

FLORIDA | Board of Pharmacy

Rules Committee

Meeting Minutes

October 2, 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, October 2, 2017 at 1:00 PM

Call to Order - The meeting was called to order by the Committee Chair, Dr. Mesaros, at 1:03 p.m.

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

Board Members

Jeffrey J. Mesaros, PharmD, JD, Chair
Goar Alvarez, PharmD
David Bisailon
Jeenu Phillip, BPharm, Vice-Chair

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
Jessica Hollingsworth, Government Analyst II

1. Rule 64B16-27.830, F.A.C. - Standards of Practice - Drug Therapy Management

Discussion:

Dr. Mesaros reminded the committee that they are continuing to determine the efficiency of this rule and are working with industry stakeholders on recommended language. He then requested status updates from committee members.

Dr. Alvarez informed the committee that he is still working with stakeholders. Mr. Philip reminded the committee of a previous concern regarding the ability of Pharmacists to initiate or change therapy. He asked if there was language that could be changed that would still accommodate section 465.003(13), FS. Dr. Mesaros agreed that legislative opportunities should be examined along with updating this rule.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, pointed out that section 465.003(13), FS also states a Pharmacist cannot alter a Physician's directions "unless otherwise permitted by law", which may be a reason why this rule was created, but the rule was written in a way that may contract from the statute. He further informed the committee that the Physician Practice Act has language which delegates to someone with experience or a license, which could mean a Pharmacist. Mr. Jackson stated that FPA is working with a large coalition of Pharmacy stakeholders to facilitate changes in 465, FS that would clarify what a Pharmacist can do. Dr. Mesaros asked Mr. Jackson if this effort is for the upcoming

session or future ones. Mr. Jackson answered that they are working on a piece of legislation that was filed during 2017 session and a piece of legislation that mimics SB 1180 to bring to 2018 session. He further stated that they have already identified a house sponsor and are actively engaging members of the senate. They think this bill will provide opportunities for Pharmacists to assist patients who can't see their physician. Dr. Mesaros agreed with Mr. Jackson that this rule may contract from the statute. Mr. Jackson requested confirmation in his observation that the board seems to have strong interest in this issue. Mr. Flynn answered that the board is interested but advised that all resources and energy should be given in a legislative capacity.

Mr. Philip recalled a discussion of the wording in this rule related the patient and asked if the language could be altered to make the rule more population-specific. Mr. Flynn reminded the committee that they cannot define what a patient is for a physician and that the purpose of rulemaking is to implement an existing statute, not enlarge it. He then clarified that if a doctor does not have a patient, they have nothing to delegate. Mr. Flynn also reminded the committee that this rule could be lost in a rule-challenge if interpreted incorrectly.

Dr. Alvarez asked if a Pharmacist can initiate drug therapy for a physician's patient if there is a collaborative practice agreement for any patient with a particular disease and that patient has seen the Physician.

Dr. Mesaros stated that there are two parts to the issue:

- If the board cannot make any changes, they are wasting time with discussion.
- If physicians say they cannot delegate, does this shut down hospital pharmacy practice? If it does, can this rule be changed? Many physicians already delegate to pharmacists.

Dr. Mesaros further raised concern that if this rule goes unaddressed, it could raise an issue. Mr. Flynn stated that he could not answer Dr. Alvarez's question due to potential liability and warned that even though he agreed with Dr. Mesaros' concerns, addressing this against another profession could risk that party attacking Pharmacy rules.

David Harlow, Chief Pharmacy Officer for Martin Health System and Vice-Chair of the Legislative Committee for the Florida Society of Health-System Pharmacists (FSHP), stated that he felt this rule was created with a retail pharmacy set-up in mind, which is not reality for many pharmacies. He offered to share his organization's practices on Physician and Pharmacist collaboration, which has seen a decrease in readmissions for the "worst of the worst" patients. Dr. Harlow also expressed concern that the focus of "doing the right thing" seems to associate more with following the rule than what is best for the patient.

