USP 800 Hazardous Drug Handling Guidelines

Educational Briefing for Non-Pharmacy Leaders

What is USP 800?

USP 800 sets guidelines and quality standards for healthcare personnel who handle hazardous drugs (HDs) such as chemotherapy agents. The rule applies to any personnel who handle HDs, including but not limited to pharmacists, nurses, physicians, advanced practitioners, and home health workers. The rule applies to all facilities that store, prepare, transport, and administer HDs. USP 800 adds additional guidelines to those specified in the USP 797 Sterile Compounding chapter and should be viewed as an addition not a replacement of USP 797.

How are drugs classified as hazardous?

The National Institute for Occupational Safety and Health (NIOSH) maintains a list of drugs that are considered hazardous or potentially hazardous based on the following six criteria: carcinogenicity, teratogenicity, reproductive toxicity in humans, organ toxicity, genotoxicity, and new drugs that mimic existing HDs in either structure or toxicity. The list was first published in 2004 and is updated every two years, most recently in 2016.

What are the requirements outlined in USP 800?

The following is an overview of the sections of the new finalized USP 800 rule. This is not a comprehensive list of the requirements. The full text rule is available from USP.

- **Hazardous Drug List**
  Organizations are required to maintain an internal list of HDs used in their facility. The list is to be updated at least annually, though organizations are encouraged to update it any time a new drug is used at their organization or an existing drug is added to the NIOSH list.

- **Types of Exposures**
  This section outlines the different types of hazardous drug exposures based on the activity being performed, including dispensing, compounding, administration, patient care, spills, receipt, and storage.

- **Designation of a Compounding Supervisor**
  Each organization must designate a compounding supervisor whose responsibilities include developing and implementing procedures, managing personnel training and assessment, and establishing a medical surveillance program for employees. The medical surveillance program is intended to measure employee health over time compared to their own baseline health status.

- **Protective Equipment**
  All employees handling HDs should have the required gloves, gowns, head, hair and sleeve covers, eye and face protection. Disposal of these items must also follow specific guidelines.

- **Facility**
  There are four categories of facility requirements: receipt, storage, compounding, and supplemental engineering control. This section updates USP 797 to allow some sterile and nonsterile drugs to be stored together based on the new stratification of HDs by NIOSH.

- **Environmental Quality and Control**
  Organizations must perform twice yearly surface wipe testing. If this testing uncovers contamination, the compounding supervisor must document and contain the contamination as well as creating a plan to prevent future contamination.

Receipt, Storage and Administration of Hazardous Drugs
Labeling, packing, and transporting HDs within the organization must follow guidelines to protect from damage, leakage, contamination or degradation. Compounding HDs must follow all guidelines outlined in USP 797. Administration of HDs should follow the Oncology Nursing Society (ONS) Safe Handling of Hazardous Drugs.

Disposal of Hazardous Drugs
Personnel responsible for disposal of HDs must follow personal protective equipment protocols while cleaning areas where HDs were used. The area must be deactivated, decontaminated, cleaned, and disinfected. There are additional guidelines on spill control and disposal of left over HDs.

Timeline for Review and Enforcement of Proposed Rule

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<th>March 2014</th>
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<th>February 2016</th>
<th>July 2018</th>
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<tr>
<td>USP 800 First Published for Comments</td>
<td>Revision Published and Opened for Comments</td>
<td>General Chapter Published</td>
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How is USP 800 enforced?
Enforcement of USP 800 falls mostly to state boards of pharmacy. Most state boards have one sweeping guideline that covers compliance to all USP compounding chapters, though some explicitly reference USP 797 and 800. The Food and Drug Administration can enforce USP guidelines, but usually only intervenes in cases of death or specific complaints.

How does USP 800 impact provider organizations?

Clinical
USP 800 does not explicitly dictate changes to clinical workflows for administering hazardous drugs though it recommends full compliance with the ONS Safe Handling of Hazardous drugs guidelines.

Financial
The cost of organizations becoming USP 800 compliant will vary depending on the current protocols in place. Financial considerations should include staff time for training and annual retesting, changes to personal protective equipment to meet new requirements, and facility design and upgrades to ensure compliance with transporting and storing HDs.

Operational
USP 800 requires the most effort operationally. The new designated compounding supervisor will need to establish new employee training protocols and education programs for everyone handling HDs including those delivering drugs to their facility as well as developing and maintaining the medical surveillance program. The current physical plant may not meet compliance requirements which will necessitate possible facility redesign or workarounds. Current equipment, including personal protective equipment, may not be compliant and necessitate a change in supplier.

What do provider organizations need to do to prepare for USP 800?
Status quo for most organizations is unlikely to be immediately compliant with USP 800. It is important to have a plan in place to address areas of noncompliance as soon as possible.

- Talk to pharmacists and compliance team about current protocols and organizational compliance to USP 797
- Perform a gap analysis to determine where there are areas of noncompliance to USP 800
- Designate or hire a compounding supervisor as outlined in Section 4 of USP 800 to lead the compliance effort
- Create a defined strategy to achieve compliance in the future
- Approach C-Suite as soon as possible to illustrate the impact of non-compliance
- Create protocols to ensure that any future facility planning incorporates and adheres to USP 800 guidelines