

## Improving USP <800> Compliance in a Community Healthcare Organization

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## Disclosures

- IRB Status: Exempt
- Co-investigators
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  - Todd Koepp, BSPH
  - Uma Hingorani, Pharm.D., BCPS
- Conflicts of Interest : none
- Project Sponsorship: none



## Learning Objectives

- Recognize or implement strategies to improve USP <800> compliance in health care settings



St. Vincent Healthcare  
Frontier Cancer Center  
Billings, Montana



St. Vincent Healthcare  
Main Campus  
Billings, Montana



## Background

- USP <800> is a published Chapter in the United States Pharmacopeia
- USP <800> provides standards for safe handling of hazardous drugs
- Compliance may be enforced by regulatory agencies
- By becoming compliant we can keep patients and employees safe from hazardous drugs



## Background- Development of USP <800>

- Chapter published for public comment 03/2014
  - Final revisions 02/2016
  - Federally enforceable date 07/2018
    - Extension 12/2019
- Enforcement
  - State Boards of Pharmacy
  - The Joint Commission
  - Medicare/ Medicaid Services
  - Federal Drug Administration



## USP <795>, USP <797>, USP <800> ???

- USP <795> (non-sterile compounding)
- USP <797> (sterile compounding)
  - Has a chapter on hazardous drugs that will eventually be eliminated
- USP <800> (handling hazardous medications)
  - All hazardous drugs must be unpacked, stored, and compounded in a negative pressure room

United States Pharmacopoeial Convention, General chapter <800>: hazardous drugs—handling in healthcare settings, USP 40: NF 35, 2017.  
United States Pharmacopoeial Convention, General chapter <797>: pharmaceutical compounding—sterile preparations, USP 40: NF 35, 2017.  
United States Pharmacopoeial Convention, General chapter <795>: pharmaceutical compounding—nonsterile preparations, USP 40: NF 35, 2017.

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## USP <800> Scope

United States Pharmacopoeial Convention, General chapter <800>: hazardous drugs—handling in healthcare settings, USP 40: NF 35, 2017.

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## Chapter Review

- Introduction and Scope
- Engineering Controls
- Personal Protective Equipment (PPE)
- Handling Hazardous Medications
- Assessment of Risk
- Cleaning
- Medical Surveillance

United States Pharmacopoeial Convention, General chapter <800>: hazardous drugs—handling in healthcare settings, USP 40: NF 35, 2017.  
Kocaeli PC, The Chapter <800>: Hazardous Drugs, Bethesda, MD: American Society of Health-System Pharmacists, 2017.

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## Methods

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## Gap Analysis

- Compare standards in USP <800> to current practices
  - Elucidate the gaps
  - Discover barriers
- Develop an Action Plan to move from non-compliance to compliance
  - Planning/ Construction
  - Engineering
  - Stakeholders
  - Assessment of Risk
  - Education
  - Surveillance

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## Gap Analysis

The 2017 USP Chapter <797> & <800> Compliance Study. Available at <http://www.usp.com>. Accessed September 1, 2017.

