AGENDA
DEPARTMENT OF HEALTH
BOARD OF PHARMACY
STERILE COMPOUNDING COMMITTEE

December 10, 2015
Immediately following Rules Committee meeting

Residence Inn Tallahassee Universities at The Capitol
600 W. Gaines St.
Tallahassee, Florida

Committee Members:
Michele Weizer, Pharm D, Chair
Mark Mikhael, PharmD
Debra Glass, BPharm

Board Counsel:
David Flynn, Assistant Attorney General

Board Staff:
Allison Dudley, Executive Director
Emily Roach, Program Operations Administrator
Amber Greene, Regulatory Specialist III

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

Chair Michele Weizer called the meeting to order at 4:11 p.m., Thursday, Dec. 11, 2015.

1. Update on FDA's 797 Revisions – Michele Weizer

Dr. Weizer gave highlights of the FDA's call-in on the USP 797 revisions. See the audio for full comments:
http://ww10.doh.state.fl.us/pub/bop/Audio/Compounding%20Rules%20Committee/2015/Sterile_Compounding_Committee_12102015/

The following is a summary:

- 797 will no longer delineate low-, medium- and high-risk compounding, but will identify Category 1 and Category 2 types.
- Hazardous materials has been moved to USP 800.
- Batching requirements are changing.
- Category 2 will included extended guidelines for BUD.

Dr. Weizer said the Board's inspection form has been in use for less than a year and needs more data before being changed again. She said she anticipated it would take some time before the Board would be ready to implement 797 revisions. She did note that questions during the October 797 workshop regarding nail polish, earrings and facial hair had been clarified: They are not allowed.

Mark Mikhael asked about the effects of pharmacies shipping into the state if the new USP guidelines say 45 days for BUD, which differ from requirements in Florida. Board counsel David Flynn said Florida regulatory language indicates six months.

2. Presentations on rapid sterility testing technologies

a. BioMérieux and Eagle Analytical Services

BioMerieux Business Development Manager Phil Robertson made a presentation to the committee. For full content, refer to the audio: http://ww10.doh.state.fl.us/pub/bop/Audio/Compounding%20Rules%20Committee/2015/Sterile_Compounding_Committee_12102015/

J.D. Willey of Eagle Analytical Services and John Voliva, Legislative Relations director for PCCA, supported Mr. Robertson's presentation with information about testing their labs have done with the bioMerieux equipment and protocols.

b. PallChek/Pharmetric Laboratory

David Kazarian of Infuserve America made a presentation to the committee regarding the rapid testing services his lab offers. David Joseph joined him to clarify points. For full content, refer to the audio: http://ww10.doh.state.fl.us/pub/bop/Audio/Compounding%20Rules%20Committee/2015/Sterile_Compounding_Committee_12102015/

Executive Director Allison Dudley asked what the committee wanted to do next. Some conversation included suggestions of having a special committee to review and make recommendations. Mr. Flynn asked that the committee have a microbiologist in the room. Ms. Dudley said a special committee should include experts.

3. 64B16-27.700

Mr. Flynn said he wants to clean up 27.700 and the definition of compounding to put all rules relating to compounding into the same chapter. Also, rules allows non-sterile office use, which is not exempted from the key provisions of 503A, which would make it a new drug. And the

Board needs to preserve the integrity of veterinary compounding until the federal government is able to address that.

4. 64B16-27-797

Mr. Flynn said the rule needs to address BUD and what "authoritative literature" means for the stability aspect.

5. 64B16-28.802

Mr. Flynn said proposed language on the special sterile compounding permits makes it clear what is required for outsourcing facilities within the state of Florida. Clarifies that standalone outsourcing facility must follow cGMP requirements. The facility will continue to have a pharmacy permit, but it will have to comply with cGMP, which was always required.

Ms. Dudley said in-state facilities got a permit from the Board before registering with the FDA. Currently, there is not a separate permit application. Mr. Flynn said the current SSCP application incorporates outsourcing. He said he clarified 28.802 to reflect what already exists in multiple places in state law and rule.

Dr. Mikhael said non-resident permits require an inspection within the past six months that shows compliance.

Motion by Dr. Mikhael to accept the rule language as proposed. Motion carried.

Motion by Dr. Mikhael that there is no impact because the amended language clarifies what is in another rule, and the pharmacies have to be compliant with federal regulations. Motion carried.

6. 64B16-30.002 (taken out of order)

Attorney Ed Bayo asked the committee to look at this rule or another to allow pharmacies to correct minor deficiencies before they become final. He said he would provide suggested language.

Motion by Dr. Mikhael to open the rule for amendment. Motion carried.

7. 64B16-28.905 (proposed)

Mr. Flynn said the rule will be effective Dec. 24 but he needs to open it to fix two "mays" which should be changed to "shalls."

Motion by Dr. Mikhael to open the rule. Motion carried.

Motion by Debra Glass to adjourn at 6:25 p.m. Motion carried.