Tuesday, December 13, 2016
Rules Committee Meeting

The meeting was called to order by Dr. Mesaros, Chair, at approximately 10:15 a.m.
Those present for all or part of the meeting included the following:

COMMITTEE MEMBERS PRESENT:
Jeffrey J. Mesaros, PharmD, JD,Chair
Goar Alvarez, PharmD
Leo Fallon, BPharm, PhD
Jeenu Philip, BPharm

STAFF PRESENT:
Adrienne Rodgers, Bureau Chief, HCPR
Bianca Bell, Program Operations Administrator
Aaron Coker, Regulatory Specialist III

BOARD MEMBERS IN ATTENDANCE:
Mark Mikhael, PharmD
Michele Weizer, PharmD
David Bisaillon
Debra Glass, BPharm

BOARD MEMBERS EXCUSED:
Gavin Meshad

BOARD COUNSEL:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

1.Roll Call

2. Rule 64B16-26.200, FAC: Examination requirements; current competency; passing scores

This rule received comment from JAPC. Subsection 2 of the rule talks about establishing a current clinical competency examination but nothing has been put into effect yet. The board has decided that the PAR is to be established as the standard once effective. NABP established the score of 75% as minimum on the NPJME and has the psychometrically sound basis for the score. Dr. Fallon moved to open the rule for development, second by Mr. Philip. Vote unanimous. Discussion of economic impact and impact on regulatory cost. Mr. Philip moved that there is no economic impact or impact on regulatory cost and no SERC is required to be made, seconded by Dr. Fallon. Dr. Fallon moved that regulatory costs will not be more than 1 million dollars in 5 years, seconded by Dr. Alvarez. Motion carried.

3.Rule64B16-26.2033, FAC: Pharmacy Intern registration and Intern requirements

The board has voted that Rule 26.2032 will be for licensure and new Rule 26.2033 will be the standard for approval of internship programs. Moving forward, there were concerns at the previous board meeting regarding the supervision of foreign pharmacy interns. Rule 26.2033 will implement language that requires foreign pharmacy interns to be supervised on a 1:1 basis. Dr. Weizer commented that 1A needs correction from "pharmacological" to "pharmaceutical". JAPC may have asked for the change. Mr. Philip said the website says "pharmacy". Motion to open Rule 64B16-26.2033, F.A.C. made by Dr. Fallon and seconded by Mr. Philip. Dr. Mesaros opened the floor for public comment. Mr. Jackson (Florida Pharmacy Association) asked if this was only applicable

to newly graduated foreign students that are applying for internship. Mr. Harris stated that the answer to his question would be "yes" and reminded that rules are only effective after the date they're adopted, so anyone who is currently enrolled in a program wouldn't be effected. Mr. Harris opened the discussion of economic impact and impact on regulatory cost. Dr. Fallon made a motion that there is no economic impact or impact on regulatory cost and no SERC is required made, seconded by Dr. Alvarez. Dr. Fallon also moved that regulatory costs will not be more than 1 million dollars in 5 years, seconded by Dr. Alvarez. Motion carried.

4.Rule 64B16-26.351, FAC: Standards for approval of registered pharmacy technician training programs

Mr. Harris stated that JAPC expressed concerns about the language from the August 2016 meeting. The language has been modified as proposed to satisfy their concerns. The intent of striking the previously proposed language is to ensure that these programs get approved. Dr. Weizer makes a correction to page 1, (1C), states that SHSP should be amended to ASHP. Dr. Weizer also states page 9 Bates#2946 item #5 needs to be corrected to read as "pharmacy education programs". Motion to amend language by Dr. Alvarez and seconded by Mr. Philip. Motion carries. Motion by Dr. Fallon that there is no economic impact or impact on regulatory cost and no SERC is required made. Motion seconded by Mr. Philip. Dr. Fallon moved that regulatory costs will not be more than 1 million dollars in 5 years, seconded by Mr. Philip. Motion carried.

