

FLORIDA | Board of Pharmacy

Rules Committee

Meeting Minutes

August 14, 2017

Embassy Suites Fort 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, August 14, 2017 at 1:00 PM

Call to Order - The meeting was called to order by the Committee Chair, Dr. Mesaros, at 2:28 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
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth, Government Analyst II

1. Posting of Licenses (Rule 64B16-27.100)

Discussion:

Mr. Harris explained the intent of the proposed rule change, which would no longer require pharmacies to post all licenses on the wall while keeping them easily retrievable for inspectors and the public. He suggested that pharmacies hang one sign stating that proof of licensure is available upon request. Mr. Harris further suggested not mandating a specific size/font for the new sign.

Richard Montgomery, with Adventist Health System, requested clarification on how licenses would be available to view upon request. It was brought up that the license, a duplicate/copy of the license, or reference to the MQA license verification database would be sufficient as proof of licensure.

Mr. Philip suggested giving pharmacies the option of keeping all licenses on the wall or having language on the wall for proof of licensure readily available instead of mandating that all pharmacies switch to the new procedure. Discussion ensued regarding how to incorporate this verbiage into the rule. Dr. Mikhael suggested striking subsection 3 from the rule. Mr. Harris stated that subsection may have been added due to statute but he would research further.

Tom Cuomo, a Florida Pharmacist, explained that the intent behind this rule change was to mitigate concern of personal addresses being printed on licenses. He felt that keeping licenses behind counters and available by request would promote privacy and safety of Florida pharmacists.

Discussion ensued regarding whether subsection 3 is duplicative language. Mr. Harris informed the board that striking this language was their decision, but advised they keep it. Robert Difiore, Pharmaceutical Program Manager, explained the hardship of inspectors in ensuring licenses posted on walls are kept current. Due to no recall of examples in which subsection 3 was needed and due to Mr. Difiore's comment, the board agreed to strike subsection 3 from the rule.

A motion was made by Mesaros to approve the suggested amendments, to strike subsection 3, and to accept the language read by Mr. Harris in subsection 1, sentence 2 for Rule 64B16-27.100, FAC. Motion passed unanimously.

A motion was made by Philip to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that this rule would not likely increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Alvarez to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

A motion was made by Philip to propose language to Rule 64B16-30.002, FAC to add a violation of this rule as a minor violation, which could be corrected through issuance of a notice of non-compliance. Motion passed unanimously.

2. Institutional Pharmacies / Permits (Rule 64B16-28.301 and Rule 64B16-28.501, FAC)

Discussion:

Mr. Harris requested the board to authorize language changing Rule 64B16-28.301 and Rule 64B16-28.501, FAC., as shown in the agenda. Discussion ensued to include the following:

- Adding clarification that there is one document with the list of controlled substances and a designated are for witness signatures in Rule 64B16-28.301(2), FAC
- Adding language to clarify definition for "associated to the facility" in Rule 64B16-28.301(2)(d)
- Keep language in Rule 64B16-28.501(1) and (2), FAC
- The definition of supplemental in "supplemental drug regimen review" of Rule 64B16-28.501, FAC

A motion was made by Philip to authorize a notice of change to correct the JAPC comments and authorize Mr. Harris to respond in writing to answer remaining questions for Rule 64B16-28.301 and Rule 64B16-28.501, FAC. Motion passed unanimously.

A motion was made by Philip to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory

costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that these rules would not likely increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Mesaros to acknowledge that any section of these rules is not designated as a minor violation. Motion passed unanimously.

3. Automation (Rule 64B16-28.141 and Rule 64B16-28.608)

Discussion:

Mr. Harris advised the board to include a definition in Rule 64B16-28.608(1) for the system drug identifier database in Rule 64B16-28.608(2), FAC, which was decided as the automated pharmacy system's database that positively identifies the drug to be dispensed. Mr. Harris also advised striking "loaded" and adding "stocked" to Rule 64B16-28.608(5)(e), FAC.

A motion was made by Bisailon to authorize a notice of change with the discussed updates to correct the JAPC comments and authorize Mr. Harris to respond in writing to answer remaining questions for Rule 64B16-28.608. Motion passed unanimously.

A motion was made by Alvarez to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Alvarez to acknowledge that this rule would not likely increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Mesaros to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

Mr. Harris briefly discussed the notice of proposed rule for Rule 64B16-28.118, FAC and that there not no JAPC comments at this time.

Mr. Flynn reminded the board that Rule 64B16-28.141, FAC was on the June agenda and gave a brief overview of the proposed language.

Dr. Weizer and Dr. Mikhael expressed concern of storing controlled substances in these machines due to the possibility of a machine malfunction. Dr. Alvarez suggested adding that automated machines should not be used for controlled substances. Mr. Philip disagreed and expressed that he felt these machines were safe.

Edward Rickert, an Attorney with Quarles & Brady, LLP, expressed the need to for automated machines to dispense controlled substances in emergency settings. Tom Cuomo, a Florida Pharmacist, expressed his stance against controlled substances in automated machines and how they could add to the opioid crisis.

