

## **MEETING MINUTES**

### **DEPARTMENT OF HEALTH BOARD OF PHARMACY RULES COMMITTEE MEETING**

**October 18, 2016  
Embassy Suites Lake Buena Vista South  
4955 Kyngs Heath Rd  
Kissimmee, FL 34746**

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#### **Committee Members**

Jeffrey J. Mesaros, PharmD, Chair  
Jeenu Philip, BPharm  
Lee Fallon, PhD., BPharm  
Goar Alvarez, PharmD

#### **Board Staff**

Allison Dudley, Executive Director  
Bianca Bell, Program Operations Administrator  
Alexandra Meredith, Regulatory Supervisor

#### **Board Counsel**

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

#### **1. Roll Call**

Dr. Mesaros called the meeting to order. 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.

## **2. Rule 64B16-26.2032, Pharmacy Intern Registration Internship Requirements (U.S. Pharmacy Students/Graduates)**

**a. Form DH-MQA 104, Pharmacy Intern Application for U.S. Pharmacy Students/Graduates and Instructions**

**b. Form DH-MQA 102, Pharmacy Intern Application for Foreign Graduates and Instructions**

**c. Form DH-MQA 1153, "Foreign Graduate Registered Intern Work Activity Manual"**

## **3. Rule 64B16-26.2033, Pharmacy Intern Registration and Internship Requirements (Foreign Pharmacy Graduates)**

## **4. Rule 64B16-26.400, Pharmacy Interns; Registration; Employment-Withdrawn**

Discussion: Mr. Harris discussed all three rules above together. The rules were discussed with JAPC attorneys. These were discussed at August meeting for revisions and there will be small revisions to be presented to the JAPC attorneys again. Rule 64B16-26.2032 has no changes. Rule 64B16-26.2033 is one rule now for all registration and intern requirements. The foreign graduate manual is not included. Mr. Harris advised that this form does not need to be reviewed for changes as it is incorporated in another rule that has already been reviewed and adopted. Rule 64B16-26.400 is to be reviewed for changes. The board reviewed in August and decided that there is a limited time that someone can be an intern. Mr. Harris advised that he is still looking at this with Mr. Flynn as this issue is more complicated than previously thought. Mr. Harris asks board to consider removing previously discussed language in August with time limitation to look further into what can be done and will bring back to the committee in the future for review. Dr. Alvarez inquired about language with direct supervision of foreign graduate from pharmacist. Dr. Weizer discussed that the language displaying 1 to 1 ratio is not currently in rule and it should be included. Mr. Philip states that if this ratio of 1 to 1 is put into one rule then it should be applied to all. Mr. Mikhael discussed that this was previously reviewed for discrimination of foreign graduates in relation to US graduates. Ms. Glass advised that the rule reads this

way for the ratio for foreign graduates. Dr. Weizer states that it is not only the ratio but the training manual that is important to require for foreign graduates. Mr. Harris advised that Rule 64B16-26.2033 and 64B16-26.400 should be reviewed for further changes and brought back in December with the cleanup completed. Rule 64B16-26.2032 can be moved on now.

Motion: by: Mr. Philip ,to approve language to Rule 64B16-26.2032 to proposed and subsequent applications, Rule 64B16-26.2033 to be reviewed to clean up the language, and delete the language on time limitation on Rule 64B16-26.400 that was previously approved in August as well as reviewing the supervision ratio. Rule 64B16-26.2033 and 64B16-26.400 to be brought back in December after language cleanup has been completed. Motion carried.

## **5. Rule 64B16-26.204, Licensure by Endorsement**

**a. Rule 64B16-26.204, as proposed July 21, 2016**

**b. Letter from JAPC, dated August 8, 2016**

**c. Form DH MQA 100 Pharmacist Licensure by Endorsement Application and Instructions (U.S. Graduates)**

**d. Form DOH/MQA 1196 Pharmacist Licensure by Endorsement Application and Instructions (Foreign Graduates)**

Discussion: Mr. Harris advised of the forms with the changes to the forms and some changes to rule language. Mr. Harris advised that proposed changes included on page 3 from Ms. Holiday's letter showing under Form DOH/MQA 1196 application to explain why this application refers to the passing of exam. Mr. Harris advised that this is included to refer to the statute. The second change on page 3 of the letter is why the endorsement application refers to examination refusal as well. Mr. Harris advised that this also comes straight out of the statute. The next change is on page 4 of the letter which refers to explaining why the rule text and the application does not refer to the passing score by the NABP. Mr. Harris advised that this is set by NABP and not by the board. Ms. Glass advised that the score is also re-evaluated everything few years by the NABP, and the

board is not given the authority to do so. The board confirmed that Mr. Harris is correct in each of the responses to Ms. Holiday's questions within the letter. A discussion of endorsement applications in regards to the CE's that are board approved and how that is defined took place. Mr. Harris is to add a sentence to the end of the rule to define what a board approved CE is.

Motion: by: Dr. Fallon, to approve the three accepted changes in the language discussed and to respond to Ms. Holiday in writing. Motion carried.

Motion: by: Dr. Fallon, these proposed rules will not adversely affect small business in excessive of \$200,000. Motion carried.

