FLORIDA | Board of Pharmacy

Rules Committee

Meeting Minutes

April 3, 2018
Residence Inn Tallahassee Universities at the Capitol
600 West Gaines Street
Tallahassee, Florida 32304
850-329-9080

Jeffrey Mesaros, PharmD, JD
Committee Chair

C. Erica White, MBA, JD
Executive Director

Tuesday April 3, 2018

Those present for all or part of the Florida Board of Pharmacy Rules Committee Meeting included the following:

COMMITTEE MEMBERS PRESENT:

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

BOARD MEMBERS PRESENT:

- Mark Mikhael, PharmD
- David Wright, BPharm
- Richard Montgomery, BPharm, MBA

BOARD COUNSEL:

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

STAFF PRESENT:

- C. Erica White, MBA, JD, Executive Director
- Savada Knight, Regulatory Supervisor

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

The Committee Meeting convened at approximately 9:00 a.m.

Chair Mesaros opened the meeting by providing greetings and having introductions by staff, Committee members and non-voting Board members.

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

   Mr. Flynn requested to continue this discussion to the next meeting (June 2018), since there are presentations scheduled on automated pharmacy systems during the April 2018 Board meeting. Mr. Flynn would like to start working with Dr. Mesaros on comments to current proposed rule changes received from the Joint Administrative Procedures Committee (JAPC).

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

   Dr. Mesaros discussed the fact that there was some information presented to the Board (in the Legislative Committee) regarding data and information from around the country regarding pharmacy technician duties. The data and information deals with expansion of technician duties in other states, and the information which has been compiled will be disseminated to the Board members and Board Counsel for review and discussion at a future Board meeting.

Mr. Harris discussed the fact that the Board voted to make changes to the rule to update the dates by when pharmacy technician programs must be accredited on from April 1, 2017, to April 1, 2018. There were also no JAPC Comments which were received; however, Mr. Harris mentioned that Ms. White provided information regarding a change to an accrediting body located in 64B16-26.351(1)(g), F.A.C. - Standards for Approval of Registered Pharmacy Technician Training Programs, relating to the Middle States Commission on Secondary Schools (MSCSS). The MSCSS has now been official "split" into two (2) separate accrediting bodies. The other accrediting organization is the Middle States Commission on Higher Education (MSCHE), which also approves pharmacy technician training programs, especially for programs located in Puerto Rico.

Mr. Harris asked the Committee to vote on filing a Notice of Change to the rule which would result in updating the 2017 date for accreditation to 2018, and to also add the MSCHE to Rule 64B16-26.351(1)(g), F.A.C. Motion to file Notice of Change made by Mr. Bisaillon, seconded by Dr. Hickman. Motion carried.

Mr. Harris asked the Committee to vote on whether the Notice of Change would have an adverse impact on small business or increase regulatory costs in excess of $200,000. Motion that the Notice of Change would not have an adverse impact on small business or increase regulatory costs was made by Mr. Bisaillon, and the Motion was seconded by Dr. Hickman. Motion carried.

Mr. Harris asked the Committee to vote on whether the Notice of Change would result in increased costs in excess of $1,000,000 within five (5) years of the change being implemented. Mr. Bisaillon made a Motion that this Notice of Change will not increase costs in excess $1,000,000 costs within five (5) years of the change being implemented, and the Motion was seconded by Dr. Hickman. Motion carried.

Mr. Harris asked the Committee to vote on the question of 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. Bisaillon made a Motion that a violation of any part of this rule would not require the issuance of a Notice of Non-Compliance as a Minor Violation, and the Motion was seconded by Dr. Hickman. Motion carried.

Discussion and Public Comment regarding Rule 64B16-26.351, F.A.C.:

Tim Koch, Senior Director of Pharmacy Practice Compliance at Walmart also appeared to discuss Rule 64B16-26.351, F.A.C. Walmart uses an in-house training program that is powered by Pharmacy Technicians University. The total amount of training is over 300 hours of training for every technician that is hired as part of their onboarding training. The training program has gotten more robust over time, and Walmart is finding it more difficult to complete the program within six (6) months as required by Rule 64B16-26.351, F.A.C. If a pharmacy technician does not complete the training within six (6) months, regardless as to the reason, they are removed from the program and from employment with Walmart. Mr. Koch stated that it is not good for business or good for the employee to have them removed from working at Walmart after investing a significant amount of time in almost completing the program.

