

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 be knowledgeable about those that directly influence their practice.

#### KEYWORDS

antineoplastic agents; occupational exposures; personal protective equipment; standards

#### DIGITAL OBJECT

#### IDENTIFIER

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# 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 promote 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](http://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