

## **Guidance Regarding Proposed Revisions to USP General Chapters 795 and 797**

In light of the September 1, 2021 release by USP of proposed updates to USP General Chapters <795> and <797>, the California State Board of Pharmacy (Board) wishes to update its stakeholders on the anticipated next steps the Board will be taking and also remind stakeholders about the current status of legal requirements for pharmacies compounding drug preparations. It is the Board's understanding that USP published proposed revisions to USP General Chapter <795> Pharmaceutical Compounding – Nonsterile Preparations and General Chapter <797> Pharmaceutical Compounding – Sterile Preparations for public comment. It is the Board's understanding that comments may be submitted on or before January 31, 2022. Further, USP will host virtual Compounding Open Forum Series in January 2022.

The Board understands that based on the appeals to the 2019 proposed revisions to Chapters <795> and <797>, further changes were made to these proposed chapters. Accordingly, the current Chapters <795> (last revised in 2014) and <797> (last revised in 2008) remain the official versions of USP standards. In addition, all licensees must adhere to all relevant sections of Pharmacy Law and regulations, including but not limited to the Board's current regulations – title 16, California Code of Regulations, section 1735 et. Seq (Article 4.5, Compounding); section 1751 et. Seq. (Article 7, Sterile Compounding); and section 1708.3 to section 1708.5 (related to radioactive drugs) – and Business and Professions Code section 4126.8 and other relevant state and federal provisions.

It is the Board's understanding that USP is not offering any additional changes to Chapter <800> or Chapter <825>. Because Chapter <800> and Chapter <825> are not referenced in the current versions of Chapters <795> and <797>, Chapters <800> and <825> appear informational and not compendially applicable (or a required standard under USP) until the amendments in Chapters <795> and <797> are finalized. Like USP, the Board encourages utilization of amended Chapter <800> in the interest of advancing public health before it becomes a required USP standard by USP adoption of revised Chapters <795> and <797>. States and other regulators with jurisdiction, also may incorporate USP chapters that are not compendially applicable (required USP standards) into their own statutes or regulations, or "through other steps in accordance with their own policy making processes" to apply or enforce chapters that are not yet required USP standards.

As required in Business and Professions Code section 4127(c), the Board's Enforcement and Compounding Committee intends to resume its discussion of the new proposed revised chapters. Although it is the Board's goal to seek conformity with USP where possible, consistent with the Board's consumer protection mandate and the authority granted to the Board by the Legislature in Business and Professions Code section 4126.8, it is anticipated that the Board's efforts may result in updates to its current regulations, including higher standards if deemed necessary for public protection. Information on meetings will be posted on the website and meeting materials made available in advance.

Approved 10/27/2021