<u>Standards Affected by Postponements of <795> Pharmaceutical Compounding — Nonsterile Preparations, <797> Pharmaceutical Compounding — Sterile Preparations, and <825> Radiopharmaceuticals — Preparation, Compounding, Dispensing, and Repackaging</u>

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On June 1, 2019, USP published revisions to <a href="mailto: Pharmaceutical Compounding – Nonsterile Preparations and <a href="mailto: Assumptions, as well as a new chapter, <a href="mailto:825 Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging. After publication of the revised and new compounding standards, USP received appeals on certain provisions in 795, 795, 795, 797, and 825. While the appeals process is pending, USP postponed the official date of the revised and new standards.

USP has identified several other standards that reference revised sections of <795>, <797>, and new chapter <825>. In each of these cases, the revised or new text referenced in the affected standards has been affected by the postponements of revisions to <795> and <797>, as well as the postponement of <825>. A list of the standards impacted, including the currently official text and revised (postponed) text can be found here.

Standards that contain references to <795> and <797> were updated to align with the revisions to the chapters or to the existence of a new chapter, including:

- · updating section numbering,
- adding new concepts on assigning beyond-use dates (BUDs) for compounded sterile preparations (CSPs) (e.g., risk levels and Categories),
 or
- referencing the new standalone radiopharmaceutical compounding standards in <825>.

Compendial users therefore should be aware of the potential postponement-related discrepancies in these cross-references. Refer to the <u>list</u> of standards impacted. If applying the currently official <795> and <797>, refer to the text under the column for "Currently Official Text." For users early adopting the revised standards (see USP General Notices 3.10), refer to the cross-references under the column for "Revised Text."

