

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

Type of Posting: Publication Announcement

Posting Date: 24-Apr-2020

Expert Committee: Compounding Expert Committee

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>, ultimately resulting in the remand of revised <795> and <797> to the Compounding Expert Committee and the denial of the appeal to <825>. See [Appeals Panel decisions](#) for further details.

When the revised and new chapters were published on June 1, 2019, USP identified several monographs that referenced the revised <795> and <797>, some of which required revisions to modify these references. The references were updated and published in *USP 43-NF 38*.

Since the revised <795> and <797> were remanded and the currently official versions of <795> (last revised 2014) and <797> (last revised in 2008) remain official, the changes to cross-references previously published in *USP 43-NF 38* will be reversed to reflect the text as it existed prior to June 1, 2019. A list of the standards that will be modified can be found [here](#).

All modifications to the monographs listed will become official on May 1, 2020.

Please also see the Compendial Notice: [New Revision Markup for Reference Changes in USP–NF](#) for details on the revision markup used to identify the reference updates.

Interested stakeholders are encouraged to alert USP staff of any impact they may experience related to the update of these monographs.