

# **AGENDA**

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

December 10, 2015  
Immediately Following the Board Meeting

Residence Inn Tallahassee Universities at the Capitol  
600 West Gaines Street  
Tallahassee, FL  
(850) 329-9080

### **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.

Chair Jeffrey Mesaros called the meeting to order at 2:31 p.m.

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

All members were present.

#### **2. Rules**

- 64B16-26.1001 – Examination and Application Fees

Board counsel Larry Harris said the word “nonrefundable” needed to be deleted in sections 1, 3 and 4 per a letter from JAPC indicating that only applications designated in statute as having nonrefundable fees should indicate a nonrefundable status in rule. No

refund has to be sent if action has been taken, according to an Attorney General Opinion, but Mr. Harris said “taking action” has not been defined.

Motion by Lee Fallon to remove “nonrefundable” from Rule 64B16-26.1001 per recommendation. Motion carried.

Motion by Jeenu Philip that the 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.

- 64B16-28.1081 – Regulation of Daily Operating Hours

MQA Enforcement Bureau Chief Mark Whitten appeared before the committee to talk about reasons that some baseline number of hours is needed for inspectors to be able to conduct unannounced inspections. With no minimum hours nor required posting of hours, inspectors would have to make an appointment.

Dr. Mesaros asked if the rule required 20 hours and pharmacies had to apply for permission to open fewer hours.

Dr. Whitten said the inspectors need to understand how the pharmacy is working and need to be able to hold the pharmacy to its posted hours. The hours of operation affect patient access.

Board member Debra Glass, who reviews reduction-of-hours requests, said there are too many emergency situations already. She said the Board needs a tracking mechanism to monitor the status of pharmacies that request a waiver of the 40-hour rule because the pharmacy is waiting on a DEA registration number, which is a common request.

Attorney Brian Kahan said, as someone who represents pharmacies, he would like to see options and deadlines. He explained that pharmacies that experience a long delay in getting a DEA number face operational hurdles in opening before they can dispense controlled substances. He suggested putting the burden on the pharmacy to notify the Department of Health when it is ready to open.

The committee discussed the language in the rule -- “commences to operate” – and what that means for the permittee’s requirement to meet 40-hour requirements after receiving the permit. Board counsel David Flynn said the term needs to be better defined. The committee asked that Mr. Harris bring language to the February committee meeting to better define “commencing” with the assistance of Mr. Whitten and the attorneys who commented.

- 64B16-28.2021 – Change of Ownership

Dr. Mesaros asked attorneys Brian Kahan and Martin Dix to share the issues that were raised at the previous regarding change of ownership.

Mr. Kahan said the Board should be notified within 30 days of new principles and would be required to provide fingerprints. That would stop interruption of business and satisfy needs of the department to know the new equity shareholders. Consequence is that the burden falls on people involved in business transaction to do background checks within 30 days.

Mr. Flynn said there's an issue of ownership versus affiliates.

Board member Michele Weizer, who is not on the committee, said the Board needs a permit to have authority to require fingerprints.

Ms. Dudley said send a notice. Section 465.022, F.S., addresses fingerprinting requirements for an application. If it is just a stock transfer, she is concerned about the Board's authority to background fingerprint new owners. Possibly we could call it an application for stock transfer, but keep the current permit number for this category. That gives us the authority to review and fingerprint. She said she is concerned about the disciplinary process if one of those new owners gets a hit on the background check.

Mr. Kahan asked if the rule could include language that said if there is a change in ownership of at least 5 percent, would have a fingerprint notification to update the existing record. He is concerned with the DEA, because if the permit number changes that agency requires a new registration number. Also, if impose this, he thinks it would add an additional expense and require ratification by the Legislature.

Dr. Mesaros said the committee should ask Mr. Harris to bring language to the next rules committee meeting.

Motion by Goar Alvarez to ask Mr. Harris to bring revised language for the rule or a proposed application to the committee for the February meeting. Motion carried.

### 3. New Business

- 64B16-26.300 – Consultant Pharmacists

Mr. Harris said he is reviewing all pharmacy applications in conjunction with the Board office. He thanked Beth Ranne, regulatory supervisor, for her work on the applications. A summary of changes was included with the committee materials.

Motion by Mr. Philip to open the rule for development and amend the application as proposed. Motion carried.

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

Motion by Dr. Fallon that it 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.

- 64B16-26.303 – Nuclear Pharmacists

Mr. Harris said the nuclear pharmacist application has also been reviewed and proposed amendments were detailed in the committee materials. The committee asked Mr. Harris to fix some typographical mistakes in both applications.

Motion by Dr. Fallon to open the rule for development and amend the application with the language proposed in the committee materials, including reference to the website where the form is located. Motion carried.

Motion by Dr. Fallon that the 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. Repeal

- 64B16-26.603

Mr. Harris said the rule was identified after a review conducted earlier this year to identify unnecessary and outdated regulation that can be repealed, and thus was not included in the rules the committee reviewed previously for repeal. Because licensees must now provide documentation through CE Broker of their continuing education certifications in order to renew their licenses, a rule is no longer needed to require that they keep the documentation.

Motion by Mr. Philip to repeal 64B16-26.603. Motion carried.

Dr. Mesaros asked for suggestions of rules that committee or any attending Board member wanted to consider for revision. He said he would like review of 64B16-28.451 and in light of revisions made in the central fill rule, he thought nondispensing pharmacies may not need sinks and similar items. He wanted a review so that the rules would reconcile.

Dr. Mikhael said the hours and responsibilities for Prescription Department Managers need to be reviewed, which continues discussions the Board has been having regarding PDMs.

Motion by Dr. Fallon at 3:54 p.m. to adjourn. Motion carried.