

FAWKS NEWS

USP <800> in the Ambulatory Surgery Center (ASC)

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Chapter 800 in the United States Pharmacopeia (USP) that establishes standards for the safe handling of hazardous drugs (HDs).

NIOSH list

National Institute for Occupational Safety and Health (NIOSH) list is a publication that identifies drugs considered dangerous to workers in the healthcare setting.

Assessment of Risk (AOR)

An AOR is a written justification showing that the facility understands how it handles hazardous drugs and has implemented appropriate, proportional safety measures to protect staff and patients.

Hazardous Drugs in the Healthcare Setting

While USP <800> is written primarily for compounding pharmacies, several sections apply directly to surgery centers, even those that do not compound.

Hazardous drugs are defined by the [NIOSH list](#) and include certain chemotherapy agents, hormones (e.g., progesterone, testosterone), and antivirals. ASCs often encounter these medications.

What does USP <800> mean for ASCs?

Most surgery centers administer hazardous drugs but do not compound or manipulate them beyond the package insert. This distinction determines which parts of USP <800> are enforceable.

If your ASC does not compound, USP <800> compliance focuses on:

- **Identification:** Maintain a list of NIOSH-listed drugs your facility uses. Document an [Assessment of Risk \(AOR\)](#) for every HD in every dosage form
- **Safe Handling:** Use PPE (chemotherapy gloves, protective gowns if splashing possible) during preparation and administration.
- **Storage:** Segregate HDs from non-hazardous stock; label shelves or bins “Hazardous Drug.”
- **Spill Control:** Keep a spill kit accessible anywhere HDs are handled or stored.



FAWKS Call to Action!

If your ASC uses any NIOSH-listed drug, you must:

- 1 Maintain a Hazardous Drug Inventory
- 2 Label storage and waste containers appropriately
- 3 Train all staff who handle HDs annually
- 4 Equip with spill kits and PPE (i.e. ASTM 6978 gloves)
- 5 Document everything! AORs, SOPs, policies, and training (along with attestations)

Remember: USP <800> isn't just for regulatory compliance - it's about protecting our staff!



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- **Disposal:** Dispose of trace HD waste (syringes, vials, tubing) in yellow chemo containers.
- **Training:** Train staff annually on HD risks, handling, PPE, and spill procedures.

What ASCs don't need

If your ASC does not compound hazardous drugs, you typically do not need:

- Negative pressure compounding rooms
- Containment hoods (C-PECs)
- Wipe sampling or environmental monitoring
- Beyond-use dating or sterile compounding documentation

However, if medications are mixed, diluted or repackaged beyond manufacturer labeling, they become compounded sterile products (CSPs) then USP <797> and <800> standards for "immediate-use" compounding apply - Careful here!

Most Common HDs seen in ASCs

Category	Example	Considerations
Antineoplastics	Mitomycin, Gemcitabine	PPE and Chemo waste disposal
Hormones	Oxytocin, Premarin	Use "chemo" gloves for preparation and administration
Other	Phenytoin, Temazepam	Labeling storage bins

From a Consultant Pharmacist's Perspective

1. Policy & Documentation - Every ASC should maintain a written Hazardous Drug Handling Policy outlining identification, PPE, spill management, and waste disposal.
2. Staff Safety - Focus compliance efforts on exposure prevention, not infrastructure. A strong training and documentation program satisfies most accreditor expectations (SOP plus Attestation)
3. Practical Oversight - Flag new NIOSH additions annually.
4. Survey Readiness - Have your policy, training logs, and labeled HD storage ready for review - These are the top target!