Preparing for USP Chapter <800>: Now is the Time to Get Ready

Presented as a Midday Symposium and Live Webinar at the 50th ASHP Midyear Clinical Meeting and Exhibition

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www.ashpadvantage.com/800ready

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Agenda

11:30 a.m. - 11:40 a.m.
Welcome & Introductions
Patricia Kienle, B.S.Pharm., M.P.A., FASHP

11:40 a.m. - 12:50 p.m.
USP Chapter <800>: Now is the Time to Get Ready by Turning Regulations into Action
Ryan A. Forrey, Pharm.D., M.S., FASHP
Patricia Kienle, B.S.Pharm., M.P.A., FASHP

12:50 p.m. - 1:00 p.m.
Faculty Discussion and Audience Questions
All Faculty

Faculty

Patricia C. Kienle, B.S.Pharm., M.P.A., FASHP, Activity Chair
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions
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Activity Overview

This educational activity will provide an overview and update of USP Chapter <800> along with procedures pharmacists can initiate now to comply with the new chapter. Participants will hear firsthand perspectives from an organization that has operationalized USP Chapter <800> requirements. A step-by-step approach to implementing best practices from receipt and storage to administration of hazardous drugs will be described.

Learning Objectives

At the conclusion of this application-based educational activity, participants should be able to

- Analyze examples of implementation of USP Chapter <800> standards for the handling of hazardous drugs during receipt, storage, compounding, dispensing, administration, and disposal.
- Demonstrate operationalization of USP Chapter <800> requirements for storage areas in which hazardous drugs will be housed and manipulated.
- Plan the pharmacist’s likely role in promoting best practices in the handling of hazardous drugs.
- Utilize examples to illustrate how organizations might implement best practices in administration of hazardous drugs.

Additional Educational Opportunities about USP Chapter <800> Coming in 2016

- Web-based activity - Based on today’s live symposium (1.5 hours of CPE, please note that individuals who claim CPE credit for the live symposium or webinar are ineligible to claim credit for the web-based activity)

For more information and to sign up to receive e-mail updates visit

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Live Activity ACPE #: 0204-0000-15-479-L03-P
On-Demand Activity ACPE #: 0204-0000-15-479-H03-P

Complete instructions for processing continuing education credit online are listed on the last page.

Webinar Information

Visit www.ashpadvantage.com/800ready to find:

- Webinar registration link
- Group viewing information and technical requirements
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Patricia C. Kienle, B.S.Pharm., M.P.A., FASHP, *Activity Chair*
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Laflin, Pennsylvania

Patricia Kienle, B.S.Pharm., M.P.A., FASHP, is the Director of Accreditation and Medication Safety for Cardinal Health Innovative Delivery Solutions.

Ms. Kienle received her Bachelor of Pharmacy degree from the Philadelphia College of Pharmacy and Science, and Masters of Public Administration from Marywood University in Scranton, Pennsylvania. She completed an Executive Fellowship in Patient Safety from Virginia Commonwealth University and is Adjunct Associate Professor at Wilkes University in Wilkes-Barre, Pennsylvania.

She has served on the Board of Directors of ASHP and as President of the Pennsylvania Society of Hospital Pharmacists. She is a Fellow of ASHP, was named Pharmacist of the Year by the PSHP, and received the Distinguished Achievement Award in Hospital and Institutional Practice from the American Pharmaceutical Association Academy of Pharmacy Practice and Management, and the Distinguished Leadership Award from ASHP. She has served on the Pharmacotherapy Specialty Council of the Board of Pharmaceutical Specialties, as the pharmacist member of the Hospital Professional and Technical Advisory Committee of the Joint Commission, and on the Board of Governors of the National Patient Safety Foundation. She is a current member of the USP Expert Committee on Compounding, and Chair of the Subcommittee and Expert Panel on Hazardous Drugs.

Ms. Kienle is the author of *Compounding Sterile Preparations: ASHP’s Visual Guide to Chapter <797>* video and Companion Guide and co-author of *Assuring Continuous Compliance with Joint Commission Standards: A Pharmacy Guide, 8th edition*. She also served as editor of *Understanding JCAHO Requirements for Hospital Pharmacies*.

