Changing Regulations, Changing Roles: DEA, EPA, USP <800> & The Pharmacy Buyer

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Legal Disclaimer

The information provided in this seminar is for educational and informational purposes only, and should not be construed as legal advice or as an offer to perform legal services on any subject matter.

Objectives

- Describe when an outdated or unwanted controlled substance needs to be sent through reverse distribution, versus disposed in a sequestration device.
- Outline the steps to determine the appropriateness of a consumer medication take-back program for your facility
- Compare the 6 definitions of an EPA hazardous waste to the 6 definitions of an OSHA hazardous drug as defined by NIOSH
- Outline steps for operationalizing appropriate management of hazardous drugs and hazardous waste to comply with USP Chapter <800> and state and federal environmental regulations
- Explain current and proposed EPA regulatory changes to pharmacy management and staff

Regulatory Agencies

- Drug Enforcement Administration
- Environmental Protection Agency
- OSHA
  - NIOSH
- USP <800>

The Controlled Substances Act

- Enacted in 1970 and enforced by the Drug Enforcement Administration (DEA)
- DEA is a federal law enforcement agency under the Dept. of Justice
- Restricted access to controlled substances to those registered to manufacture, distribute, prescribe or dispense such products.
- All regulated substances are placed into one of five "schedules"

The DEA Drug Disposal Regulation, 21 CFR 1318

- Regulations implement the Secure and Responsible Drug Disposal Act of 2010
- Published September 9th, 2014; took effect October 9th, 2014
- Requirements to govern the secure disposal and destruction of controlled substances by both DEA registrants and ultimate users
  - Expands options for take-back events
  - Creates mail-back programs and collection receptacle options

The DEA Disposal Regulation

- Authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies and **hospitals/clinics with on-site pharmacies** to voluntarily participate
- Pharmacies (Retail and hospital/clinic) are authorized to maintain collection receptacles at long term care facilities
- Reorganizes and consolidates regulations on disposal and role of reverse distributors

Who is an "Ultimate User"?

- An "ultimate user" is a patient (or animal) for whom the drug has been legally prescribed
- Once a prescription has been dispensed to a patient, it is out of the DEA closed loop of registrants
- The primary purpose of the Drug Disposal Regulation is to provide options for ultimate users and their legal representatives to dispose of unwanted/excess/outdated controlled substances in their possession
- Ultimate users include residents in a long term care facility
- In case of death, the patient's executor may dispose of the controlled substance in accordance with the regulation

Healthcare Sectors Impacted by DEA Changes

- Registrant Disposal
  - **Hospitals**, clinics, physicians, veterinarians, dentists
  - Retail Pharmacies including LTCF Provider Pharmacies
  - Reverse Distributors
- Non-Registrant Disposal
  - "Ultimate User" collection programs
    - Mail-back
    - Receptacles (kiosks)
    - Single day events
  - "Ultimate User" long term care facilities (LTCFs)
    - Receptacles provided and managed by retail pharmacies

Registrant Disposal Concerns Expressed to DEA

- Definition of "non-retrievable" limited to incineration
- Ability to render a drug "non-retrievable" in an institutional setting
- Ability to transfer drug wastage to a reverse distributor for incineration from an institutional setting
  - Requirement to double witness the destruction of the CS until it is rendered non-retrievable

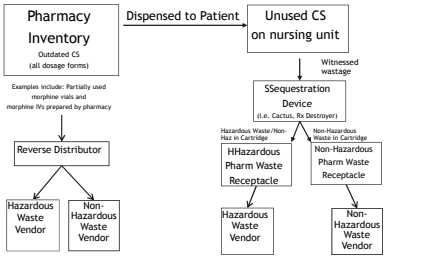
DEA Clarification Letter: October 17, 2014

- "…once a controlled substance has been dispensed to a patient by an institutional practitioner on the basis of an order for immediate administration to a patient at the registrant's registered location, the substance is no longer in the practitioner's inventory. For example, after a pre-filled syringe or a single-dose vial or syringe is administered to a patient, any remaining substance in the syringe or vial **is not required to be destroyed in accordance with new Part 1317."**
- Such wastage cannot be disposed in a receptacle for ultimate user collection (take-back kiosk)
- Controlled substances from the pharmacy's inventory cannot be disposed in a receptacle for ultimate user collection (take-back kiosk)
- All destruction must be in accordance with Federal, State, tribal, and local laws and regulations