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### Gap Analysis

Domain	Score	Date Last Modified
AF: Ancillary Endpoints Testing	n/a	n/a
AG: Filter Integrity Test	n/a	n/a
AJ: Final Release Checks	80% (8 of 9 items in compliance)	4/27/2017 4:57:19 PM
AI: Inventory Storage and Handling/Delivery of CSRs	80% (4 of 5 items in compliance)	4/27/2017 4:58:57 PM
AJ: USP 800: Hazardous Drug List	66% (2 of 3 items in compliance)	6/5/2017 2:12:38 PM
AK: USP 800: Responsibilities of Personnel	50% (1 of 2 items in compliance)	6/5/2017 2:15:02 PM
AL: USP 800: Facilities and Engineering Controls	38% (5 of 13 items in compliance)	4/27/2017 5:07:26 PM
AM: USP 800: Personal Protective Equipment	82% (14 of 17 items in compliance)	6/5/2017 2:17:38 PM
AN: USP 800: Hazard Communication Program	0% (0 of 3 items in compliance)	5/3/2017 5:27:46 PM
AO: USP 800: Personnel Training	0% (0 of 3 items in compliance)	5/3/2017 5:28:55 PM
AP: USP 800: Receiving	42% (3 of 7 items in compliance)	5/3/2017 5:37:40 PM
AQ: USP 800: Labeling, Packaging, Transport and Disposal	40% (2 of 5 items in compliance)	5/22/2017 1:07:49 PM
AR: USP 800: Dispensing Final Dosage Forms	100% (1 of 1 item in compliance)	5/3/2017 5:54:27 PM
AS: USP 800: Compounding	100% (2 of 2 items in compliance)	5/3/2017 5:55:15 PM
AT: USP 800: Administration	100% (3 of 3 items in compliance)	5/22/2017 1:08:29 PM
AU: USP 800: Decontamination, Cleaning and Disinfection	83% (9 of 11 items in compliance)	5/3/2017 6:01:38 PM
AV: USP 800: Spill Control	0% (0 of 1 item in compliance)	5/3/2017 6:02:40 PM
AW: USP 800: Documentation and SOPs	33% (1 of 3 items in compliance)	5/22/2017 1:08:53 PM
AX: USP 800: Important but Non Required, Non Scored Items	not scored	5/22/2017 1:42:39 PM
AY: Radiopharmaceuticals as CSRs	n/a	n/a
AZ: Alternative Routes as CSRs	n/a	n/a
BA: Conclusion	not scored	5/22/2017 1:41:31 PM

The 2017 USP Chapter <797> A -<800> Compliance Study. Available at: <http://www.797update.com>. Accessed September 1, 2017.

- ### NIOSH List
- National Institute for Occupational Safety and Health
  - Updated every two years
  - Classifies hazardous medications
    - Antineoplastics
    - Non-antineoplastics
    - Reproductive hazard
- NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. Publication number 2016-101. Available at: <http://www.cdc.gov/niosh>. Accessed September 1, 2017.

- ### Assessment of Risk
- Options to handle hazardous drugs
    - Antineoplastics
      - require following containment strategies and work practices listed in USP <800>
    - Antineoplastics that require only counting and packaging, non-antineoplastics, or reproductive hazardous agents
      - follow containment strategies and work practices listed in USP <800> (or)
      - perform an Assessment of Risk to develop and use alternative containment strategies and/ or work practices
- USP Frequently Asked Questions. Available at: <http://www.usp.org/frequently-asked-questions>. Accessed September 1, 2017.

- ### Development of Assessment of Risk Process
- What is an Assessment of Risk?
    - Analyzing hazardous drugs to identify factors that pose potential harm
  - How do we perform an Assessment of Risk?
    - Establish a protocol and utilize tools to evaluate hazardous drugs
  - What tools do we recommend?
    - Worksheet
    - Fillable Assessment of Risk form

### AoR Worksheet

Drug: \_\_\_\_\_

Form: \_\_\_\_\_

Reason for exception: \_\_\_\_\_

Activity	USP-800- Requirement and NIOSH Recommendation	Operational Policy		
		Follow	N/A	Daily Examples
Receiving	Inspect in sealed, normal pressure area, hold for and requires analysis			
Transport from Receiving	In container that minimizes risk of leakage or leakage			
Storage	Separate from non-HD, in separate area that is separate, secure, locked and not at least 12 ACFT			
Transfer from Storage	In container that minimizes risk of leakage or leakage			
Compounding (solid)	Compendium control			
Transfer from Storage	In container that minimizes risk of leakage or leakage			
Dispensing (solid)	Meets USP-797 and 800- requirements			
Compounding (liquid)	Meets USP-797 and 800- requirements			
Transfer from Storage	In container that minimizes risk of leakage or leakage			
Dispensing (liquid)	Meets USP-797 and 800- requirements and NIOSH HD for recommendations			
Transfer from Storage	In container that minimizes risk of leakage or leakage			
Dispensing (parenteral)	Meets USP-797 and 800- requirements and NIOSH HD for recommendations			
Transfer from Storage	In container that minimizes risk of leakage or leakage			
Dispensing (parenteral)	Meets USP-797 and 800- requirements and NIOSH HD for recommendations			

### AoR Form

#### Hazardous Drug Assessment of Risk (AoR)

Drug Name: \_\_\_\_\_ Date AoR Initially Performed: \_\_\_\_\_ Date AoR Reviewed or Revised: \_\_\_\_\_

