FLORIDA | Board of Pharmacy

Rules Committee

Draft Meeting Minutes

December 11, 2017
Rosen Plaza Hotel
9700 International Drive
Orlando, FL 32819
Contact Hotel: 407-996-9700

Jeffrey Mesaros, PharmD, JD
Committee Chair

C. Erica White
Executive Director

Monday, December 11, 2017 at 9:00 AM

Call to Order - The meeting was called to order by the Committee Chair, Dr. Mesaros, at 9:04 a.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 Bisaillon

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

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

Discussion:
Mr. Flynn informed the Board that the JAPC is looking for the definition of an establishment and what does it mean that a thoroughfare would not break up the continuity of the concept of an establishment. Should he sit with colleagues in Drugs, Devices, and Cosmetics to establish the definition of establishment? Rule limits a half-mile rule for geographical location of pharmacies for automated systems. Do we want this limitation impacting patient access?

Mr. Philip asked if JAPC is looking for a definition of a thoroughfare? Mr. Flynn responded that we probably need to add something about continuity of ownership of the property. Mr. Flynn will work on language and work on half-mile limit. Ms. Rivera said that it may be good to ask what is the definition of common ownership, especially in complex systems.

Ms. Rivera stated she was most concerned about patient education of use of automated pharmacy system. We want to augment the face-to-face communication and not put something in place to diminish that. Mr. Flynn responded that there has to be a form of counseling that is available through interface with the machine. The rule just says as long as it is in person, digital, or electronic. If you what to enhance the concept to ensure a heightened quality interface, it would need to be worked on. Dr. Mikhael mirrors what Mr. Flynn is saying and follows guidelines for any dispensing and would be ok if it followed current guidelines. We are testing waters because statute has concept of automated pharmacies, trying to tie together with whole practice act.

Dr. Mikhael commented that his understanding of where the verbiage comes from is to help increase patient access. If the pharmacy is open then patients have access. Health systems now have around the clock discharging so patients need access. The overarching goal is to allow patient access without having to have pharmacy open. Mr. Flynn responded that a pharmacy is open as along as a portion of the pharmacy is open because the machine is an extension of the

pharmacy. You have an open pharmacy if you have a pharmacist taking that call. Can the machine be sitting on a college system outside? Do we want to take the step that these can be outside? Reading JAPC's letter, they believe the machines are interior/adjacent.

Mr. Philip addressed the piece on supervision. The pharmacist needs to be physically present or available by electronic means and following all of the policy and procedures that they have created for themselves. Ms. Rivera stated she has looked at these systems. Need to look at everything. She was confused about the dispensing machines, because she looked at two different systems. One machine, you are putting in scripts that are finalized to be picked up in the machine; this may be used by employees who need to pick up scripts in the middle of the night. Overnight patient communication is important. The second type of machine is more in a physician office based practice; it fills the scripts for you. If the pharmacy is not open, then you are leaving it up to the machine what pharmacists do daily. Look at different scenarios and find how to implement them to keep the public safe.

Dr. Mesaros stated that if we are going through the exercise to look at rule and respond to JAPC, we need to figure out where the Board is going and where the rule needs to go. Mr. Flynn sees this in 3 steps; this is part of the pharmacy establishment. The next big concept is putting them in any license healthcare facility or physician office. The future may see wholly automated, operated pharmacies separate and apart from the pharmacy. What do we want to accomplish with this rule? Does not want to constrict or expand what the Board wants to do. Common ownership and operation could be very broad. Cannot circumvent the statute we have. Go with expansive as far as premises. Look at it maybe as interior building premises for this first step. Mr. Flynn will work on the contiguous nature of the property to clarify thoroughfare issues.

Mr. Bisaillon commented that it is clear from Mr. Flynn's comments that conceptionally this will be an evolutionary process. Mr. Flynn's approach may be the wisest and most productive. Dr. Hickman commented that it is almost two separate issues. One is granting access to prescriptions that are ready versus how do we remotely get prescriptions entered, filled, verified when there is no one around? The second gives more pause than the first. Dr. Mesaros stated there are two things. Figure out what we can do now and where we want to go. Stake holders will be surprised if entire piece is off the table. To move this discussion towards February to work with parallel agencies is probably prudent.