DEA Clarification Letter: October 17, 2014

- "Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations (e.g., § 1304.22(c))"
- "Although Part 1317 does not apply to pharmaceutical wastage, the DEA strongly encourages all practitioners to continue to adhere to security controls and procedures that ensure pharmaceutical wastage is not diverted. For example, most institutional practitioners have implemented policies that require two persons to witness and record destruction of pharmaceutical wastage."
- http://www.deadiversion.usdoj.gov/drug_disposal/dear_practitioner_pharm_waste_101714.pdf

Federal Controlled Substance Decision Tree*



* Some state environmental regulations, such as California, prevent customary reverse distribution of RCRA CS.

Examples of Controlled Substance Sequestration Systems

Cactus Smart Sink®

Rx Destroyer™

Summary of Controlled Substance Disposal in Healthcare Facilities

- If in the pharmacy's inventory, the controlled substance must be sent to a reverse distributor
- State and city regulations add another layer of complexity
- If the controlled substance has been dispensed to a patient, any remaining drug can be sequestered in a device and the device placed in either the white/blue non-hazardous waste container or the black hazardous waste container and managed by the appropriate waste vendor
  - No transfer between registrants is needed at this point based on DEA's clarification
  - Must be properly recorded, stored, and destroyed in accordance with DEA regulations (e.g., § 1304.22(c))
  - Must comply with all State, Federal, tribal and local laws and regulations

Quick Check

According to the DEA guidance letter, controlled substances that remain after the dose has been administered:

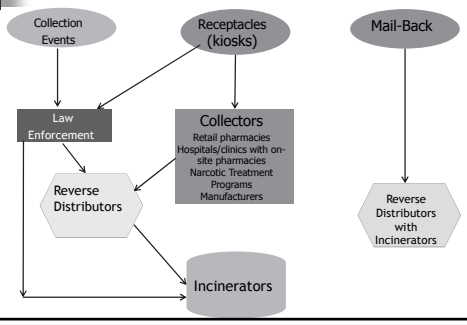
A) Must be sent through reverse distribution
B) Must be disposed in a manner that prevents diversion
C) Must be properly recorded, stored, and destroyed in accordance with DEA regulations (e.g., § 1304.22(c))
D) Must be disposed in a manner that complies with all environmental rules and regulations

B, C, & D

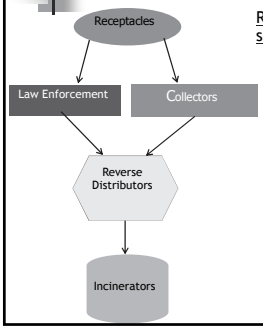
Implementing a Consumer Take-Back Program

- Two options: mail-back envelopes and kiosk program
- Resources needed:
  - Initial funding
  - Security assessment
  - Operational budget & personnel
- Benefits:
  - Public relations
  - Environmental responsibility
  - Response to the opioid crisis

DEA Regulated Ultimate User Options



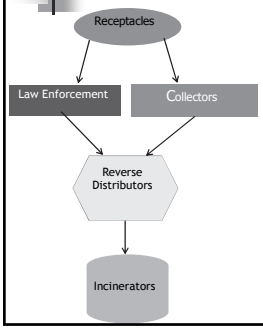
Collection Receptacles



Registrants authorized to collect controlled substances from ultimate users: 1317.40

Retail pharmacies,
Hospitals/clinics must have on-site pharmacy,
Narcotic treatment programs,
Manufacturers,
Distributors,
Reverse distributors,
Long term care facilities at which registered hospitals/clinics with on-site pharmacies or retail pharmacies are authorized to maintain collection receptacles

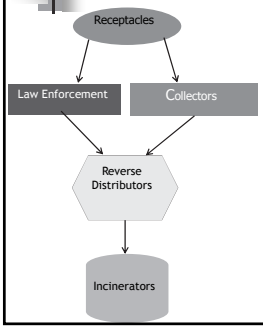
Collection Receptacles



Collection Receptacle Requirements: 1317.75(e)

