



IX

Resolution

Year 1 Resolution Update: Compounding

Resolution

USP will continue to collaborate with stakeholders on standards to help ensure the quality of compounded drug preparations. New and revised standards for compounding, including beyond-use dates, will be developed based on data, scientific evidence, and input from recognized healthcare professionals and state and federal regulators.

Alignment with USP's Mission

USP engages with stakeholders to advance compounding quality, promote patient safety, and respond to evolving public health needs. Through its education and training programs as well as stakeholder engagement, USP helps strengthen practitioner awareness of appropriate circumstances and settings for compounded drug preparations, including how to consistently follow procedures that promote patient safety. USP informs the development and revision of standards by monitoring relevant advancements in science and patient safety issues related to compounding.

Year 1 Update

Key progress areas over the past fiscal year include:

Stakeholder Collaboration – USP has continued to collaborate with stakeholders on standards development, including on recently proposed revisions to *USP* General Chapters <795> *Pharmaceutical Compounding—Nonsterile Preparations* and <797> *Pharmaceutical Compounding—Sterile Preparations*, to help ensure the quality of compounded drugs.

- ▶ Related stakeholder engagement activities brought together groups with diverse perspectives representing a broad range of practice settings in which USP compounding standards are implemented. The groups provided feedback and reviewed public comments on earlier proposals to revise compounding general chapters (<795> and <797>).
- ▶ USP interviewed certain stakeholders to gain further understanding and clarification on the feedback received.
- ▶ To further determine the scope and breadth of new and revised compounding standards, USP held roundtable discussions and Open Forum meetings with healthcare practitioners, state and federal regulators, veterinarians, and others, attracting a total of 800+ participants.

Planned for Year 2

- ▶ USP's Compounding Expert Committee will continue to consider

- stakeholder input on the need for new/revised compounding standards.
- ▶ USP will review anticipated public comments on new proposed revisions to compounding general chapters (<795> and <797>). The proposed revisions were pre-posted on USP's website in September 2021, ahead of their planned publication in the *Pharmacopeial Forum*.
 - ▶ USP plans additional Open Forum sessions in January 2022 to continue to gather feedback on the proposed

compounding standards revisions. This follows two initial Open Forum sessions in September 2021 where Compounding Expert Committee members discussed the proposed revisions with stakeholders and took questions.

Contact

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