St.Vincent's HEALTH SYSTEM | ASCENSION

Date: April 5, 2018

☒ Inter-professional ☐ Single Discipline

Attendance Roster

"USP800"

Instructor:
Brad Nix
Credits: 1.00
☒ Direct Sponsored
☐ Jointly Sponsored

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Name (Please Print)	Hospital/Ministry/ Business	(Pharmacy) DOB & NABP #	Check That Apply
			☐MD ☐ DO ☐ NP ☐ PA ☐RN ☐ Pharmacist ☐ RPh ☐Pharmacy Tech ☐OT ☐ PT ☐Social Worker ☐Student ☐Other
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			☐MD ☐ DO ☐ NP ☐ PA ☐RN ☐ Pharmacist ☐ RPh ☐Pharmacy Tech ☐OT ☐ PT ☐Social Worker ☐Student ☐Other
			☐MD ☐ DO ☐ NP ☐ PA ☐RN ☐ Pharmacist ☐ RPh ☐Pharmacy Tech ☐OT ☐ PT ☐Social Worker ☐Student ☐Other
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			☐MD ☐ DO ☐ NP ☐ PA ☐RN ☐ Pharmacist ☐ RPh ☐Pharmacy Tech ☐OT ☐ PT ☐Social Worker ☐Student ☐Other
			☐MD ☐ DO ☐ NP ☐ PA ☐RN ☐ Pharmacist ☐ RPh ☐Pharmacy Tech ☐OT ☐ PT ☐Social Worker ☐Student ☐Other
			☐MD ☐ DO ☐ NP ☐ PA ☐RN ☐ Pharmacist ☐ RPh ☐Pharmacy Tech ☐OT ☐ PT ☐Social Worker ☐Student ☐Other

Physicians: St. Vincent's Health System is accredited by the Medical Association of the State of Alabama to provide continuing medical education for physicians. Designation Statement: The St. Vincent's Health System designates this live activity for a maximum of see above *AMA PRA Category 1.00 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

Nurse: Ascension Health is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation. Provider Number: P0340. This activity is approved for 1.0 Contact Hours continuing education.

Pharmacists: The St. Vincent's Health System is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education. Completion of this knowledge-based activity provides for 1.0 contact hour (0.1 CEU) of continuing pharmacy education credit.

Faculty/Course Director/Planners: STVHS has selected all faculty participating in this activity. It is the policy of STVHS that all CME/CE planning committees, faculty, authors, editors, and staff disclose relationships with commercial interests upon nomination or invitation of participation. Disclosure documents are reviewed for potential conflicts of interest and if relevant, they are resolved prior to confirmation of participation. Only those participants who have no conflict of interest or who agreed to an identified resolution process prior to their participation were involved in this activity.

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Post-Test

Test Questions

1. Which of the following best describes USP Chapter 800?
    a. Written by experts from the DEA to control opiate addiction; official date October 2016
    b. Written by experts from OSHA to control occupational exposure to toxic chemical waste; official date January 2018
    c. Written by experts from multiple federal panels to reduce hazardous drug exposure; official date December 2019
    d. Written by experts from NIOSH to replace USP Chapters 795 and 797; official date December 2019

2. Which statement is true concerning an entity's list of Hazardous Drugs?
    a. An entity that does not compound chemotherapy is not required to have a list of Hazardous Drugs.
    b. An entity may use the latest NIOSH List as its list of Hazardous Drugs.
    c. An entity must update its list of Hazardous Drugs with every NIOSH update.
    d. An entity must maintain a list of Hazardous Drugs and review it at least annually and whenever a new agent or dosage form is used.

3. Which statement best describes strategies for meeting the USP Chapter 800 Containment Requirements for Hazardous Drugs?
    a. Antineoplastic hazardous drugs that require manipulation and hazardous drug active pharmaceutical ingredients must follow the containment requirements of USP Chapter 800, but all other hazardous drugs must follow containment requirements according to Assessments of Risk.
    b. Only antineoplastic hazardous drugs that require manipulation must follow the containment requirements of USP Chapter 800.
    c. All hazardous drugs, regardless of dosage form, must follow the containment requirements of USP Chapter 800.
    d. Antineoplastic hazardous drugs that require manipulation and hazardous active pharmaceutical ingredients must follow the containment requirements of USP Chapter 800, other hazardous drugs may follow alternative containment strategies determined by Assessments of Risk, and antineoplastic dosage forms that do not require further manipulation must follow the containment strategies required by the manufacturer.

