USP Chapter 800
Hazardous Drugs – Handling in Healthcare Settings

The Kentucky Board of Pharmacy
serves the Commonwealth to promote, preserve, and protect the public health, safety, and welfare through effective regulation of the practice of pharmacy.

Kentucky Statute

KRS 217.015(31) – “Official compendium” means the official United States Pharmacopoeia, official homeopathic pharmacopoeia of the United States, official national formulary, or any supplement to any of them.

Progression to USP 800

1990 ASHP TAB
2004 NIOSH Alert
2008 Revised USP <797>
2014 Draft USP <800>
2016 USP <800>

USP 800 Sections

- 19 Sections
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  - Section 2 – List of Hazardous Drugs (HD)
  - Section 3 – Types of Exposure
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  - Section 16 – Spill Control
  - Section 17 – Disposal
  - Section 18 – Documentation and Standard Operating Procedures
  - Section 19 – Medical Surveillance
Section 1: Purpose of USP 800

- Describe practice and quality standards for handling hazardous drugs in healthcare settings to minimize exposure

- Goal to help promote:
  - Patient safety
  - Worker safety
  - Environmental protection

Section 1: Scope of USP 800

- Applies to all healthcare personnel
- Applies to all healthcare facilities
  - Receipt
  - Store
  - Prepare
  - Transport
  - Administer
  - Disposal
- Applies to sterile and nonsterile hazardous drug products (commercially available) and preparations (compounded)

USP 800 applies to all pharmacies in Kentucky that have drugs.

Section 2: What is a Hazard Drug?

- National Institute for Occupational Safety and Health (NIOSH) maintains a list of hazardous drugs used in healthcare setting

- Not OSHA Hazardous Drugs
- Not EPA Hazardous Drugs
Section 2: What is a Hazardous Drug?
- Any drug exhibiting at least one of the following criteria:
  - Carcinogenicity
  - Teratogenicity
  - Reproductive toxicity in humans
  - Organ toxicity at low doses in humans or animals
  - Genotoxicity
  - New drugs that mimic existing hazardous drugs in structure or toxicity

Section 2: Classification of Hazardous Drugs
  - Updated every other year in even years.
  - Most recent version September 2014
  - Next version due Fall of 2016

Section 2: List of Hazardous Drugs
- Format of NIOSH List revised in 2014 to include three groups of hazardous drugs:
  - Antineoplastic HD
  - Non-antineoplastic HD
  - Drugs with reproductive effects

Section 2: Examples of Hazardous Drugs
- Antineoplastic Drugs
  - Fluorouracil
  - Hydroxyurea
  - Megestrol
  - Methotrexate
  - Tamoxifen

- Non-antineoplastic Drugs
  - Carbamazepine
  - Estrogens
  - Progesterone
  - Phenytoin
  - Spironolactone

- Drugs with Reproductive Effects
  - Clonazepam
  - Fluconazole
  - Paroxetine
  - Testosterone
  - Topiramate
  - Warfarin
Section 2: Containment Requirements

- Review NIOSH list
- Make list of NIOSH drugs and dosage forms
  - Reviewed annually, documented
  - Reviewed anytime new drug introduced in pharmacy
- Determine containment strategy
  - Follow all USP 800 required containment
  - Assessment of risk

Example of a list of HDs:
- Methotrexate – tablet
- Topiramate – tablet
- Clonazepam – tablet
- Paroxetine – tablet
- Megace – liquid
- Progesterone – API

Date reviewed 09/07/2016 by Signature of Designated Person
Date reviewed 10/18/2016 by Signature of Designated Person
Ordered Spironolactone tablets on 10/18/16

Section 2: Containment Requirements

- Must follow all containment requirements:
  - Any antineoplastic HD requiring manipulation
    - Exception: final antineoplastic dosage forms not requiring manipulation other than counting
  - Any HD Active Pharmaceutical Ingredient (API)
  - Not performing an assessment of risk
- Assessment of risk performed for:
  - All other hazardous drugs on NIOSH list
    - Determine alternative containment strategies and work practices