Mr. Bisaillon commented that in February there may be some concepts to discuss that show progress, but are not the advanced position as the first point. Mr. Flynn clarified that the advancement was not to limit patient access where they are already filled or a script comes in. Mr. Flynn's point was the interior of the building and the premises. There were 3 sets of stake holders that presented three different models. If the model can comply with 465 and the machine can create the product, as long as the pharmacist reviews the prescription, you have complied with 465. Not cutting out pre-packaged common drugs in machines.

Mr. Flynn would like to move the ball forward. Has about 4-5 parts to fix. Need to invite Mr. Ricker and Mr. Burgess back and have them present technology of what it does. The miss fill will be on the pharmacist. Ms. Rivera is in full agreement. The technology that she saw did not include the review by the pharmacist. What she saw was mainly for physician based practices. Mr. Flynn said that we should all be in agreement, you cannot dispense a drug without a pharmacist review in compliance with 456. Mr. Flynn has 4-5 bullet points to tighten up rule. In the interim, reach out to the presenters. Dr. Mesaros asked to include Mr. Austin White. He presented a more sophisticated system; don't want to go down this path without including Mr.

White.

Mr. Philip asked if there was discussion regarding whether verification could take place before dispensing; when it is stocked? Mr. Flynn responded that there is a set-up that the verification is in the calibration. Ms. Rivera added that there are two verification types for dispensing machines in institutional setting. Dr. Mikhael does not want to mess with what we currently have in place. Dr. Mesaros stated that the message is that we are not going to answer JAPC today. Take back to multiple parallel agencies; friendly proactive outreach to interested parties. Courtesy to go above and beyond normal notices. Dr. Montgomery wants to ask vendors to go through failure effects; narrow scope of concerns instead of presentation.

2. **Rule 64B16-28.301, F.A.C.** – Destruction of Controlled Substances – Institutional Class I Pharmacies (Nursing Homes)

   Rule 64B16-28.303, F.A.C. – Destruction of Controlled Substances All Permittees (Excluding Institutional Class I Nursing Homes)

   Discussion:
   No discussion.

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

   Discussion:
   Mr. Harris presented redrafted materials and provided an overview of past discussions on proposed changes. Language to consider based on Board's instruction at October meetings. Dr. Mikhael thinks we are going to keep seeing this; NABP supports a no pharmacist to tech ratio; deregulate and put back on PDM; no way to encompass every practice setting in pharmacy; in complete favor of a no ratio in Florida.

   Mr. Flynn read the provision of 465.014(1), F.S. Dr. Mikhael would like freedom of pharmacy manager to determine what they can do to have the greatest clinical impact by taking clinical services. Mr. Philip echoed comments by Dr. Mikhael; asked about new line 7; thinks entire rule should be that one line; PDM should be responsible for setting up ratio instead of Board setting by some arbitrary number; makes sense of PDM to say I need extra people today; limit number of untrained people in the pharmacy. Twenty states have eliminated tech ratios. What other health professionals limit number of ancillary help? Nothing proves having more ratios is safe.

   Ms. Rivera is the complete opposite opinion; does not think PDM will dictate to the big companies how many people they will have; should bring in more pharmacist, not more techs. Florida is leaner in everything we do; does not think she could supervisor 10 techs; more techs does not make it safer. On a smaller scale, community pharmacy, having more techs for sake of money, is not safe to do.

   Mr. Bisaillon commented that PDMS are looked at as being the manager of the operation; corporation is going to try to push the envelope; concept of #7; an upper limit; some number that it breaks. PDM having flexibility to make these determinations is good.

   Dr. Hickman commented that in general from experience at high volume community pharmacies; days that were stressful were the days that there was not enough help; was responsible for scheduling to place techs as PDM; other trend, since tech ratio has gone up, the number of hours

to schedule techs has gone done; no other profession regulates number of people.

Mr. Philip commented to take into account the different types of models; all prescriptions are being reviewed by pharmacists not on the premises; duties can be taken away by different models. Dr. Hickman talked about techs doing none critical duties to free up pharmacist to do counseling, prescription verifications. Mr. Montgomery would feel more comfortable that techs are doing non-critical duties; have guardrails.

Dr. Mesaros asked Mr. Harris if he thinks we need to continue to discuss or vote on current language? Mr. Harris indicated that there are a couple of options. One option is to move forward with the new rule. A second option is to scrap the ratios and move to no ratio and set guidelines. Going in a totally different direction. Another option is to direct Mr. Harris to draft language and have a special teleconference call. Dr. Mikhael likes option a and b; by putting on restrictions, limiting pharmacist to practice; should allow pharmacist to exercise their judgment.

