



# USP General Chapter <800> Hazardous Drugs—Handling in Healthcare Settings

## Context for Implementation

### Scope and Intended Applicability

On December 1, 2019, USP <800> becomes official, and is **informational only** and not [compendially applicable](#). “Informational” means that it is not required and does not contain any mandatory tests and assays unless otherwise specified by regulators and enforcement bodies.

USP <800> applies to handling of hazardous drugs (HDs) where there is a risk of exposure to patients, healthcare workers, and the environment. The future intent is for USP <800> to become applicable to compounding activities through reference in USP <795> and <797>, for nonsterile and sterile compounding. In keeping with this intent, this means that only when a practitioner is engaged in compounding (as that term is defined in USP <795> and <797>) would USP <800> be applicable. For example, since administration and dispensing final dosage forms are out of scope of USP <795> and <797>, USP <800> would not apply in this context.

### Assessment of Risk

**USP <800> requires an assessment of risk, which is a consideration of the type of HD, dosage form, risk of exposure, packaging, and manipulation.** The chapter describes containment requirements only for HD Active Pharmaceutical Ingredients (APIs) and antineoplastic drugs requiring manipulation. For all other dosage forms, facilities must perform an assessment of risk to determine if alternative containment strategies and/or work practices are necessary. An assessment of risk is a consideration of the type of HD, dosage form, risk of exposure, packaging, and manipulation. Further, USP <800> permits final dosage forms of HDs that do not require any further manipulation to be dispensed without any further containment requirements unless required by the manufacturer.

### Resources and Tools

USP is committed to providing implementation support to advance the public health goal of USP <800> while preserving patient access to medications. USP will continue ongoing engagement and collaboration with stakeholders and to offer tools and resources to support the implementation of USP <800>. Our goal is to ensure our stakeholders have the information needed to best protect patients and healthcare workers while providing access to quality medicines.

For additional information on USP <800>, see <https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare>.