

**BOARD OF PHARMACY
COMPOUNDING COMMITTEE
DRAFT MINUTES
February 4, 2020
Sheraton Orlando North
600 N Lake Destiny Road
Maitland, FL 32751
(407) 660-9000**

Participants in this public meeting should be aware that these proceedings are being recorded
and that an audio file of the meeting will be posted to the board's website.

I. CALL TO ORDER/ROLL CALL

Dr. Rivera called the meeting to order at 1:30 p.m. ET.

MEMBERS PRESENT

Blanca Rivera, PharmD, MBA, Chair
Mark Mikhael, PharmD
Rich Montgomery, BPharm, MBA
David Wright, BPharm
Jonathan Hickman, PharmD
Jeenu Philip, BPharm

STAFF PRESENT

Jennifer Wenhold, Bureau Chief
Traci Zeh, Program Administrator

BOARD COUNSEL

David Flynn, Esq.
Senior Assistant Attorney General
Christopher Dierlam
Assistant Attorney General

COURT REPORTER

Cindy Green
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II. DISCUSSION ITEMS

a. USP 800

Dr. Rivera addressed the Committee and the public regarding USP 800 and the update regarding the USP Compounding Standards. She opened the floor to the Committee for discussion.

Mr. Wright addressed the Committee regarding the scope of USP 800 and conveyed that it does not only affect compounding pharmacies, this also affects community pharmacies.

Dr. Rivera indicated there are twenty-seven states reviewing and considering implementing USP 800.

Dr. Mikhael addressed the Committee with his concerns and the additional regulation implementing this Chapter would cause.

Mr. Philip agreed with Dr. Mikhael and read to the Committee “The Scope and Intended Applicability” that was published by USP in the Context of Implementation.

David Joseph addressed the Committee regarding compounding and the importance of protecting not only the patient receiving the medication, but the Pharmacists compounding and handling the hazardous drugs.

Mr. Flynn, Board Counsel, addressed the Committee and conveyed that based on the discussion, before discussing the possibility of implementation, he recommends outlining what is not already being done within the guidelines in order to avoid duplicative regulation.

Andrea Ledford, Pharmacist, addressed the Committee.

Mr. Montgomery addressed the Committee and recommended dividing up USP 800 by sections per Committee Member to allow time to research and answer the outlined OFFAR questions regarding rule making, costs affects, and the possibility of duplicative regulation and bring back recommendations at a future meeting.

After discussion, the Committee agreed to divide the sections as followed:

- Mr. Wright – Sections 2, 3, and 4
- Dr. Mikhael – Sections 5, 6, and 7
- Mr. Montgomery – Sections 8, 9, 10, 11, and 12
- Dr. Hickman – Sections 13, 14, and 15
- Dr. Rivera – Sections 16 and 17

The Committee agreed to have a Compounding Committee meeting in April and will review sections 2-7, a meeting in June to review sections 8-17, and a meeting in August for a full discussion.

b. USP 800 Inspections

Robert Difiore, Investigation Services Manager, addressed the Committee regarding inspections.

Mr. Flynn addressed the Committee and indicated if a Non-Resident inspection is received the inspection must meet Florida’s requirements to be accepted.

c. Informational Materials

- i. NABP Launching New Compounding Pharmacy Accreditation Program
- ii. Certification Information

The Committee discussed the BPS Certification regarding Compounded Sterile Preparations.

Motion: by Dr. Rivera to recommend the program for to be completed by the DOH Inspectors should this program be available to them

Second: by Dr. Mikhael

Vote: Unanimous

III. PUBLIC COMMENT

No public comments.

IV. ADJOURNMENT

There being no further business, the meeting adjourned at 3:05 p.m.