

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

June 7, 2016

Immediately Following the Board Meeting

Boca Raton Marriott
5150 Town Center Circle
Boca Raton, Florida 33486
(561) 392-4600

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

Board Counsel

Lawrence Harris, Assistant Attorney General
David Flynn, Assistant Attorney General

Tuesday, June 7, 2016 – Rules Committee Chair Jeffrey Mesaros called the meeting to order at 2:04 p.m.

1. Roll Call

Committee members present: Jeffrey Mesaros, Jeenu Philip, Lee Fallon, Goar Alvarez
Other Board of Pharmacy members present: Debra Glass, Mark Mikhael, Michele Weizer

2. Rules report

Rules Committee Attorney Larry Harris summarized the rules report.

3. Old Business

Dr. Mesaros asked Board Member Goar Alvarez to work with the Omnicare/CVS group that presented at the April meeting regarding long-term care issues and potential rule changes.

a. 64B16-27.104

Mr. Harris said that the JAPC letter asks for more specific requirements for the Prescription Department Manager but the committee had not wanted to put minimum restrictions on what the PDM was required to do because Florida Statutes requires the PDM be responsible for what happens in the pharmacy.

After some discussion by committee members, Mr. David Flynn said that he and Mr. Harris would review the proposed language to see if it would diminish the ability of prosecution to pursue cases against PDMs. The rule was tolled.

b. 64B16-28.1081

Mr. Harris said the JAPC response asks that CGI be spelled out and cited.

Motion: by Mr. Philip to publish a notice of change and amend the language as proposed.
Motion carried.

Mr. Harris said clear there would be no impact from these changes.

Motion: by Mr. Philip, 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.

4. New Business

a. Pharmacy Interns

64B16-26.2032 and incorporated forms
64B16-26.2033
64B16-26.400

Mr. Harris said he redrafted 26.2032 to include U.S. and foreign interns and left only language about approved intern program in 26.2033. He said 26.400 had been stripped down and saved for future rule making.

Dr. Michele Weizer said requirements for 1-to-1 pharmacist oversight should be added for U.S.-educated interns, but Dr. Alvarez and others explained that many intern opportunities in U.S. pharmacy programs were higher oversight ratios and it would have a significant impact to college programs.

Motion: by Mr. Philip to amend the rule language and forms as proposed, which changes the date on the applications to July 2016 and removes the medication errors continuing education requirements and Section 456.0635 violations.

Mr. Harris said the rules would be brought back in August to address the needed language for approved intern programs.

Motion: by Dr. Fallon, 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.

b. Pharmacist by Endorsement

64B16-26.204 and incorporated forms

Mr. Harris said the changes combine U.S. and foreign-educated pharmacists into the same rule. It also amended forms as required by HB 941 changes.

Motion: by Dr. Fallon to remove the medication errors certification requirements and change the date on the application to July 2016.

Motion: by Dr. Fallon, 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.

c. Pharmacy technicians

64B16-26.350 and incorporated form

64B16-26.351

64B16-26.355

Ms. Dudley said she asked 26.351 to be added to the regulatory plan. The accrediting bodies mostly do Eastern and Southeastern schools and need to look at accrediting bodies that operate more in Western states. The list of accrediting bodies are long, however, and research needs to be done to determine which may be appropriate.

Dr. Mesaros said 26.351 needed to be opened for development so the research can be done about whether accrediting list needs to be expanded.

Motion: by Dr. Mesaros to open 65B16-26.351 for development. Motion carried.

Mr. Harris said the proposed language for 26.350 and forms addressed the changes required by HB 941: changing the application date to July 2016, deleting the requirement for certified court records, removing the requirement for medication errors continuing education on initial licensure and Section 456.0635.

Motion: by Dr. Fallon to make the proposed changes to 64B16-26.350 and form. Motion carried.

Motion: by Dr. Fallon, 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.

No action was taken on 26.355.

Mr. Philip asked about reviewing 26.351 regarding pharmacy technicians transferring in from other states.

ADD:

Mr. Harris asked the committee to add 64B16-26.203 and 26.2031 to the agenda, because he received JAPC comments Friday afternoon on these rules about licensing by exam. He

said the request was for two changes that could be done easily because they were HB 941 changes that the committee was also making for other application rules and forms.

First, JAPC said the new legal requirement mean the removal that certified copies are needed for criminal copies. Also the changes revised the application deadlines and remove the medication errors requirements.

Motion: by Mr. Philip to make the proposed changes to address JAPC's points. Motion carried.

Motion: by Dr. Alvarez, 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.

d. Continuing Education
64B16-26.103 and incorporated forms

Mr. Harris said JAPC said the ACPE approval date needed to be included in order for the course to be a Board-approved course. He suggested a date, but after some debate, it was deferred to August to make sure any cited date doesn't discredit any course that was already approved and taken.

No public comment was made.

Motion: by Dr. Fallon to adjourn at 3:45 p.m. Motion carried.