Mr. Harris mentioned rule applies to all pharmacy permits and not just community pharmacies. Mr. Harris's recommendation is to do it in stages. If the Board wants to do no ratio, do that first; look at all rules that have to be changed as a result of that. Would like to do a parallel rule for COR that mirrors what they did for the PDM rule. Takes 90-100 days to get a rule through. Recommend two stage process. Route of no ratio would have time to search for all rations.

Ms. Rivera expressed concern about voting on a rule indicating no tech ratios, but we have not heard from the PDMs. Believes that the PDM does not dictate ratio; it is the corporation. Mr. Bisaillon thinks that by getting rid of setting of ratios, will drive a lot of change and pressure from the corporation. The PDM will be in the middle of an operation that will be evolving. Trust the PDM and give them the authority and responsibility to manage what they are being held accountable for. As a consumer, does not want to jeopardize the welfare of the individuals on the receiving end of the product. Likes the idea guardrails. Help them to understand boundaries.

Mr. Jackson commented that FPA is supportive of current rule in place and having tech ratios in place. Interested in Boards conversation in uncharted waters in removing tech ratios. The concern in removing the ratios, what affect will it have in the market. Perhaps Board can do a survey during license renewal process. Reported changes in the practice environment for pharmacies over the year. The tasks, duties and responsibilities of PDMs have changed significantly. There are a lot of added tasks. Pharmacist have to do immunizations; cannot be delegated to tech. Delegated tasks to techs are responsibility of PDM and have to sit before the Board if there are issues. If going with route to phase out tech ratios, guidelines must be iron clad. Recommends that in section 7, handing off the decision making, there needs to be a process in place on the back end if there is a violation of that standard. Mr. Flynn added that we would start disciplining the permits and we would see more permit holders before the board.

Mr. Philip referred to Dr. Hickman's comment that it was standard that most pharmacies are given a budget to determine the number of pharmacists/techs inside. Dr. Hickman stated the trend is that most physicians are employees and not the boss anymore; clinicians use ancillary staff to do not critical duties. Most physicians and other extenders are employed like pharmacist. Just adding more employees does not increase the business.

Mr. Montgomery gave counter points about budget. Compared to other offices, most extenders are licensed professionals that have some degree of liability in the patient. A registered tech is not licensed, so there is a degree of liability that transfers back to the pharmacist.

Mr. Philip would like to amend 8:1 to include current dispensing pharmacies and increase 4:1 to 6:1 and 6:1 to 8:1. Mr. Harris recapped the options.

- Option A is to recommend to full board moving forward with amendments to 27.410 as shown in the materials with the correction to 6(b).
- Option B is to not move forward with this rule and direct him to continue to work on it.
- Option C is to recommend getting rid of prescriptive ratios, move to no ratio and come up with language to set the guidelines if the pharmacy is going to exceed 1:1. Asks for input from full Board to get guidelines right.

Mr. Flynn suggested setting a February rule development workshop. Move 8:1 forward and work on a ratio guideline approach. Mr. Montgomery asked who were the voting members for the Rules Committee. Mr. Philip, Mr. Bisaillon, and Dr. Mesaros are the voting members, then it will go before full board Tuesday during committee report.

Mr. Philip stated that as much as he would like to see going to a no ratio, it may be a shock to the system. He would be ok with doing a step approach. Move forward with expanding the ratio now and look at rule workshop down the road. Mr. Philip recommends choice A to amend #5 from 4:1 to 6:1 and amend #6 from 6:1 to 8:1. Mr. Philip made the motion. Dr. Mesaros added, including the language related to PDMs, either current language or reference to PDM responsibility rules as well as to incorporate CORs, either within this language or reference to COR rules. Is the workshop piece a part of a different discussion? Mr. Philip thinks they should push off the workshop to a year from now, it is necessary. He thinks the requests will stop once they move to 6:1 and 8:1.

Dr. Mesaros asked Board counsel if they have this discussion tomorrow and they recognize a need for a potential technician workshop, can they add it? Mr. Flynn responded in the affirmative. Mr. Flynn raised a concern for a party that was not present. When you look at (4), 3:1 for sterile compounding, which is not changing, data entry is not part of the 3:1 ratio. The Board wanted to cut out the concept of data entry. Dr. Mesaros's question goes back to 8:1 list; we are excluding date entry. Mr. Harris advised the JAPC attorney has a hot button issue with sterile compounding. Mr. Flynn asked that if you were sterile compounding and you read this rule, would you understand that the technician would be able to enter the prescription? M.s Rivera responded "no."

