



california pharmacists association

March 21, 2023

Maria Serpa, Chair Enforcement and Compounding Committee
California Board of Pharmacy
2720 Gateway Oaks Dr, Ste 100
Sacramento, CA 95833

Re: Proposed Changes to Regulations Related to Pharmaceutical Compounding of Sterile Preparations

Dear Chair Serpa,

The California Pharmacists Association (CPhA) appreciates the discussion and work of the Enforcement and Compounding Committee Meeting in relation to the regulations related to pharmaceutical compounding of sterile preparations.

CPhA writes to encourage the Board of Pharmacy to provide direct communication to pharmacies of their interpretations of proposed regulation and enforcement expectations as it relates to compounded sterile preparations (CSP). Furthermore, CPhA highlights that the Board's purpose of protecting California consumers also includes ensuring timely and appropriate access to safely compounded sterile preparations and the development of regulations based on USP Chapters 1000 and above which would establish them as a regulatory requirement. These USP Chapters are not the actual standards for enforcement, but are intended to be informational.

We also request that the Board inspectors allow pharmacies the appropriate time to ensure compliance of the USP official date of November 1, 2023. This will allow pharmacists the necessary time to implement the updated USP 797 guidelines in a safe and effective manner to ensure the continued care and safety of our communities.

In regards to the proposed changes to the regulations related to pharmaceutical compounding of sterile products, CPhA would like to provide some feedback for consideration for the following sections:

- 1) Section 1736 (a) "Certificate of Analysis" as defined requires the COA to be produced by the manufacturer, however there are instances that products may be obtained from wholesale suppliers and the original COA may not be available.

*Recommendation: "Certificate of Analysis" (COA) means a document produced by the manufacturer **or wholesaler** that certifies...*

- 2) Section 1736 (d) "Essentially a copy" as proposed includes an addition of the word "comparable" may be ambiguous and cause unintended interpretations and is not consistent with the current FDA definition. For example, different dosage types may be considered comparable or same class of drugs may be considered comparable.

Recommendation: Remove the term "comparable" from Section 1736 (d)

- 3) Section 1736.2 Personnel Training and Evaluation (d) may potentially reduce access to CSP as a pharmacist providing direct oversight may be ineligible to supervise if they were to fail an aseptic manipulation evaluation even if they do not regularly compound themselves.

Recommendation: "...who fail any aspect of aseptic manipulation evaluation shall not be involved in compounding **or oversight of the preparation** of a CSP

- 4) Section 1736.3 Personnel Hygiene and Garbing (b) "...shall not allow personnel to enter the compounding area with non-removable piercings..." in 797 FAQ #65 allows for an adhesive bandage or head cover to be used to cover non-removable jewelry.

Recommendation: Either modifying language to "**visible** non-removable piercings" or allowance of adhesive bandages to cover non-removable piercings

- 5) Section 1736.6 (b) "...Professional judgement shall be used to determine the appropriate action.." the professional judgment should be interpreted as that of the pharmacist involved with the CSP

Recommendation: "...the professional judgment **of the pharmacist supervising** shall be used to determine appropriate action..."

- 6) Section 1736.16 USE OF CSPS AS COMPONENTS – "...provisions of this article including Category 1, Category 2, and Category 3" to clarify that components cannot meet all three categories

Recommendation: "...provisions of this article including Category 1, Category 2, **and or** Category 3."

- 7) Typo of "CNSP" in Sections 1736.1 (c) and 1736.9 (c) should read **CSP**

We appreciate the opportunity to comment and provide feedback to the Board on ensuring patients in the state continue to receive optimal pharmacists delivered care. Should you have any questions about this recommendation, please feel free to contact me at rvidya@cpha.com.

Founded in 1869, the California Pharmacists Association (CPhA) is the largest statewide association representing the pharmacy profession in all practice settings. Our mission is to advance the practice of pharmacy for the promotion of health.

Thank you for your consideration.

Sincerely,



Rajan Vaidya, PharmD
Vice President, Practice & Professional Development