Section 2: Assessment of Risk

- Type of HD (antineoplastic, non-antineoplastic, reproductive risk)
- Dosage form (tablet, capsule)
- Risk of exposure
- Packaging
- Manipulation
- Documentation of alternative containment strategies and/or work practices
- Reviewed annually, documented

Section 3: Types of Exposure

- Dispensing
- Compounding
- Administration
- Patient-care activities
- Spills
- Receipt
- Transport
### Section 3: Types of Exposure

- **Compounding:**
  - Crushing tablets or opening capsules
  - Pouring oral or topical liquids from one container to another
  - Weighing or mixing components
  - Constituting or reconstituting powdered or lyophilized HDs
  - Withdrawing or diluting injectable HDs from parenteral containers
  - Expelling air or HDs from syringes
  - Contacting HD residue present on PPE or other garments
  - Deactivating, decontaminating, cleaning, and disinfecting HD areas
  - Maintenance activities for potentially contaminated equipment and devices

### Section 4: Designated Person

- **Qualified and trained to be responsible for:**
  - Developing and implementing appropriate procedures
  - Overseeing entity compliance
  - Ensuring competency of personnel
  - Ensuring environmental control of storage and compounding areas
  - Monitoring of facility
  - Maintaining reports of testing and/or sampling performed

### Containment Strategies

- **Examples**
  - **Assessment of Risk**
    - Yaz, Ocella, Yasmin, Drospirenone/estradiol, Prempro
      - Non-antineoplastic drug
      - Unit dosed tablet
      - Risk of exposure – none, tablets are unit dosed and employees are not exposed directly to the tablet and do not manipulate
      - Containment strategy:
        - Tablets will not be removed from unit dose packaging
      - Reviewed 09/07/16 by: Signature of Designated Person
**Containment Strategies**

**Tamoxifen**
- Antineoplastic drug
- Enteric Coated Tablet
- Risk of exposure – counting manufactured tablets with no further manipulation
- Containment strategy:
  - Employee will use dedicated counting tray and spatula to count tamoxifen
  - Employee will immediately clean dedicated counting tray/spatula with alcohol by spraying the paper towel and wiping the tray/spatula or washing the tray/spatula with warm water and soap.
- Reviewed 09/07/16 by: Signature of Designated Person

**Megestrol acetate liquid**
- Antineoplastic drug
- Liquid
- Risk of exposure – possible spillage during pouring
- Containment strategy:
  1. Employee will use ATSM rated chemo gloves when pouring megestrol from the stock bottle to the dispensing bottle.
  2. Employee will place a plastic backed preparation mat on counter to absorb any spills when pouring from the stock bottle to the dispensing bottle.
  3. Once pouring is complete, employee will wipe outside of stock bottle and outside of dispensing bottle alcohol wipes, using a new wipe for each bottle.
  4. Gloves and mat will be disposed of in the hazardous waste container.
  5. Employee will clean area where worked with alcohol.
- Reviewed 09/07/16 by: Signature of Designated Person

**Topiramate suspension, compounded**
- Drug with reproductive risk
- Risk of exposure – crushing tablets to compound a suspension
- Containment strategy:
  - Only employees of non-reproductive age will compound
  - Employee will use ATSM rated chemo gloves and face mask to compound
  - Employee will use the dedicated mortar and pestle to crush topiramate tablets in the dedicated back corner of the pharmacy
  - No topiramate tablets will be pre-crushed. Only crush the amount needed to make the compound
  - Employee will wipe down all drug containers touched during the compounding (outside of topiramate stock bottle, outside of cherry syrup bottle, outside of dispensing bottle) with alcohol wipes, using a new alcohol wipe on each container.
  - Employee will immediately clean mortar and pestle with soap and warm water
- Reviewed 09/07/16 by: Signature of Designated Person

**Progesterone vaginal suppositories**
- Non-antineoplastic drug
- Compound using First Progesterone VGS Vaginal Suppository Kit
  - Kit contains progesterone powder (API)
  - Containment strategy, cannot use an alternate strategy, must follow all USP 800 Containment Requirements:
    - Must compound in a negative pressure room with at least 12 ACPH
    - Must compound in an appropriate C-PEC
    - Must use appropriate PPE

