SAFETY

The U.S. Pharmacopeial Convention’s “Chapter <800> Hazardous Drugs—Handling in Healthcare Settings” is a new part of the National Formulary that describes standards—expectations for practice—for all aspects of handling and administering hazardous drugs (HDs). Some of the standards will require changes in policies, procedures, and practices for nurses. This article provides an overview of the new standards and the impact they will have on nurses who prepare and administer chemotherapy and other HDs.

AT A GLANCE

■ New standards for the safe handling of antineoplastic drugs and other hazardous medications were published by the U.S. Pharmacopeial Convention in 2016. These standards are enforceable by state boards of pharmacy and by the U.S. Food and Drug Administration.

■ The standards address every aspect of hazardous drug handling, including receipt, storage, preparation, administration, and disposal.

■ The standards must be fully implemented by July 1, 2018, in all healthcare settings in which hazardous drugs are present, so nurses must knowledgeable about those that directly influence their practice.

U.S. Pharmacopeial Chapter <800>

Be ready to comply by July 2018

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The U.S. Pharmacopeial Convention (USP) is a well-established organization that sets standards for the “identity, strength, quality, and purity of medicines, food ingredients, and dietary supplements manufactured, distributed, and consumed worldwide” (USP, n.d., para. 1). Most of USP’s standards address the safety of pharmaceuticals for the protection of consumers. Nurses are likely familiar with labels on IV bags, such as “Lactated Ringers Solution, USP,” indicating that the product was manufactured according to specific quality standards. Pharmacists must comply with many USP standards related to drug preparation (e.g., standards ensuring the sterility for drugs and IV solutions [USP, 2015]). The new USP standards for hazardous drug (HD) safety describe the requirements for receipt, storage, preparation, administration, and disposal of HDs (USP, 2016). The purposes of the standards are to protect patient and worker safety and to protect the environment.

The USP standards for HD safe handling are consistent with guidelines from professional organizations (American Society of Health-System Pharmacists [ASHP], 2006; Polovich, 2011) and federal agencies (National Institute for Occupational Safety and Health [NIOSH], 2004; Occupational Safety and Health Administration [OSHA], 2016) that have been in place for many years. What makes the new USP Chapter <800> standards important is that they carry an unusually strong regulatory weight. USP standards are enforceable by state boards of pharmacy and the U.S. Food and Drug Administration. All organizations and all healthcare workers will be required to comply by July 2018 or face potential citation, fines, or loss of accreditation. A general overview of the requirements is provided in Figure 1. All requirements of the 18 sections of USP Chapter <800> are available from USP in the 2016 Compounding Compendium at www.usp.org/store/products-services/usp-compounding-compendium.

Hazardous Drug List

Organizations will be required to develop and maintain a list of all HDs handled in their facilities. NIOSH publishes a formal list of HDs, which is updated every two years. Any drug present in a facility that is on the NIOSH list must be on the facility list. The purpose of the list is to identify those drugs to which the specific handling requirements, such as storage, preparation, and labeling, apply. This is also important in organizations where chemotherapy is not present because 53% of HDs are not antineoplastic agents (NIOSH, 2016). All HDs, regardless of the class or formulation, are subject to the USP Chapter <800> standards; therefore, non-oncology settings must also be familiar with the requirements for safe handling. The NIOSH (2016) list divides all HDs into categories (i.e., antineoplastic drugs, non-antineoplastic drugs, and non-antineoplastic drugs with primarily adverse reproductive effects), reducing

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the time needed to develop a facility-specific list.

**Responsible Personnel**

All organizations in which HDs are present must designate a person to oversee HD handling. That individual is responsible for implementing the standards, monitoring compliance, and keeping records related to compliance. The designated person must be knowledgeable about all aspects of HD safety and may be a pharmacist or safety officer. In small practices, nurses may need to assume this responsibility. All personnel who are responsible for HD handling must also be knowledgeable about the policies, procedures, and practices that are aimed at reducing worker and patient exposure and environmental contamination of the work environment.