Mr. Philip commented that in writing the rule that sometimes the Board did not see the unintended consequences, which end up in creating hardship, which is what is happening with Walmart. He said that it doesn't make sense to have pharmacy technicians to complete 300 hours of training, and then not allow them to continue with employment because they did not complete the training within 180 days (six (6) months). Dr. Hickman asked if the six (6) month range was enough to complete

160 hours as required by the rule. Dr. Hickman also stated that he also doesn't want people to drag their feet by extending the time of training too long. Mr. Wright stated that the same situation happened at his pharmacy with a pharmacy technician who could not complete the training in six (6) months due to family situations.

Dr. Mesaros discussed the option of re-enrollment option in a pharmacy technician training program if an employee did not finish a pharmacy technician program within the six (6) month timeframe. Mr. Philip stated that he does not see an economic impact to the state with this option. Mr. Koch stated that it would be a positive impact to the pharmacy for allowing the re-enrollment option for an employee who did not previously complete the program.

There was also discussion with Mr. Koch and Mr. Harris regarding the possibility of extending the time allotted to an employee who completed a pharmacy technician training program. The amount of time extended would be on a case-by-case basis which would depend the circumstances of the employee. Mr. Wright stated that in his practice (community pharmacy), he would prefer the option of re-enrollment if a pharmacy technician did not complete the first (six) months.

Mr. Koch stated that in the scenario with Walmart, the re-enrollment would not be automatic, and would take some time of "intervention" by the employer before re-enrollment could occur. Mr. Bisaillon also commented about the "intervention" action by the employer (human being), and he thinks that this practice is better than an automatic action of re-enrollment in the training program.

Dr. Mikhael stated that he liked option of having the re-enrollment period, and if the pharmacy training program exceed a certain number of hours (i.e. – 250 hours), then additional time would be allotted for the employee to complete the program. Dr. Mesaros also commented that he liked the option of having a dual course of action (re-enrollment or additional time to complete a training program whose hours exceed more than the standard 160 hours).

Mr. Montgomery stated that we need to put a number on the hours which must be required in order for a pharmacy technician training program to qualify for additional hours. Dr. Mesaros suggested that training programs which had more than 200 hours of training would qualify for additional time. Dr. Hickman stated that he did not want to penalize people for providing additional hours of training beyond the 160 hours, and that companies should be rewarded for going beyond the minimum training hours of 160 as provided for in the rule. Mr. Philip suggested that for every additional thirty hours of technician training offered over the 160-hour requirement, the employer would receive an additional month (30 days) of time to have the employee to complete the training program.

Mr. Harris stated that he would go back and draft language to be considered on this matter at the June 2018 Committee Meeting. The options to be included:

- Escalator clause for additional time of 30 days to be provided to employers for each additional 30 hours over the 160-hour requirement; and
- A one-time re-enrollment option for pharmacy technicians who don't complete the initial pharmacy technician training program within the first six (6) month period.

Mrs. Rivera made a Motion to have Mr. Harris go back and work on changes to the rule based on the comments received by Mr. Koch and the Board members for changes to Rule 64B16-26.351, and the Motion was seconded by Mr. Bisaillon. Motion carried, no opposition.

3. **<u>Rule 64B16-27.410, F.A.C.</u> - Registered Pharmacy Technician to Pharmacist Ratio**

Mr. Harris stated that the Board has proposed changes to the current rule, Rule 64B16-27.410, F.A.C., and stated that he did get comments from JAPC, which Mr. Harris was able to respond to without bringing this matter back to the Board. Mr. Harris also indicated that he got a number of public comments regarding the Boards proposed changes (3 written comments received). Mr. Harris stated that under Florida law, the Board must consider the comments received and determine if the comments would result in the Board changing its current course of action with respect to the rule.

