

## USP CHAPTER 800

USP published Chapter 800, Hazardous Drugs – Handling in Healthcare Settings, on February 1, 2016 with an implementation date of July 1, 2018. USP Chapter 800 applies to every healthcare setting where hazardous drugs, as defined by the National Institute for Occupational Safety and Health (NIOSH) are handled. NIOSH divides hazardous drugs into 3 groups:

Group 1 – Antineoplastic drugs.

Group 2 – Non-antineoplastic drugs that meet one or more of the NIOSH characteristics for a hazardous drug (see below).

Group 3 – Drugs that primarily pose a reproductive risk to both men and women.

A drug is considered hazardous if it exhibits one or more of the following characteristics:

1. Carcinogenic
2. Teratogenic or other developmental toxicity
3. Reproductive toxicity
4. Organ toxicity at low doses
5. Genotoxicity
6. Structure and toxicity profiles of new drugs that mimic existing hazardous drugs

USP Chapter 800 has the following containment requirements:

1. All antineoplastic drugs requiring manipulation (see below) and Active Pharmaceutical Ingredients (APIs) of any drug on the NIOSH list, must follow all containment requirements of USP Chapter 800 (to be discussed in a future article).
2. Final dosage forms of compounded hazardous drug preparations and manufactured available hazardous drugs, including antineoplastic drugs that do not require manipulation, only counting or repackaging, do not have to follow all the containment requirements if a risk assessment is done (to be discussed in a future article).
3. For other dosage forms of hazardous drugs, a risk assessment may be performed to determine alternative containment strategies and/or work practices.

Compounding and other manipulations include:

- Crushing or splitting tablets
- Opening capsules
- Pouring oral or topical liquids from one container to another
- Weighing or mixing components
- Constituting or reconstituting powder or lyophilized hazardous drugs
- Withdrawing or diluting injectable hazardous drugs from parenteral containers
- Expelling air or hazardous drugs from syringes

- Contacting hazardous drug residue present on protective personnel equipment (PPE) or other garments
- Deactivating, decontaminating, cleaning and/or disinfecting areas contaminated with or suspected of being contaminated with hazardous drugs
- Maintenance activities for potentially contaminated equipment and devices

NIOSH updates the List of Antineoplastic and Other Hazardous Drugs in the Healthcare Setting in even years. Currently the most current version was published in 2014.

Link to NIOSH List:

<http://www.cdc.gov/niosh/docs/2014-138/pdfs/2014-138.pdf>