**Physical Facilities and Safety Equipment**

The requirements for the physical facilities and engineering controls described in the standards are not new but have been recommended by ASHP, the Oncology Nursing Society, OSHA, and NIOSH for years. For example, the standards require that HDs be stored separately from non-HDs in a negative-pressure room with special ventilation requirements. HDs must be prepared in a containment primary engineering control (C-PEC) (e.g., a biologic safety cabinet or a compounding aseptic containment isolator) that is externally vented. The C-PEC must be located in a containment secondary engineering control (C-SEC), which is a room with special ventilation requirements. The need for negative pressure and external venting may require new construction. Organizations should seek consultation from engineers with expertise in facility design specific to pharmaceutical compounding and HD containment.

The USP standards describe the need for closed-system transfer devices (CSTDs), to which they refer as supplemental engineering controls. CSTD components reduce leakage during the transfer of HDs from vials to syringes or IV bags during preparation and from syringes or IVs to patients during administration. According to the standards (USP, 2016), CSTDs should be used for HD preparation and must be used for administration of antineoplastic agents when the dosage form allows. This includes IV and injectable administration. CSTDs may not be feasible for other routes, such as oral, intravesicular, or peritoneal administration. C-PECs and C-SECs provide worker protection during drug preparation, but CSTDs are the only engineering controls available to reduce HD exposure during drug administration. Despite evidence for the effectiveness of CSTDs in reducing HD exposure (Clark & Sessink, 2013; Miyake, Iwamoto, Tanimura, & Okuda, 2013; Turci et al., 2011), CSTD use is reported by only a minority of nurses (Boiano, Steege, & Sweeney, 2015). This will require a major practice change for many organizations and nurses.

Organizations will be required to provide personal protective equipment (PPE)

"Compliance with the U.S. Pharmacopeial Chapter <800> standards may require implementing new procedures and safety measures."
the HCS related to HDs. One specific statement requires employees who are capable of parenting a child to “confirm in writing that they understand the risks of handling HDs” (USP, 2016, p. 92). To be in compliance with this standard, facilities will have to develop a mechanism for communicating and documenting acknowledgment of the risks of HD exposure around childbearing.

USP Chapter <800> describes the need for initial and periodic education and training for all personnel who are responsible for HD handling that is specific to their job responsibilities. The required elements of that education include at least the following:

- The list of HDs and their risks
- Policies and procedures for safe handling
- Proper use of PPE
- Use of safety equipment
- Proper disposal of HDs and HD waste
- Management of HD spills
- Management of acute exposure.

Section 18 of USP Chapter <800> addresses the need for employers to follow the health of workers who handle HDs. The purpose of medical surveillance is early identification of potential adverse effects of HD exposure. Elements of medical surveillance include a baseline assessment of health, including medical and reproductive history, and prospective, periodic monitoring for exposure and health changes. Physical examination and laboratory studies may be appropriate, depending on updated health and exposure history.

**Discussion**

Compliance with the USP Chapter <800> standards may require implementing new routines, procedures, and safety equipment. In some settings, construction may be necessary to meet the ventilation and external venting requirements. The changes may result in additional costs for organizations not currently meeting the standards. Any budget implications must be addressed quickly so that organizations can plan for the July 2018 deadline.

Several aspects of the USP Chapter <800> standards directly affect oncology nursing practice. Nurses must be knowledgeable about the standards so that they can communicate with managers, supervisors, and others responsible for implementation. For example, nurses should be prepared to do the following:

- Participate in the evaluation and selection of safety equipment such as CSTDs and chemotherapy-tested PPE.
- Use the standards to inform institutional policies and procedures.
- Plan and implement safe-handling education and training.
- Model appropriate precaution whenever handling HDs.

Nurses who handle HDs must cooperate with pharmacists and administrators in their facility to implement the USP HD standards. Organizations should begin with a baseline assessment to identify areas of compliance and noncompliance. The assessment can be used to develop a plan with specific actions, timelines, and responsible individuals for each requirement. Several resources are available to assist with the process (see Figure 2).

**Conclusion**

Nurses will be called upon to accept and implement the USP Chapter <800> standards as an important step in improving HD safety. This may require individuals to change attitudes about their personal risk of HD exposure and their handling practices. The standards are based on the best evidence currently available for reducing occupational HD exposure. Implementation of the USP Chapter <800> standards will increase safety for nurses and other healthcare professionals caring for patients receiving hazardous medications.

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The author takes full responsibility for this content. Polovich was a member of the U.S. Pharmacopeial Convention USP Compounding With Hazardous Drugs Expert Panel, which assisted the USP Committee during the development of USP Chapter <800>.

**REFERENCES**


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