## **6. Rule 64B16-27.450, Prescription Department Manager Responsibilities**

### **a. Form DOH/MQA/PH10**

Discussion: Mr. Harris advised that this is being brought back before the board for the form to be considered in regards to PDM's. Mr. Harris advised that he reached out to PSU to inquire if there were any issues of concern. Mr. Harris advised that there was no response from PSU, but he received a response from Robert Difiore in regards to the amount of semi-annual visits being included and also heard back from inspectors about fingerprinting in regards to the clearinghouse and ensuring that the already conducted process be included in the rule. The board discussed that the language should state minimum of semi-annual visits with an understanding that more visits should be completed and how to have language clear that there should be more visits completed in order to have PDM efficiently run the pharmacy. Mr. Bayo to speak on the rule requesting to consider a rule that will list the responsibilities of the PDM. Mr. Harris and Mr. Flynn state that this is an issue because the "included but not limited to" language is the issue that the board previously discussed. Mr. Philip and Dr. Mikhael propose being able to use an attestation of responsibility. Mr. Harris advises that there cannot be an attestation, but a statement may be included regarding understanding PDM responsibilities above the signature line. Mr. Harris to propose change to last sentence stating no less than every six months instead of semi-annually to make timeline clear and the second change is under paragraph 1c regarding fingerprints to read submission of fingerprints for new PDM's to comply with fingerprint

requirement. Mr. Harris to change Form PH10 to include sentence in section to be completed by new PDM to state that they have read and understand the statutes in regards to PDM responsibilities. Michael Jackson spoke on closing the knowledge gap for new PDM's and developing courses to help new practitioners understand how to run a pharmacy business. Mr. Quomo speaks on the negative impacts of this rule on PDM's. Mr. Quomo advises that this checklist would be a burden on PDM's. Mr. Harris advises that if board feels this is new rule then board will need to require a SERC as the board could not answer the adversely affecting small business question.

Motion: by: Dr. Fallon, to approve two changes to the language proposed and the sentence added to Form PH10. Opposed by Dr. Alvarez. Motion failed.

Motion: by: Mr. Mesaros, to approve changes proposed by Mr. Harris within 27.450 with changes to the Form PH10 proposed by Mr. Philip to include statement. Motion carried.

Motion: by: Dr. Fallon, these proposed rules will not adversely affect small business in excessive of \$200,000. Motion carried.

Break 1:38pm  
Return 2:49pm

## **7. 64B16-30.001, Disciplinary Guidelines**

### **a. Suggested Amendment**

### **b. Chapter 2016-222, Laws of Florida, added a new disciplinary violation to 456.072**

Discussion: Mr. Harris suggests a first violation of this section would be up to six months suspension, one year probation, and fine for \$1,000. For a second violation, fine for \$5,000, one year suspension, and one year probation or revocation. Dr. Mesaros asks if there could be a lower minimum fine placed for first time offense. Dr. Weizer inquires as to what constitutes a violation of this

general business practice. Mr. Harris provides definitions and examples of what violations would be considered under this. Mr. Bayo advises that if there is not a guideline then you cannot punish the practitioner. Dr. Mesaros suggests to begin at a lower starting point for first violation and may need to revisit at a later time. Mr. Harris amends to reprimand and fine for \$250 for first offense, and the second offense should be one year of probation up to revocation and a fine for \$500.

Motion: by: Dr. Alvarez, to approve the discipline guidelines language proposed by Dr. Mesaros for the first and second offense. Motion carried.

Motion: by: Mr. Philip, these proposed rules will not adversely affect small business in excessive of \$200,000. Motion carried.

## **8. Review of rules relating to automation**

**a. 64B16-28.605 Class II Institutional Pharmacies – Automated Distribution and Packaging.**

**b. 64B16-28.606 Remote Medication Order Processing for Class II Institutional Pharmacies.**

**c. 64B16-28.607 Automated Pharmacy System – Long Term Care, Hospice, and Prison.**

**d. 64B16-28.608 Automated Filling Systems within a Pharmacy.**

Discussion: Mr. Harris advised that this committee should consider remote order processing rules due to the several requests for the board to review this year and have the board be proactive in these processes being implemented. Mr. Harris advises that opening these rules for development would decrease individual requests and provide clarity and certainty in the rules regarding automation. Dr. Mesaros advised that these rules will need to be discussed further before opening up for development. Mr. Harris asks the board if the machines that are being used for automation are all the same across the board for different facilities. Dr. Weizer advised that the technology is similar, but the packaging may be different based

on which environment the automation is taking place. FSHP's chair for regulatory consult, Gary Dalen, spoke stating that it may be difficult to roll all automation into one rule even with subsections. Dr. Mesaros advised that this will be something to be considered as rule language is developed and that there may be a need as this happens to piece out each type of automation on its own. Mr. Harris advises that he will bring some rule language to the December meeting for this.

Motion: by: Mr. Philip, to approve opening up rules above for development. Motion carried.

## **9. New Business**

Discussion:

Mr. Harris and Dr. Alvarez will have a long-term care package presented in the future. This was from Omnicare. Mr. Harris is waiting on Omnicare to respond with proposed language for review.

Mr. Philip discussed next year's legislative process and requests that there be discussion of language and the next year's rules to be reviewed. Ms. Dudley states that this cannot be done as a departmental package as this has already be done for next year, but there can be a discussion of suggested language. Flynn advised that he will provide a list of the do's and don'ts for the legislative process.

## **10. Public Comment**

No public comment.

Motion: by: Dr. Fallon, to adjourn the meeting. Motion carried.

Meeting adjourned at 3:38 pm.