HD Drug Category:  Antineoplastic  Non-antineoplastic  Reproductive Risk Only

Design form:  Sterile dosage form manufactured or compounded by an approved vendor and not requiring additional manipulation (select one)  
 Dosage form of conventionally manufactured antineoplastic product that requires only packaging or counting  
 Dosage form of conventionally manufactured non-antineoplastic or reproductive hazard product that requires only packaging or counting  
 Other (specify): \_\_\_\_\_

Describe Drug and Packaging: \_\_\_\_\_

Rationale for not requiring all <800> containment strategies	Specific Alternative Administrative, Engineering and Work Practice Control Strategies
Risk of exposure: _____	<input type="checkbox"/> Specific Alternative Administrative, Engineering and Work Practice Control Strategy <input type="checkbox"/> Training in the following strategies was provided and documented: <input type="checkbox"/> Specific actions have been added to this Hazardous Drug competency on _____ <input type="checkbox"/> Other: _____
Recommendation: _____	Label: _____

Based on Assessment of Risk will proceed as follows:  Follow alternative strategies documented above  Follow all USP <800> requirements

Assessment of Risk written by: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewed by Pharmacy Manager: \_\_\_\_\_ Date: \_\_\_\_\_

### AoR Form Requirements

**Hazardous Drug Assessment of Risk (AoR)** SCL Health

Drug Name: \_\_\_\_\_ Date AoR Initially Performed: \_\_\_\_\_ Date AoR Reviewed or Revisited: \_\_\_\_\_

**HD Drug Category:**  Antineoplastic  Non-antineoplastic  Reproductive Risk Only

**Design form:** (select one)  
 Specific design form manufactured or supplied by an approved vendor and not requiring additional manipulation  
 Design form of conventionally manufactured antineoplastic product that requires only packaging or counting  
 Design form of conventionally manufactured non-antineoplastic or reproductive hazard product that requires only packaging or counting  
 Other (specify): \_\_\_\_\_

**Describe Drug and Packaging:** \_\_\_\_\_

**Rationale for not requiring all <800> containment strategies** **Specific Alternative Administrative, Engineering and Work Practice Control Strategies**

**Risk of exposure:**  Specific Alternative Administrative, Engineering and Work Practice Control Strategies  
 Training in the following strategies was provided and documented:  
 \_\_\_\_\_  
 Specific actions have been added to the Hazardous Drug competency on:  
 Other: \_\_\_\_\_

**Recommendation:** \_\_\_\_\_ **Label:** \_\_\_\_\_


Based on Assessment of Risk, will proceed as follows:  Follow alternative strategies documented above  Follow all USP <800> requirements  
 Assessment of Risk written by: \_\_\_\_\_ Date: \_\_\_\_\_  
 Reviewed by Pharmacy Manager: \_\_\_\_\_ Date: \_\_\_\_\_

United States Pharmacopoeial Convention. General chapter <800>: hazardous drugs—handling in healthcare settings. USP 40-NF 35, 2017.

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### SCL Health Assessment of Risk

- Collaboration with other Care Sites
  - Montana
  - Colorado
  - Kansas
- Meet monthly
  - Local
  - System
- Shared drive



United States Pharmacopoeial Convention. General chapter <800>: hazardous drugs—handling in healthcare settings. USP 40-NF 35, 2017.

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### Results

- Frontier Cancer Center construction project 99% completed
- Inpatient construction projects 75% completed
- 2018- 85% overall compliance (153/180)
- 2018- 84% USP <800> compliance (76/90)
- 2018- 37% of AoRs NIOSH drugs on Table 1, 2, & 3 (57/153)
- SCL Health projects in process
  - Hazardous Drug Policy
  - Educational Modules
  - Surveillance Planning

United States Pharmacopoeial Convention. General chapter <800>: hazardous drugs—handling in healthcare settings. USP 40-NF 35, 2017.

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### <USP> 800 Moving Forward

- System wide policy development/approval
- Construction projects
- Gap analysis
- Assessments of Risk
- Education
- SOPs
- Policies
- Surveillance

United States Pharmacopoeial Convention. General chapter <800>: hazardous drugs—handling in healthcare settings. USP 40-NF 35, 2017.