Mr. Philip stated that Mr. Harris' response to JAPC was well written, and proceeded with discussion on the two (2) written comments which were received. He stated that the comments were providing the opinion of the writers, and not based on actual facts or data from other states. Mr. Philip also stated that the comments made by the writers were also previously discussed at length, so there were no new points raised in the written commentary

Mr. Philip made a Motion not to make changes to the current Notice of Change to Rule 64B16-27.410, and the Motion was seconded by Dr. Hickman. The Vote was 4 YEAs, and 1 Nay by Mrs. Rivera. Motion carried.

4. **<u>Rule 64B16-27.450, F.A.C.</u> – Prescription Department Managers and Change in Prescription Department Manager - DH-PH10**

Mr. Harris stated that this rule, along with Rule 64B16-28.501, F.A.C. - Institutional Permit – Consultant Pharmacist and Change in Consultant Pharmacist of Record - DH-MQA 1184, and Rule 64B16-28.100, F.A.C. - Pharmacy Permits, are all related. They are related to the massive project taken on to do the major rewrite to the pharmacy permit applications. The Board previously decided to also make changes for Prescription Department Managers and Consultant Pharmacist of Record.

Mr. Harris stated that he did receive comments from JAPC, and has written draft responsive comments for the Board's consideration and review. Although Mr. Harris believes that the necessary corrections to the rule are minor (conforming changes to the application forms and the rule), based on JAPC's comments and will not be difficult to make, he still needs the Board to vote to authorize a Notice of Change to the rule. Motion to file Notice of Change made by Dr. Hickman, seconded by Mr. Bisaillon. Motion carried, no opposition.

Mr. Harris asked the Committee to vote on whether the Notice of Change would have an adverse impact on small business or increase regulatory costs in excess of $200,000. Motion that the Notice of Change would not have an adverse impact on small business or increase regulatory costs was made by Mr. Bisaillon, and the Motion was seconded by Dr. Hickman. Motion carried, no opposition.

Mr. Harris asked the Committee to vote on whether the Notice of Change would result in increased costs in excess of $1,000,000 within five (5) years of the change being implemented. Mr. Bisaillon made a Motion that this Notice of Change will not increase costs in excess $1,000,000 costs within five (5) years of the change being implemented, and the Motion was seconded by Dr. Hickman. Motion carried, no opposition.

Mr. Harris asked the Committee to vote on the question of 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. Bisaillon made a Motion that a violation of any part of this rule would not require the issuance of a Notice of Non-Compliance as a Minor Violation, and the Motion was seconded by Dr. Hickman. Motion carried, no opposition.

5. **<u>Rule 64B16-28.501, F.A.C.</u> – Institutional Permit – Consultant Pharmacist and Change in Consultant Pharmacist of Record - DH-MQA 1184**

Dr. Mesaros stated that similar to the comments made regarding Rule 64B16-27.450, F.A.C. – Prescription Department Managers and Change in Prescription Department Manager, the comments received from JAPC are minor (conforming changes to the application forms and the rule, and correction to a cross-reference), based on JAPC's comments; however, Mr. Harris still needs the Board to vote to authorize a Notice of Change to the rule. Motion to file Notice of Change made by Mr. Bisaillon, and the Motion was seconded by Dr. Hickman. Motion carried, no opposition.

Mr. Harris asked the Committee to vote on whether the Notice of Change would have an adverse impact on small business or increase regulatory costs in excess of $200,000. Motion that the Notice of Change would not have an adverse impact on small business or increase regulatory costs was made by Mr. Bisaillon, and the Motion was seconded by Dr. Hickman. Motion carried, no opposition.

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6. **<u>Rule 64B16-27.630, F.A.C.</u> - Additional Immunizations or Vaccines Which May Be Administered**

This item has been pulled, because the rule was filed for adoption and becomes effective on April 12, 2018. Dr. Mesaros stated that the Board saw this change coming last December and the Board was very proactive in getting this rule adopted. Dr. Mesaros thanked Mr. Harris for acting expeditiously in order to get the updates to the rule done very quickly.

