



The American Academy of Ophthalmology and the American Glaucoma Society are writing to provide guidance to our members regarding United States Pharmacopeia (USP) hazardous drug compounding and handling standards. The U.S. Pharmacopeia (USP) is a nonprofit organization that establishes standards for medicines, food ingredients, dietary supplement products, and ingredients. These standards are used by regulatory agencies and manufacturers to ensure that these products are of the appropriate identity, strength, quality, purity, and consistency.

USP General Chapter <800> provides standards for safe handling of hazardous drugs to minimize the risk of exposure to healthcare personnel, patients, and the environment. These standards became official on December 1, 2019, but only in an informational status. Compliance with these standards was not required until Chapter <800> was referenced by another official chapter. Under USP Chapter 800, hazardous drugs are identified by their presence on the National Institute of Occupational Safety and Health (NIOSH) [hazardous drug list](#). Several drugs used in ophthalmology (mitomycin and 5-fluorouracil) are included on this list due to concerns of reproductive toxicity.

On November 1, 2023, USP Chapters <795> *Pharmaceutical Compounding-Nonsterile Preparations* and <797> *Pharmaceutical Compounding-Sterile Preparations* will become final. As described in USP's [Role and Applicability of USP General Chapter <800> Related to Safe Handling of Hazardous Drugs](#), "Chapters <795> and <797> contain reference to USP Chapter <800> making it applicable and compendially required **only to the extent to which USP General Chapters <795> and <797> apply**. For hazardous drugs, this means only when a practitioner is "compounding" (as that term is defined in USP <795> and <797>) would <800> be applicable and compendially required. Since administration is out of scope of USP <795> and <797>, General Chapter <800> would not be applicable or compendially required in this context."

State agencies (e.g., State Boards of Pharmacy), other regulators (e.g., Occupational Safety and Health Administration), and oversight organizations (e.g., The Joint Commission) may make their own determinations regarding the applicability and enforceability of Chapter <800> for entities within their jurisdiction. While USP is engaged with regulators, accreditation organizations, and stakeholders about USP chapters, they do not play a direct role in enforcement.

Our organizations support a surgeon's ability to use mitomycin and 5-fluorouracil in hospital outpatient departments and ambulatory surgery centers. Both commercially available and sterile compounded agents must be used with closed-system transfer devices and appropriate personal protective equipment. In accordance with USP Chapter 800 recommendations, we encourage ophthalmologists to work with hospital outpatient departments and ambulatory surgery centers to develop appropriate Assessments of Risk (AoR) for the use of these products in these settings. These protocols should include information about the drug, training affected personnel with their acknowledgment of the specific risk of the agent. Documents addressing the following issues need to be available in the facility and reviewed annually:

- Type of Hazardous Drug
- Dosage Form
- Risk of Exposure
- Packaging
- Manipulation
- Alternative Containment Strategies or Work Practices to Minimize Occupational Exposure