- Be securely fastened to a permanent structure so that it cannot be removed
- Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner
- The outer container shall include a small opening to allow contents to be added
- The outer container shall prominently display that only Schedules II-V controlled are acceptable (no illicit drugs)
- Collector may choose to accept non-controlled substances also
- Small opening shall be locked or made inaccessible when an employee is not present (e.g. when pharmacy is closed)

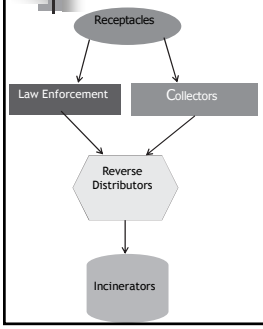
Collection Receptacles



Inner liner requirements 1317.60

- Waterproof, tamper-evident, tear-resistant
- Removable and sealable immediately upon removal with no touching of contents
- Contents not viewable from outside
- Size of the inner liner clearly marked e.g. 5 gallon, 10 gallon, etc.
- Inner liner bears a permanent, unique ID number that can be tracked
- Access restricted to employees of the collector
- Sealed by two employees immediately upon removal
- Shall not be opened, x-rayed, analyzed or otherwise penetrated

Collection Receptacles



Collection Receptacle Usage: 1317.75

- Only schedule II, III, IV & V in lawful possession can be accepted
- Non-controlled drugs may be commingled
- Only ultimate users and other authorized non-registrants can use
- No counting, sorting, inventorying or handling once deposited

Collection Placement: 1317.75

- Retail pharmacy: immediate proximity of pharmacy inventory and at which an employee is present
- Hospital/clinic: **Area regularly monitored by employee; NOT in emergency or urgent care area**

Collection Receptacles

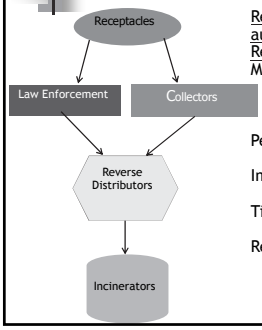
Records for Collectors: 1304.22

- Date each unused inner liner acquired, Unique ID number, size
- Date liner is installed, address of location, unique ID number, size, registration, number of collector, names and signature of 2 employees witnessing installation
- Date liner is removed and sealed, address of location, ID number, size, registration number, names and signatures of 2 employees witnessing removal
- Date, etc. that liner is transferred to storage
- Date, etc. that each liner is transferred for destruction, address and registration number of reverse distributor to whom transferred, unique ID number, size of liner, names and signatures of 2 employees

Summary Table of Recordkeeping for Collectors Using Receptacles/Inner Liners

Inner Liner Records	Acquisition	Installation	Removal & Sealing	Transfer to Storage	Transfer for Destruction
Date	X	X	X	X	X
Unique ID #	X	X	X	X	X
Size	X	X	X	X	X
Address of Registrant		X	X		
Registration # of Collector		X	X		
Names/ Signatures 2 employees		X	X	X	X
Address of RD					X
Registration # of RD					X

Collection Receptacles



Reverse Distributors and Distributors authorized to acquire CS from collection Receptacles 1317.55

May pick up CS from a registrant or collection site or receive CS delivered by common or contract carrier, or delivered directly by non-practitioner registrant

Personally received by RD employees at registered location

Immediately store in accordance with security controls

Timely destroy CS or cause destruction no later than 30 calendar days after receipt

Record of destruction to include DEA Form 41

Collection Receptacles: Receptacle and Liner Examples

Consumer Take-back Evaluation Considerations

- Does Administration support the concept?
- Has a risk analysis been done based on the location of the hospital?
- Does the Pharmacy Dept. have the bandwidth to manage the program?
- Is funding available to support the program long term?
- Are there other options readily available in the community, e.g. Walgreens, CVS, law enforcement?
- Does this activity affect HW generator status? No, exempted under the household hazardous waste exclusion

Quick Check

Setting up and managing a consumer take-back program:

A. Demonstrates commitment to the community

B. Can be set up in the ER or Urgent Care area for convenience

C. Requires considerable time, effort, and resources

D. Impacts the organization's hazardous waste generator status

A, C

Hazardous Drug? Hazardous Waste?

