Presented as a Midday Symposium at the 49th ASHP Midyear Clinical Meeting and Exhibition

Wednesday, December 10, 2014 Anaheim, California



Action Reminder

Planned and conducted by ASHP Advantage and supported by an educational grant from BD.





Agenda

11:30 a.m. – 11:35 a.m.	Welcome and Introduction Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP
11:35 a.m. – 11:55 a.m.	USP General Chapter <800>: An Overview Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP
11:55 a.m. – 12:15 p.m.	The Updated NIOSH Hazardous Drug List: Key Concepts and Recommendations Thomas H. Connor, Ph.D.
12:15 p.m. – 12:35 p.m.	Accreditation Standards Related to Hazardous Drug Safety Jeannell M. Mansur, Pharm.D., FASHP, FSMSO, CJCP
12:35 p.m. – 12:50 p.m.	Point-Counterpoint Discussion on Factors to Consider in Implementation of Chapter <800>: A Matter of Perspective All Faculty
12:50 p.m. – 1:00 p.m.	Questions and Answers All Faculty

Food and beverage are no longer provided at Midday Symposia. This ASHP policy considers the varied internal policies of commercial supporters related to the Physician Payments Sunshine Act.

Faculty

Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP

Activity Chair
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions
Laflin, Pennsylvania

Thomas H. Connor, Ph.D.

Research Biologist Division of Applied Research and Technology National Institute for Occupational Safety and Health Cincinnati, Ohio

Jeannell M. Mansur, Pharm.D., FASHP, FMSMO, CJCP

Practice Leader, Medication Safety Joint Commission Resources Joint Commission International Oak Brook, Illinois

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- Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP, declares that she is an employee and stockholder of Cardinal Health, as well as a member of the USP Compounding Expert Committee.
- Jeannell M. Mansur, Pharm.D., FASHP, FSMSO, CJCP, declares that she is an employee of the Joint Commission Resources.
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Activity Overview

This educational activity will provide an overview and update of the new proposed USP General Chapter <800> and explain the implications of the chapter on current policies and procedures in the health system. Specific areas addressed in the chapter regarding the identification and handling of hazardous drugs will be reviewed and discussed by a panel of pharmacy stakeholders. The current status of federal regulations, accreditation standards, and state activities aimed at protecting health care workers from exposure to hazardous drugs will also be discussed.

Learning Objectives

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

- Review key processes in the proposed USP General Chapter <800> and the likely effect on current procedures for the preparation, storage, transportation, and administration of hazardous drugs.
- Review how available technologies for reducing health care workers' exposure to hazardous drugs will be implemented to address provisions in the proposed USP General Chapter <800>.
- Explain the process for placement of medications on The National Institute for Occupational Safety and Health (NIOSH) Hazardous Drug list.
- Define the medication management, environment of care, and related accreditation standards that deal with hazardous drugs and protection of healthcare workers.

Continuing Education Accreditation



The American Society of Health-System Pharmacists is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. This activity provides 1.5 hours (0.15 CEUs, no partial credit) of continuing pharmacy education credit (ACPE activity #0204-0000-14-708-L03-P).

This activity qualifies for law CPE.

Complete instructions for receiving your statement of continuing pharmacy education credit online are on the next page.

ACTION REMINDER EMAIL



Have ideas about what YOU want to remember to do as a result of what you are learning in this educational session? Use the Action Reminder tool via your smart device, and you will be sent an email reminder from YOURSELF next month.

If you do not have a smart device, access the Action Reminder for this activity at www.ashpadvantage.com/go/usp800/remindme



CPE Instructions for Pharmacists and Technicians

Per ACPE, CPE credit must be claimed <u>no later than 60 days</u> from the date of the live activity or completion of a home study activity. All ACPE accredited activities which are processed on the eLearning site will be reported directly to CPE Monitor. To claim pharmacy 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 <u>www.MyCPEMonitor.net</u> for information and application. Please follow the instructions below to process your CPE credit for this activity.

