

Meeting Minutes

DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

April 5, 2016
Immediately Following the Board Meeting

Hilton Altamonte Springs
350 Northlake Blvd.
Altamonte Springs, FL 32701
(407) 830-1985

Committee Members

Jeffrey J. Mesaros, PharmD, Chair

Jeenu Philip, BPharm

Lee Fallon, BPharm

Goar Alvarez, PharmD

Board Staff

Allison Dudley, J.D., Executive Director

Emily Roach, Program Operations Administrator

Amber Greene, Regulatory Specialist III

Board Counsel

Lawrence Harris, Assistant Attorney General

David Flynn, Assistant Attorney General

Dr. Mesaros called the meeting to order at 1:05 p.m.

Committee members Jeffrey Mesaros, Jeenu Philip, Lee Fallon and Goar Alvarez were present. Also present were Michele Weizer, David Bisailon, Mark Mikhael and Debra Glass.

Mr. Harris stated we were making good progress with the rules and to expect larger rules agendas for the June and August committee meetings. He noted five rules were recently adopted and there were six outstanding rules.

Rule 64B16-26.300 - Consultant Pharmacist Licensure

Mr. Harris advised the board he had received JAPC letters regarding rule 64B16-26.300. He noted he would respond to JAPC regarding concerns with the rules. We will delete the word “non-refundable” from rule text and respond with the importance of needing the applicant’s date of birth. Mr. Harris stated he will remove the words “within the State of Florida” from 26.300(3)(b).

Motion: by Dr. Fallon, to allow Mr. Harris to respond to JAPC letters. Motion carried.

Motion: by, Dr. Fallon that there will not be an increase in regulatory cost in aggregate of \$200,000 in the first year. Motion carried.

Rule 64B16-26.303 - Nuclear Pharmacist Licensure

Mr. Harris stated he had received a JAPC letter concerning 26.303. He advised he will respond the same way he did with 26.300.

Mr. Harris said he would clarify to JAPC that the use of “certify” at the end of the application indicates a requirement for confirmation in writing, and not the legal definition that requires an oath.

Motion: Dr. Alvarez, to allow Mr. Harris to respond to JAPC letters. Motion carried.

Regarding 26.203 - Pharmacist Licensure by Examination (U.S. Graduates); Application and 26.2031 - Licensure by Examination (Foreign Graduates), Mr. Harris said the applications were resolved during the business portion of the full board meeting. If the Governor signs the bill the Board will need to modify the rule language.

Rule 64B16-27.104 - Conduct Governing Pharmacists and Pharmacy Permittees; Prescription Department Managers

Mr. Harris provided the committee with revised rule language. He stated he had made some minor changes, including an enumerated list of responsibilities for Prescription Department Managers.

Dr. Mikhael commented that somehow the rule needs to be strengthened with proximity and accountability. Dr. Alvarez agreed with Dr. Mikhael. Dr. Mesaros expressed concern with proximity. He stated some pharmacies in certain areas may be underserved. Dr. Weizer stated the rule needed to be centered on responsibility.

There was discussion surrounding the number of days before the PDM of record had to conduct the on-site visit. The committee wanted to see the number of days be consistent or the very least changed from 7 to 14 days.

Motion: by Dr. Fallon, to accept the rule language with the change of 7 days to 14 days. Motion carried.

Motion: by Dr. Fallon, that the proposed change causes no adverse economic impact on small business, nor does it directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after implementation. Motion carried.

Rule 64B16-28.1081 - Regulation of Daily Operating Hours; commencement of operations

Mr. Harris provided the committee with revised language for rule 28.1081. He stated this rule would require the establishment to be open for a minimum of 20 hours per week and require a sign to be posted with after-hours contact information. Required timeframes were changed from seven to 14 days to notify the Board office if commencement would be delayed. The rule would also require the permittee to notify the board of commencement of operation within two days of that date.

Mr. Harris noted this rule is intended to allow flexibility in assisting the permittee to gather all required permits. Attorneys Brian Kahan and Martin Dix said they liked the revisions.

Motion: by Mr. Philip, to accept the rule language revisions as drafted. Motion carried.

Motion: by Dr. Fallon, that the proposed change causes no adverse economic impact on small business, nor does it directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after implementation. Motion carried.

