FLORIDA | Board of Pharmacy

Compounding Committee

Meeting Minutes

August 14, 2017
Embassy Suites Fort Lauderdale
1100 SE 17th Street
Ft Lauderdale, FL 33316
Contact Hotel: 954-315-1326

Michele Weizer, PharmD
Committee Chair

C. Erica White
Executive Director

Monday, August 14, 2017 at 1:00 PM

Call to Order - The meeting was called to order by the Committee Chair, Dr. Weizer, at 1:00 p.m.

Roll Call - Those present during the meeting included the following:

Board Members

Michele Weizer, PharmD, Chair
Debra Glass, BPharm
Mark Mikhael, PharmD
Jeenu Phillip, BPharm

Attorneys

Board Counsel:
David Flynn, Assistant Attorney General
Lawrence Harris, Assistant Attorney General

Board Staff:

C. Erica White, Executive Director
Savada Knight, Regulatory Supervisor
Jessica Hollingsworth, Government Analyst II

1. **Nonresident Sterile Compounding Mandatory Inspections**

   Discussion:

   Mr. Flynn informed the board that they have the authority to require inspections under circumstances other than initial licensure and renewal of licensure if they choose to. He recommended input from the Bureau of Enforcement in moving forward with this. Dr. Mikhael recommended a standard inspection form to bring uniformity to the inspection process. Mr. Flynn informed the board that attaining uniformity would need to be a national discussion.

   Dr. Weizer raised concern with the growing number of recalls and not having an established protocol/process for when they occur. Dr. Mikhael suggested there should be a validation process on shipping products into Florida after recalls. Dr. Weizer agreed and felt an inspection should take place before the product enters the state. Mr. Flynn suggested working with the Bureau of Enforcement on this and further suggested having a report or presentation from Enforcement of the current process for recalls on sterile products at the next committee meeting. Discussion ensued on how the board is notified after a voluntary recall is made. Dr. Mikhael made the point that if the department chooses to punish for voluntary recalls, there may be the unintended consequence of future recalls being buried.

2. **Special Sterile Compounding Permits - Dispensing for Outpatient Use versus Inpatient Use**

   Discussion:

   Dr. Weizer explained the origin on the Special Parenteral/Enteral Permit in that they were needed for hospitals to send patients home with antibiotics. She further clarified the appropriate permit

depending on the circumstance of the patient for permit holders and inspectors:

- While a patient receives therapy on site, a Special P & E is not needed.
- If a patient is sent home with therapy, a special P & E permit is needed.

Dr. Mikhael requested further clarification on the appropriate permit for starting in the hospital and then going home, which Dr. Weizer answered.

3. Assignment of Prescription Department Managers or Consultant Pharmacist of Record for Special Sterile Compounding Permits

Discussion:

Dr. Weizer informed the board that this topic also serves as clarification due to recent confusion noticed. She explained the following for the record:

- In an institution, a Consultant of Record can be a Prescription Department Manager of SSCP, but does not have to be.
- A consultant license cannot be used in a retail setting.
- A Prescription Department Manager must use their PS license in a retail setting.
- A PU license may only serve as the SSCP in an institutional setting.
- The SSCP permit must be associated with a PS license in a community setting.

Mr. Flynn discussed the issue of processors approving SSCP applications that list a consultant pharmacist in a community pharmacy setting. He advised for staff review and remove Consultant Pharmacists from all SSCPs for community pharmacies because legal action cannot be taken if they appear on probable cause. He further suggested for this to be clarified in rule or in the SSCP application, which he and board staff will review along with all other Pharmacy applications for necessary updates. Dr. Weizer added the clarification that a SSCP cannot exist alone, but must be added to another existing permit.

4. Old Business

A. Rule 64B16-27.797, F.A.C.

Dr. Weizer reminded the board that this rule was opened for development at the last meeting, which was last updated in 2013, and acknowledged that the board has been asked multiple times when the rule will be updated. She observed that Florida has a compliance rate close to 80% for current compounders in the state, which is a vast improvement from 2012 when many weren't educated on compounding. She stated that because Florida has better compliance and education, the board is not yet ready to update this rule. However, the board acknowledges the 2013 version as a minimum requirement and will not fault anyone for achieving a higher standard. She welcomed the board and the public to address items not clear enough in the 2013 standard at which no one expressed issues.

A motion was made by Mikhael to close Rule 64B16-27.797, F.A.C.. Motion passed unanimously.

B. Rule 64B16-28.802, F.A.C.

Mr. Flynn referred the board to the letter from JAPC in the agenda and explained the requested changes, which he agreed with.

A motion was made by Mikhael to approve the comments reflected in the JAPC letter. Motion passed unanimously.

A motion was made by Weizer to acknowledge that the proposed amendments would not have an adverse effect on small businesses. Motion passed unanimously. A motion

was made by Philip to acknowledge that the proposed amendments would not likely directly or indirectly increase regulatory costs to any entity including government in excess of $200,000 in the aggregate in Florida within one year after the implementation of the rule. Motion passed unanimously. A motion was made by Mikhael to acknowledge that any section of this rule is not designated as a minor violation. Motion passed unanimously.

5. New Business

See agenda items 1 – 3.

6. Public Comment

There was no discussion from committee members.

Donn W. Davis, PS 37801, asked for clarification on 7-day stability items in relation to the 48-hour rule for transport and storage, specifically if it is a violation of the compounding inspection form. Dr. Weizer clarified that the rule only refers to the item prior to hanging on the patient and not during.

7. Adjournment

The meeting adjourned at 2:14pm