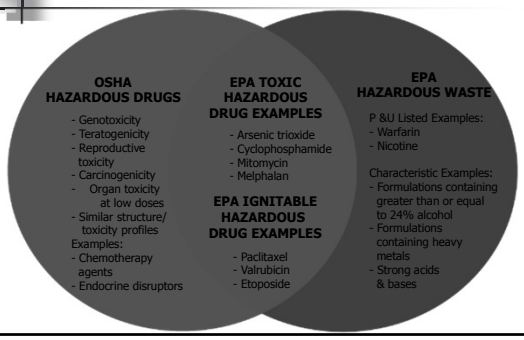
Defining "Hazardous" in a Hospital

- **OSHA Hazardous Drug:** a risk to employees due to occupational exposure; may be a product or a waste
  - NIOSH 2016 Hazardous Drug List/USP <800>
- **EPA Hazardous Waste:** meets one of the definitions of hazardous waste federally or at the state level; must be a waste
- **DOT Hazardous Material**: a risk to health and safety while in transit; may be a product or a waste
- **Biohazardous:** meets the definition of an infectious risk at the state level; may be a product or a waste
  - Regulated medical waste, includes some drug e.g. albumin

Hazardous Drug vs Hazardous Waste

- Hazardous Drug: a danger to the employee and patient
- Hazardous Waste: a danger to the environment

Hazardous Drugs vs Hazardous Waste: Where OSHA and EPA Meet



EPA: Environmental Protection Agency

- Resource Conservation and Recovery Act, RCRA (40 CFR 260 – 262)
  - Congress passed the Act in 1976; EPA published final regulations in 1980
  - Defines hazardous waste in the US and applies to all businesses
  - Approximately 5% of drugs and drug formulations in the marketplace become a RCRA hazardous waste when discarded
  - The generator of this hazardous waste is highly regulated as are the treatment, storage and disposal facilities (TSDF) that perform final disposition such as incineration

Hazardous Pharmaceutical Waste Under RCRA

- **P-listed pharmaceuticals (acutely hazardous)**
  - Sole active ingredient; unused; empty containers
  - LD50 (oral) 50mg/kg
  - Examples: nicotine, warfarin
- **U-listed pharmaceuticals (toxic)**
  - Sole active ingredient; unused
  - Examples: cyclophosphamide, mitomycin, lindane, selenium sulfide
- **Pharmaceuticals that exhibit a *characteristic* of hazardous waste (D codes)**
  - Ignitability D001
  - Toxicity D004 – D043
  - Corrosivity D002
  - Reactivity D003

Examples of P-Listed Pharmaceutical Waste

Arsenic trioxide (chemo)	P012
Epinephrine base*	P042
Nicotine	***P075***
Nitroglycerin** (weak)	P081
Phentermine (CIV)***	P046
Physostigmine Salicylate	P188
Warfarin >0.3%	***P001***

* Salts excluded federally as of Oct. 15th, 2007 and in most states
** Excluded from the P list federally and in most states
***Salts excluded federally, first communicated October, 2010. Most states have accepted this position

Examples of U-Listed Pharmaceutical Waste

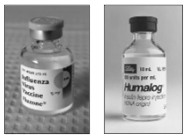
- Chloral Hydrate(CIV) U034
- Chlorambucil U035
- Cyclophosphamide U058
- Daunomycin U059
- Lindane U129
- Melphalan U150
- Mitomycin C U010
- Streptozotocin U206
- Selenium Sulfide U205

Special Attention

- Nicotine P075:
  - The "used" patch is technically non-hazardous based on the definition of a P-listed waste as a commercial chemical product. The best management practice is to manage it as a RCRA hazardous waste due to the large percentage of drug remaining.
  - The wrapper must be managed as a RCRA hazardous waste until we obtain regulatory relief, hopefully with the EPA pharm waste regulation due to be published in October, 2018.
- Warfarin >0.3% P001:
  - Any "unused" warfarin is a P-listed hazardous waste, as is the stock bottle, blisterpak, or "Bingo card"* that held it, due to the empty container rule.

* Unit dose dispensing card often used in long term care facilities, usually 15 or 30 days supply.

