USP compounding standards: Prepare with care

Know the current standards.

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IF YOU PREPARE medications to meet unique patient needs, stop and ensure you are up to speed on United States Pharmacopeia (USP) standards to help ensure patients receive quality medications that are free of contaminants.

In the United States, millions of medications are compounded (prepared) each year to meet the unique needs of individual patients. Compounding provides access to medication for patients who may not be able to use commercially available formulations because of dosing requirements, allergies, rare diseases, or other health conditions.

Compounded medications can be sterile or nonsterile. Understanding the risks inherent in each and incorporating established standards into daily clinical practice are essential to patient safety. Although compounding is essential to meeting specific patient healthcare needs, compounded drugs made without the guidance of standards may be subpotent, superpotent, or contaminated, exposing patients to significant risk of adverse events or even death.

Compounded sterile preparations are potentially more hazardous to patients because they're more likely to be administered into sterile body spaces such as the central nervous or vascular system, eyes, or joints. These spaces are typically microbe free, and the introduction of contaminants can lead to infection, serious injury, or even death. In addition, incorrect ingredients or incorrect quantities of ingredients can result in medicine that is not therapeutically effective or is toxic to the patient.

To help reduce patient risks, USP provides standards, such as USP General Chapters <795>, <797>, and <800>, for preparing quality compounded medications. (See *At a glance: USP compounding chapters*.)

USP is a not-for-profit, science-driven organization that has an established process for convening independent experts in the development and maintenance of healthcare quality standards.

Staying up-to-date is an important aspect of public health advancement, so USP is revising the compounding chapters to better align the standards with changes and advances in science and clinical practice and to help ensure quality compounded preparations. The chapters are anticipated to be official in December 2019.

At a glance: USP compounding chapters

The United States Pharmacopeia (USP) compounding chapters <795>, <797>, and <800> are undergoing revision, but the published versions are official until December 2019.

USP <795> Pharmaceutical compounding—Nonsterile preparations

Standards for compounding quality nonsterile medicine. The chapter describes requirements for the compounding process, facilities, equipment, components, documentation, quality control, and training. This chapter also provides general guidelines for assigning beyond-use dates to nonsterile preparations.

USP <797> Pharmaceutical compounding—Sterile preparations

Standards for compounding quality sterile medicine. The objective of this chapter is to describe conditions and practices to prevent harm, including death, to patients that could result from microbial contamination, excessive bacterial endotoxins, variability in the intended strength of correct ingredients, unintended chemical and physical contaminants, or ingredients of inappropriate quality.

USP <800> Hazardous drugs—Handling in healthcare settings

Standards to help protect healthcare workers from the risks associated with handling hazardous drugs. This chapter contains sections related to types of exposure, personnel and facility responsibilities for handling hazardous drugs, appropriate use of personal protective equipment, deactivation/decontamination, cleaning, and disinfection.

Learn more about compounding safety (usp.org/compounding/updates-on-standards) and sign up for USP's healthcare quality & safety updates (usp.org/hqs-signup-form) to stay informed about standards on compounding and safe handling of hazardous drugs.

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