**Summary for All Pharmacies**
- Goes into effect Federally on July 1, 2018
- Designate a person to be responsible for HD
- Make a list of HD in pharmacy, including dosage form
  - Review and document annually
- Perform an assessment of risk
  - Review and document annually
  - If not done, must follow all containment strategies

APPLIES TO ALL PHARMACIES THAT HAVE DRUGS
Section 5: Facilities

- Designated areas for:
  - Receipt and unpacking of antineoplastic HDs or HD APIs
  - Storage of HD
  - Nonsterile compounding, if performed
  - Sterile compounding, if performed

- No exemption for low volume hazardous sterile compounding (USP Chapter 797)

Section 5.1: Receipt

- Antineoplastic HD and HD APIs
  - Unpack = remove from external shipping container
  - Must be done in neutral/normal or negative pressure area

- For sterile compounding:
  - Cannot unpack in sterile compounding areas
  - Cannot unpack in positive pressure areas

Section 5.2: Storage

- Stored to prevent breakage or spillage
- Cannot store on the floor
- Can be stored with other drugs:
  - Non-antineoplastic HD
  - Reproductive risk only HD
  - Final dosage forms of antineoplastic HD

- Stored separately in a negative pressure room with at least 12 Air Changes Per Hour (ACPH)
  - Antineoplastic HDs requiring manipulation
  - HD APIs
5.2: Storage, continued

- Sterile and nonsterile HDs may be stored together
  - **Exception:** Only HDs used for sterile compounding may be stored in the negative pressure buffer room

- Refrigerated antineoplastic HDs must be stored in a dedicated refrigerator in a negative pressure room with at least 12 ACPH
  - May place refrigerator in negative pressure buffer room for sterile compounding

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Section 5.3

**COMPOUNDING**

5.3.1 – NONSTERILE COMPOUNDING
5.3.2 – STERILE COMPOUNDING

Section 5.3 Compounding: Facility Design for Compounding

- Containment primary engineering control (C-PEC)
  - Ventilated device used when directly handling HDs

- Containment secondary engineering control (C-SEC)
  - External ventilation
  - Physically separated
  - Appropriate ACPH
  - Negative pressure relative to all adjacent areas

- Supplemental engineering controls
  - E.g. Closed-system drug-transfer device (CSTD)

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Section 5.3.1: Non-Sterile Compounding

**C-PEC**

- Externally vented or redundant-HEPA filters in series
- CVE, Class I or II BSC, CACI
- Is not required to have unidirectional airflow or ISO classification

**C-SEC**

- Externally vented
- 12 ACPH
- Negative pressure (0.01 to 0.03 inches of water column)
- Surfaces: smooth, impervious, free from cracks and crevices, and non-shedding

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Section 5.3.2: Sterile Compounding C-PEC

- BSC or CACI
- ISO 5 Classification
- Externally Ventilated
- Located within Clean Room setup or Containment Segregated Compounding Area (C-SCA)
Section 5.3.2: Sterile Compounding C-SEC

Clean Room
- ISO 7 buffer room entered from ISO 7 room
- Externally vented
- 30 ACPH
- Negative pressure (0.01 to 0.03 inches of water column)

C-SCA
- Unclassified air
- Externally vented
- 12 ACPH
- Negative pressure (0.01 to 0.03 inches of water column)
- Limited BUD
- Low and medium risk CSP

Section 5.3.2: Sterile Compounding Clean Room

- Non-preferred Set up
- Requires additional containment measures

Section 5.3: Combined Compounding

- Non-sterile in sterile C-PEC
  - Not at same time as sterile compounding
  - Occasional use
  - Decontaminated, cleaned, and disinfected before resuming sterile compounding

- Both non-sterile and sterile in same C-SEC
  - No particle-generating activity when sterile compounding
  - Maintain ISO 7 throughout non-sterile compounding activity (clean room)
  - C-PECs 1 meter apart
Section 5.4

**Containment Supplemental Engineering Controls**

- Closed System Transfer Device (CSTD)

Section 6

**Environmental Quality and Control**

- Surface Wipe Sampling Recommended
  - Recommended practice to detect surface HD residue
  - Useful tool to evaluate exposure controls and verify containment
  - Done initially and at least every 6 months
  - C-PEC interior; equipment; pass-through; work areas near and adjacent to C-PEC; areas immediately outside HD buffer room/C-SCA; and administration areas
  - Data is lacking regarding sampling method and contamination limits
  - If measurable contamination is detected, action must be taken and validated by repeat wipe sampling
  - Verify sampling kits have been properly tested (none currently certified)