7. **<u>Rule 64B16-28.100, F.A.C.</u> – Pharmacy Permits**
   - **Community Pharmacy Permit – DH MQA 1214**
   - **Institutional Pharmacy Permit – DH MQA 1215**
   - **Internet Pharmacy Permit – DH MQA 1216**
   - **Nuclear Pharmacy Permit – DH MQA 1218**
   - **Special Pharmacy Permit – DH MQA 1220**

- **Special Sterile Compounding Pharmacy Permit – DH MQA 1270**

Dr. Mesaros stated that similar to the comments made regarding Rule 64B16-27.450, F.A.C. – Prescription Department Managers and Change in Prescription Department Manager, and Rule 64B16-28.501, F.A.C. - Institutional Permit – Consultant Pharmacist and Change in Consultant Pharmacist of Record, the comments received from JAPC are minor (conforming changes to the application forms and the rule, and correction to a cross-reference to the Internet Pharmacy Permit.)

Dr. Mesaros provided a history of the amendments to the application, and acknowledged the hard work of both the Board members and Board staff in getting these amendments done over the last several months. Dr. Hickman stated that it had been several years since the applications had been updated. Mr. Flynn stated that he wanted to commend Mr. Harris and Ms. White put in behind the scenes to get the changes to the applications done, because there were so few JAPC comments.

Based on JAPC's comments Mr. Harris still needs the Board to vote to authorize a Notice of Change to the rule as proposed to make the confirming changes to the rule and to MQA 1215 and MQA 1218. Motion to file Notice of Change made by Mr. Bisaillon, and the Motion was seconded by Dr. Hickman. Motion carried, no opposition.

8. **<u>Rule 64B16-30.001, F.A.C.</u> - Disciplinary Guidelines; Range of Penalties; Aggravating and Mitigating Circumstances**

Mr. Harris stated that the original goal was to have revised disciplinary guidelines for the Committee to look at, but he was not able to get actual draft language drafted for the April 2018 meeting. Mr. Harris stated that he is going to bring a draft for review and discussion to the June 2018 meeting. Mr. Harris stated that he is going to follow what other Boards do, which is to have a penalty range for a 1st offense and a 2nd and/or subsequent offense. Mr. Harris also said that he was going to "tweak" some of the guidelines to some of the other rules, which had not been updated in quite some time.

Mr. Harris also stated that he was going to be adding new penalty violations associated with HB 21. There are two big areas:

- Acute Pain – which consists of prescriptions for acute pain where the pharmacist filled a prescription without having the required written words "Acute Pain" on the face of the prescription as requirement pursuant to HB 21; and
- Prescription Drug Monitoring Program (PDMP) violations:
    - Failure to check the PDMP
    - Failure to report the new prescription to the PDMP
    - Unauthorized access.

Mr. Harris also suggested that there be disciplinary guidelines when a pharmacist fills a prescription related to the opioid antagonists (i.e. – Naloxone). Mr. Philip stated that he doesn't think that a pharmacist should be disciplined for a prescriber requirement, and Mr. Flynn agreed, and stated that that this proposed disciplinary guideline would be taken off of the table. Mr. Flynn stated that what the focus should be on whether or not all valid parts of the prescription are present when filling the prescription. Additionally, Mr. Flynn stated that the citation rule has to be updated to add failure to check the PDMP.

Mr. Harris stated that the purpose of the disciplinary guidelines is to put the public/licensees on notice regarding the penalties for law violations. Mr. Harris also stated that disciplinary guidelines needed to be put in place for HB 351 – Prescription Drug Pricing Transparency, which was passed during the 2018 Session.

Dr. Mesaros also mentioned participation in the Multi-Board meetings relating to this area. Mr. Philip also mentioned that there is nothing in Chapter 465, which ties a pharmacist to begin disciplined for failure of a prescriber to following statutory guidelines. Mr. Flynn is going to get with Mr. Harris to check the rules and cross-referenced this matter with the statute on this matter.