She is a frequent presenter to professional groups, with special interests in promoting medication safety, compounding sterile preparations, accreditation and regulatory issues.
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Ryan A. Forrey, Pharm.D., M.S., FASHP
Director, Department of Pharmaceutical Services
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Ryan A. Forrey, Pharm.D., M.S., FASHP, is Director of Pharmacy Services, at Emory University Hospital Midtown in Atlanta, Georgia, and Clinical Assistant Professor at The Ohio State University (OSU) College of Pharmacy, Columbus, Ohio.

Dr. Forrey has published articles in the field of medication errors and prevention, operational efficiency and productivity measurement, and hazardous drug safe handling. He has presented on numerous topics, USP Chapter <797>, USP Chapter <800>, hazardous medication handling and preparation, and pharmaceutical waste management. In his role at Emory, he leads and directs the Department of Pharmacy for Emory University Hospital Midtown, which includes the outpatient infusion pharmacy areas for the Emory Winship Cancer Institute.

Dr. Forrey currently serves on the United States Pharmacopeial Convention (USP) Compounding Expert Committee for 2015-2020. He is also an active member of the Hematology/Oncology Pharmacists Association (HOPA), ASHP, and the International Pharmaceutical Federation (FIP). He currently represents HOPA on the Oncology Nursing Society (ONS) Safe-Handling Taskforce.
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Learning Objectives

1. Analyze examples of implementation of USP Chapter <800> standards for the handling of hazardous drugs (HDs) during receipt, storage, compounding, dispensing, administration, and disposal.
2. Demonstrate operationalization of USP Chapter <800> requirements for storage areas in which hazardous drugs will be housed and manipulated.
3. Plan the pharmacist’s likely role in promoting best practices in the handling of hazardous drugs.
4. Utilize examples to illustrate how organizations might implement best practices in administration of hazardous drugs.
When did the first guidance concerning handing HDs appear in the pharmacy literature?

a. Mid-1980s  
b. Mid-1990s  
c. Early 2000s  
d. Publication of proposed USP <800> in 2014

Overview of <800>

• To protect patients, personnel, and the environment from hazardous drug contamination  
• Applies to all healthcare personnel  
• Applies in all healthcare settings

Sections in <800>

1. Introduction and Scope
2. List of Hazardous Drugs
3. Types of Exposure
4. Responsibilities of Personnel Handling HDs
5. Facilities and Engineering Controls
6. Environmental Quality and Control
7. Personal Protective Equipment
8. Hazard Communication Program
9. Personnel Training
10. Receiving
11. Labeling, Packaging, Transport, and Disposal
12. Dispensing Final Dosage Forms
13. Compounding
14. Administering
15. Deactivating, Decontaminating, Cleaning, and Disinfecting
16. Spill Control
17. Documentation and SOPs
18. Medical Surveillance
19. Glossary
20. Appendices

Agenda

- Determine your HD list
- Develop an Assessment of Risk
- Train personnel
- Ensure appropriate facilities
- Deactivate HD areas
- Monitor for compliance

SOPs = Standard Operating Procedures


Determine Your HD List
What types of drugs do you need to consider for your HD list?

a. Antineoplastics in the 2014 NIOSH list
b. All drugs in the 2014 NIOSH list
c. Drugs identified as hazardous waste
d. AHFS drugs categorized as 10:00.00

NIOSH = National Institute for Occupational Safety and Health
AHFS = The American Hospital Formulary Service

NIOSH List of HDs

- Sorts HDs into three categories
  - Antineoplastic
  - Non-antineoplastic
  - Reproductive-only hazards
- Different from Environmental Protection Agency (EPA) hazards


List of Hazardous Drugs

- Review all HDs in the 2014 NIOSH List of Hazardous Drugs
- Identify the drugs and dosage forms you handle
- Determine if you will handle all as HDs or if you will identify some entity-exempt dosage forms based on Assessment of Risk
Who should be involved in the creation of an institution’s HD list?

