BOARD OF PHARMACY
COMPOUNDING COMMITTEE MEETING
October 13, 2021
1:00 p.m. ET
Hyatt Regency Orlando International Airport
9300 Jeff Fuqua Boulevard
Orlando, FL 32827
407-825-1234

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. Segovia called the Compounding Committee meeting to order at 1:00 p.m. ET.

MEMBERS PRESENT
Dorinda Segovia, PharmD, MBA, Chair
David Wright, BPharm
Patty Ghazvini, PharmD, BCGP
Maja Gift, BPharm, MHA, CPh

STAFF PRESENT
Jessica Sapp, Executive Director
Traci Zeh, Program Administrator

BOARD COUNSEL
David Flynn, Esq.
Senior Assistant Attorney General

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II. DISCUSSION

a. USP Compounding Standards
   i. 795 Pharmaceutical Compounding – Nonsterile Preparations
   ii. 797 Pharmaceutical Compounding – Sterile Preparations

Dr. Segovia opened the Committee discussion with USP 795 and 797.

Mr. Wright addressed the Committee regarding the flavoring of medication.

Chad Backer, FlavoRx, addressed the Committee, indicating other states have adopted language to specify that flavoring is not a part of compounding.

The conversation ensued with the Committee reviewing the proposed revisions of USP 795 and 797.

Mr. Philip addressed the Committee regarding the definition of simple compounding stating simple compounding takes place in pharmacies without additional regulations and suggested that language be reintroduced to avoid access barriers to patients.

David Joseph, Rph, addressed the Committee.

Lillete Smith, Rph, addressed the Committee and expressed concerns regarding the change to the definition of immediate use and emergency use.

Edwin Bayo, Esq., addressed the Committee

After discussion it was suggested the Committee review the revisions in comparison to the current USP 795 and 795 and submit comments to be reviewed at the next Compounding Committee meeting in December.

b. FDA Compounding Guidance

Dr. Segovia provided an overview of the FDA compounding guidance

c. 64B16-27.797, F.A.C., The Standards of Practice for Compounding Sterile Products
d. 64B16-28.802, F.A.C., Special Sterile Compounding Permits for Pharmacies and Outsourcing Facilities
e. 64B16-28.820, F.A.C., Sterile Products and Special Parenteral/Enteral Compounding
f. 64B16-28.860, F.A.C., Special Pharmacy – Parenteral/Enteral Extended Scope Permit

The Committee reviewed the provided rule language and discussed the possibilities of streamlining the permitting process through application and rule amendments. This will be a future discussion once the Board begins the application revision process.

III. ADJOURNMENT

There being no further business the meeting adjourned at 5:00 p.m. ET.