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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor



To: Board Members

Subject: Discussion and Consideration of Draft Proposed Policy Statement Related to Implementation of USP General Chapters 795 Pharmaceutical Compounding – Nonsterile Preparations; 797 Pharmaceutical Compounding – Sterile Preparations; 800 Hazardous Drugs – Handling in Healthcare Settings; and 825 radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging.

Background

Following completions of revisions to USP Compounding General Chapters 795 and 797, USP announced that the USP Compounding Expert Committee voted to extend the date on which the chapters become official to November 1, 2023, to allow for increased flexibility and engagement for adoption. With this extension the official date, Chapter 800 and Chapter 825 were also updated to November 1, 2023.

Following publication of the revised Chapters 795 and 797, and new General Chapters 800 and 825, the Enforcement Compounding Committee convened several public meetings to consider the Board's regulations and determine what if any changes were necessary to implement, clarify, or make more specific requirements related to the respective chapters.

Summary of Enforcement and Compounding Committee Discussion and Action

During the July 18, 2023, Enforcement and Compounding Committee Meeting, members considered a draft statement intended to convey to stakeholders, the Board's policy related to licensees transitioning to the updated USP General Chapters and actions under consideration by the Board.

Members noted support for the policy statement and recommended revision to the policy statement to include the specific USP chapters covered in the policy statement.

Committee Recommendation: Recommend approval of the proposed policy statement with revisions to include the specific USP General Chapters.

Following this memo is a copy of the revised draft statement.

Draft Compounding Policy Statement

In light of the November 1, 2023, compendial date for several USP General Chapters, included General Chapter 795 Pharmaceutical Compounding – Nonsterile Preparations, 797 Pharmaceutical Compounding – Sterile Preparations, 800 Hazardous Drugs – Handling in Healthcare Settings and 825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging, the California State Board of Pharmacy (Board) wishes to update its stakeholders on its policy related to licensees transitioning to the updated USP General Chapters as well as actions under consideration by the Board.

There are several provisions of state and federal law governing the practice of pharmacy. Most notably related to compounding are provisions in the Federal Food, Drug and Cosmetic Act including exemptions provided under Section 503A; California Sherman Food, Drug, and Cosmetic Act; and several provisions within the Business and Professions Code including Sections 4126.8 and 4342.

As required by law, the Board has undertaken a review of its compounding regulations and identified changes necessary to clarify or make more specific requirements of Federal Law and USP General Chapters. These efforts resulted in the Board voting, as part of its April 2023 Board Meeting, to promulgate new regulations that are in addition to USP Standards. Additional information is available [here](#). The effective date of the newly updated state regulations is yet to be determined.

During this intervening period, the Board encourages licensees to begin transitioning to the new standards established in USP to ensure compliance with state and federal law. It is the Board's expectation that as compounding practices transition to new requirements, including provisions related to establishing beyond use dates (BUDs), that standard operating procedures must be updated and staff appropriately trained prior to implementing new practices and BUDs.