Karen Sando, Clinical Associate Professor for Nova Southeastern University and Chair of Legal and Regulatory Affairs Council for FSHP, recalled working in a family medicine clinic where Physicians delegated patients to Pharmacists, which helped provide high-level care to patients. She further described problems experienced with her billing and compliance office in regards to other things her Physicians asked her to do and predicted this will become more difficult as healthcare moves away from the "fee for service" standard.

Dr. Mesaros stated that the patient is the forefront of this issue and that there are two interpretations to this rule, one making it difficult and one making it easy for the patient. Dr. Mesaros further suggested that making the rule clearer could leave little room to use the difficult interpretation and could create a more productive collaborative practice. Mr. Flynn agreed that this

rule is not clear on everything and that it is possible to remove it entirely but added he is concerned if the committee shares the ideology of a Pharmacist assisting a patient who has not seen a Physician.

David Harlow, Chief Pharmacy Officer for Martin Health System and Vice-Chair of the Legislative Committee for the Florida Society of Health-System Pharmacists (FSHP), informed the committee that his organization uses the normal channels of their hospital to create protocols. He gave the example of a “care document” they created for different diseases so when a Physician refers a patient, the Physician knows the protocol Pharmacists will follow based on the “care document” for that disease. Based on this example, Dr. Harlow suggested eluding to policies and procedures at the institutional level.

Tom Cuomo, Florida Pharmacist, suggested that incorporating more collaborative practice could help Pharmacists work with Physicians on ensuring patients are taking medication correctly and can afford the medication they were prescribed.

Mr. Harris requested clarification on the intent of the rule change, as he heard members of public discuss widening a pharmacist’s scope of practice for patients that physicians refer to them, which differed with earlier discussion on scope of practice for walk-in patients. Dr. Mesaros pointed out that other states allow a wider scope of practice for walk-in patients than Florida.

Edwin Bayo, Attorney, suggested that if a Pharmacist initiates drug therapy based on directions from a Physician, it could be interpreted as not initiating. Mr. Harris agreed with Mr. Bayo on his interpretation. Mr. Flynn expressed his belief that this is already the interpretation, which is why collaborative agreements already exist between Physicians and Pharmacists. Mr. Flynn asked if a Physician has never seen a patient, can a relationship be established with the Physician through the Pharmacist? Mr. Bayo answered that this could be done if the patient is under a health plan which is assigned to a Physician.

Dr. Mikhael asked Dr. Harlow if his organization collects data which proves that intervention with Pharmacists has led to better outcomes for the patient. Dr. Harlow confirmed that they do track, using dashboards for all patients, and they work with the University of Texas on impact study. Mikhael requested for Dr. Harlow to send the data to Ms. White so the board may review it for the next meeting.

Mr. Philip asked if this discussion could serve as an opportunity for telehealth medicine, specifically allowing Pharmacists to act as a conduit for Physicians in certain cases. Dr. Mesaros agreed that telehealth should also be considered.

Martin Dix, an Attorney with Akerman, suggested adding a short rule that refers to protocols. Ms. Rivera pointed out differences between a collaborative practice agreement and a protocol, which may have to be outlined in the rule that Mr. Dix suggested.

Fritz Hayes, a former board member, explained the intent of originally defining certain terms in the rule, which he recognized could be more harmful than helpful and suggested removing some of these definitions.

Mr. Cuomo explained that medication therapy management is billed by the Pharmacist but the collaborative practice is not and it is important to remember there are two separate practices. He further agreed with Mr. Dix on creating a separate rule and addressing them differently.

Dr. Mesaros thanked everyone for the discussion and encouraged Mr. Dix, Mr. Bayo, and Mr. Hayes to work with Mr. Harris and Mr. Flynn on recommended changes to the rule.

2. Rule 64B16-27.831, F.A.C. – Standards of Practice for the Filling of Controlled Substance Prescriptions; Electronic Prescribing; Mandatory Continuing Education

This agenda item was moved to the Controlled Substance Meeting.

