Resolution VII: Quality Standards for Compounded Medicines

USP will continue working with stakeholders to develop and maintain practice and quality standards for sterile and nonsterile compounding. USP will increase the availability of its compounding standards, expand stakeholder engagement and education, and promote adoption of these standards by compounding professionals and regulatory authorities.

On June 1, 2019, USP published revisions to General Chapter <795> Pharmaceutical Compounding—Nonsterile Preparations and <797> Pharmaceutical Compounding—Sterile Preparations, as well as new General Chapter <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Developed in response to stakeholder feedback to address the unique characteristics of radiopharmaceuticals. Revisions to General Chapters <795> and <797> and new General Chapter <825> reflect advancements in science and practice.

The Expert Committees reviewed more than 7,000 comments from patients, healthcare practitioners, policymakers, academicians and industry to help ensure that broad perspectives are included in the standards while maintaining a focus on patient safety and access to quality compounded preparations. In addition to the public comment process, USP engaged stakeholders through roundtables, open microphone sessions and discussion forums to gather input on the chapter.

These new and revised standards, along with General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings, provide a comprehensive set of standards for all healthcare workers to help ensure the preparation of quality compounded preparations and the safe handling of hazardous drugs throughout the healthcare system.

These chapters are anticipated to become official on December 1, 2019.

USP also published 11 new compounded preparation monographs, providing formulations to meet the unique needs of patients when there is no suitable commercially available product. The Compounded Preparation Monograph Donation Program continues to garner increasing attention from the compounding community, receiving nine new donations and forming collaborations with four new donors this year.

The <800> HazRx® Mobile App, launched last fiscal year, has been downloaded by more than 2,400 users. This app helps the individual healthcare worker identify if the drug being handled is hazardous and provides guidance to help reduce their risk based on established standards such as General Chapter <800> and NIOSH/CDC guidance. We also launched the HazRx® Data Set to integrate hazardous drug identification and handling information into existing institutional workflow systems.

We continue to offer live and virtual compounding-related courses; trained more than 2,300 students directly, and by establishing strategic partnerships, we have created a Compounding Certification Program.

Finally, USP is planning its second annual USP Workshop on the Evolution and Advances in Compounding to convene experts and stakeholders from around the world to discuss quality of compounding to improve patient safety.

(Continued on next page)
Key Accomplishments

- Final and revised standards for nonsterile and sterile compounding published in General Chapters <795> and <797>
- New standards for radiopharmaceutical compounding published in General Chapter <825>
- Over 7,000 public comments reviewed on revisions to General Chapters <795> and <797>
- Nine new donations received for the development of compounded preparation monographs
- HazRx® Mobile App downloaded by more than 2,400 users
- Over 2,300 students trained on USP compounding standards