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- 1. The **ASHP eLearning** site allows participants to obtain statements of continuing education credit conveniently and immediately using any computer with an internet connection. Type the following link into your web browser to access the e-Learning site: http://elearning.ashp.org/mv-activities
- 2. If you already have an account registered with ASHP, log in using your username and password.
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- 3. Once logged in, click on the name of the conference under Your Conferences.
- **4.** At the top of the page is a field for redeeming Attendance Codes (formerly called 'CE codes"). Enter the attendance code that was announced during the activity, and click **Submit**.
 - Helpful Tip: If your code is not redeeming successfully, verify that you have clicked on the title of your conference in order to access the <u>Attendance Code</u> field, not the Enrollment Code field.
- **5.** Each session will be listed under **Your Sessions**. Click **Claim Credit** for a particular session.
- **6.** Complete any requirements for each session by clicking on the name of that activity and following the instructions.
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9. After successfully claiming credit, you may print your statement of credit by clicking on **Print**. If you require a reprint of a statement of credit, you can return here at any time to print a duplicate. Please note that for CPE credit for pharmacists and technicians, printed statements may not be necessary because your credit is reported directly to CPE Monitor.

NEED HELP? Contact <u>eLearning@ashp.org</u>

Date of Activity:	Wednesday December 10, 2014	Code:		CPE Hours:	1.5
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Patricia C. Kienle, M.P.A., B.S.Pharm., FASHP

Activity Chair
Director, Accreditation and Medication Safety
Cardinal Health Innovative Delivery Solutions
Laflin, Pennsylvania

Patricia Kienle 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 Health-System 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.

Thomas H. Connor, Ph.D.

Research Biologist
Division of Applied Research and Technology
National Institute for Occupational Safety and Health
Cincinnati, Ohio

Dr. Connor is currently Research Biologist in the Division of Applied Research and Technology at NIOSH. He received his doctoral degree from the University of Texas Medical Branch and was a member of the faculty of the University of Texas, School of Public Health in Houston for 20 years.

Dr. Conner was a primary contributor to the NIOSH Alert on Hazardous Drugs and is responsible for updating the Alert and periodic updates to the list of hazardous drugs in the Alert. He was awarded the 2008 ASHP Board of Directors' Award honoring non-pharmacists for their contribution to the practice of pharmacy. In 2010 he received the International Society of Oncology Pharmacy Practitioners' Achievement Award for developing the ISOPP Standards of Practice for Safe Handling of Hazardous Drugs. His research has focused on occupational exposure to hazardous drugs in healthcare settings. Dr. Connor has published and lectured extensively on hazardous drug exposure topics.

Jeannell M. Mansur, Pharm.D., FASHP, FMSMO, CJCP

Practice Leader, Medication Safety Joint Commission Resources Joint Commission International Oak Brook, Illinois

Jeannell Mansur, Pharm.D., FASHP, FMSMO, CJCP, is the practice leader for medication safety for Joint Commission Resources (JCR) and Joint Commission International. In this role, she provides direction to hospital leaders with respect to patient safety, which includes medication safety design, medication system optimization, and technology implementation. Organizations have sought her expertise in Lean Six Sigma and change acceleration performance improvement methods and tools to implement effective and sustainable improvements to challenging issues. Also in her role as practice leader, Dr. Mansur provides expertise to the Joint Commission enterprise on medication system themes.

Dr. Mansur completed training with the Institute for Healthcare Improvement in medication safety under the direction of Drs. Donald Berwick and Lucian Leape. As a result of this training Dr. Mansur was able to craft a systems-based approach to medication safety that is in line with Dr. Mansur's philosophies.

Dr. Mansur has extensive experience in all aspects of medication system design and implementation. Dr. Mansur was Director of Pharmaceutical Services at the University of Chicago Medical Center for 12 years before she became Executive Director for Pharmacy Informatics. As the Executive Director for Pharmacy Informatics she was involved in the planning, building, and implementation of the organization's electronic medical record.

Dr. Mansur received her Bachelor of Science degree in Pharmacy from the University of Michigan and her Doctor of Pharmacy degree from Wayne State University.

Dr. Mansur has consulted throughout the United States, and internationally in Europe, Asia, Africa, Central and South America, the Far East, and the Middle East.