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

Discussion:

Mr. Harris informed the board that the updated language for this rule stemmed from a Petition to Initiate Rulemaking, which was filed by Mr. Bayo, and to address concerns from JAPC on the association of technicians to sterile compounding. Mr. Harris listed the following changes:

1. Section 7 was added, introducing a ten to one (10:1) supervision ratio for office-related duties.
2. The addition of language that ratios over 3:1 must exclude tasks relating to sterile compounding

Mr. Flynn discussed improperly delegating tasks to pharmacy technicians and how it can ultimately harm altering the ratio rule.

Mr. Philip asked where the language referring to sterile compounding came from and stated he felt technicians should be able to perform prescription data entry related to sterile compounding. Dr. Weizer disagreed due to the complexity of the entry entailing the prescription and the protocol. Mr. Flynn asked how data entry works in regards to a call center environment. Dr. Mikhael agreed with Dr. Weizer that there is a level of complexity for compounded sterile products but added that they may not be more complex than many other products with multiple ingredients that technicians can enter data for. He clarified for Mr. Flynn that data entry in a call center can be done at a 6:1 ratio. Dr. Mikhael also stated that most pharmacies think the 3:1 ratio is for actual compounding of the drug and not data entry. Dr. Mikhael said that based on this thought, he is concerned that the board is potentially becoming more restrictive on what the intent of the rule is, when there is no proof that they need to be.

Dr. Weizer asked if prescriptions sent to 503B Pharmacies get re-entered or if those Pharmacies pull information from the original data entry. Dr. Mikhael clarified that at the 503B facility he worked for, electronic prescriptions were not re-entered but prescriptions faxed to the facility were.

Ms. Rivera agreed with Dr. Weizer that most prescriptions are already entered when sent to a 503B Pharmacy so data is not re-entered. She also stated that based on her level of experience, having a ratio greater than 6:1 could cause Pharmacists to lose quality in their reviews and therefore an increase in errors.

Edwin Bayo, Attorney, recalled concern at the August meeting on the 10:1 ratio but expressed worry over it leaking to other ratios in this meeting. He reminded the committee that there seems to be no issue with existing ratios and asked that the 10:1 ratio be discussed independently. Mr. Philip agreed with Mr. Bayo in not considering the existing ratios and that increasing the ratio tied to data entry has not been proven to cause errors.

Tom, Cuomo, a Florida Pharmacist, listed his concerns in raising the ratio. Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, requested clarification on the differences between section 6 and section 7. He further requested the definition of "limited duties call center", which was added to section 7.

Break: 2:49 p.m. – 3:18 p.m.

Dr. Mesaros brought the discussion back to the comparison of the 6:1 and 10:1 ratio, where Mr. Bayo clarified the difference between the two ratios.

Dr. Rivera requested clarification on why specific functions were included in the rule which are not necessarily technician functions. Mr. Bayo clarified that those specific functions are an additional reason why 10:1 ratio is appropriate.

Dr. Mesaros asked the committee for their thoughts on removing section 7. Dr. Mikhael agreed that the listed tasks aren't related to pharmacy, which could have a negative impact if they were to be added to the Pharmacy Practice Act. Mr. Bayo requested a consensus from the committee on the items that are not pharmacy-related, in which an agreement was made on #4-8.

Mr. Philip provided information from a call he participated in regarding positive outcomes from eliminating ratios. Mr. Flynn advised that more evidence is needed before making a decision on changing ratios, specifically comparisons of ratios in other states and the average of misfills in states with no ratios. Dr. Alvarez agreed that more research is needed.

Ms. Glass pointed out that misfills are only recorded if the consumer files a complaint and many states do not investigate that issue. She also felt that researching other states for comparison may be like comparing apples to oranges and will therefore be pointless.

Mr. Flynn suggested a hearing for the public to offer testimony and data related to the rule-change. Dr. Mesaros agreed that evidence is needed before a decision is made. Mr. Dix stated that he had a few clients who would benefit from the 10:1 ratio and will request for them to attend the December meeting.