- Pharmacists
- Nurses
- Physicians
- All of the above

Creating an HD List

- Create a committee to decide on the facility list of HDs
  - Include pharmacists, nurses, physicians
  - Group should have specialty in oncology, women’s health, infectious diseases, neurology, rheumatology, and transplant
- Most debate/discussion will likely focus on antineoplastic HDs in final form

Creating an HD List

- Know which HDs are used at your facility
  - Run reports of purchase data from wholesaler(s) as well as direct purchases
  - Compare to each section of the NIOSH drug list
    - Excel VLOOKUP function works well for this
- Review purchases against facility formulary
  - Decision Point
    - Inclusion or exclusion of non-formulary HDs
Inclusion of Non-formulary HDs

Pros
• Assurance that appropriate safe practices are used
• Alignment with the NIOSH list

Cons
• System build and maintenance needed
• The meaning of formulary is diluted
• Extra work that may not be needed

Creating an HD List

• Antineoplastic HDs
  – Clearly outlined by the 2014 NIOSH list
  – Must identify which items are in final dosage form or not manipulated (risk-assessment required)
    • e.g., oral chemotherapy
  – New antineoplastic HDs approved since 2014 list
  • Review FDA website for approvals
    – http://www.fda.gov/Drugs/InformationOnDrugs/ApprovedDrugs/ucm279174.htm
  • Seek resources from professional organizations

• Monoclonal antibodies
  – Decision Point
    • Should monoclonal antibodies* be included as antineoplastic HDs?
    • Does your current list already include monoclonal antibodies?
    • Is there a middle road?
      – Non-antineoplastic HD
      – "Biological" agent category
      – Pharmacy special handling category

*Antibodies not conjugated to an antineoplastic HD

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Inclusion of Monoclonal Antibodies

Pros
- Staff comfort if already on facility list
- Consistent operations for the oncology areas/satellites

Cons
- Not included on NIOSH HD list (in any category)
- Full compliance with USP <800>, even if not used for oncology purpose

Non-antineoplastic HDs

- Include all items on 2014 NIOSH list
- May include monoclonal antibodies depending on facility decision
- Include new items approved since the creation of the 2014 NIOSH list
  - Depend on specialists in each therapeutic area
  - Review Pharmacy and Therapeutics committee formulary approvals since the NIOSH list was created
    • Similar mechanism of action as another HD

Reproductive-only HDs

- Meet only the reproductive hazard category for classification by NIOSH
- Pose a risk only to those who are actively trying to conceive, are pregnant, may become pregnant, or are breast-feeding
- Include any items from the 2014 NIOSH list plus those items that have been added to formulary since the 2014 list was created
Develop an Assessment of Risk

Potential for Assessment of Risk
- All containment strategies must be used for
  - Any HD active pharmaceutical ingredient (API)
  - Any antineoplastic, except those that only require counting or packaging
- Assessment of Risk can be considered for
  - Antineoplastics that require only counting or packaging
  - Non-antineoplastic HDs
  - Reproductive-only HDs

Assessment of Risk
- Must include
  - Type of HD
  - Dosage form
  - Risk of exposure
  - Packaging
  - Manipulation
- Must identify for each entity-exempt dosage form
  - Alternative containment strategies
  - Alternative work practices
  - Review and document at least every 12 months
Risk Assessment

- While USP <800> allows for a risk-assessment to be done for non-antineoplastic, reproductive-only, and antineoplastic HDs requiring no further manipulation
  - That DOES NOT mean that they can be handled like non-HDs
  - The risk assessment must be completed for each category of HD and each category may have different handling requirements

Risk Assessment Factors

- All hazardous drugs, regardless of the formulation, should be labeled as such
- The actual risk is dependent on
  - How the HD is manipulated
  - Frequency of handling
  - Engineering controls used
  - Personal protective equipment (PPE) used

Risk Assessment Factors: Manipulation

- Manipulation in order of risk
  - Opening a unit dose (UD) package poses little risk
    - Nursing
  - Counting tablets from a bulk bottle is a higher risk
    - Dispensing pharmacist/technician
  - Repackaging a bulk bottle is an even higher risk
    - Repackaging pharmacist/technician
  - Crushing a tablet to create a suspension is the highest risk
    - Compounding pharmacist/technician
Risk Assessment Factors: Frequency