PREPARING FOR USP GENERAL CHAPTER <800> HAZARDOUS DRUGS – HANDLING IN HEALTHCARE SETTING: WHAT THE PHARMACIST NEEDS TO KNOW

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Learning Objectives

- Review key processes in the proposed USP General Chapter <800> and the likely effect on current procedures for the preparation, storage, transportation, and administration of hazardous drugs.
- Review how available technologies for reducing health care workers' exposure to hazardous drugs will be implemented to address provisions in the proposed USP General Chapter <800>.
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- Define the medication management, environment of care, and related accreditation standards that deal with hazardous drugs and protection of healthcare workers.

USP General Chapter <800>: An Overview

Patricia C. Kienle, B.S. Pharm., M.P.A., FASHP

Activity Chair

Director of Accreditation and Medication Safety Cardinal Health Pharmacy Solutions Wilkes-Barre, Pennsylvania

<800>: What's the Purpose?

- <800> deals with containment of hazardous drugs, as defined in the NIOSH list
- No federal enforceable standard exists to protect healthcare workers
- The scope of <800> is wider than that of other compounding chapters



Protecting Patients and Practitioners

- USP <795>: Hazardous Drugs (HDs) shall be stored, prepared, and handled ... under conditions that protect the healthcare workers and other personnel
- USP <797>: HDs shall be prepared under conditions that protect healthcare workers and others in preparation and storage areas
- USP <800> applies to both nonsterile and sterile compounding

Major Sections of <800>

- · List of HDs
- · Responsibilities of personnel
- Personal protective equipment
- Facility design and engineering controls
- Receiving
- Compounding
- Administering
- Cleaning
- Environmental control
- Medical surveillance



Where is your biological safety cabinet (BSC) or Compounding Aseptic Containment Isolator (CACI) located?



- a. Positive pressure cleanroom
- b. Negative pressure cleanroom
- c. Outside a cleanroom
- d. Compound outside a primary engineering control

Key Elements: Facility Design

- Designed to protect the patient, the preparation, healthcare personnel, and the environment
- Storage
 - Negative or normal/neutral pressure
- Compounding
 - Certified BSC or CACI
 - Separate room
 - Negative pressure
 - Externally vented
 - Appropriate air changes per hour



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Low Volume Exemption

- <797> allows this for low volume PROVIDED that a secondary containment device is used
 - Closed system drug-transfer device
- <797> does <u>not</u> allow this to be done in a segregated compounding area
- Proposed <800> does <u>not</u> allow the exemption for low volume
- Proposed <800> includes a Containment Segregated Compounding Area (C-SCA) that can be used for preparation of HDs

Proposed Containment SCA

- Containment Segregated Compounding Area
- Limitation: maximum 12 hour beyond-use time
- Requirements
 - Separate room
 - Contains BSC or CACI
 - Negative pressure
 - Externally vented
 - At least 12 air changes per hour (ACPH)
- Room does not need to be ISO 7

Key Elements: Garb

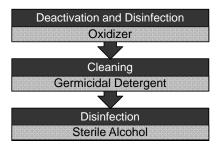
- Personal Protective Equipment (PPE)
- Details for PPE based on function being performed
- ASTM-tested chemotherapy gloves
- Impervious gown

What do you use to clean your BSC or CACI?



- a. Alcohol and water
- b. Bleach
- c. Bleach and sodium thiosulfate
- d. Commercial product designed for deactivating hazardous drugs

Key Elements: Cleaning



Do you use closed-system drug-transfer devices?



- a. For both compounding and administering
- b. Only for administering
- c. No
- d. I don't know

Key Elements: Administering

- <797> defines Primary and Secondary Engineering Controls
- <800> adds in Supplemental Engineering Controls
- Closed-system drug-transfer devices
 - Should be used when compounding
 - Shall be used when administering



Photo courtesy of BD

Action Steps

- Become familiar with <800>
- Update list of hazardous drugs
- Evaluate facilities
- Review PPE used
- Review and reinservice policies



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The Updated NIOSH Hazardous Drug List: Key Concepts and Recommendations

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- Member of USP 800 Expert Panel, but comments are not those of USP

U.S. Guidelines for Safe Handling of Hazardous Drugs

ONS-1982 Chemotherapy ■ ASHP-1983, 1985 Cytotoxic Drugs OSHA-1986 Cytotoxic (Antineoplastic) Drugs ■ ASHP-1990 Cytotoxic and Hazardous Drugs ■ NIH-1992, 2002 Cytotoxic Drugs OSHA-1995 Hazardous Drugs ■ NIOSH-2004 Antineoplastic and Other Hazardous Drugs ■ ASHP-2006 Hazardous Drugs ■ USP -2008 Sterile (Hazardous) Drugs ONS-2011 Hazardous Drugs ■ NIOSH-2014 Antineoplastic and Other Hazardous Drugs ■ USP 800-2015 Hazardous Drugs

Who developed the first list of hazardous drugs in the US?