4. Which statement is true concerning pharmacy construction according to USP Chapter 800 requirements?
    a. All pharmacies must provide a negative-pressure buffer room for compounding sterile hazardous drugs.
    b. A pharmacy that compounds sterile hazardous drugs must provide a negative-pressure buffer room adjacent to a positive-pressure buffer room.
    c. A pharmacy that compounds non-sterile hazardous drugs must provide a negative-pressure buffer room separated from all other pharmacy areas.
    d. A pharmacy may compound both sterile hazardous drugs and sterile non-hazardous drugs in the same buffer room.

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5. Which of the following includes expected harmonized revision(s) in USP Chapter 797 and USP Chapter 800 for compounding hazardous drugs?
    a. A low volume of hazardous drugs may be compounded in a Biological Safety Cabinet or Compounding Aseptic Containment Isolator placed in a non-negative pressure area.
    b. All hazardous drug compounding must be performed in a separate area designated for hazardous drug compounding.
    c. Low and Medium Risk hazardous drug compounded sterile products may be prepared in a Biological Safety Cabinet or Compounding Aseptic Containment Isolator located in a separate negative pressure room with 12 air changes per hour.
    d. Both A and C
    e. Both B and C

6. Which statement most accurately describes the C-SEC differences in meeting USP Chapter 800 requirements for hazardous drug compounded sterile products?
    a. A hazardous drug sterile compounding buffer room must have an externally vented C-PEC, while a containment segregated compounding area may provide a redundantly HEPA filtered C-PEC.
    b. A hazardous drug sterile compounding buffer room must provide 30 ACPH to provide an ISO Class 7 environment, while a containment segregated compounding area must provide 12 ACPH to provide an ISO Class 7 environment.
    c. A hazardous drug sterile compounding buffer room must maintain negative pressure compared to adjacent areas, while a containment segregated compounding area may maintain negative or neutral pressure compared to adjacent areas.
    d. A hazardous drug sterile compounding area must provide an ISO Class 5 C-PEC within an ISO Class 7 C-SEC to produce sterile products with BUD > 12 hours, while a containment segregated compounding area may provide an ISO Class 5 C-PEC within an unclassified C-SEC to produce sterile products with BUD < 12 hours.

7. Which of the following USP Chapter 800 ***recommendation(s)*** is/are considered Ascension ***requirement(s)***?
    a. Personal protective equipment may be re-used if there is no visible contamination
    b. Environmental wipe sampling should be performed routinely
    c. Closed-system transfer devices (CSTD) should be used when compounding hazardous drugs when the dosage form allows
    d. Both A and C
    e. Both B and C

8. What effect do the NIOSH Criteria for defining “hazardous drug” have on current “chemotherapy” cultures?
    a. The NIOSH Criteria expand the definition of “hazardous drug” beyond antineoplastic agents to include any agent that exhibits one or more characteristic to cause carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity, or genotoxicity to humans or animals.
    b. The NIOSH Criteria limit the definition of “hazardous drug” to include only antineoplastic agents in support of the “chemotherapy” culture.

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c. The NIOSH Criteria expand the definition of “chemotherapy” to include any agent that exhibits one or more characteristic to cause carcinogenicity, teratogenicity, reproductive toxicity, organ toxicity, or genotoxicity to humans or animals.
d. The NIOSH Criteria provide suggestions for categorizing “chemotherapy” as antineoplastic agents or reproductive risk agents.

9. When considering USP Chapter 800 defined levels of exposure, what two factors cause *escalation* of potential exposure to hazardous drugs?
    a. Neutral pressure hazardous drug receiving area and lack of adequate signage.
    b. Drug characteristics that increase the potential for unintentional entry into the body and handling activities that increase the potential for contamination.
    c. Inappropriate layers of personal protective equipment and loss of ISO Class 7 environment.
    d. Potential exposure levels are absolute and cannot escalate.

10. An injectable NIOSH Group 3 Hazardous drug was spilled onto a nurse prior to administration of the dose to the patient. What is the most appropriate course of action the nurse take to reduce the potential exposure?
    a. Implement appropriate chemotherapy spill protocol, remove and discard all PPE and waste, report the spill as hazardous contamination.
    b. Implement appropriate chemotherapy spill protocol, perform D/D, C&D according to the drug’s SDS, discard all waste as contaminated.
    c. Clean the spill, remove and discard all PPE and waste, regard the spill as harmless due to the NIOSH Group.