Mr. Philip suggested changing the ratio to 8:1 to make everyone more comfortable, which Dr. Mesaros agreed with. Mr. Jackson suggested amending section 6 to an 8:1 ratio and leaving everything else the same. He also suggested adding language requiring some technicians to be PTCB certified. Dr. Weizer stated that the Pharmacy Technician Certification Board is moving toward requiring training to take their exam. Mr. Philip expressed that he felt requiring PTCB certifications is unnecessary.

Dr. Mikhael pointed out that if the board is working to have Pharmacists practice at the top of their licenses, they should not inhibit others, such as technicians, to practice at the top of their licenses. He further added that something such as data entry is within their scope of practice and should not be an issue to delegate to them.

Mr. Jackson suggested specifying in rule that the PDM has power over how their Pharmacy is run, such as how many technicians they think they need. Mr. Flynn offered to add guidelines into the rule, which he and Mr. Harris will bring to the December meeting.

A motion was made by Dr. Alvarez to accept the proposed amended language of changing the ratio from 6:1 to 8:1 and to add guidelines of authority for PDMs under Rule 64B16-27.410(6), FAC. Motion passed unanimously.

4. Rule 64B16-27.1001, F.A.C. - Delegation to and Supervision of Pharmacy Technicians; Responsibility of Supervising Pharmacist

This agenda item was discussed under agenda item #3.

5. Discussion of Board Rules:

Discussion:

Dr. Mesaros informed the committee that after Hurricane Irma, there is a need to clarify how Pharmacists in Florida and other states can help in the event of an emergency. Board members were asked to think of rule-changes, statute-changes, or examples of what they experienced to send to the board office for discussion at the December meeting.

Dr. Mesaros gave examples of questions Pharmacists had, which included mobile pharmacy units in regards to waiving the half-mile rule or including out-of-state units, allowing out-of-state Pharmacists to come assist, allowing temporary license provisions, allowing FL Pharmacists to help other states in an emergency, and what Pharmacists can do after the state of emergency ends.

Dr. Mesaros asked if it was possible to hold an emergency meeting that falls outside of the notice requirement in the event of an emergency so an action-plan can be made and so the board office, the board, and the patients are as prepared as possible.

Martin Dix, an Attorney with Akerman, requested clarification on refrigerated drugs and protocol in the event of a power-outage, specifically in keeping drugs at the appropriate temperature.

David Harlow, Chief Pharmacy Officer for Martin Health System and Vice-Chair of the Legislative Committee for the Florida Society of Health-System Pharmacists (FSHP), stated that there was a lack of clarity in the executive order on how to assist patients with prescriptions that would help get them out of the facility during the event of an emergency.

Mr. Philip suggested that the board should make a list of recommendations to provide to the Department ahead of time that they can refer to in the event of an emergency, which Dr. Mesaros agreed with and clarified that is the intent of the discussion.

Dr. Mikhael informed Dr. Harlow that FSA was working closely with the Department of Health, in which there was communication on prescriptions, dispensing, and decompressing, and suggested working through FSHP or FHA for future emergency situations. Dr. Mesaros agreed and asked Dr. Harlow to communicate with them and bring back notes to the December meeting.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, thanked the Department and the Governor's office for their timely response to the hurricane. He discussed FPA's experience for those who came to Florida from Puerto Rico and used it as an example to express the importance of knowing what should be done in those situations. Dr. Mesaros thanked Mr. Jackson and requested for him to bring any research he can to the next meeting.

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

Due to the meeting running late, Dr. Mesaros continued this agenda item to the December meeting. Mr. Flynn informed the committee that a lot of changes were made to these applications and asked the committee to review and provide input to board staff or counsel as soon as possible. Dr. Mesaros suggested assigning applications to board members for review, work with board counsel, and to present at future meetings, which Mr. Flynn agreed with. Assignments will be made tomorrow during the full board meeting.

7. Old Business / New Business

None.

8. Public Comment

Ms. Glass informed the board that a lot of addendum material was given to the board members that needs to be reviewed before the full board meeting tomorrow afternoon.

9. Adjournment

The meeting adjourned at 5:31 p.m.