Mr. Flynn and Dr. Mesaros clarified that there will still be a requirement for whoever is operating the machine. Dr. Mesaros clarified that they will need to know the patient to some extent and the machine will not take over judgement or medical assessment of the patient. Mr. Ricker agreed and added for this reason, the machine should not add to the opioid epidemic. Dr. Mikhael pointed out that all previous presentations on automatic machines have stated they would not carry controlled substances. Dr. Mesaros clarified that if there is an incorrect fill from an automatic machine, the pharmacist is responsible because the pharmacist is placing their trust in the machine.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, informed the board that he appeared before the Telehealth Advisory Council to share his thought-process of the pharmacist role behind telehealth and offered to share those comments with the board as well. He asked the board if this version of the rule comes from Section 465.0235, FS, which limits an automated pharmacy system to three areas. Mr. Flynn answered that he did not see a limitation to the three areas based on his interpretation of the law.

Tom Cuomo, a Florida Pharmacist, asked the board who would be disciplined if there was a machine malfunction. Mr. Cuomo also raised concern of hacking. Mr. Flynn confirmed that the pharmacy would be held responsible if there is an incorrect fill, even if it is due to a machine malfunction. Mr. Cuomo raised the concern of carrying drugs, including controlled substances, a long distance to fill a machine that may not be near its respected pharmacy.

Dean Pedalino, a Consultant Pharmacist, compared using automated machines to using other new devices for the first time, in that they are unfamiliar and must be used cautiously, but could work.

Edward Rickert, an Attorney with Quarles & Brady, LLP, requested clarification for Pharmacist supervision when stocking machines outside of Pharmacies. Mr. Flynn confirmed that a Pharmacist did need to be present. Mr. Flynn further clarified re-packaging vs. pre-packaging when transporting medication to a machine outside of a pharmacy.

A motion was made by Phillip to propose the discussed language for Rule 64B16-28.141, FAC, assuming it does not allow violation of federal law. Motion passed unanimously.

A motion was made by Bisailon to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that this rule would not likely increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Bisailon to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

4. Drug Therapy Management (Rule 64B16-27.830, FAC)

Discussion:

Dr. Mesaros opened discussion by pointing out that this rule has not been updated it for quite some time and he would not be opposed to reviewing for changes.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, commented that he believed there is an opportunity in revising this rule and expressed interest in working with the board on proposing changes. He requested that the board allow him to bring suggestions for rule changes to the next meeting, to which Dr. Mesaros agreed.

Gary Daylen, with Boca Raton Regional Hospital and representative of FSHP, informed the board that he has been working with FPA in viewing legislation and getting stronger language in statute.

5. Returns by In-Patients

No discussion due to no JAPC comments.

6. Telehealth/Telepharmacy/Supervision

Discussion:

Dr. Mesaros informed the board that Rule 64B16-27.410 was created from the analysis that Dr. Mesaros formed after the Multi-Board Workgroup discussion on telehealth. Mr. Flynn gave an overview on Rule 64B16-27.410 from the last meeting and further discussed the variance and waiver to add a 10:1 ratio, which was on the agenda for full board.

Dr. Mesaros discussed supervision and the use of technology within Rules 64B16-28.109 and 64B16-27.4001. He further reviewed the definition of direct supervision in various practice acts of other health professions to assist the board in developing their own definition. Mr. Philip expressed his belief that “direct supervision” and “direct and immediate supervision” should be treated as two separate definitions.

Tom Cuomo, a Florida Pharmacist, expressed concern with relying heavily on technology, specifically the sharing of patient information. Mr. Flynn reminded the board that regardless of technological advances, Pharmacists are still responsible for following federal and state law.

Richard Montgomery, with Adventist Health System, suggested allowing Pharmacists to supervise with cameras, making supervision more accurate and for record-keeping purposes. Dr. Weizer clarified that cameras would be added without taking the Pharmacist out of the location or changing the ratio.

A motion was made by Mesaros to propose the amended language regarding the removal of “on the premises” from Rule 64B16-27.4001(2)(a). Motion passed 3/4 with Alvarez in opposition.

A motion was made by Philip to acknowledge that the proposed amendments would not have an adverse effect on small businesses and would not likely directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that this rule would not likely increase cost to any entity in excess of \$1,000,000 within five years after implementation of the rule. Motion passed unanimously. A motion was made by Philip to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

7. Old Business / New Business

Covered in other discussions.

8. Public Comment

Tom Cuomo, a Florida Pharmacist, requested clarification on whether Pharmacies must disclose to patients that their prescriptions may not be filled on the premises. Mr. Flynn advised for Mr. Cuomo to consult private counsel.

Michael Jackson, Executive Vice-President and CEO of the Florida Pharmacy Association, expressed concern for patients calling pharmacies but reaching outsourced call centers without knowledge. Mr. Jackson also informed the board how FPA is developing the 8-hour continuing education course that is now required for Pharmacists who wish to administer a long-acting antipsychotic medication by injection, through Section 465.1893, FS.

9. Adjournment

The meeting adjourned at 5:45 p.m.