USP Publishes New and Revised Compounding Standards

Standards help ensure quality compounded preparations to safeguard the well-being of patients

FOR IMMEDIATE RELEASE

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Rockville, MD, June 3, 2019 – USP released new and revised standards to help ensure the quality of compounded medicines. The updates pertain to the USP General Chapters on compounding nonsterile medicines (USP <795> *Pharmaceutical Compounding—Nonsterile Preparations*), compounding sterile medicines (USP <797> *Pharmaceutical Compounding—Sterile Preparations*) and new standards for compounding radiopharmaceutical drugs (USP <825> *Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging*).

Collectively, these USP General Chapters are a set of standards that assist healthcare practitioners with consistently producing quality compounded medicines to help ensure patients receive medicines that are the right strength, quality and free of contaminants. USP General Chapter <800> *Hazardous Drugs—Handling in Healthcare Settings* is another relevant chapter for compounding to help promote the safe handling of hazardous drugs by healthcare workers.

“From the time a medication is compounded until the moment the patient takes it, we want to help ensure patient benefit and reduce risks,” said Ronald T. Piervincenzi, Ph.D., chief executive officer, USP. “The updated USP standards will help ensure quality preparations for patients who rely on compounded medicines, while minimizing the risk of exposure to hazardous drugs for healthcare personnel.”

“The revised USP standards recognize risks associated with nonsterile and sterile compounding and tighten controls in areas that directly affect the quality and safety of compounded medicines,” said Janet Woodcock, M.D., director of the Center for Drug Evaluation and Research, U.S. Food and Drug Administration (FDA). “The changes to these USP chapters should improve the quality of compounded products and help protect public health.”
Revisions to chapters <795> and <797> and the implementation of the new chapter <825> reflect new science and evidence based on updated guidance documents, best practices and new learnings. The revisions also incorporate stakeholder input and clarify topics that are frequently misunderstood.

“We appreciate the thoughtful feedback from stakeholders within the public health community,” said Jaap Venema, Ph.D., chief science officer, USP. “Participation in our public

comment process is critical to ensuring the standards we develop have the intended effects of advancing quality and patient safety."

"Furthermore, we realize in this ever-changing industry it can at times be challenging for healthcare organizations to implement new standards, which is why we are committed to providing innovative solutions to help healthcare teams successfully translate the new standards into their practice settings," said Dr. Venema.

USP offers educational programs and practical tools to support healthcare practitioners and organizations with adopting the updated standards and ensuring the safety of patients and healthcare workers. Key resources include:

- **Complimentary access to Chapters:** From June 1, 2019 – January 1, 2020, access the updated and new standards for FREE digitally to prepare for compliance.
- **USP Education Courses:** Participate in live and recorded courses and webinars to better understand the standards and tips for implementation.
- **HazRx® Mobile App and HazRx® Data Set (Institution Solution):** Keep a trusted source at your fingertips to help know your exposure to hazardous drugs.

For more information on the USP General Chapters for Safe Compounding and Handling of Hazardous Drugs, visit www.usp.org/compounding.

About Safe Compounding
Millions of medicines are compounded each year in the U.S. to meet the unique needs of patients. Compounding practice is essential to provide tailored therapy to vulnerable patient populations, including patients who may not be able to use commercially available formulations due to dosing requirements, allergies or rare diseases. Compounded medicine made without the guidance of standards may expose patients to significant risk of adverse events or even death.

About Safe Handling of Hazardous Drugs
During the routine care of patients, more than 8 million healthcare workers in the U.S. may be exposed to hazardous drugs every year. Improper handling of these drugs increases the risk that healthcare workers and patients may suffer serious health effects, including cancer, infertility and reproductive outcomes.

About USP
USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality standards for medicines, dietary supplements, and food ingredients. Through our standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and food for billions of people worldwide. For more information about USP, visit www.usp.org.