5.Rule 64B16-26.400, FAC: Pharmacy Interns; registration; employment

The rule proposes to put in place a restriction on the number of years an intern certification would be valid. It is recommended that the language as proposed be amended to implement some form of "expiration date". This rule is an attempt to implement a standard for approval which would require these registered programs to report semi-annually or annually a list of all currently enrolled students. If it is noticed that a licensee is no longer enrolled, the board can send them a letter requesting explanation of the findings. Ms. Glass pointed out that there are other boards that have similar language already implemented into their rules set. Mr. Philip has concerns regarding the time limit if a student is perhaps studying for the NAPLEX. Mr. Flynn points out that this may end up being a "legislative fix" and urges the board to keep that in mind during this discussion. Dr. Mesaros pointed out guidelines for the process may be needed pertaining to what constitutes a "credible response" by licensees. Mr. Cuomo provided public feedback that setting a time limit may cause further issues overall. He suggested setting a time limit on the intern license and have them re-apply for that license at the end of that term. Motion to amend Rule 64B16-26.400, F.A.C. to delete previously proposed language and add alternative language to the rule made by Dr. Fallon and seconded by Dr. Alvarez. Motion carried. Motion by Mr. Philip that there is no economic impact or impact on regulatory cost and no SERC is required made. Motion seconded by Dr. Alvarez. Mr. Philip moved that regulatory costs will not be more than 1 million dollars in 5 years, seconded by Dr. Alvarez. Motion carried.

6.Rule 64B16-27.450, FAC: Prescription Department Manager Responsibilities

a. Board Counsel suggested revisions

b. DOH/MQA/PH10 form
c. JAPC letter

Mr. Harris mentions that subsection 1, paragraphs A and B, have amended language due to concerns from JAPC. Previously there was an incorrect reference to an existing rule as well as the incorrect name for an application. These changes were strictly technical in nature to satisfy all concerns. Mr. Harris also proposes the addition of 2 new subsections. Proposing new language stating PDM's may not oversee more than one location unless otherwise approved by the board. This would require completion of an application submitted to the Board office for approval. Dr. Alvarez inquired into if the new language and any form of disciplinary action if a pharmacy does not have a designated PDM. Mr. Harris said that this will need a revised disciplinary guideline for use of prosecution services. Mr. Harris requested a motion to submit a proposal of change. Motion to submit a proposal of change for Rule 64B16-27.450, F.A.C. made by Dr. Alvarez and seconded by Dr. Fallon. Motion by Dr. Fallon that there is no economic impact or impact on regulatory cost and no SERC is required made. Motion seconded by Dr. Alvarez. Dr. Fallon moved that regulatory costs will not be more than 1 million dollars in 5 years, seconded by Dr. Alvarez. Motion carried

7.Rule 64B16-27.830, FAC: Standards of Practice – Drug Therapy Management

Mr. Flynn will keep this rule and work on pulling all applicable statutes. Dr. Mesaros offered to collaborate with Mr. Flynn while he works on the language for the rule. There was public comment from Mr. Jackson, Mr. Dix and Mr. Bayo regarding the history and creation of the rule. Mr. Philip asked if we should open the rule today. Mr. Flynn suggested holding a separate committee meeting with stakeholders involved. No vote needed, moving on to item #12.

12.Rules relating to non-resident pharmacies

a. 64B16.28.100, FAC, Pharmacy permits, applications and permitting
b. 64B16-28.800, FAC, Special pharmacies
c. 64B16-28.840, FAC, Special Non-resident pharmacies (mail service)
d. 64B16-32.021, FAC, Initial application/permit and permit renewal fees for all non-resident pharmacies

Motion that 28.100 is moved to 32 and asked to move subsection 7, moved by Dr. Alvarez and seconded by Dr. Fallon. Vote is unanimous, motion carried. Looking at Chapter 32 28.800 it's been recommended to delete 1D. Motion by Dr. Alvarez, seconded by Dr. Fallon to strike 1D of subsection D. Vote is unanimous, motion carried. Looking at 28.840 it's requested to appeal entirety of the rule since it's already in 32. Motion by Dr. Alvarez, seconded by Dr. Fallon. Vote is, unanimous motion carried. Looking at 32.021 Fees for initial applications and renewal fees, the board moves for a set renewal fees of $250. Moved by Dr. Alvarez, seconded by Dr. Fallon. Vote is unanimous motion carried.

