**BOARD OF PHARMACY**
**COMPOUNDING COMMITTEE MEETING**
**MINUTES DRAFT**
**December 15, 2021**
**1:00 p.m. ET**
**Hyatt Regency Grand Cypress**
**One Grand Cypress Blvd**
**Orlando, FL 32836**
**407-239-1234**

**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

**MEMBERS ABSENT**
Maja Gift, BPharm, MHA, CPh

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

**BOARD COUNSEL**
David Flynn, Esq.
Senior Assistant Attorney General
Christopher Dierlam, Esq.
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.

During the October meeting the Committee determined the members would review the revisions in comparison with the current USP 795 and 797. Those comparisons were provided for review.

The Committee reviewed 797 by section to review the changes.

Dr. Segovia addressed the Committee regarding Sections 1 and 1.4 Scope, as it relates to the definition of sterile compounding.

Jeff Bush, FSHP addressed the Committee regarding the definition of sterile compounding.

Mr. Flynn addressed the Committee and conveyed the definition of sterile compounding matches the federal definition.

Carmen Zaldivar addressed the Committee.

The Committee agreed to make comments to USP on Section 1 and 1.4 as it is unclear of the definition of sterile compounding.

Dr. Segovia addressed the Committee regarding Emergency for Immediate Use in agreeance with the proposed change of eliminating “only for emergency situations”.

Dr. Michelle Weizer addressed the Committee in agreeance with the change as it strengthens patient safety.

Conversation ensured regarding the new definition of the Beyond Use Date (BUD).

Mr. Flynn conveyed that if the Committee’s comments are not addressed with USP, they can be addressed by way of rulemaking.

Dr. Ghazvini addressed the Committee and provided an overview of Section 2, Personnel Training and Evaluation, of the proposed changes.

David Joseph addressed the committee regarding the original version of the BUD definition.

There were no comments to consider for Sections 3-6.

Dr. Weizer addressed the Committee regarding Section 7, Cleaning and Disinfecting requirements. Conversation ensued the cleaning and disinfection requirements.

There were no comments to consider for Sections 8-11.

Tyler Harrold, practicing pharmacists at a compounding pharmacy, addressed the committee regarding the limitation of testing outlined in Section 12, Release Inspection. The conversation ensued regarding the limitation of batch testing.

Mr. Wright addressed the Committee regarding Section 13, Labeling, and conveyed the Board should move forward with reviewing the labeling requirements and streamline the current rules.

Dr. Segovia addressed the Committee regarding Section 14, Establishing Beyond Use Dates and suggested the Committee comment to the USP on the intention of the definition.

There were no comments to consider for Sections 15-21.

The Committee reviewed Chapter 795 by each section to review the changes.

There were no comments to consider for Sections 1-4.

The Committee discussed what the process would be to adopt USP 795 within the current Florida pharmacy rules.

There were no comments to consider for Sections 5-8.

The Committee discussed Section 9, Labeling.

Juan Lopez, Pharmacists, addressed the Committee regarding Section 10, Establishing Beyond Use Dates.

There were no comments to consider for Sections 11-15.

Robert Difiore, Pharmaceutical Program Manager, addressed the Committee and suggested the Department of Health Pharmacy Inspectors be a part of the Committee discussions when considering adoption of Chapter 795.

The Committee concluded their review of the proposed changes of 795 and 797.

Motion: Mr. Wright to delegate Dr. Segovia to draft the comments to be submitted to USP.
Second: by Dr. Ghazvini
Vote: Unanimous

Mr. Flynn explained the process of the submission of the comments.

Mr. Bayo addressed the Committee regarding compounding of Human Chorionic Gonadotropin (HCG) as it is deemed a biologic product.

## III. ADJOURNMENT

There being no further business the meeting adjourned at 4:30 p.m. ET.