BOARD OF PHARMACY
COMPOUNDING COMMITTEE MEETING
December 14, 2022
DRAFT MINUTES
9:00 a.m. ET
Rosen Plaza Hotel
9700 International Drive
Orlando, FL 32819
(407) 996-9700

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

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

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BOARD COUNSEL
David Flynn, Esq.
Senior Assistant Attorney General
Kara Aikens, Esq.
Assistant Attorney General

II. DISCUSSION

a. FDA Guidance on Biologics

Dr. Segovia provided an overview of the guidance provided by the FDA.

She indicated that desiccated thyroid extract (DTE) is considered a biologic product by the FDA. She encouraged all pharmacists to follow the guidance if preparing the product.

David Joseph addressed the Committee regarding the compliance and enforcement actions and indicated the FDA is not currently taking action.

b. USP Compounding General Chapters
   i. USP 795

On November 1, 2022, USP published updates to the USP General Chapters on compounding nonsterile and sterile preparations.

Dr. Segovia opened the discussion regarding the changes to the USP General Chapters.

Mr. Wright conveyed that the Board should consider adopting USP 795; however, would need to consider the best course of action and what the economic impact adoption would make.

After discussion the Committee determined to prioritize the chapters. The Committee will focus on USP 797, followed by USP 800, and conclude with USP 795.

Mr. Flynn will research federal law and regulatory options for implementing USP 795 and ways to educate compounders as the Committee is revising rule language.

ii. USP 797

Dr. Segovia provided an overview of the revised USP 797 standards and summarized the commentary published by USP.

Mr. Flynn suggested the Committee set up a cross walk of current regulations with the new standards, request comments from stakeholders, and what impacts the new standards will have. He indicated pharmacy inspectors will have a transition process and all current rules should be followed until new Florida rules are implemented.

The Committee ensued conversations regarding the best methods when implementing the new standards which included, The Joint Commission (JAHCO) requirements, OSHA requirements, and requirements for maintaining hazardous drugs.

iii. USP 800

Richard Montgomery addressed the Committee conveying that USP 797 and 800 are intertwined and recommended implementing together. He expressed many hospitals are moving towards the new USP 800 standards.

Andrea Ledford, Oncology Pharmacist, addressed the Committee expressing implementation of these standards will not be fast due to several issues including gaining access to the new chapters, the required buildouts, and construction supply.

Dr. Segovia suggested pulling out certain parts of the Chapter during implementation so the process could be completed in sections.

Patty Keenly, Member of USP Committee, addressed the Committee indicating that the USP 800 standards are minimum standards in place to protect healthcare workers. She expressed that implementing the chapters in sections would not be appropriate, putting emphasis on the Beyond Use Date's (BUD's).

Mr. Flynn explained the Statement of Estimated Regulatory Costs (SERC) process to incorporate requirements that have cost impacts as JAHCO expects to have to incorporate the new standards by January 2024.

David Joseph expressed to the Committee regarding reaching out to independent pharmacies regarding compliance and the economic impact.

After discussion the Committee moved forward with forming a Sterile Compounding Committee to include the current members of the Compounding Committee and the following additional advisors:

Richard Montgomery
Patty Keenly
Gillian Staikos
David Joseph

The Sterile Compounding Committee will hold a Workshop on February 8, 2023, to continue discussing the implementation of USP 797 and any updates in USP 800 that relate to 797. The time and location of the meeting can be found on the board's website, https://floridaspharmacy.gov/meeting-information/, once finalized.

iv. USP 825

Dr. Segovia provided an overview of USP 825 and conveyed that addressing USP 797 will also address the changes to USP 825.

Ms. Keenly expressed the nuclear pharmacists are currently implementing these standards.

III. ADDENDUM

The following item was added to the agenda by the Committee Chair for good cause shown.

a. Hybrid Pharma, LLC.

Individuals from Hybrid Pharma, LLC., addressed the Committee.

After discussion, no action was taken by the Committee.

Mr. Montgomery addressed the Committee regarding 64B16-27.700, F.A.C., Definition of Compounding. After the discussion the Committee moved to open the rule for development for future amendments.

IV. ADJOURNMENT

There being no further discussion the committee adjourned at 12:00 p.m. ET.