

## [USP General Chapters <795>, <797>, <800>, and <825>](#)

**Type of Posting:** Notice of Intent to Revise

**Posting Date:** 23-Sep-2019

**Official Date:** December 1, 2019; TBD

**Expert Committee:** Compounding, Chemical Medicines Monographs 4

On June 1, 2019, USP published revisions to [<795> \*Pharmaceutical Compounding – Nonsterile Preparations\*](#) and [<797> \*Pharmaceutical Compounding – Sterile Preparations\*](#), as well as a new chapter [<825> \*Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging\*](#). After publication of the [revised and new compounding standards](#), USP received appeals on certain provisions in <795>, <797>, and <825>.

In accordance with [USP's Bylaws](#), the responsible Expert Committees worked with a sense of urgency to consider the information raised in the appeals and issued decisions on the appeals (see [Decisions on Appeals to USP <795> and <797>](#) and [<825>](#)). In accordance with USP's [formal appeals process](#), stakeholders who submitted appeals on the compounding chapters have requested further review by an appointed Panel.

USP's [Bylaws](#) provide that the official date of a standard under appeal must be postponed while an appeal is pending. Therefore, **USP is postponing the official dates of the revised <795> and <797>, and the new general chapter <825> until further notice.** In the interim, the currently official chapters of [<795>](#) (last revised in 2014) and [<797>](#) (last revised in 2008) including the section *Radiopharmaceuticals as CSPs* will remain official. The decisions on the appeals to <795>, <797>, and <825> do not foreclose the possibility of future revisions to these chapters.

[General Chapter <800>](#) is not subject to any pending appeals and will become official on December 1, 2019. During the postponement and pending resolution of the appeals of <795> and <797>, <800> is informational and not compendially applicable. USP encourages utilization of <800> in the interest of advancing public health.

USP plays no role in enforcement. State and other regulators may make their own determinations regarding the enforceability of <800>. USP remains committed to advancing public health and to promoting the quality of compounded preparations and the safe handling of hazardous drugs. USP will continue to communicate updates on the compounding chapters and the appeals process. For any questions, please contact the Healthcare Quality & Safety Team at [CompoundingSL@usp.org](mailto:CompoundingSL@usp.org).