

Compounding Policy Statement

In light of the November 1, 2023, compendial date for several USP General Chapters, including 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.

Approved September 12, 2023