Edwin Bayo, Esq., made a comment and strongly urged the Board to consider non-disciplinary citations as a starting point for violations of this type. Dr. Mesaros stated that if a pharmacist is going to be disciplined for failure of a prescriber to meet a prescriber requirement on a prescription, then he wants to know what type of corresponding discipline is going to be taken against the prescriber the responsible licensing board.

Dr. Hickman wants to ensure that the Board of Pharmacy is not acting as the "police" to catch the mistakes of prescribing practitioners. Mr. Philip does not want the Board of Pharmacy to create discipline for licensee's failure to catch or detect prescriber requirements, which would result in the pharmacist denying a prescription because they don't want to be disciplined for errors made by the prescribing practitioner.

Mrs. Rivera asked if we could wait until the Multi-Board disciplinary meeting to have this time of discussion, and perhaps some of these issues would be discussed. Mr. Wright stated that the pharmacists are acting as the police for the prescribing practitioners, and this is part of pharmacists' duty to the patient to make sure that prescriptions are properly scrutinized to detect any mistakes (intentional or unintentional) from a prescribing practitioner. Mr. Wright's suggestion is to slow down creating disciplinary guidelines for pharmacists as this new rule is being implemented.

Dr. Mesaros commented that discipline as a result of the changes to the law be come for final resolution by a Board a couple of years from now. Attorney Bayo made a comment that the Board should implement changes to the disciplinary guidelines as slow as possible. Dr. Hickman volunteered to serve as a resource to Board Counsel when drafting changes to the disciplinary guidelines, and agreed with Attorney Bayo's comments that changes to the disciplinary guidelines should go as slow as possible.

Mr. Flynn said that he wanted to focus on establishing disciplinary guidelines for failure to consult the PDMP for right now. Dr. Mesaros stated that he appreciated the discussion around this topic at the Board level, and at the Multi-Board level, so that everyone can understand how the changes brought about by HB 21 get operationalized at the Board and Department level.

Mr. Harris asked that suggestions or comments for changes to the disciplinary guidelines be provided to him.

9. **<u>Rule 64B16-30.002, F.A.C.</u> - Minor Violations**

Mr. Harris stated that Minor Violations of a rule that do not pose a risk to public safety of health, and are considered to be a prelude to discipline, and not actual discipline. The language added to the rule pertains to adding a "grace period" of 14 days for designating a Prescription Department Manager (PDM) or Consultant Pharmacist of Record (COR).

Mr. Montgomery wanted to know the timing of the start and stop of the designation for the PDM or COR. Mr. Harris said that the timing is based on when one PDM /COR is dropped, until the time the new PDM / COR is designated. The clock stops once the licensee sends the necessary PDM / COR change paperwork to the Board Office.

Mr. Philip asked if the citation for failure to designate the PDM could be added to the Administrative Complaint. Mr. Harris indicated that the citation (for a first-time offense) would not be added to the Administrative Complaint, because the matter would have already been resolved through issuance of a Minor Violation. Dr. Mesaros asked if the 14 days would be "calendar" or "business" days, and suggested that the "business" days be utilized in the proposed rule changes. Mr. Montgomery also thinks that "business" days is more appropriate.

Mrs. Rivera suggested that the language be amended to 15 business days – i.e. 3 weeks. Brian Kahn, Esq., stated that if you have a PDM which is leaving, it is standard practice to give two (2) week's notice – i.e. 14 days. Dr. Hickman made a Motion to accepting the amendment in the draft Minor Violations rule to reflect 15 business days, and the motion was seconded by Mr. Bisaillon. Motion carried, no opposition.

Mr. Harris asked the Committee to vote on whether the Notice of Change to Rule 64B16-30.002, F.A.C. would have an adverse impact on small business or increase regulatory costs in excess of $200,000. Motion that the Notice of Change would not have an adverse impact on small business or increase regulatory costs was made by Mr. Bisaillon, and the Motion was seconded by Dr. Hickman. Motion carried, no opposition.