9. Rule 64B16-30.001, FAC, Disciplinary Guidelines; range of penalties; aggravating and mitigating circumstances

Per Mr. Harris, this tab was simply a placeholder in case this rule received comment from JAPC. He states that the timeline for comment hasn't yet run out, so if necessary the board will mention this during the February 2017 meeting. No vote needed, moving on to item #10.

10. Rule 64B16-30.003, FAC, Citations

Per Mr. Harris, this was placed on the agenda due to a discussion from a prior board meeting about disciplinary action for pharmacies that are open less than 40 hours a week. This was simply an informative item to show that the Department has a system in place to take care of these issues on a Department level rather than a Board level. No vote needed, moving on to item#8.

8. Chapter 64B16, FAC: Rules related to automation

Mr. Philip like the concept proposed by Mr. Harris to put all into one rule which can be more easily utilized.
Dr. Weizer looks at the definition of the decentralized system and its lack of clarity and supports the creation of a rule which will again offer more clarity. After much discussion between the board and audience members, the consensus seems to be that a section on automation would be beneficial to the Pharmacy industry in Florida. It also seems to be acknowledged that this would likely require multiple subsections to address different areas of practice. There was discussion pertaining to disciplinary actions of these automated systems and who would be held accountable should any compliance issues arise. Mr. Harris thanked the board and audience members for their feedback and will work on some conceptual rules to bring forth at the February meeting. No vote needed, moving on to item #11.

11.CVS/Omnicare proposed rule revisions for long term care

Dr. Mesaros recused himself as chair due to appearance of conflict given his role in CVS. Acting as Chair is Dr. Alvarez.
Director of Regulatory Affairs at Omnicare, Mr. Rocchio presented 5 sections for rule changes, including language suggestion. Mr. Rocchio states that these revisions come from looking at long term care rules from a patient's perspective. A main point of discussion was Section 1: Rule 64B16-28.301, FAC, which requires a pharmacist to be present for destruction of schedule II drugs. Mr. Rocchio stated that many other states as well as the DEA do not have this requirement. Mr. Rocchio states the required number of witnesses for the destruction is currently 3, with 1 of these witnesses being a pharmacist. Mr. Rocchio proposes that the number of witnesses can stay the same, however feels it's unnecessary for one of them to be a pharmacist. Mr. Flynn asked if the board wants the rule revised to mandate that a pharmacist need not be required. Dr. Fallon moved to reduce from 3 to 2 so long as they are not within the same area. Since this is merely conceptual, no vote needed now. Other rules that were brought into this discussion were the following: Rule 64B16-27.503, FAC, Rule 64B16-28.606, FAC, Rule 64B16-27.100, FAC, Rule 26.300, FAC, and Rule 64B16-28.830, FAC. Mr. Harris stated that these revisions would impact many rules and statutes, so this should be treated as a conceptual matter for today and not as opening the rule for development. Mr. Flynn and Mr. Harris will work on some conceptual rule revisions for the February 2017 meeting.

13. New business

Tab #9 was set aside in case of JAPC comment receipt. Comments were not received and will need to be on the February agenda if necessary. Tab #10 was an item asked to be placed on the agenda with language found to already exist in Rule 30.003.

14. Public comment

Mr. Dix brought forth comments regarding 28.608, mainly to discuss a triple check system and the language used within the rule. He stated he has no issue with the concept of direct supervision. Mr. Flynn as Department's legal counsel is not comfortable with the rule as it is currently worded. Mr. Harris states his intent was to bring this before the board for a conceptual discussion.

Motion to adjourn by Dr. Fallon, seconded by Mr. Philip. Vote unanimous; Motion carried. Meeting adjourned at approximately 4:55 PM.