Rule 64B16-28.2021 - Change of Ownership

Mr. Harris provided the committee with revised rule language. He stated the rule allows a corporate change of owner without a corporate change of identity without requiring a new permit, which is keyed on the person or entity's Federal Employer Identification Number (FEIN) remaining the same following the sale. If the FEIN is the same before and after the sale, the old permit will need to be closed and a new one opened.

He noted section (2)(b) of the rule would require all persons, members, partners, officers, directors, and agents having an ownership or other financial interest of greater than 5 percent, and all persons who directly or indirectly manage, oversee, or control the operation of the

business entity, must file with the board a set of fingerprints as specified in Rule 64B16-28.100(1)(c), F.A.C.

Ms. Dudley expressed that the fingerprinting could be an issue and may have to be addressed.

Mr. Philip suggested removing subsection (3) and leave (2)(b). Martin Dix suggested moving the revised language to the end of section (3). Mr. Harris stated we could remove the 30 days section of (3). Both Mr. Kahan and Mr. Dix agreed with removing 30 days from (3).

Motion: by Dr. Mesaros, to remove the following from subsection (3) the permittee has thirty (30) days to remove any person(s) so identified from ownership/financial interests or. Motion carried.

Motion: by Dr. Fallon, that the proposed change causes no adverse economic impact on small business, nor does it directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after implementation. Motion carried.

28.451 - Pharmacy Common Database

Mr. Harris provided the committee with revised language. Mr. Harris stated this rule was consistent with Rule 64B16-28.450. He then stated this rule would allow a pharmacy permittee which solely performs prescription drug processing for other pharmacies pursuant to this rule, and at which medicinal drugs are not compounded, dispensed, stored or sold, nor are prescriptions filled or dispensed, and which notifies the Board that its pharmacy practice is limited solely to prescription drug processing shall be exempt from the following rules:

- a) Rule 64B 16-28.102, Sink and Running Water, Sufficient Space, Refrigeration, Sanitation, Equipment;
- b) Rule 64B16-28.1035, F.A.C., Patient Consultation Area:
- c) Rule 64B16-28.1081, F.A.C. Regulation of Daily Operating
- d) Rule 64B16-28.109(1), F.A.C. relating to signage

Motion: by Dr. Alvarez, to accept language as written. Motion carried.

Motion: by Dr. Fallon, that the proposed change causes no adverse economic impact on small business, nor does it directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after implementation. Motion carried.

New Business

Rule 64B16-27.630 - Additional Immunizations or Vaccines Which May Be Administered and Rule 64B16-26.1031 - Vaccine Certification Program

Mr. Harris stated 27.630 was a new rule created to incorporate new vaccines as the CDC adds them to the Adult Immunization schedule. The Board will be able to add them to 27.630, and Rule 26.1031 needs to reference 27.630.

Motion: by Mr. Philip, to accept Rule 64B16-27.630 as a new rule. Motion carried.

Motion: by Dr. Fallon, that the proposed change causes no adverse economic impact on small business, nor does it directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000 in aggregate in Florida within one year after implementation. Motion carried.

General discussion: Updating Rules Regarding Long Term Care Facilities

John Rocchio, director of Pharmacy Regulatory Affairs for CVS, and Charlie Hartig, regulatory compliance counsel at CVS Health, addressed the committee regarding rules surrounding Long Term Care Facilities. They stated they have been evaluating state rules across the U.S. regarding long-term care facilities because of CVS's purchase of Omnicare. They stated that Florida has exceptional rules. They are looking to fill potential gaps and enhance patient access and patient safety. They suggested a stakeholder committee to review pharmacy rules in Florida.

Mr. Flynn suggested to identify a few rules and converse with Mr. Harris and Dr. Mesaros. Mr. Flynn said Mr. Harris would be very busy responding to new legislation in the coming months and that the Board would not want him to log a lot of hours on the topic until it was narrowed down. Mr. Flynn expressed to both representatives his and Mr. Harris' commitment to the Board and working on priorities identified by the Board and Ms. Dudley. He recommended the CVS representatives provide a one page list of rules to Mr. Harris. Dr. Alvarez said he is an expert in long-term care and can also assist.

Motion: by Dr. Fallon, to ADJOURN at 3:09 p.m. Motion carried.