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10. **<u>Rule 64B16-26.200, F.A.C.</u> - Examination Requirements; Passing Scores**

Mr. Harris asked that this rule be added to the agenda for "good cause shown". There are no materials associated with this additional agenda item. At the February 2018, the Pharmacist Assessment and Remediation Examination (PARE) is no longer being offered by NABP, the national organization who administered this exam.

JAPC provided a comment to Mr. Harris, to delete the reference to the PARE in the rule and the cross-reference to the statute, Chapter 456.036(0), Florida Statutes. This would require the Board to vote on a Notice of Change to this rule to make these minor changes. Motion to file Notice of Change made by Mrs. Rivera, and the Motion was seconded by Mr. Bisaillon. Motion carried, no opposition.

Mr. Harris asked the Committee to vote on whether the Notice of Change would have an adverse

impact on small business or increase regulatory costs in excess of $200,000. Motion that the Notice of Change would not have an adverse impact on small business or increase regulatory costs was made by Mr. Philip, and the Motion was seconded by Mr. Bisaillon. Motion carried, no opposition.

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11. **2018 Legislation: Required Rulemaking**
    - **HB 21**
    - **HB 675**

Mr. Harris stated that HB 675 related to Class III Institutional Pharmacies, and he will be working with Mr. Montgomery on a Subcommittee related to drafting language to implement this legislation. Mr. Harris indicated that there was already discussion in the Legislative Committee held on April 2, 2018, related to these bills.

Public Comment was received by Mr. Tom Wilverti, President of Central Ad Mixture Pharmacies. Mr. Wilverti had a couple comments regarding HB 675, and to reduce additional permits required for operation of his pharmacies in Florida. He is concerned about the vagueness of some of the language in the legislation is not prescriptive enough to determine what other areas could be impacted. Specifically, the term "other pharmaceutical services" was referenced as an example. Mr. Wilverti offered up his assistance to the Subcommittee in the rulemaking / drafting process.

Mr. Flynn stated that he did not think that there will not be overlapping of 503B permit facilities and Class III Institutional Pharmacies as a result of HB 675, and that federal law would still be controlling. Mr. Montgomery stated that HB 675 does not change any laws, but just removes a few barriers.

12. **Old Business / New Business**

13. **Public Comment**

Michael Jackson, Executive VP and CEO – Florida Pharmacy Association (FPA) , made a comment regarding Section 465.00276, F.S., pertaining to dispensing practitioners. There is language in the statute which talks about dispensing of investigational drugs found in Section 465.00276(1)(b)(4), F.S.:

465.0276 Dispensing practitioner.—

(1)(b) A practitioner registered under this section may not dispense a controlled substance listed in Schedule II or Schedule III as provided in s. 893.03. This paragraph does not apply to:

4. The dispensing of a controlled substance listed in Schedule II or Schedule III pursuant to an approved clinical trial. For purposes of this subparagraph, the term "approved clinical trial" means a clinical research study or clinical investigation that, in whole or in part, is state or federally funded or is conducted under an investigational new drug application that is reviewed by the United States Food and Drug Administration.

Internally, within the FPA there are some members who are involved in investigational drug studies, and they are working with practitioners who are dispensing drugs to consumers. The question that Mr. Jackson is getting regarding Section 465.00276(1)(b)(4), F.S., can dispensing practitioners also dispense drugs which are not Schedule II or Schedule III? In order to address this question, Mr. Jackson has advised his members to comply with the requirements of Section 465.00276, F.S., regarding labeling.

Mrs. Rivera stated that she had the understanding that when you are doing research you have to comply with FDI 21 Chapter in FDA, and within that Chapter there are very specific guidelines which are provided. She is sure that the physicians should know that when dispensing these investigational drugs. Mr. Harris' understanding of this section is that did not prevent prescribing practitioners from dispensing Schedule IV and V drugs.

Dr. Mesaros thanked the students from FAMU College of Pharmacy for attending. Motion to Adjourn made by Dr. Hickman, and seconded by Mr. Bisaillon.

The Committee Discussion concluded at approximately 11:30 a.m.