Pharmaceuticals Exhibiting the Characteristic of Toxicity



Preservatives: thimerosal and m-Cresol

Heavy metals: selenium and silver

Nutritionals containing chromium and/or selenium depending on Concentration, e.g. Centrum Silver®

Characteristics of Ignitability

- Aqueous solution containing 24% alcohol or more by volume and flash point < 140°F
- Non-aqueous solutions with flash points < 140°F
- Oxidizers
- Flammable aerosols e.g. Kenalog® aerosol spray
- Hazardous waste code D001
- Examples:
  - Rubbing alcohol
  - Topical preparation: Clindamycin
  - Some injections: Paclitaxel
  - Silver nitrate sticks

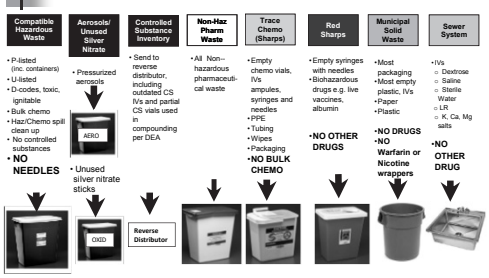
Definition of "Empty"

- To be "RCRA empty", P-listed containers must be triple rinsed and rinsate discarded as hazardous waste; only used syringes excluded – (in practice, no triple rinsing occurs)
- EPA requires **P-listed wrappers and packaging** to be managed as RCRA hazardous waste because of the **residue** remaining in them
- U-listed and D codes: empty if all removed that is reasonably possible
- Pressurized Aerosols – medications never considered "empty" – too difficult/dangerous to determine; manage in pharmacy as a RCRA Aerosol waste

Satellite Accumulation Area

- A location at or near any point of generation where RCRA hazardous waste is initially **accumulated** in containers
- May accumulate up to 55 gallons of hazardous waste or one quart of P-listed hazardous waste up to one year at or near the point of generation
- Must be labeled as "Hazardous Waste"
- Under the control of the operator: line of sight or locked compartment controlled by operator
- Must move within 3 days of reaching 55 gallon or 1 quart limit
  - Must date the container when the limit is reached and moved to Central Accumulation Area

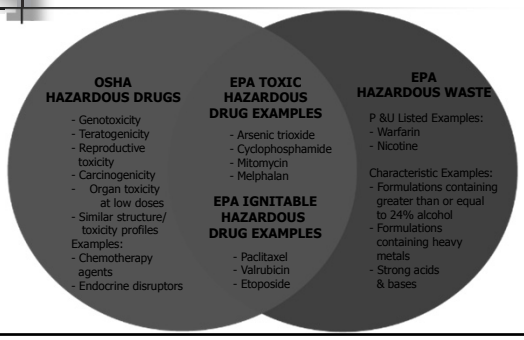
Summary of Recommended Pharmaceutical Waste Streams: Pharmacy



RCRA Hazardous Waste Challenges vs USP <800> Challenges

RCRA Challenges	USP <800> Challenges
▪ Static list of P & U drugs ▪ Four well-defined characteristics ▪ Only applies when a drug becomes a waste ▪ Regulations very specific even if not appropriate to healthcare ▪ Management required from the point of waste generation ▪ Compliance required since 1980	▪ Evolving list based on professional judgment ▪ Six more general characteristics ▪ Applies throughout the life cycle of the drug ▪ Standards require risk assessment by each facility ▪ Management depends on process involved, starting with receipt through waste management ▪ Compliance required Dec. 1, 2019

Hazardous Drugs vs Hazardous Waste: Where OSHA and EPA Meet



Hazardous Drug Handling: Protect the Patient, the Employee and the Environment

- "*It's not just about hazardous pharmaceutical waste anymore…*"
- Confusion exists:
  - HD = HW
  - HD ≠ HW
  - HW ≠ HD

Pharmaceutical Hazardous Waste (HW) vs. Hazardous Drug (HD)

HD and/or HW	EPA CODE	FULL/PARTIAL	EMPTY	ADMIN SET
Warfarin (HD = HW)	P001	Black	Black	NA
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	Table 3	Black	Black	Trash

HD and/or HW	EPA CODE	FULL/PARTIAL	EMPTY	ADMIN SET
Arsenic Trioxide (HD = HW)	P012	Black for vial	Black for vial	Black (IV bag, IV tubing)
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	Table 1	Black	Black for vial, IV bag, IV tubing	Trace chemo unless overtly soiled then Black

Pharmaceutical Hazardous Waste (HW) vs. Hazardous Drug (HD)

HD and/or HW	EPA CODE	FULL/PARTIAL	EMPTY	ADMIN SET
Nicotine (HW ≠ HD)	P075	Black	Black	NA
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	NA	Black	Black	Trash

HD and/or HW	EPA CODE	FULL/PARTIAL	EMPTY	ADMIN SET
Divalproex (HD ≠ HW)	Non-haz	White/Blue	Trash	NA
	NIOSH	**FULL/PARTIAL**	**EMPTY**	**PPE**
	Table 2	White/Blue	Trash	Trash

Quick Check

Which of the following statements are true?

