

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

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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>. 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 [list](#) 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.”

Should you have any questions, please contact Jeanne Sun, Senior Manager, Healthcare Quality and Safety (CompoundingSL@usp.org).

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