- Administering occasionally to patients
- Administering daily to patients
- Counting or repackaging occasionally
- Counting or repackaging daily
  - Items may only be administered by nursing staff occasionally, but may be handled by pharmacy staff daily
  - Risk assessment should be appropriate for each role

Risk Assessment: Engineering Controls

- Are primary and secondary engineering controls available?
- Should additional PPE be required when engineering controls are not present?
  - Respiratory protection (e.g., N95 mask)

Risk Assessment: PPE Used

- Are solid oral dosage forms administered without touching?
  - From UD container into soufflé cup
  - Patient self-administered medication
- Are gloves used when touching any solid oral dosage form?
- What PPE is required for injectable non-hazardous and reproductive-only HDs?
Risk Assessment: Antineoplastic HDs

- Policy review
  - Chemotherapy administration policy
    - Appropriate PPE for administration
    - Chemotherapy safety process (e.g., double check)
  - "Do Not Crush" medication list
  - Education requirements for staff
    - e.g., chemotherapy competency
  - Pharmacy sterile compounding policies
    - Special handling requirements for medications
      - e.g., blood and blood products

Risk Assessment: Antineoplastic HDs

- Determine risk based on normal handling and administration practices
  - Solid oral dosage forms may be excluded unless crushing is needed
  - Do you create a "crushed" version of each antineoplastic HD in electronic medical record (EMR)?
    - May require special labeling to indicate that it is a HD
      - "Do Not Crush"
      - "Medication Exposure Precautions"

Risk Assessment: Antineoplastic HDs

- Antineoplastic medications used for non-oncology purposes
  - Methotrexate tablets for rheumatoid arthritis
    - Could be excluded based on risk assessment
  - Methotrexate injection for ectopic pregnancy
    - Must follow all of the requirements

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Risk Assessment:
Non-antineoplastic HDs
- Includes many hormonal agents
  - Consider if API will be used to compound creams and suppositories
- Review manufacturer special handling requirements
- Do the risk assessment and safe handling requirements adequately protect against all of the risks appropriately?

Risk Assessment:
Reproductive-only HDs
- How likely is it that formulary dosage forms are going to be manipulated?
  - Crushing of tablets
  - Injectable agents that require compounding
    - Oxytocin pre-mixed vs. vials for compounding
- Are there different risks for different agents?
  - Finasteride vs. clonazepam
- Can a universal policy for safe-handling be created?

Train Personnel
Responsible Individual

- Each entity must have a designated person who is qualified and trained to be responsible for
  - Implementing appropriate procedures
  - Overseeing entity compliance
  - Ensuring competency of personnel
  - Ensuring environmental control of the storage and compounding areas


All Personnel Who Handle HDs

- All personnel who handle HDs must be responsible for
  - Understanding the fundamental practices and precautions
  - Continually evaluating procedures and quality of the HDs
  - Minimizing exposure to personnel
  - Minimizing contamination of the work and patient-care areas


Compounding Supervisor

- Compounding supervisor can be site-specific or over multiple sites
  - Many oncology practices have only 1-2 pharmacists overseeing compliance at all sites
  - Large multiple hospital systems may have one designated compounding supervisor for the system
    - Must still oversee compliance with all aspects of HD compounding

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Compounding Supervisor

- Compounding/Sterile Products Committee
  - Comprised of representatives (technicians and pharmacists) from all compounding areas
  - Shared governance structure to aid organizational and staff acceptance
    - Ownership of the policies, procedures, and compliance
  - Each area/hospital has its own designated compounding supervisor

Compounding Supervisor

- Must have a compounding supervisor at pharmacies, physician offices, veterinary clinics, etc.
  - Anywhere HDs may be compounded
- Compounding supervisor does not have to be pharmacist
  - Physician
  - Nurse
  - Technician

Training and Competency

- HD safe handling impacts healthcare workers throughout the facility
  - Receiving personnel
  - Pharmacy personnel
  - Nursing personnel (including patient care technicians)
  - Patient transporters
  - Environmental services staff
Training and Competency