- a. American Society of Health-System Pharmacists
- b. National Institute for Occupational Safety and Health
- c. Occupational Safety and Health Administration
- d. Oncology Nursing Society

OSHA Hazardous Drug Lists

- 1986
 - 39 Antineoplastic drugs listed
- 1995
 - 61 Drugs listed
 - Majority antineoplastics
 - Some hormonal agents and antivirals
 - Composite from several sources

OSHA: Occupational Safety and Health Administration

ASHP Technical Assistance Bulletin

- First definition of a "hazardous drug"
 - Genotoxicity in short-term test systems
 - Carcinogenicity in animal models, treated patients, or both
 - Teratogenicity or fertility impairment in animal studies or treated patients
 - Serious or other toxicities at low doses in animal models or treated patients

American Society of Hospital Pharmacists. ASHP technical assistance bulletin on handling cytotoxic and hazardous drugs. Am J Hosp Pharm. 1990; 47:1033–49.

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History of Hazardous Drug Lists

- Early lists included primarily "antineoplastic drugs"
- NIOSH list expanded list to cover "antineoplastic and other hazardous drugs"
- 2004 NIOSH list was a composite of 5 lists
- NIOSH list has been updated and revised every 2 years since 2010
- · Current list is based on NIOSH definition
- More non-antineoplastic drugs, drugs with reproductive effects, and oral drugs are being added

2004 NIOSH Alert on Antineoplastic and Other Hazardous Drugs

- · Modified ASHP definition
- Any drug identified by at least one of the following six characteristics
 - Carcinogenicity
 - Teratogenicity or developmental toxicity
 - Reproductive toxicity in humans
 - Organ toxicity at low doses in humans (<10 mg/day) or animals (<1mg/kg/day)
 - Genotoxicity
 - New drugs that mimic existing hazardous drugs in structure or toxicity



NIOSH 2004 List of Hazardous Drugs

- List from 4 institutions and Pharmaceutical Research and Manufacturers of America (PhRMA)
 - National Institutes of Health
 - Johns Hopkins University
 - University of Michigan
 - Northside Hospital

NIOSH Process for Updating the List of Hazardous Drugs

- Review all new FDA drug approvals (2 years)
- Review all new warnings on existing drugs (2 years)
- Review drug information (NIOSH internal committee)
- Meet with external expert and stakeholder panel
- Review by external expert and stakeholder panel

NIOSH Process for Updating the List of Hazardous Drugs

- Public comment period in Federal Register (60 days)
- Perform final review (NIOSH internal committee)
- Respond to comments from Federal Register Notice
- Obtain final approval by Office of Director
- Post in Federal Register and on NIOSH website

Updates to NIOSH Hazardous Drug List

- 2010
 - 31 drugs added
 - 0 drugs removed
 - 10 drugs with manufacturers' warnings
- 2012
 - 33 drugs added
 - 15 drugs removed
 - 7 drugs with manufacturers' warnings



Hazardous Drug List Update

- 2014 Update
 - 28 drugs added
 - 12 drugs removed
 - 6 drugs with manufacturers' warnings



New Format for NIOSH Hazardous Drug List (2014)

- Previously: recommended "standard" or "universal" precautions
- Not applicable in all situations
- Three groups:
 - Group 1. Antineoplastic drugs (AHFS 10:00)
 - Group 2. Non-antineoplastic hazardous drugs
 - Group 3. Drugs with reproductive effects

2016 Update to NIOSH Hazardous Drug List

- Total: 330 drugs met criteria for initial review
- 67 drugs reviewed by NIOSH Committee
- 45 drugs reviewed by panel of peer and stakeholder reviewers

USP General Chapter <800> Use of NIOSH Hazardous Drug

 USP General Chapter <800> currently cites the NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings, 2014



How many states have adopted the NIOSH Alert into state regulations?



