USP <800>

Preparing for the changing standards in hazardous drug handling

Why does USP <800> matter now?

The Current Status of USP <800> and the OSHA Hazard Communication Standard

Why does USP <800> matter now that it is not currently enforceable? USP <800> was scheduled to go into effect on Dec. 1, 2019, but the U.S. Pharmacopeia postponed enforcement while appeals on related provisions in USP <795> and <797> are resolved. During this appeals process, USP <800> will be "informational and not compendial applicable. USP encourages utilization of <800> in the interest of advancing public health."

Yet even without USP <800> enforcement, CMS, DHSS and the Joint Commission all have enforcement capacity for the safe management of sterile and non-sterile hazardous drugs.

The bottom line is that the absence of USP <800> enforceability does not provide a rationale for not meeting current, similar standards and regulations. Failure to follow these other hazardous drug handling standards and regulations may result in accreditation deficiencies, OSHA violations or civil liabilities.

When the appeals process is complete, USP <800> will become enforceable at the federal level primarily by the Occupational Safety and Health Administration (OSHA) and the state level by the various state boards of pharmacy. Organizations that wait to implement changes will have to catch up quickly to remain compliant. Therefore, it is in the best interest for all healthcare facilities to meet the standards prior to enforcement.

How do we ensure compliance?

Any organization that receives, stores, dispenses, or administers medication is required to designate a trained individual to oversee internal procedures, staff competency and environmental control of storage and compounding areas. This compliance leader should know all USP <800> guidelines so that they can serve as a single point of contact for accountability and dissemination of information.

A good starting point for the compliance leader is to conduct an initial risk assessment. This process will help identify areas of potential exposure within a facility. A risk assessment provides important information needed to develop operational and engineering controls, as well as standard operating procedures and employee training to utilize the correct personal protective equipment, prevent exposure and understand the health and reproductive risks associated with hazardous drugs.

- **Check the list:** An assessment should include review of the "NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings" to see if a facility handles any of the listed drugs. Once identified, all of these drugs must be documented by type and dosage, along with an analysis of how they are packaged, stored, manipulated and moved throughout the facility.

- **Identify relevant staff members:** The assessment should also include a list of all staff who may encounter hazardous drugs while performing their job duties—even non-medical staff. USP <800> mandates that these individuals must thoroughly understand the requirements and how to properly perform their job function. For example, a custodian will need to know how to recognize a dangerous spill and the appropriate steps for escalation so that the issue is contained.
- **Document processes and procedures:** Maneuvering through the compliance process involves extensive documentation of assessments, equipment and processes, standard operating procedures, personal protective equipment, and employee training and competency.

Given all these steps and components, compliance may seem overwhelming for some facilities. Fortunately, there are online resources available now to help.

Where can we turn to for help?

There are now comprehensive compliance management solutions with toolkits to simplify documentation and education. These toolkits include resources such as:

- Templates for risk assessments
- Up-to-date hazardous drug lists
- Customizable safety data sheets
- Policy templates
- Employee training and competency assessments
- Reporting functions

Policy templates are particularly beneficial as they enable facilities to custom create electronic policy manuals, detailing everything from floor plans and diagrams for how drugs move throughout the facility, to instructions and logs for equipment use and maintenance. By making policy manuals available in a digital format, it is easier for facilities to track who has received and read each policy and ensures that everyone has the most up-to-date information.

Online training courses are a convenient way to educate staff on the hazardous drug handling guidelines. This type of education is accessible from any connected device and provides the added benefit of being able to digitally monitor who has completed the required training—and remind those who have yet to complete a course. Moreover, staff members can complete the courses on their own time, so they don't have to take time away from patients to attend lengthy, scheduled seminars.

Compliance management platforms also provide instant access to real-time reporting that streamlines management, review and audit processes. To learn more about online resources for compliance management and how to bring your facility up to speed on USP <800> standards, contact a MedTrainer representative or email compliance@medtrainer.com.

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