• Receiving personnel
  – How to identify packages that may contain HDs
  – How to appropriately handle HD-containing packages
  – Who to contact if there is suspicion of broken HD container

Training and Competency

• Spill management and handling of excreta for patients on HDs should be a component of training for all healthcare workers
• Transporters may need special training for patients actively receiving a HD during transport
  – At a minimum, how to identify patients on a HD
• Environmental services staff may have special cleaning required for HD patient rooms

Training and Competency

• Since negative pressure compounding technique is required for HDs, specific competencies should focus on this
  – Minimize exposure risk
• Closed-system drug transfer devices (CTSDs) for administration of HDs
  – Must document competency using these systems
  – If using for compounding as well, must have documentation of competency
Ensure Appropriate Facilities

Facilities - Receiving

- Must be in either negative pressure or neutral/normal pressure area
- Must NOT be in positive pressure area

Facilities - Receiving

- Ensure wholesaler designates HDs separately from non-HD medications
  - Separate colored totes
  - Separate account for ordering
  - Separate “ship to” location
- Direct orders and drop shipped items must also be received appropriately
  - Develop a process with hospital receiving to expedite to the appropriate area

Facilities - Storage

Where are your antineoplastic medications stored?

a. With other medication stock
b. Separate shelf or bins in same area as other medications
c. In separate room under negative pressure
d. In negative pressure buffer room

Storage and Compounding Requirements

- USP Chapter <797> has required separate storage since 2008
- Room (with fixed walls) separate from non-hazardous drugs
- Vented to the outside
- Negative pressure
- Appropriate number of air changes per hour

Two Compounding Options

- Negative pressure buffer room with positive pressure anteroom
  - Same as USP Chapter <797>
- Containment Segregated Compounding Area (C-SCA)
  - Room (with fixed walls) separate from non-hazardous drugs
  - Vented to the outside
  - Negative pressure
  - At least 12 air changes per hour

Facilities - Storage Requirements

- Refrigerated antineoplastic HDs must be stored in a separate refrigerator
  - Refrigerator must be in negative pressure
  - CAN be located in the buffer room or the C-SCA
- Place the refrigerator near a room exhaust, located near the refrigerator compressor

Facilities – Infusion Center

Used with permission from R. Forrey
Facilities – Buffer Room

Used with permission from R. Forrey

Facilities- C-SCA

• May decrease renovation costs for outpatient infusion centers and physician offices
  – Most infusions are going to be used within a 12 hour beyond-use date (BUD)
  – Does not require as extensive HVAC engineering controls
• Aligns with BUD requirements of non-HD compounding but adds the safety precautions

HD and Non-HD Compounding

• Physician offices and outpatient infusion centers may be particularly challenged on space
  – Increased pharmacy space could mean decreased patient treatment space
• Many outpatient infusion centers are focused on HDs, with some non-HD compounding
  – Justification for 2 separate buffer rooms (HD and non-HD) may be difficult for a few preparations
**HD and Non-HD Compounding**

- Options for reducing space requirements
  - USP Chapter <800> allows for non-HD compounding in the HD compounding space provided
    - The preparation is placed in a protective outer wrapper before removal from containment primary engineering control (C-PEC)
    - Prevents any contamination from being spread
    - Must be labeled as requiring full HD PPE
      - May be difficult to achieve compliance
    - Add a non-HD PEC in a separate SCA
      - Place a small PEC in a space in the pharmacy work area

**The Special Case of BCG**

- Bacillus Calmette-Guerin (BCG) is listed as an antineoplastic HD
- It is often compounded by urologists in office/clinic and sometimes at bedside
- NIOSH states
  - To avoid cross-contamination, parenteral drugs should not be prepared in areas where BCG has been prepared
  - Does this mean a separate C-PEC for BCG?