Section 7

**Personal Protective Equipment (PPE)**

- Gloves
- Gowns
- Head, hair, shoe, and sleeve covers
- Eye and face protection
- Respiratory protective equipment
- Disposal of used PPE

**NIOSH**

- Provides some guidance for possible scenarios
- Gloves, gowns, head, hair, shoe covers required for sterile and nonsterile compounding
- Gloves required for administering antineoplastic HD
- Gowns required for administering injectable antineoplastic HD
### Section 7: PPE

- Appropriate PPE worn during:
  - Receipt
  - Storage
  - Transport
  - Compounding (sterile and nonsterile)
  - Administration
  - Deactivation/Decontamination, Cleaning, Disinfecting
  - Spill Control

### Section 7.1: Gloves

- Tested to American Society for Testing and Materials (ASTM) standard D6978 (or successor)
- Powder-free
- Inspected for physical defects before use
- Must be changed:
  - Every 30 minutes
  - When torn, punctured, or contaminated

### Section 7.2: Disposable Gowns

- Must be shown to be resist permeability
- Made of polypropylene or other laminate materials
- Close in the back
- Long sleeved
- Closed cuffs (elastic or knit)
- No seams or closures that could allow HDs to pass through
- Changed per manufacturer information for permeation
  - If not manufacturer information, change every 2 - 3 hours
  - Change immediately after spill or splash
  - Cannot be worn in other areas

### Section 7.3 – Head, Hair, Shoe, Sleeve Covers

- Must wear head, hair, beard, shoe covers
- Shoe covers cannot be worn in other areas
- Sleeve covers – RECOMMENDED

#### Sterile compounding:
  - Second pair of shoe covers donned before entering buffer room
  - Remove second pair of shoe covers when leaving buffer room

### 7.4 and 7.5: Eye and Respirators

- Must wear if working outside a C-PEC (spills)
  - Goggles, not safety glasses, are appropriate
  - Face shield with goggles provide protection against a splash versus face shield alone
  - Fit tested NIOSH certified respirator

### 7.6 – Disposal of Used PPE

- PPE used in compounding should be disposed of in proper waste container before leaving C-SEC
- Gloves worn during compounding must be removed and discarded in the C-PEC or contained in a sealable bag for discarding outside the C-PEC
- Potentially contaminated clothing must not be taken home
Section 8: Hazard Communication Program

- **Policy and Procedures**
  - Ensure worker safety during all aspects of handling HD
  - Training
    - Proper labeling
    - Transport
    - Storage
    - Use of Safety Data Sheets (SDS, formerly MSDS)
      - Readily accessible for every hazardous chemical used

Section 9: Personnel Training

- Applies to all personnel based on job function
  - Receipt, storage, compounding, repackaging, dispensing, administering, disposing
- Must occur before independently handles HD
- Must be demonstrated by each employee
- Reassessed:
  - Every 12 months
  - When new HD or new equipment is used
  - With a new or significant change in process or PnP
- Confirm in writing that personnel of reproductive capabilities understand the risks of HDs

Section 9: Personnel Training

- Training must include:
  - Overview of pharmacy’s list of HD and their risks
  - Review of PnP related to HD
  - Proper use of PPE
  - Proper use of equipment and devices (e.g., engineering controls)
  - Spill management
  - Response to known or suspected HD exposure
  - Proper disposal
  - Documentation of training

Section 10: Receiving
Section 10: Receiving

- Have PnP for receiving HD
- Should come from supplier sealed in plastic
- Must be delivered to HD storage area immediately
- Must wear appropriate PPE, including ASTM-tested, powder-free chemotherapy gloves
- Spill kit accessible in receiving area
- Table 4 Summary of Requirements for Receiving and Handling Damaged HD Shipping Containers

Section 11

LABELING, PACKAGING, AND TRANSPORT

Section 11.1: Labeling

- HD requiring special handling precautions must be clearly labeled at all times during their transport throughout the facility