- a. 11
- b. None
- c. 3
- d. 20+

State Activities on Hazardous Drugs

- Washington: Adopted alertCalifornia: Adopted alert
- North Carolina: Adopted alert
- Maryland Occupational Safety and Health (MOSH): Considering adoption of alert

Accreditation Standards Related to Hazardous Drug Safety

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Hazardous Medication The Joint Commission Definition

Hazardous medications are those in which studies in animals or humans indicate that exposures to them have a potential for causing cancer, developmental or reproductive toxicity, or harm to organs.

Hazardous Materials The Joint Commission Definition

- Materials for which handling, use and storage are guided or defined by:
 - Local, state, or federal regulations, such as the Occupational Safety and Health Administration's Regulations for Bloodborne Pathogens regarding the disposal of blood and blood-soaked items and the Nuclear Regulatory Commission's regulations for the handling and disposal of radioactive waste.
 - Hazardous vapors (e.g., gluteraldehyde, ethylene oxide, nitrous oxide)
 - Hazardous energy sources (e.g., ionizing or nonionizing radiation, lasers, microwave, ultrasound).
 - Although The Joint Commission (TJC) considers infectious waste in this category of materials, federal regulations do not define infectious or medical waste as hazardous waste.

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Have you had a finding relating to hazardous medications or hazardous materials in your last accreditation survey? a. Yes b. No c. Don't work in an setting that is accredited Medication Management **MM.01.01.03** The hospital safely manages high-alert and hazardous medications. • (EP 1) The hospital identifies, in writing, its high-alert and hazardous medications. (See also EC.02.02.01, EP 8) • (EP 2) The hospital has a process for managing highalert and hazardous medications. (See also EC.02.02.01, EP 8; MM.03.01.01, EP 9) . (EP 3) The hospital implements its process for managing high-alert and hazardous medications. (See also EC.02.02.01, EPs 1 and 8) **Environment of Care Standards** EC.02.02.01 The organization manages risks related to hazardous materials and waste. (EP 1) Hospital maintains a written, current inventory of hazardous materials and waste that it uses, stores, or generates. (D) (EP 3) The hospital has written procedures, including the use of precautions and personal protective equipment, to follow in response to hazardous material and waste spills or exposures. (D) (EP 4) The hospital implements its procedures in response to hazardous material and waste spills or exposures. (EP 5) The hospital minimizes risks associated with selecting, handling, storing, transporting, using, and disposing hazardous chemicals. **{M}**

Environment of Care Standards	
EC 03.01.01	
Staff and licensed independent practitioners are	
familiar with their roles and responsibilities relative to the environment of care.	
(EP 1) Staff and licensed independent practitioners can	
describe or demonstrate methods for eliminating and minimizing physical risks in the environment of care. (M)	
Environment of Care Standards	
Standard EC.04.01.01 The organization plans activities to minimize risks in the environment of care.	
(EP 1) The hospital establishes processes for continually monitoring, internally reporting, and	
investigating the following: Hazardous materials and waste spills and	
exposures. (D) Based on its processes, the hospital reports and	
investigates the following: - (EP8) Hazardous materials and waste spills and exposures (See also EC.04.01.03,EP 1)	
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Human Resources	
Human Resources	
HR.01.04.01 Staff orientation	
(EP2) The hospital orients its staff to the key safety content before staff provides care, treatment and particle Completion of this.	
treatment, and services. Completion of this orientation is documented.	

Leadership LD.01.01.01 The governing body is ultimately accountable for the safety and quality of care, treatment, and services. LD.02.01.01 The mission, vision, and goals of the organization support the safety and quality of care, treatment, and services. Leadership **LD.02.03.01** The governing body, senior managers and leaders of the organized medical staff regularly communicate with each other on issues of safety and quality. **LD.03.06.01** Those who work in the organization are focused on improving safety and quality. Leadership LD.04.04.05 The hospital has an organization-wide, integrated patient safety program. (EP 3) The scope of the safety program includes the full range of safety issues, from potential or no harm errors (sometimes referred to as near misses, close calls, or good catches) to hazardous conditions and sentinel events. LD.04.01.01 The organization complies with law and regulation.

