BOARD OF PHARMACY
STERILE COMPOUNDING SUBCOMMITTEE
DRAFT MINUTES
February 8, 2023
9:00 a.m. ET
Embassy Suites by Hilton Orlando Lake Buena Vista South
4955 Kyngs Heath Road
Kissimmee, FL 34746
(407) 597-4000

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
Dorinda Segovia, PharmD, MBA, Chair
Patty Ghazvini, PharmD, BCGP
Maja Gift, BPharm, MHA, CPh

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

SUBCOMMITTEE MEMBERS
Richard Montgomery, BPharm, MBA
Mark Mikhael, PharmD
Gillian Staikos, RPh, CISCI
David Joseph, BPharm
Michelle Weizer, PharmD, BCPS
Dianeysis H. Avendano Pharm.D., CPh., BCPS, BCSCP

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

ABSENT MEMBERS:
Patricia Kienle, RPh, MPA, FASHP

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II. DISCUSSION

a. USP 797 Pharmaceutical Compounding – Sterile Preparations

Dr. Segovia opened the meeting and summarized the purpose of the Sterile Compounding Subcommittee. She indicated the Subcommittee will be reviewing the updates to USP Chapter 797 and gather concerns and any implementation roadblocks that could occur.

Prior to the meeting, Dr. Segovia assigned each section of USP 797 to a designated subcommittee member. The Subcommittee reviewed each section and allowed public comments.

Dr. Segovia provided an overview of the changes in Section 1, Introduction and Scope.

No comments from the Subcommittee or public were received.

Dr. Ghazvini provided an overview of the changes in Section 2, Personnel Training & Evaluation.

Dr. Ghazvini expressed that the training increased from every twelve months to every three to six months depending on the category of CSP's (compounding sterile preparations).

Dr. Mikhael expressed this increase in training should be at no increased cost as most compounding pharmacies are already implementing this training requirement.

Donte Cazironia addressed the Subcommittee regarding cost of additional training.

Ms. Gift provided an overview of the changes to Section 3, Personal Hygiene and Garbing.

She expressed section 3 is very similar except for no earbuds, electronic devices, no polish or artificial nails, and no hand dryers permitted. Hand hygiene depends on the placement of the sink. Full garbing is required and cannot be reused for category 3.

Steven Propper addressed the Subcommittee regarding garbing and possible inclusion of allowances and exceptions addressed in Florida rules.

Jason Kimble addressed the Subcommittee regarding media fills.

Mr. Flynn explained to the Subcommittee and members of the public that the USP 797 are standards put in place, not a requirement.

Dr. Mikhael expressed that 85% of contamination is touch contamination; therefore, personal hygiene is important.

Mr. Montgomery provided an overview of the changes to Section 4, Facilities and Engineering Controls.

Andrea Ledford addressed the Subcommittee regarding institutional pharmacies and HVAC systems and the impact the ISO standards for air quality could have on facilities. She encouraged the Board to allow a grandfather period for health systems to adapt to the updates.

Dr. Hickman inquired if these updates will be built into the JAHCO requirements.

Mr. Flynn explained not all facilities are required to be JAHCO accredited, and the importance of the Subcommittee was to focus on the requirements. Health Systems can apply to be JAHCO accredited at their own discretion.

Dr. Mikhael explained the process to become JAHCO accredited and conveyed that the facility would be required to comply with the USP standards.

Dr. Mesaros addressed the Subcommittee regarding facility build outs and the potential supply chain issues and encouraged the public to communicate those issues to the

Subcommittee.

Dr. Staikos provided an overview of the changes to Section 5, Certification and Recertification.

Dr. Avendano inquired how often should the certification of the airflow occur, and how the certification captured.

Dr. Staikos explained facilities indicate the certification in their standard operating procedures (SOP's).

The conversation ensued regarding airborne and particle sampling.

Ms. Staikos provided an overview of the changes in Section 6, Microbiological Air and Surface Sampling.

Elizabeth Jimmerson addressed the Subcommittee regarding identifying organisms and the Board's expectations if living organisms are identified.

Mr. Flynn addressed the public and reiterated the purpose of the Subcommittee today was to review and address concerns the updates to USP could have on Health Systems. The comments made today are not recommendations of the Board. The Full Board will address and make recommendations if and when the updates are adopted.

