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Best practices for the safe handling of hazardous drugs – How to prepare for USP <800>

Healthcare is not just about taking care of patients. It's also about taking care of your staff. Exposure to hazardous drugs can have a material impact on the physiology of anyone who comes in contact with the drugs – Patients, providers and material handlers. New USP<800> standards are designed to protect all involved. Failure to comply with these new standards can not only impact the health of your staff, it can also result in fines for your health system.

On Dec. 1, the United States Pharmacopeia (USP) <800> standards will officially take effect. These standards offer new protocols for the safe handling of hazardous drugs. The National Institute for Occupational Safety and Health defines hazardous drugs as any drugs that can cause physical changes to the human body[1].

These substances are used in a variety of care settings, ranging from hospitals to ambulatory surgery centers, physicians' offices, men's and women's specialties, cancer centers, post-acute care and even at home in the form of infusion therapies.

With December just months away, health systems need to prepare for the effect USP <800> will have on their operations from the supply chain all the way down to clinician touch points.

Regulatory compliance is rarely easy. However, we must protect our patients, providers and material handlers that come in contact with hazardous drugs. The time to develop a USP<800> compliance strategy is now.

What is USP <800>?

USP <800> provides new guidelines for preventing hazardous drug exposure[2]. These include:

- Creating, maintaining and enforcing a policy on meeting the new standards
- Wearing personal protective equipment when administering hazardous drugs, including gowns, head and shoe coverings and double gloving
- Using protective medical equipment like closed-system transfer devices, needleless equipment and plastic pouches for pill crushing
- Deactivating, decontaminating, disinfecting and cleaning contact areas and the surrounding environment
- Storing, receiving and handling hazardous drugs separately from nonhazardous drugs

As a scientific, nonprofit organization, the USP will not enforce USP <800> compliance. However, the Occupational Safety and Health Administration, some state pharmacy boards and some state laws can mandate compliance with the new standards. Health systems determined to be noncompliant could face financial penalties.

How USP <800> will affect the supply chain and the clinical environment

Hazardous drugs pose risks from the moment they are shipped to the point of disposal. As a result, healthcare systems must consider how USP <800> will affect both the supply chain and clinical environment. For example:

- *Warehousing, handling, storage and distribution*. In addition to storing hazardous drugs separately, staff in centralized receiving areas and distribution centers must understand how to protect themselves from hazardous drug spills.

  Rick Taylor, senior director of category management at McKesson Medical-Surgical, noted, "All personnel who deal with hazardous drugs need personal protection. They should double glove and wear the proper personal protection. These employees must be just as aware of the safety issues as frontline healthcare providers."

[1] https://www.cdc.gov/niosh/docs/2016-161/default.html

[2] https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare

- *Healthcare system pharmacies.* Pharmacists compounding, mixing or preparing hazardous drugs should conform to USP <800> guidelines. Pharmacy facilities may need to be renovated so hazardous drug containment systems meet USP <800> requirements. There are specific engineering requirements designed to help contain the hazardous drug and protect the worker. At a minimum these include an externally vented BSC or CACI, which is located in a negative pressure room with a minimum number of air changes per hour.
- *Clinicians.* Individual healthcare providers who administer hazardous drugs to patients need to conduct an assessment of risk to determine how they should protect themselves: with gowns, double gloves and other personal protective equipment. The disposal of hazardous drugs can also put providers at risk for exposure. With each drug having unique properties, USP<800> provides guideline for the safe disposal of these drugs.

Best practices for implementing USP <800> across the continuum of care

To ensure adequate preparation for USP <800>, many leading health systems are turning to supply chain experts like McKesson for help. McKesson Specialty Health, for example, consults with community oncology clinics to identify critical gaps in their USP <800> policies and procedures.

"One component of our USP <800> toolkit is an Excel-based readiness assessment that covers each section of the USP <800> chapter," explained Julie Cothren, pharmacist and clinical specialist with the McKesson Provider Advisory Services team. "The readiness assessment identifies which aspects of USP <800> are mandatory and which are discretionary. Providers can see where they are today and where they need to be."

McKesson is helping health systems comply with USP <800> in several other ways, including:

- *Clinic walk-throughs*. McKesson is working with physician-owned, community oncology clinics to flag engineering or construction changes required for USP <800> compliance. If a drug is in Table 1 of National Institute for Occupational Safety and Health 's hazardous drug list and requires manipulation, USP <800> mandates that it must be treated with specific containment strategies and engineering controls. Biological safety cabinets must be externally vented and housed in negative pressure rooms in which the air changes 12 times per hour.

  "When we conduct walk-throughs for clients, many practices have a hood, but it's not vented outside. Or they may have an externally vented hood, but it's not in a negative pressure room and the room doesn't support the proper number of air changes," Ms. Cothren said.

- *USP <800> compliant product formularies.* McKesson's comprehensive formulary of compliant medical-surgical products includes closed chemotherapy transfer devices; personal protective equipment that meets American Society for Testing Materials' standards; needleless equipment; gloves, gowns, hoods and shoe covers; cleaning and decontamination products and waste disposal systems. "We've worked closely with our manufacturer partners to ensure their products meet USP <800> guidelines," Mr. Taylor said.

  This formulary is loaded into a health system's ordering platform, so it's easy for both acute and non-acute facilities to find products that have been vetted against USP <800> standards. As Deb Delisi, RN, clinical affairs manager at McKesson Medical-Surgical, noted, "Non-acute facilities need to adhere to the same USP <800> standards as acute facilities, so it's important they have access to the same formulary of approved products."

- *USP <800> education programs.* For over two years, McKesson has been working on USP <800> compliance program. The company believes that education and communication is key to protecting both patients and providers from exposure to hazardous drugs. As a result, McKesson hosts webinars on the topic and sends clients regular emails outlining readiness steps. "Our goal is to break USP <800> compliance down into manageable pieces, so providers aren't overwhelmed. We want to help them work toward readiness one step at a time," Ms. Cothren explained.

- *USP <800> Toolkit.* McKesson worked with MedTrainer to design a Toolkit that could help clients seeking a more formal approach to employee training for USP <800>. The Toolkit features assistance in the identification and assessments of hazardous drugs, guides for creating and maintaining standard operating procedures (SOPs), and a library of training modules, just to name a few of the resources available.

Conclusion

With December nearing, the time to develop and implement a compliance strategy for USP <800> is now. Healthcare entities can check with their state regulatory bodies to get answers on enforcement.

Regulatory compliance is rarely easy. However, we must protect our patients, providers and material handlers that come in contact with hazardous drugs. The time to develop a USP<800> compliance strategy is now. "We're just a few months away from the date when USP <800> becomes official," Ms. Cothren said. "If any facility is handling a hazardous drug, they need to take this deadline seriously. Healthcare entities can check with their state regulatory bodies to get answers on enforcement." ■

For more information on USP<800> and the resources mentioned in this article, visit:
https://mms.mckesson.com/usp

Hazardous drugs put your staff at risk

Let's keep them safe with better USP <800> compliance

More than 12 billion doses of hazardous drugs are administered in the U.S. every year.* With each of these doses comes the chance that medical staff—from clinicians to custodians to delivery handlers—will be exposed to substances that put their health on the line.

This December, USP <800> will set new standards for handling hazardous drugs. McKesson is here, ready to assist, with tools and support that can keep your workplace USP <800> compliant and keep your staff safe.

8 million+
healthcare workers are exposed to hazardous drugs in the U.S. every year*

Learn more at **mms.mckesson.com/usp**

The distributor of the non-acute continuum.

*Source: USP.org

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