Mr. Montgomery asked if it would make sense to tie it back to the practice of pharmacy? The 8 bullet points excluded are not related to the practice of pharmacy. Ms. Rivera stated that in most of the sterile compounding world, the data entry piece is done by a pharmacist, not a tech. Mr. Flynn said they should have left it at "engaged in sterile compounding"; remove "or any tasks…".

Mr. Philip made a motion to accept all changes discussed. Motion passed unanimously.

Break at 11:28. Reconvened at 11:46 a.m.

4. **Rule 64B16—27.630, F.A.C.** – Additional Immunizations or Vaccines Which May Be Administered

- Newly Approved Shingles Vaccine (SHINGRIX)

Discussion:

Dr. Mesaros – aware of new vaccine and wants to make sure that we are ahead of it and providing guidance to pharmacies and pharmacist to facilitate as timely as possible.

Mr. Harris – a lot of press on this. Think of amending the rule in advance. Until CDC amends guidelines, we cannot amend the rule. Suggests opening for development. In the event it is released, then we propose the rule immediately adding SHINGRIX under medicocle.

Mr. Harris – propose to take action today; Board directing him to drop the proposed rule in the FAR. Vote today, direct to publish language in response. Motion made by Mr. Bisaillon to open 27.630 for development and in the event the adult immunization schedule is released adding SHINGRIX, then we propose the rule immediately. Motion passed unanimously.

Mr. Harris asked the Board to consider and respond to the required questions regarding their proposed rule amendment:

1. Will the proposed rule amendment have an adverse impact on small business;
2. Will the proposed rule amendments result in an increase in regulatory costs to any entity, including the government, in excess of $200,000.00 within 1 year of the effective date of the rule? If the answer to either of the questions is "yes," a SERC is required. Mr. Philip made a motion that it does not. Motion passed unanimously.

3. Will the proposed rule amendment have a net increase in cost in excess of $1,000,000.00 within 5 years of the last portion of the rule to be effective? If the answer is "yes," the rule must be submitted to the Legislature for ratification. Mr. Philip made a motion that it does not. Motion passed unanimously.

4. Could a violation of this rule, or any part of it, be determined a minor violation that could be resolved through an issue of non-compliance? Dr. Mesaros made a motion that this could not be resolved with a minor violation. Motion passed unanimously.

   Dr. Mesaors requested that the yellow questions be included in the Board packets for each meeting.

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

- Community Pharmacy Permit – DH MQA 1214 (Philip)
  Discussion:
  Ms. White discussed the requirement for fingerprints; pulled from AHCA; need permission from PDM/affiliate to pull fingerprints; do not have legal authority; doing adhoc, causing delay in processing the permit. Changes to all permits: fingerprint language; background screening; pharmacy questions are more restrictive; questions in forms reflect practice act; permits have not been touched since 2010, 2012; update websites, rule sites. Plan to get feedback from members; attempt to get back and make changes; have a special board meeting in the new year; vote out second round forms. The 21 days for JAPC comments start to run. Prioritize to get forms done and help licenses get issued more quickly. Dr. Mesaros reviewed applications assigned to the former board members.

  Mr. Philip recommended the following changes: Bates 33 - third paragraph about PDM; old language from rule that has been repealed from 27.440. Replace with language from 27.450. Bates 35 – under licensure process; add 3rd bullet point with language from 28.1081. Bates 36

– question regarding “shall deny”. Is there a leeway for discretion? Mr. Harris – legislature has not given discretion; need to make change or amend application. Mr. Philip asked about “j.” Dr. Mesaros asked if the applicant would be able to challenge that if Florida did not review the underlying facts? Mr. Harris answered, if the applicant says “yes,” the applicant would have the opportunity to present to the Board. Bates 42, question #23, some states/boards require arrest to be reported on application as well. Mr. Philip asked if we choose only convicted because of something that is in statute? Mr. Harris indicated it would be a policy choice; not uncommon for people to get arrested; charges are dismissed or nolle prosse; expunged or sealed records. Mr. Flynn said you should not ask for arrest records if you do not have statutory authority. Strict believer in not soliciting information. Sealed/expunged does not apply for purposes of Board. Dr. Mesaros commented that the individual/entity ends up before the Board; determine if failed to disclose is sneaky; board is able to sniff out if someone is trying to hide information in a devious way.

