacy which are physically separated from the area where sterile compounding is performed.

Mr. Harris discussed that the 6:1 ratio proposed language is applicable as long as the pharmacy technicians are not engaged in sterile compounding. 8:1 ratio proposed language is applicable in which the pharmacy does not dispense medicinal drugs and are not engage in sterile compounding.

Tim Koch, made comments regarding the proposed language, and suggested that the language “other activities not involving sterile compounding” be utilized. Dr. Mikhael stated that he would like to see Florida go to a “no ratio” state (i.e. – pharmacy technician to pharmacy ratio). Ed Bayo, attorney, suggested using language “other non-sterile compounding activities”.

Mr. Harris informed the board of the issues the inspector will face in conducting an inspection. Motion to approve the amended language was made by Mr. Philip, and seconded by Mr. Bisailion.

Mr. Harris requested to bring back updated language back on a recommendation for amending the Notice of Non-Compliance relating to the area of pharmacy technician ratios. Motion to approve this action was made by Mr. Philip, and was seconded by Mr. Bisailon.

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

Discussion: Mr. Harris gave an overview of the proposed changes to the rule. He has some draft language in three sets of updates:

- Draft updates to Rule 64B16-28.110, F.A.C.;
- Draft language for the Minor Violations rule - Mr. Harris suggested creating a range for penalties; and
- Draft language for the Citation rule – Mr. Harris suggested to create a range for penalties.

Ed Bayo, attorney, suggested striking the language that references to Chapter 499, F.S., in the proposed Rule 64B 16-28.110(1), F.A.C., based of the historical knowledge he possesses from working in the profession. He suggested striking the second sentence in Rule 64B16-28.110 (1), F.A.C.

Ms. Rivera suggested to change the order of 64B16-28.110(2), F.A.C., and place it before 64B16-28.110(1), F.A.C. The Committee also discussed the issue that may arise by not stating that there must be an active stock. They also discussed the effects to the practice requiring the expired medication to be place in the quarantine area. Michael Jackson from the Florida Pharmacy Association explained the history of developing the rule. Mr. Jackson explained that a pharmacist can clear all expired medication, and the next day another medication could expire -- and if inspected such an action can result in a citation. Mr. Jackson voiced his concerns on how a minor violation could lead to a pharmacist being disciplined by the Board. Dr. Mesaros asked if Mr. Jackson had any suggestions on the proposed language the Committee should considered. Mr. Jackson informed the Board he will do some research and report his findings to the Board.

Robert DiFiore, Pharmaceutical Program Manager for the Division of Medical Quality Assurance agrees with Ms. Rivera's suggestion to change the order of 64B16-28.110(2), F.A.C., and place it before 64B16-28.110(1), F.A.C. Mr. DiFiore discussed his viewpoint regarding expired drugs, which is that no expired drugs should be on the shelf. He also stated that currently most inspectors will not open up a disciplinary case just because an inspector finds an expired drug during an inspection.

Mr. Philip made a Motion to Accept the proposed change made by Mrs. Rivera to change the order of 64B16-28.110(2), F.A.C., and place it before 64B16-28.110(1), F.A.C., and accept Ed Bayo's suggestion of striking the language that references to Chapter 499 in 64B16-28.110(1), F.A.C. Ms. Rivera seconded the motion. Motion passed unanimously.

Mr. Harris gave an overview of the proposed language in the Rule 64B16.30.002 (1)(a), F.A.C. The Committee discussed what factors should be considered in determine when an outdated prescription offense should be deemed a minor violation versus being deemed a citation. Committee discussed the difference in inventory based on the size of the pharmacy and whether the size of the inventory that should be a factor considered on the level of disciplinary action should be taken.

Ms. Rivera made a Motion which suggested leaving the original language in Rule 64B16.30.002(1)(a), F.A.C., and striking all the other proposed language. The Motion was seconded by Mr. Bisailon, and said Motion passed unanimously.

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

Discussion: Committee discussed possible fines under the fines Rule 64B16-30.003, F.A.C. – Citations. The Committee also discussed placing a possible fine of \$100 within Rule 64B16-30.003 (3)(p), F.A.C. Committee further discussed placing a \$500 fine within Rule 64B16-30.003 (3)(q), F.A.C. Motion was made by Dr. Mesaros to accept the proposed fines and to have the language in 64B16-30.003 (3)(q), F.A.C to mirror the language in the Rule 64B16.30.002(1)(a), F.A.C., for a minor violation. Motion seconded Mr. Bisailon. Motion passed unanimously.

The meeting recessed at 10:55 a.m., and reconvened at 11:10 a.m.

The Committee had a discussion with Mr. DiFiore about the process for issuing and following up on Citations which have been issued. Mr. Harris suggested striking the language from Rule 64B16-30.003(2), F.A.C., because it is not necessary.

Dr. Mesaros made a Motion to amend the language of Rule 64B16-30.003(1), F.A.C., to align with the statute, and to strike Rule 64B16-30.003(2), F.A.C, and renumber all subsequent subsections. Mr. Bisailon seconded the motion. Motion passed unanimously.

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

Discussion: Mr. Flynn has suggested to continue this discussion to the December Board meeting to allow the Board to have all relevant information before further discussion or a vote can take place.

Michael Jackson from the Florida Pharmacy Association (FPA), discussed the Board communicating all information to the foreign graduates who would be affected by the Board's action.

6. Old Business / New Business:

No Discussion.

7. Public Comment:

No Discussion.

8. Adjourn:

Motion to adjourn by Dr. Mesaros. Motion seconded by Mr. Philip. The meeting adjourned at 11:55 a.m