3 Tips to Prepare Your Facility for USP <800>

To help protect employees, patients and the environment, the United States Pharmacopeia (USP) has developed comprehensive standards for the safe handling of hazardous drugs—USP <800>.

According to the Centers for Disease Control and Prevention (CDC), over 8 million healthcare personnel in the United States are exposed to hazardous drugs each year. This exposure presents significant risks for acute and chronic health conditions, including skin rashes, hair loss, adverse reproductive health, vision problems, and even cancer.
Virtually all types of practices—from community health centers and ambulatory surgery centers, to skilled nursing facilities and hospitals—will have to meet the new compliance standards. The USP standards will initially be enforced by the state boards of pharmacy; however, enforcement may come from the Food and Drug Administration (FDA) due to the 2013 Drug Quality and Safety Act focused on patient safety. Accreditation organizations such as the Joint Commission and Accreditation Association for Ambulatory Health Care (AAAHC) may also enforce the standards during accreditation surveys. Further, the Occupational Safety and Health Administration (OSHA) already has enforcement authority wherever worker safety is concerned.

USP <800> is a direct evolution of USP <797>, which describes the guidelines, procedures and compliance requirements for compounding sterile preparations and sets the standards that apply to all settings in which sterile preparations are compounded. However, USP <797> only serves as a guideline for sterile compounding and contamination prevention. Going into effect Dec. 1, 2019, USP <800> will cover the complete end-to-end process, from receipt to disposal.

Therefore, the new standard will impact not only facilities where compounding takes place, but also anywhere someone may come into contact with hazardous drugs. While USP <800> compliance might be a natural progression for compounding facilities, it can be overwhelming for organizations unfamiliar with previous hazardous drug management standards. They will have to make sure their policies and procedures are up to par, and that employees are well-trained in best practices and expectations.
USP <800> covers a vast number of requirements for hazardous drug management, including receiving, storage, administration, documentation, engineering controls, quality control, personal protective equipment, spill prevention, cleaning and disposal, among others. To manage the implementation of these requirements, facilities should appoint one experienced person as the compliance leader. They may be a pharmacist, practice manager or member of the administration. The compliance leader should have a solid understanding of USP <800> guidelines so that they can serve as a go-to person for accountability and dissemination of information.

An initial assessment is vital in identifying current areas for risk within a facility. This involves documenting all hazardous drugs by type and dosage, and analyzing how they are packaged, stored, manipulated and moved throughout the practice. It should also include a list of all staff members who may come into contact with hazardous drugs while performing their job duties. By performing a risk assessment, organizations can determine what needs improving, and make the necessary policy and facility adjustments for each drug.
Assessments provide a roadmap to compliance, helping to ensure that organizations have implemented new standard operating procedures clearly aligned to USP <800> requirements prior to Dec. 1.

USP <800> clearly states that everyone who handles hazardous drugs must understand the requirements. This goes beyond people who are responsible for compounding or administering the drugs to encompass even non-medical staff, such as shipping and receiving personnel and housekeeping. In addition to education on the new standards, each person must be trained on how to properly perform their job function. For instance, a housekeeper will need to know how to recognize a dangerous spill and who within the organization can address the situation in the safest manner. The level of competency across the organization should be assessed every 12 months, as well as when a new hazardous drug is introduced to the facility.

To help healthcare facilities prepare for the rollout of USP <800>, online toolkits are now available—including through Medtrainer. Healthcare organizations can thereby make it easy for their employees to comply through tools that are enabled in a digital format. These online toolkits include resources for risk assessments, glossary of terms, up-to-date hazardous drug lists, customizable safety data sheets and policy templates. Notably, the templates are fully customizable and enable facilities to create electronic policy manuals, detailing everything from floor plans and diagrams for how drugs move in and out, to instructions for equipment use and maintenance. Since the policy manuals are distributed electronically, it is easy to keep track of who has received them, holding people accountable for best practices and job tasks.

Training offerings on general safety guidelines can be particularly beneficial to facilities less familiar with hazardous drug management. They can cover the critical steps and precautions in identification, segregation and disposal, including hazardous communication programs and different cleanup kits. External resources for toolkits and training can simplify compliance greatly for healthcare organizations, in the days leading up to December and thereafter.