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### Surveillance

- Recommended (not required)
- Pharmacy, Nursing, & Physicians
  - Identify employees with exposure
  - Develop baseline assessments
  - Wipe samples every 6 months

United States Pharmacopoeial Convention. General chapter <800>: hazardous drugs—handling in healthcare settings. USP 40-NF 35, 2017.

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### Post-Presentation Questions

- USP <800> is defined as?
  - a. the updated and revised edition of USP <797>
  - b. a general chapter in the United States Pharmacopeia that addresses safe handling of hazardous drugs
  - c. a drug identified as hazardous by the National Institute for Occupational Safety and Health (NIOSH)
  - d. not enforceable in the United States
  - e. all of the above statements are true

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Beaus HE. USP <800>: Adds Significant Safety Standards: Facility Upgrades Needed to Protect Employees From Hazardous Drugs. P.T. 2017;42(5):336-339.

## Post-Presentation Questions

- An assessment of Risk does not include?
  - a. drug name and dosage form
  - b. risk of exposure
  - c. NIOSH designation
  - d. personal Protective Equipment (PPE) requirements
  - e. mechanism of action

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## Questions???

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## References

1. United States Pharmacopoeial Convention. General chapter <800>: hazardous drugs—handling in healthcare settings. USP 40-NF 35, 2017.
2. United States Pharmacopoeial Convention. General chapter <797>: pharmaceutical compounding—sterile preparations. USP 40-NF 35, 2017.
3. United States Pharmacopoeial Convention. General chapter <795>: pharmaceutical compounding—nonsterile preparations. USP 40-NF 35, 2017.
4. Lexicomp [database online]. Wolters Kluwer; 2017. Available at: <https://online.lexi.com>. Accessed September 1, 2017.
5. UpToDate [database online]. Wolters Kluwer; 2017. Available at: <https://online.uptodate.com>. Accessed September 1, 2017.
6. Kinnick PC. The Chapter <800> Answer Book. Bethesda, MD: American Society of Health-System Pharmacists; 2017.
7. ASHP. ASHP technical assistance bulletin on handling cytotoxic drugs in hospitals. Am J Hosp Pharm. 1990; 47(5):1033-1049.
8. ASHP. ASHP guidelines on handling hazardous drugs. Am J Health-Syst Pharm. 2006; 63:1172-1193.
9. NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2016. Publication number 2016-161. Available at: <http://www.cdc.gov/niosh>. Accessed September 1, 2017.
10. Occupational Safety and Health Administration. Controlling occupational exposure to hazardous drugs. Available at: <http://www.osha.gov>. Accessed September 1, 2017.
11. Centers for Medicare & Medicaid Services. State Operations Manual, Appendix A—Survey Protocol, Regulations and Interpretive Guidelines for Hospitals. Available at: [https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/osm17top\\_a\\_hospitals.pdf](https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/osm17top_a_hospitals.pdf). Accessed September 1, 2017.
12. Centers for Disease Control and Prevention. NIOSH Workplace Solutions, Medical Surveillance for Health Care Workers Exposed to Hazardous Drugs. 9007. Publication number 2013-103. Available at: <http://www.cdc.gov/niosh/docs/wsp-solutions/2013-103/pdfs/2013-103.pdf>. Accessed September 1, 2017.
13. Polovich M. Safe Handling of Hazardous Drugs, 2nd ed. Pittsburgh, PA: Oncology Nursing Society; 2011.
14. The 2017 USP Chapter <797> & <800>: Compliance Study. Available at: <http://www.797spot.com>. Accessed September 1, 2017.
15. USP Frequently Asked Questions. Available at: <http://www.usp.org/frequently-asked-questions>. Accessed September 1, 2017.
16. Neuss MN, Gilmore TR, Belderson KM, et al. 2016 Updated American Society of Clinical Oncology Oncology Nursing Society Chemotherapy Administration Safety Standards, Including Standards for Pediatric Oncology. J Oncol Pract. 2016;12(12):1262-1271.
17. Beaus HE. USP <800>: Adds Significant Safety Standards: Facility Upgrades Needed to Protect Employees From Hazardous Drugs. P.T. 2017;42(5):336-339.