

Meeting Minutes

DEPARTMENT OF HEALTH BOARD OF PHARMACY RULES COMMITTEE MEETING

February 9, 2016

Immediately Following the Board Meeting

Hyatt Regency Jacksonville Riverfront
225 East Coastline Drive
Jacksonville, Florida 32202
(904) 588-1234

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

PARTICIPANTS IN THIS PUBLIC MEETING SHOULD BE AWARE THAT THESE PROCEEDINGS ARE BEING RECORDED.

Committee Chair Jeffrey Mesaros called the meeting to order at 3:55 p.m.

1. Roll Call

All members were present.

2. Old Business

- 64B16-26.1031 - Vaccine Certification Program

Mr. Harris advised the committee that the board office purchased two CDC Yellow Books. He said one copy will be filed with Department of State and the other will be kept at the board office as an “official copy”. The CDC has be incorporated by reference in Rule 64B16-26.1031.

Motion by Mr. Philip that proposed changes causes no adverse economic impact on small business. Motion carried.

Motion by Mr. Philip that it does not 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.

3. New Business

- 64B16-27.104 - Conduct Governing Pharmacists and Pharmacy Permittees

Mr. Harris provided draft language to the committee with proposed the proposed changes to Rule 64B16-27.104. Dr. Mikhael stated his concern with PDM responsibilities is when you have a PDM in one state and the pharmacy is located in another, the PDM may never see the pharmacy.

Mr. Philip stated the proposed change in 5(b)2(b) would need more clarification on the types of documentation required.

Dr. Mesaros suggested to table this rule language until the next meeting. He would like to keep gathering information and identify any gaps.

- 64B16-26.600 - Tripartite Continuing Education Committee

Mr. Harris provided the committee with draft language to add new Controlled Substance Standards continuing education being approved by Tripartite committee. Mr. Harris stated added 2(b) 10, Validation of Prescriptions for Controlled Substances. He also cleaned up 3(c) and 3(h).

Ms. Dudley advised the committee she will review the board staff process for dividing up material amongst the committee members and provide an update at the April committee meeting.

Motion: by Mr. Philip, to accept proposed language as written with the removal of “each” from subsection 1. Motion carried.

Motion: by Dr. Fallon, that the proposed change will have no adverse economic impact on small business. Motion carried.

Motion by Dr. Fallon, that it does not 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.

- 64B16-28.2021 - Change of Ownership

Mr. Harris provided the committee with draft language on Rule 64B16-28.2021. Ms. Dudley is concerned with sharing background information. She thinks this may be an issue. She stated she will have to look into what information can be shared. This rule will be place on the April rules agenda.

- 64B16-28.1081 - Regulation of Daily Operating Hours

Mr. Harris provided draft rule language to the committee. Attorney Brian Kahan suggested changing 7 to 14 days in section B(1), which is more consistent with business practices.

Dr. Mikhael expressed concern that the notices may be excessive and may place unnecessary work onto board staff. Dr. Mesaros said he seen the value of 2(b) but questioned whether or not 1 and 3 are necessary. Attorney Martin Dix also thought there was no need for 1.

Ms. Dudley stated she would like to talk with Chief of Enforcement, Mark Whitten and find out the additional workload involved for board staff. She recommended tabling this rule until we have more clarification.

- 64B16-28.451 - Pharmacy Common Database

Mr. Harris provided draft language to the committee.

Dr. Mesaros felt there was disconnect between 28.450 and 28.451. Dr. Mesaros suggested speaking with Mark Whitten. This rule will be placed on the April rules agenda.

- 64B16-26.203 - Licensure by Examination; Application

Mr. Harris provided the committee with proposed amendments to rule and an updated DH-MQA 101 form. Puerto Rico was removed from section 1 since Puerto Rico already considered part of United States.

Dr. Weizer who is not on the committee stated 2(b) needed modification to reflect Prevention on Medication Errors. The proposed language did not have the word "Prevention".

Motion: by Dr. Fallon, to accept proposed changes to rule with the modification to 2(b). Motion carried.

- 64B16-26.2031 - Licensure by Examination; Foreign Pharmacy Graduates

Mr. Harris provided the committee with proposed amendments to rule and an updated DH-MQA 103 form.

The proposed changes included a change to subsection 1, second line, to have the rule and DH MQA 103 form match and adding "Prevention" in section 2(d).

Motion: by Dr. Fallon, to accept proposed language and updates to form DH MQA 103. Motion carried.

Motion: by Dr. Fallon, that the proposed changes to Rule 64B16-26.203 and Rule 64B16-26.2031 will have no adverse economic impact on small business. Motion carried.

Motion by Dr. Fallon, that it does not 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 or 1 million in 5 years. Motion carried.

Motion: by Dr. Fallon, to ADJOURN at 6:03 p.m. Motion carried.

DRAFT