**The Special Case of BCG**

- NIOSH also states about BCG
  - If preparation cannot be performed in a containment device, then respiratory protection, gloves, and a gown should be worn to avoid inhalation or contact with BCG organisms.
- USP <800> requires that BCG be compounded in a C-PEC located in either a negative pressure buffer room or a C-SCA
  - Short stability of BCG creates a challenge
The Special Case of BCG

- If BCG is compounded in the same C-PEC as other sterile products
  - Should develop a risk assessment document for BCG preparation
  - Must develop standard operating procedures (SOPs) for decontamination, cleaning, and disinfection of the biological safety cabinet (BSC)
  - May consider developing standard times for BCG compounding to minimize number of times to clean the C-PEC

Nonsterile HD Compounding

- Must be done in a Containment Primary Engineering Control
  - Containment Ventilated Enclosure ("powder hood")
  - BSC
  - Compounding aseptic containment isolator (CACI)

Nonsterile HD Compounding Options

- Most hospitals will need to do some nonsterile HD compounding
  - Crushing or splitting HD doses (e.g., oral chemo)
- Should a nonsterile HD compounding space be created?
  - Could mean 3 distinct compounding spaces
    - Sterile non-HD
    - Sterile HD
    - Nonsterile HD

Nonsterile HD Compounding Options

• If using the sterile C-PEC for nonsterile compounding
  – Must ensure appropriate SOPs for decontaminating, cleaning, and disinfecting the C-PEC
  – Cannot compound nonsterile at the same time as sterile HDs
    • Consider creating a “nonsterile” HD batch at a separate time (e.g., for crushed doses)
    • Ensure adequate cleaning time

Deactivate HD Areas

What solution do you use to decontaminate your C-PEC (i.e., BSC or CACI)?

a. Sterile alcohol
b. Bleach followed with sodium thiosulfate
c. Commercial product intended for decontamination of HD areas
d. Cleaner supplied by environmental services
Decontaminating HD Areas

- Deactivate
  - HD-specific or EPA-registered oxidizer (e.g., peroxide, sodium hypochlorite)
- Decontaminate
  - Products that are proven to remove HDs
  - Germicidal detergent
- Clean
- Disinfect
  - Sterile alcohol

Considerations for HD Decontamination

- No universal deactivating agent
- Oxidizing agents may break down SOME HDs
  - By-products may also be hazardous
- Ready to use (wipes or solutions) vs. dilutions or mixtures
  - Cost considerations
  - Stability of dilutions (e.g., sodium hypochlorite)
- Dual purpose
  - Hypochlorite as both sporicidal and deactivation

Considerations for HD Decontamination

- Comprehensive process for decontamination is most important
  - Deactivation, decontamination, cleaning, and disinfection
- Example process
  - Hypochlorite wipe
  - Rinse with sterile water (must remove all residue)
  - Clean with detergent
  - Disinfect with sterile 70% isopropyl alcohol (IPA)
Considerations for HD Decontamination

- Decontamination must be performed daily or when a spill occurs
  - Will often be achieved by transferring HD residue to a wipe and disposing of the wipe
- Deactivation with an oxidizing agent can be done less frequently (e.g., weekly or after spill)
  - Must be followed by decontamination step
  - Should limit the introduction of hypochlorite to stainless steel due to corrosivity

Monitor for Compliance

Monitoring for Compliance

- USP <797> describes required environmental monitoring for microbial contamination
- USP <800> describes recommended environmental monitoring for unintended contamination by HDs
  - Wipe samples
Wipe Sample Monitoring

- Benefits include
  - Validation of decontamination process
  - Identification of potential contamination problems
    - Personnel aseptic technique problems
    - Failure to comply with donning of contaminated garb
    - Contamination of outside of commercial products
  - Identification of targets for education about safe handling

Action Plan

- Determine your HD list
- Develop an Assessment of Risk
- Train personnel
- Ensure appropriate facilities
- Deactivate HD areas
- Monitor for compliance

What is the first change you plan to make to your practice as a result of what you learned today?

a. Update departmental standards to comply with USP Chapter <800>.
b. Read current policies and procedures for handling of hazardous drugs taking into account risks to patients and staff.
c. Meet with facilities department to determine how to make any necessary facility modifications within the pharmacy for safe handling of hazardous drugs.
d. Meet with administration to make the case for any needed modifications and/or additional staff to support safe handling of hazardous drugs safe.
e. Have ongoing communication with frontline staff on the risks associated with hazardous drugs and the importance of proper safe handling procedures.
Which will be the most challenging change to make in your practice?