Handling of Hazardous Waste

- Requirement for a written plan (EC.01.01.01)
- Risk mitigation strategies for hazardous waste disposal; requirement for compliance with permits, manifests, labeling as hazardous waste (EC.02.02.01)
- Planning for emergency management of hazardous waste (EM.02.02.05)

Survey Process – Hazardous Medications

- Facilities tour: review of written plans; environmental tours
- Interviews: housekeepers; nursing staff, pharmacy staff
- Tracers: tour of chemotherapy pharmacy; observation of patient care areas
- Documentation review: chemotherapy spills; policies; lists of hazardous materials and medications

Which of the following is **not true** regarding requirements of Joint Commission standards?



- Requirements for hazardous medications are primarily found in the Medication Management chapter
- b. Inability to describe spill procedures may result in a finding in the Human Resources chapter
- c. Leadership standards may be scored for hazardous medication findings
- d. The Environment of Care chapters only contains requirements for hazardous waste
- e. A and D

CMS Requirements §482.25 Condition of Participation: **Pharmaceutical Services** The medical staff or, if delegated, the hospital's organized pharmaceutical service, develops policies and procedures that minimize drug errors, including policies and procedures that address: • The preparation, distribution, administration, and proper disposal of hazardous medications A-Tag 0490 CMS: Centers for Medicare and Medicaid Services **CMS Requirements** §482.25 Condition of Participation: **Pharmaceutical Services** • The hospital prepares medications safely. The following are examples of safe preparation procedures: - Whenever medications are prepared, staff uses safety materials and equipment while preparing hazardous medications. A-Tag 0501 **CMS Requirements Survey Process** • Determine whether the Director of Pharmacy routinely evaluates the performance and competency of pharmacy personnel? Do performance evaluations include high-risk activities such as the compounding of hazardous medications A-Tag 0492

CMS Requirements §482.41(c)(4) Condition of Participation: **Physical Environment** • Ventilation requirements are in compliance for: - Patients receiving treatments with hazardous chemicals A-Tag 0726 - Other areas where hazardous materials are stored. A-Tag 0726 **CMS Requirements** §482.11(a) Condition of Participation: Compliance with Federal, State and Local • The hospital must be in compliance with applicable Federal laws related to the health and safety of patients - Refer or report noted noncompliance with Federal laws and regulations to the appropriate agency having jurisdiction (e.g., hazardous chemical/waste issues to EPA) The Joint Commission's History

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with Hazardous Medications and Materials

The Joint Commission and USP General Chapter <800>	
Point-Counterpoint Discussion on Factors to Consider in Implementation of Chapter <800>: A Matter of Perspective	

Self-Assessment Questions

- 1. Proposed USP General Chapter <800>
 - a. Replaces USP Chapter <795>
 - b. Replaces USP Chapter <797>
 - c. Replaces USP Chapters <795> and <797>
 - d. Supplements USP Chapters <795> and <797>
- 2. Primary engineering controls ("chemo hoods") used for preparation of sterile antineoplastic compounded sterile preparations must be placed in a room that has
 - a. Positive pressure to surrounding areas
 - b. Negative pressure to surrounding areas
 - c. Neutral or normal pressure to surrounding areas
 - d. Placement is not defined in proposed USP General Chapter <800>
- 3. Which of the following websites is the best reference for determining whether a drug is considered hazardous?
 - a. OSHA website
 - b. ASHP Technical Assistance Bulletin
 - c. NIOSH website
 - d. EPA website
- 4. Which drugs are listed by NIOSH as hazardous?
 - a. Drugs with reproductive hazards
 - b. Drugs that are hazardous, but not antineoplastic drugs
 - c. Antineoplastic drugs
 - d. All of the above
- 5. The Joint Commission definition of hazardous materials includes
 - a. Hazardous medications on the NIOSH list
 - b. Hazardous medications on the NIOSH list and hazardous vapors
 - c. Hazardous medications on the NIOSH list and hazardous energy sources
 - d. Infectious waste
 - e. Hazardous medications, hazardous vapors, hazardous energy sources, and infectious waste

Answers

1. d 2. b 3. c 4. d 5. e