Dr. Avendano provided an overview of the changes in Section 7, Cleaning, Disinfecting, and applying sporicidal disinfectants and streile 70% IPA.

Jene Valdez addressed the Subcommittee regarding sterile cleaning solutions and the cost of the supply.

Sally Blair, Nuclear Pharmacist, addressed the Subcommittee regarding radioactive contamination and how this would affect USP 825. She reiterated the hardship of nuclear pharmacists complying with USP 797 as radioactive materials cannot be sterilized.

Mr. Flynn suggested identifying what the needs are based on this specialized area and have future discussions specific to USP 825.

Dr. Mikhael provided an overview of the changes in Section 8, Introducing Items to the SEC and PEC.

The conversation ensued regarding the contact time of isopropyl alcohol.

Yuan Lian addressed the Subcommittee and conveying alcohol is no longer considered a disinfectant.

Mr. Montgomery expressed the CDC clarifies disinfectant and encourages individuals to use the CDC guidance on sterilization.

Mr. Joseph provided an overview of the changes in Section 9, Equipment Supplies and Components.

No public comments received.

Dr. Weizer provided an overview of the changes in Section 10, Sterilization and Depyrogenation.

She explained there were no prominent changes, as the updates provide more guidance and prescriptive.

No public comments received.

Dr. Ghazvini provided an overview of the changes in Section 11, Master Formulation and Compounding Records.

She reiterated the updates clarify formulation and compounding processes. Specifically designating a person responsible for documentation processes.

No public comments received.

Ms. Gift provided an overview of the changes in Section 12, Release Inspection and Testing.

The Subcommittee discussed the quantity of sterility testing.

Mr. Montgomery provided an overview of the changes in Section 13, Labeling.

No public comments received.

Ms. Staikos provided an overview of the changes in Section 14, Establishing Beyond-Use Dates.

She explained that a beyond-use date is not an expiration date and reiterated this was the largest revision to USP 797; however, the revisions were clearly stated and provide clarification.

The conversation ensued regarding the beyond-use date.

Mark Wilson addressed the Committee regarding release testing for category 3 CSP's.

Dr. Avendano provided an overview of the changes in Section 15, Use of Conventionally Manufactured Products as Components.

No public comments received.

Dr. Mikhael provided an overview of the changes in Section 16, Use of CSP as Components.

Ashlee Maratta addressed the Subcommittee regarding the storage CSP's.

Mr. Joseph provided an overview of the changes in Section 17, SOP's (Standard Operating Procedures).

No public comments received.

Dr. Weizer provided an overview of the changes in Section 18, Quality Assurance and Quality Control.

She reiterated this section is a lot more prescriptive.

No public comments received.

Dr. Ghazvini provided an overview of the changes in Section 19, Handling, Storage, Packaging, Shipping, and Transport.

No public comments received.

Ms. Gift provided an overview of the changes in Section 20, Documentation.

No public comments received.

Mr. Montgomery an overview of the changes in Section 21, Compounding Allergenic Extracts.

Nisha Mathews addressed the Subcommittee regarding compounding allergenic extracts.

Dr. Segovia opened discussion regarding USP 800, Hazardous Drugs – Handling in Healthcare Settings. She expressed curiosity in what the concerns are for Florida with adopting USP 797 in relation to USP 800.

Mr. Montgomery conveyed that USP 797 is inclusive to USP 800; therefore, if you are adopting USP 797 you must consider USP 800.

Mr. Flynn addressed the Subcommittee regarding the regulatory cost procedures for adopting USP 800. The Subcommittee would need to complete assessments on what the cost impacts would be to health systems. Implementation could take legislative changes.

Dr. Segovia requested surveying facilities to determine the impact of USP 800.

Andrea Ledford, Oncology Pharmacist, addressed the Subcommittee regarding the concern in cost of storage of hazardous drugs in an exhaust.

Mr. Flynn confirmed he will outline the current rules, look at exceptions, and review the nuclear section (USP 825) to be presented at the April meeting.

The next Subcommittee will be held April 12, 2023.

III. ADJOURNMENT

There being no further business, the meeting adjourned at 2:35 p.m.