Section 11.2: Packaging

- PnP on appropriate shipping containers and insulating material
  - Based on information from:
    - Product specifications
    - Vendors
    - Mode of transport
    - Experience of compounding personnel

- Containers and materials must maintain:
  - Physical integrity
  - Stability
  - Sterility (if needed)
  - Protect HD from:
    - Damage
    - Leakage
    - Contamination
    - Degradation
  - Protect healthcare workers who transport HD
### Section 11.3: Transport
- HD being transported must be labeled, stored and handled according to all applicable laws
- Must be transported in containers to minimize breakage or leakage
  - Cannot be transported in a pneumatic tube
- When shipping outside facility:
  - Consult transport information from SDS
  - Ensure labels and accessory labeling include:
    - Storage instructions
    - Disposal instructions
    - HD category information in format consistent with courier’s policies

### Section 12: Dispensing Final Dosage Forms
- HD requiring no manipulation other than counting final dosage form may be dispensed without any further requirements for containment, unless:
  - Manufacturer requires containment
  - Visual indicators of HD exposure is present
    - HD dust
    - HD leakage
  - Assessment of risk

### Section 13: Compounding
- Must follow USP Chapters 795 and 797
- Must be done in proper engineering controls
- Sterile and nonsterile compounding must use plastic-backed preparation mat on work surface of C-PEC
  - Change mat immediately after a spill
  - Change mat regularly during use
  - Discard at end of daily compounding
- Must use disposable or clean dedicated equipment:
  - Mortars, pestles, spatulas
- Labeling cannot introduce contamination into non-HD areas

### Section 14: Administering
Section 14: Administering

- Must use protective medical devices and techniques
  - Needleless and closed systems
  - Crushing tablets in plastic sleeves
- Must wear appropriate PPE
  - Dispose of PPE appropriately
- Oncology Nursing Society (ONS) Safe Handling of Hazardous Drugs publication

Section 15: Deactivation/Decontamination, Cleaning, and Disinfection

- All areas where HDs are handled must be routinely deactivated/decontaminated and cleaned
  - During receiving, compounding, transport, administering and disposal
- All reusable equipment and devices must be routinely deactivated/decontaminated and cleaned
  - C-PEC, carts, trays
- Personnel
  - Must be trained
  - Must wear appropriate PPE
    - Two pairs of ASTM-tested chemotherapy gloves
    - Impermeable disposable gowns
    - Eye protection and face shields if splashing is expected
    - Respiratory protection if warranted

Section 15: Summary

<table>
<thead>
<tr>
<th>Step</th>
<th>Purpose</th>
<th>Example Agents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Deactivation</td>
<td>Render compound inert or inactive</td>
<td>Oxidizer – peroxide formulations, sodium hypochlorite</td>
</tr>
<tr>
<td>Decontamination</td>
<td>Remove HD residue</td>
<td>Alcohol, water, peroxide, sodium hypochlorite</td>
</tr>
<tr>
<td>Cleaning</td>
<td>Remove organic and inorganic material</td>
<td>Germicidal detergent</td>
</tr>
<tr>
<td>Disinfecting (sterile)</td>
<td>Destroy microorganisms</td>
<td>Sterile alcohol</td>
</tr>
</tbody>
</table>

Section 15: Deactivation/Decontamination

- PnP
  - Decontamination
  - Deactivation
  - Cleaning
    - Procedures
    - Agents used
    - Dilutions used
    - Frequency
    - Documentation requirements
  - Disinfection, for sterile compounding
- Must follow USP Chapters 795 and 797

Section 15.3 – Cleaning the Compounding Area

- Cleaning and Disinfecting the Compounding Area section in USP 797 applies to both sterile and nonsterile HD compounding areas.
- Decontamination must be done:
  - Between compounding different HDs
  - Any time a spill occurs
  - Before and after certification
  - Any time voluntary interruption occurs
  - If ventilation tool is moved
Section 15.3 – Cleaning the Compounding Area

- May decrease HD contamination introduced into C-PEC if wipe down HD containers:
  - Use alcohol, sterile water, peroxide, or sodium hypochlorite
  - Spray the wiper not the HD container
  - Solution used cannot alter the HD container label
- Areas under work tray of C-PEC must be cleaned monthly
  - Last area to be cleaned
  - May need to wear NIOSH-approved respirator