Follow policies established by the Occupational Safety Program based on the Assessment of Risk for the spilled drug and dosage form

St. Vincent's Health System Continuing Professional Education CME | CPE | ASCENSION **Date:** April 5 , 2018 ☒ Inter-professional ☐ Single Discipline	**CE/CME Evaluation & Credit Claim Form** **Course:** "USP800 " **Instructor:** Brad Nix, PharmD	Credits: 1.00 ☒ Direct Sponsored ☐ Jointly Sponsored

Please Check One: ☐ St. Vincent's Birmingham ☐ St. Vincent's Blount ☐ St. Vincent's Chilton ☐ St. Vincent's East ☐ St. Vincent's St. Clair ☐ St. Vincent's One Nineteen ☐ External Meeting

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Please note: a CME/CE transcript is issued only upon receipt of this completed evaluation form. PLEASE PRINT

Legal Name:		**Email Address:** *(This is where your CE/CME certificate and or transcriptwill be sent)*	
Identify which continuing education hours apply to you:	☐ MD ☐ DO ☐ NP ☐ PA ☐ RN ☐ PharmD ☐ RPh ☐ Tech ☐ Student/Resident ☐ Other ☐ PT ☐ OT ☐ Social Worker	**Ministry and Facility:**	
		PHARMACY NABP # and DOB	

The learning objectives for this activity were:

- Outline the history, authority, and scope of USP Chapter 800
- Review the Hazardous Drug List based on NIOSH Criteria
- Outline USP Chapter 800 Requirements in Terms of Containment
- Implement Standards of Practice to meet USP Chapter 800 requirements

Did the speaker(s) meet each of the objectives? ☐ Yes ☐ No

Comment: _____

	What change(s) do you plan to make in your practice and/or department as a result of this CE/CME activity?
❍	Understand the compliance with the newest regulations
❍	Recognize the risks of working with hazardous drugs
❍	Implement standards of practice to meet USP Chapter 800 requirements
	What new team strategies will you employ as a result of this activity?
❍	Develop strategies to achieve USP <800> compliance
❍	Improve multidisciplinary team roles and communication to improve decision making skills for personal protective safety
❍	This activity will not change my practice, because my current practice is consistent with what was taught

How will your role in the collaborative team change as a result of this activity

☐ Knowledge management ☐ Improve healthcare processes and outcomes ☐ Effective communication skills ☐ Patient outcomes

Did the information presented reinforce and/or improve your current skills? ☐ Yes ☐ No

Do you perceive any barriers in applying these changes?	☐ Organizational or institutional barriers ☐ Cost ☐ Patient adherence ☐ Professional consensus or guidelines ☐ Lack of resources ☐ Experience	☐ Reimbursement ☐ Administrative Support ☐ Reimbursement/Insurance ☐ Inadequate time to assess or counsel patients ☐ No barriers ☐ Other:_____

FOR CME/CE CREDIT – BOTH SIDES OF THE EVALUATION ARE REQUIRED TO BE FILLED OUT COMPLETELY

Did you perceive commercial bias or any commercial promotional products displayed or distributed. ☐ No ☐ Yes
(If yes please Comment)

What I learned in this activity has increased my confidence in improving patient outcome results. ☐ Yes ☐ No

What other CE/CME topic(s) would you like to attend?

Speaker(s) Session	Speakers knowledge of Subject Matter	Quality of Presentation & Handouts	Overall Activity
	☐ Excellent ☐ Good ☐ Average ☐ Poor	☐ Excellent ☐ Good ☐ Average ☐ Poor	☐ Excellent ☐ Good ☐ Average ☐ Poor

Comments on activity:	**Did the speaker(s) provide an opportunity for questions and discussion?** ☐ Yes ☐ No (If no please comment)

Were there problems-in-practice related to this topic that were not addressed at this CE/CME activity that you felt should have been? ☐ Yes ☐ No

I will apply the knowledge and/or skills gained during this activity in my work: ☐ Yes ☐ No

This activity created an atmosphere that fostered adequate discussion time in which input and feedback was welcome:
☐ Strongly Agree ☐ Agree ☐ Neutral ☐ Disagree ☐ Other:

PHARMACISTS & PHARMACY TECHNICIANS CREDIT ONLY (must fill out these two questions to receive credit)

Describe the personal protective equipment requirements outlined in USP General Chapter <800>:

What are some of the health risks associated with occupational exposure to hazardous drugs?

REQUEST FOR CREDIT - If you wish to receive credit for this activity, please return this **completed form**

☐ By checking the box, I certify the above is true and correct.

Signature:

Thank you for participating and we appreciate your candid feedback to improve your experience at future activities.
To receive credit all questions must be completed on the evaluation

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