- Institutional Pharmacy Permit – DH MQA 1215 (Rivera)
  Discussion: Bates page 97. Ms. Rivera did not see anything besides what was already marked. Dr. Mesaros commented that the redline version captured expectations where applications were going. Update rules across applications for consistency. Redline version was comprehensive. Mr. Harris invited Board members and public to email him an suggested updates or changes.
- Nuclear Pharmacy Permit – DH MQA 1218 (Mesaros)
  Discussion: Dr. Mesaros was comfortable with the redlining to the extent if other have comments.
- Special Pharmacy Permit – DH MQA 1220 (Mesaros)
  Discussion: Dr. Mesaros was comfortable with the redlining to the extent if other have comments.
- Special Sterile Compounding Pharmacy Permit – DH MQA 1270 (Mesaros)
  Discussion: Dr. Mesaros encouraged Mr. Montgomery and Dr. Mikael to take a look at this application because they are specific to this area. Mr. Flynn had some legal marks to make. Mr. Philip asked how does potential legislation affect changes on the institutional application? Mr. Flynn indicated it would be new permit application.
- Internet Pharmacy Permit – DH MQA 1216 (Mesaros/Bisaillon)
  Discussion: Mr. Basaillon - FDLE information added at the end of the application. If someone is not required to submit fingerprints, how do you go about vetting information? Mr. Flynn responded that the non-resident application has been vetted. JAPC asks about the fingerprinting. Ms. Rivera asked if other states require fingerprinting? NABP may have a high-level matrix. Dr. Mesaros will research. Mr. Flynn can bring back issue if the Committee wants to put on agenda to look at.
- Change in Prescription Department Manager DH-PH10 and Change of Consultant Pharmacist of Record DH-MQA 1184
  Discussion: Ms. White provided background for proposed changes. Mr. Harris commented that the PDM form was redone last year, but the COR form is from 2010. The COR is incorporated in 5 rules and 3 different versions of form. Asked committee to consider the PDM rule and is wondering if the COR should be the same. Taking the COR rule and mirror the PDM for initial designation and change. Dr. Rivera asked what happens if they cannot get the signature of the out-going COR (deceased). Ms. White advised that the form has been updated to remove “must have.” Only requiring the in-coming signature. Several suggested changes were discussed. Dr. Mesaros would like Mr. Harris to review the COR rules.

6. Old Business / New Business

Dr. Mikhael advised regarding a concern that was brought to his attention. We license interns to immunize. Once they become licensed, the intern license becomes void so their immunization does not carry over and they have to reply to be an immunizer. This is limiting their scope practice. Can the pharmacist application be amended to include immunization all under one?

Mr. Jackson shared what they are seeing in the marketplace. Pharmacists have authority to immunize patients. Running into pharmacists seeking employment; met all requirements; only missing element is the signed protocol from physician; creating employment barrier. Is signed agreement a requirement? Dr. Mesaros asked how would unemployed pharmacist go about having someone sign a protocol? Mr. Jackson responded that the pharmacist has to achieve a number of things to qualify to be employed. Many are in the pharmacists control. Pharmacist are sharing that it is difficult to obtain protocol. Statute says pharmacist must submit a protocol. Process stand point how do we get around it?

Ms. White advised that Board staff does require a copy of the protocol before putting qualification on license. Staff are keeping track in the system; cannot be waived. Ms. Rivera asked if the protocol is permit specific or individual specific? Mr. Harris responded that it is individual specific per statute.

Dr. Mesaros asked from an industry/market prospective is this an opportunity for third-party organizations to facility this? Mr. Jackson commented that the medical profession is acting as a gateway for entry as a pharmacist. This is creating a barrier for pharmacy practice that has to be fixed and will require a legislative fix. Mr. Philip commented that it is one of two avenues. Tweak legislation to allow certification to take place and protocol to be received later or eliminating the protocol and move to prescriptive authority. Mr. Flynn said both options are available by tweaking. Mr. Harris asked to move the pharmacist application to February, because of time issue. Dr. Mesaros wants this as an open item for February.

7. Public Comment

None

8. Adjournment

Mr. Bisaillon made a motion to adjourn. The meeting adjourned at 1:09 pm.