Section 16: Spill Control

- Personnel must be trained in handling spills
- Spills must be contained and cleaned immediately on by qualified personnel with appropriate PPE
- Qualified personnel must be available at all times
- Signs restricting access to spill area must be available
- Spill kits must be readily available in all areas HDs are handled
- Dispose of spill kits as hazardous waste

Section 16: Spill Control

- Document circumstances and management of spills
  - PnPs
    - Prevent spills
    - Direct clean-up of spills
    - Location and capacity of spill kits
    - Address size and scope of spill
    - Specify who is responsible for spill management and type of PPE to be used
    - Appropriate respirators if the capacity of the spill kit is exceeded or if there is exposure to vapors or gases

Section 17: Disposal

- Disposal of HD must comply with all applicable federal, state and local regulations
- Personnel removing hazardous wasted must be trained
Section 18

DOCUMENTATION AND
STANDARD OPERATING
PROCEDURES
(POLICIES AND PROCEDURES)

Section 18: PnP

- Acquisition
- Preparation
- Dispensing
- Training
- Use and maintenance of equipment and supplies
- Safe handling of HD throughout facility
- Reviewed at least annually, documented

Summary of Policies and Procedures Required

- Training
  - Overview of pharmacy’s list of HDs and their risks
  - Review of HD PnP
  - Proper use of PPE
  - Proper use of equipment and devices
  - Spill management
  - Response to known or suspected HD exposure
- Receiving HD
- Labeling HD
- Handling HD
- Packaging HD
- Transport of HD

Summary of Policies and Procedures Required

- Prevention of accidental exposures or spills
- Personnel training on response to exposure
- Use of spill kit
- Appropriate shipping containers and insulating materials
- Written procedures for decontamination, deactivation, cleaning and disinfecting
- Written procedures for cleaning:
  - Procedures
  - Agents used
  - Dilutions used
  - Frequency
  - Documentation requirements

Summary of Policies and Procedures Required

- To prevent spills
- Direct the clean-up of HD spills
  - Size and scope of spill
  - Who is responsible for spill management and type of PPE required
  - Address location and capacity of spill kits and clean-up materials
  - Use of appropriate full facepiece, respirator if capacity of spill kit is exceeded or have exposure to vapors or gases

Section 19

MEDICAL SURVEILLANCE
RECOMMENDED
### Section 19: Medical Surveillance

**Goal:** Minimize adverse health effects in personnel potentially exposed to hazardous drugs through early detection of health problems

- Useful for identifying gaps in compliance with established policies and procedures
- Provides framework for ongoing evaluation of exposure control program:
  - Engineering and Administrative Controls
  - Work Processes
  - Personal Protective Equipment
  - Personnel Training/Education

### Program Elements:

**Data Collection and Documentation**
- Baseline assessment of a worker’s health status, medical and work history, detailed history of exposure to HDs

**Monitoring**
- Periodic physical examination, lab testing, updating exposure history, recording symptom complaints
- Comparing abnormal values and findings to baseline data and expected norms to identify exposure prevention failure

**Follow-Up Plan**
- Exposure-related health changes should prompt immediate re-evaluation of primary prevention measures
- Verify and Document:
  - Operational engineering controls
  - Compliance with existing policies,
  - Proper use of PPE
- Plan of action to prevent additional exposure
- Confidential communication with employees
- Follow-up medical survey and ongoing surveillance to determine effectiveness of plan

### Additional Resources

- **ASHP Guidelines on Handling HD**
- **NIOSH Alert 2004**
- **NIOSH List of HD 2014**
- **NIOSH Occupational Exposure**
  - [http://www.cdc.gov/niosh/topics/hazdrug/](http://www.cdc.gov/niosh/topics/hazdrug/)
- **NIOSH Workplace Solutions**
  - [https://www.cdc.gov/niosh/pdfs/workplace_date_desc_nopubnumber.pdf](https://www.cdc.gov/niosh/pdfs/workplace_date_desc_nopubnumber.pdf)
- **Oncology Nursing Society (ONS) Safe Handling of HD**