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 2 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:

- USP updated its Operational Considerations for Sterile Compounding During the COVID-19 Pandemic to ensure consistency with recent changes made to the packaging of conventionally manufactured COVID-19 treatments with emergency use authorization, including recommendations for minimizing waste.
- USP updated its recommendations for compounding alcohol-based hand sanitizers to provide specific information for incorporation of additional ingredients, such as denaturants.

Updated COVID-19 Resources for Compounders – USP continued working with stakeholders to develop and provide operational strategies that enable compounders to respond more effectively to COVID-19 and potential future pandemics.

Revised Compounding Chapters – USP continued work with stakeholders on revisions to USP General Chapters <795> Pharmaceutical Compounding – Nonsterile Preparations, and <797> Pharmaceutical Compounding – Sterile Preparations to help
ensure the supply of quality compounded drugs.

- Stakeholder engagement led by the Compounding Expert Committee on proposals to revise General Chapters <795> and <797> brought together diverse perspectives representing a broad range of practice settings in which USP compounding standards are implemented. Stakeholders provided feedback and reviewed public comments on earlier proposed revisions. As a result, USP published updated proposed revisions to the general chapters in Pharmacopeial Forum in November 2021 for further public comment. Virtual open forums in January 2022 were attended by 800+ participants.

- USP published supplementary resource documents summarizing the Compounding Expert Committee’s responses to public stakeholder comments received during the revision process and the rationale for changes.

Monograph Development – USP continued to prioritize and develop compounded preparation monographs (CPMs), including key monographs to meet the needs of pediatric and veterinary patients, to help ensure the quality of compounded drug preparations. USP published five draft CPMs in Pharmacopeial Forum for public comment, and six new CPMs in USP-NF.

Planned for Year 3

- Pending the anticipated publishing of General Chapters <795> and <797> in USP-NF, USP will host open forum webinars and workshops, and will update related educational resources to support stakeholders in implementation of the revised compounding chapters.

- USP will develop resources in response to topics raised by stakeholders during the revision of <795> and <797>, including stability studies, aseptic techniques, and quality assurance in compounding.

- USP will publish Stimuli articles on 3D printers and other automated devices used in compounding.

Contact
For additional information on this Resolution, contact Brian Serumaga at BNS@usp.org.