



IX Resolution

Compounding

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.

Year 3 Update

Millions of medicines are compounded each year to meet the unique needs of patients who otherwise may not have access to their treatment in the right concentration or dosage. This includes cases where patient needs can't be met with conventionally manufactured medicines during times of shortage. USP develops standards, guidelines, and best practices for medicines that frequently need to be compounded to help ensure equitable access to a supply of quality medicines and public trust in quality compounded drug preparations.

Key areas of progress over the past fiscal year include:

Revised Compounding Chapters – USP published final versions of revised compounding chapters in the *U.S. Pharmacopeia–National Formulary (USP–NF)* in November 2022 to help ensure the supply of quality compounded medicines. Representing the culmination of 12 years of work by the USP Compounding Expert Committee (CMP EC) and related stakeholder engagement, the revised

chapters included *USP General Chapters <795> Pharmaceutical Compounding – Nonsterile Preparations* and *<797> Pharmaceutical Compounding – Sterile Preparations*.

- ▶ The final versions reflect extensive feedback from 15,000+ comments received over three public comment periods from a diverse group of stakeholders such as healthcare practitioners, state and federal regulators, academicians, and industry.
- ▶ As USP continues to encourage early implementation, the CMP EC also voted to extend the date on which the chapters become official to November 1, 2023, to facilitate adoption.
- ▶ To support understanding and implementation of the revised chapters, USP published several supplementary documents with details on the scientific considerations and rationale for the changes. USP also hosted four open forums for stakeholders to pose

questions to, and hear directly from, CMP EC members. In February 2023, USP held a hybrid workshop to explore various aspects of implementation. In addition, USP updated its related education courses on compounding and gave presentations on the revised chapters at 14 stakeholder conferences, workshops, and annual meetings.

- ▶ USP migrated the *Compounding Compendium* to the online platform for the *USP–NF* and *Pharmacopeial Forum (PF)* to enable compounders to have more timely access to the most updated USP compounding standards.

Monograph Development – USP continued to prioritize and develop compounded preparation monographs (CPMs) to help ensure the quality of compounded medicines.

- ▶ In close consultation with stakeholders, USP updated the list of CPMs prioritized for development, including several compounded injectable medicines frequently on shortage, and medicines for key populations such as pediatric and veterinary patients.
- ▶ During the year, USP published five new CPMs in the *USP–NF* and six draft CPMs in the *PF* for public comment.

Updated COVID-19 Resources for Compounders – USP worked with stakeholders to review and update resources created to support compounders in responding effectively to the COVID-19 pandemic and future pandemics.

- ▶ Updates were made to recommendations for compounding alcohol-based hand sanitizers to respond to frequently asked questions from stakeholders and to reflect changes by regulatory bodies.

- ▶ Following the end of the U.S. public health emergency declaration in May 2023, plans were made to carefully collate and archive pandemic-related resources for potential future use. The documents will also form the basis for a future pipeline of standards to be used by compounders to respond rapidly to supply chain challenges during public health emergencies and environmental or humanitarian disasters.

Planned for Remainder of the Cycle

- ▶ USP will develop resources to address topics raised by stakeholders during the revision process of <795> and <797>. Intended for publication as *Stimuli* articles in *PF* for public comment, the resources will cover topics such as development of stability studies for compounded preparations, application of technologies in pharmaceutical compounding, enhancing quality assurance and quality control, and application of aseptic techniques in pharmaceutical compounding.

Contact

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