a. Update departmental standards to comply with USP Chapter <800>.
b. Read current policies and procedures for handling of hazardous drugs taking into account risks to patients and staff.
c. Meet with facilities department to determine how to make any necessary facility modifications within the pharmacy for safe handling of hazardous drugs.
d. Meet with administration to make the case for any needed modifications and/or additional staff to support safe handling of hazardous drugs safe.
e. Have ongoing communication with frontline staff on the risks associated with hazardous drugs and the importance of proper safe handling procedures.
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Self-assessment Questions

1. What types of drugs do you need to consider for your hazardous drugs (HD) list?
   a. Antineoplastics in the 2014 NIOSH list.
   b. All drugs in the 2014 NIOSH list.
   c. Drugs identified as hazardous waste.
   d. AHFS drugs categorized as 10:00.00.

2. Mercy Apothecary is the ambulatory pharmacy for your health center. The only drug on the NIOSH antineoplastic list that Mercy Apothecary handles is oral methotrexate; it is always dispensed in the tablet form without crushing. Can this agent be included in the Assessment of Risk
   a. Yes, since it is dispensed by an ambulatory pharmacy.
   b. Yes, since it is not manipulated other than counting or packaging.
   c. No, since it is an antineoplastic.
   d. No, since it is on the EPA hazardous waste list.

3. Refrigerated antineoplastic agents may be stored in:
   a. The refrigerator in the main pharmacy, provided they are stored in marked bins.
   b. A refrigerator in a negative pressure area.
   c. A refrigerator in the anteroom containing other medications intended for sterile preparation.
   d. A refrigerator in the anteroom designated only for antineoplastic hazardous drugs.

4. Wipe samples designed for detection of hazardous drug contamination
   a. Must be completed based on requirements in USP <800>.
   b. Must be completed based on requirement in USP <797>.
   c. Should be considered to detect potential contamination.
   d. Should be completed based on recommendations in EPA guidelines.

5. USP <800> requires the use of closed-system drug transfer devices, when the dosage form allows, in which circumstance?
   a. During preparation of any hazardous drug (HD).
   b. During preparation of antineoplastic HDs or an active pharmaceutical ingredient (API) of any HD.
   c. During administration of any HD.
   d. During administration of an antineoplastic HD.

Answers

1. b
2. b
3. b
4. c
5. d
Preparing for USP Chapter <800>:
Now is the Time to Get Ready

CE Instructions

Per ACPE, CPE credit must be claimed no later than 60 days from the date of the live activity or completion of a home-study activity. All ACPE-accredited activities processed on the eLearning portal are reported directly to CPE Monitor. To claim credit, you must have your NABP e-Profile ID, birth month, and birth day. If you do not have an NABP e-Profile ID, go to www.MyCPEMonitor.net for information and application.

For Midyear Attendees in New Orleans

1. Log in to the ASHP eLearning Portal at elearning.ashp.org with the email address and password used to register for the Midyear. The system validates your meeting registration to grant you access to claim credit.

2. Click on Process CE for the Midyear Clinical Meeting and Exhibition.

3. Enter the attendance code announced during the session and click submit.

4. Click Claim for any session.

5. Complete the evaluation.

6. Once all requirements are complete (indicated with a green check mark), click Claim Credit.

7. Review the information for the credit you are claiming. If all information is correct, check the box at the bottom and click Claim. You will see a message if there are any problems claiming your credit.

For Offsite Webinar Attendees

1. Log in to the ASHP eLearning Portal at elearning.ashp.org/my-activities. If you have never registered with ASHP, use the Register link to set up a free account.

2. Enter the enrollment code announced during the webinar in the Enrollment Code box and click Redeem. The title of this activity will appear in a pop-up box on your screen. Click on Go or the activity title.

3. Complete all required elements. Go to step six above.

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<th>Wednesday, December 9, 2015</th>
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