

AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
RULES COMMITTEE MEETING

February 11, 2014

The Florida Hotel & Conference Center
1500 Sand Lake Road
Orlando, FL 32809
(407) 859-1500

Committee Members:

Jeffrey J. Mesaros, PharmD, Tampa, Chair
Debra Glass, BPharm, Tallahassee
Michele Weizer, PharmD, Boca Raton

Board Staff:

Tammy Collins, Acting Executive Director
Christy Robinson, Program Operations Administrator
Jay Cumbie, Regulatory Specialist II

Board Counsel:

Lynette Norr, Assistant Attorney General

Participants in this public meeting should be aware that these proceedings are being recorded.

Tuesday, February 11, 2014 – 9:00 a.m.

Lynette Norr provided a list of the five rules that had been adopted since the last Rules Committee meeting including rule(s): 64B16-28.901, 64B16-28.450, 64B16-30.001, 64B16-28.301, and 64B16-28.810.

Ms. Norr presented the amended language to rule 64B16-28.303 and corresponding letter from JAPC (Joint Administrative Procedures Committee) that requested the rule clarify whether or not modified institutional class II B pharmacies are required to comply with 64B16-28.301(2).

Dr. Weizer confirmed that modified institutional class II B pharmacies are required to comply with 64B16-28.301(2).

Motion: by Dr. Weizer, seconded by Mrs. Glass, to approve the amendments to the rule language. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Dr. Mesaros introduced Rule 64B16-26.2034 (Direct supervision of pharmacy technicians) as the first order of new business.

The committee reviewed other states language regarding their definition of direct supervision and discussed the various factors in determining a definition for direct supervision.

Dr. Weizer stated she liked concept behind Indiana's language for a definition for direct supervision of a technician.

Dr. Mesaros introduced Rule 64B16-26.1031 as the next agenda item.

Ms. Norr explained the minor changes to the rule including the inclusion of a rule title and an updated version of the form associated with the rule.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to approve changes to the rule. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is not an adverse economic impact on small business and that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Dr. Mesaros stated that updating various rules record retention language was next on the agenda.

Ms. Norr read off the following rules for approval of their new 4 year record retention language: Rule 64B16-26.351, 64B16-26.601, 64B16-26.603, 64B16-27.710, 64B16-27.300, 64B16-27.800, 64B16-27.851, 64B16-28.2021, 64B16-28.503, 64B16-28.605, 64B16-28.606, 64B16-28.607, 64B16-28.702, and 64B16-29.0041.

Motion: by Dr. Weizer, seconded by Mrs. Glass, to approve the updates to the above listed rule's record retention language. Motion carried.

Bob Parrado approached the committee to state that he believes the continuity of having all the retention rules being 4 years will counter any adverse impact of making this change.

Fritz Hayes approached the committee to state that increasing record retention rules to 4 year will not have any adverse impact.

Joel Parnes stated he thinks certain scenarios will have a hard time accommodating the new retention rules. Mr. Parnes gave the example of a facility that processes 2,000 prescriptions a day.

Mr. Philip responded to Mr. Parnes by stating a facility that processes 2,000 prescriptions wouldn't be considered a small business.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, that there is not an adverse economic impact on small business. Motion carried

Motion: by Dr. Mesaros, seconded by Mrs. Glass, that the changes will not directly or indirectly increase regulatory costs to any entity including government in excess of \$200,000.00 in aggregate in Florida within one year after the implementation of the rule. Motion carried.

Dr. Mesaros introduced Rule 64B16-28.101 as the next agenda item.

Mr. Brian Kahan and Mr. Martin Dix approached the committee to discuss suggested rule language for this particular rule. Mr. Kahan and Mr. Dix spoke about the possibility of advanced notice for pharmacies prior to an inspection.

Mrs. Glass expressed her concerns with an advanced notice.

Dr. Weizer stated how giving a pharmacy advanced notice gives them ability to cover up mistakes and defeats the purpose of having surprise inspections.

Dr. Mikhael reiterated the comments made by Dr. Weizer that the surprise element must be present. Dr. Mikhael then went on to state not all inspections need to be surprise inspections. He proposed possibly the first 2 inspections being surprise inspections with the rest having 24 hour notice.

Dr. Fallon stated that he doesn't see the advantage to the advanced notice due to the fact that most records can be corrected overnight.

Mr. Philip stated that he believes the advanced notice should be used as a courtesy but not required by rule.

Dr. Mesaros introduced Rule 64B16-28.450(6)(a)(1) as the next item for discussion.

Dr. Mikhael suggested the addition of language requiring the original prescription to be identified or documented as central fill.

Dr. Mesaros and Ms. Norr tabled the rule with the intention of bringing the rule back at the April rules committee meeting.

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to bring the rule back at the April rules committee meeting. Motion carried.

Motion: by Dr. Weizer, seconded by Mrs. Glass, that there is no difference from the last vote taken on this rule. Motion carried.

Dr. Mesaros rules 64B16-26.2032 & 64B16-26.2033 regarding pharmacy intern licenses as the next agenda item.

Dr. Weizer expressed concern of over the fact that pharmacy intern licenses do not expire.

Dr. Weizer then requested Board staff run a report to find out how long current pharmacy interns have held licensure.

Dr. Mesaros requested Ms. Norr do some research of what as a committee we will be able to do legally in regards to rulemaking for this issue.

Ms. Norr stated she will bring proposed language to the next meeting.

Dr. Mesaros introduced Rule 64B16-28.203 as the final item on the agenda.

Dr. Weizer stated she believes this rule supplies a loophole to transfer stock as a way to substitute for the formal application process of opening a pharmacy.

Mrs. Glass proposed language that states change of ownership by way of stock option also requires the submission of new application.

Mr. Bayo approached the committee to discuss the issue. Mr. Bayo pointed out there is an exemption in Section 499 that should be referenced in creating rule language for this matter.

Mr. Kahan approached the committee to point out the fact that when there is a change of permit, the DEA licenses for the selling entity no longer exists.

Dr. Mesaros requested the committee or members of the audience come forward with any rules that they believe need to be looked at or discussed at the next Rules committee meeting in April.

Dr. Fallon requested clarification on what was considered the “front” of a prescription.

Bob Parrado approached the Board to present the idea of changing “on the face of the prescription” to “on the prescription record.”

Motion: by Dr. Mesaros, seconded by Dr. Weizer, to adjourn at 11:00AM. Motion carried.