A) A hazardous drug is always a hazardous waste

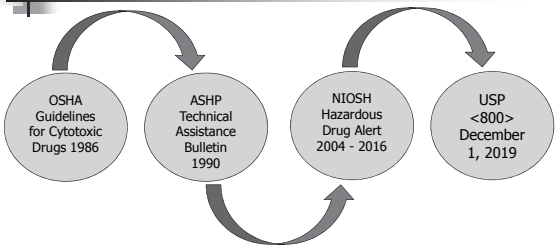
B) A hazardous waste may or may not be a hazardous drug

C) A hazardous waste is always a hazardous drug

D) A hazardous drug may or may not be a hazardous waste

B, D

The Evolution of Hazardous Drug Handling Guidance*



*A sample of major government and professional publications.

USP General Chapter<800> Hazardous Drugs – Handling in Healthcare Settings

- The purpose of the chapter is to describe practice and quality standards for handling hazardous drugs in healthcare settings and help promote patient safety, worker safety, and environmental protection.

Objectives of USP <800> Compliance

- Compliance with regulations
- Changes to Containment Strategies (CS), Work Practices (WP) or Administrative Rules (AR) as needed
- Review of Policies and Procedures (P&Ps)
- Review training programs

Defining Terms

- **A of R (assessment of risk):** assessment of risk of exposure to HD based on the manipulation of the drug product from beginning to finished dosage form. Elements include: type of HD (Table 1, 2 or 3), dosage form, risk of exposure (for all phases: receipt, preparation, transport, administration, waste, spills, patient care activities), packaging, manipulation.
- **WP (work practice):** designed to minimize environmental contamination and exposure when engineering controls are not available (examples: priming IV tubing, not touching equipment, sequence and technique of PPE removal, soap and water hand washing, regular decontamination)
- **AR (administrative rule):** administrative controls (examples: P&P, education and training, competency testing, medical surveillance)

Steps to Operationalize USP <800>

- Identify all drugs in the current inventory that meet the HD definition
- Delineate all the phases in which HD drugs are handled e.g. receiving, storing, preparing, etc.
- Conduct a risk assessment to determine if full PPE is required for a particular drug/dosage form and for which processes
- Examine containment strategies (CS), work practices (WP), and administrative rules (AR)
- Develop a comprehensive checklist
- Determine how to message/label to appropriate staff
- Document the program in a readily retrievable manner

NIOSH Hazardous Drug List 2016

- **National Institute for Occupational Safety and Health (NIOSH)**
  - Part of the Centers for Disease Control (CDC)
  - Non-enforcement "arm" of Occupational Safety and Health Administration (OSHA)
- Evaluates drugs with respect to employee exposure risks
- Publishes a list of hazardous drugs approximately every two years
- List often confused with RCRA hazardous drug waste
- Some drugs are on both lists: e.g. warfarin, cyclophosphamide, mitomycin, etc.
- NIOSH 2018 Drug List anticipated September, 2018
  - Proposed list already posted online

NIOSH Hazardous Drug Tables

- Table One: Antineoplastic drugs, including those with the manufacturer's safe-handling guidance (MSHG)
- Table Two: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug, including those with the manufacturer's safe-handling guidance (MSHG)
- Table 3: Non-antineoplastic drugs that primarily have adverse reproductive effects
- **BE SURE TO EVALUATE Tables 2 and 3! It's not just about chemotherapy!**

Pharmacy Buyer's Alert!

- "CAUTION: Drugs purchased and used by a facility may have entered the marketplace after the list below was assembled. Therefore, this list may not be all-inclusive."
- NIOSH Hazardous Drug List, 2016, page 5

NIOSH Hazardous Drug List 2016

- "If you use a drug that is not included in the list of hazardous drugs, check the available literature to see whether the unlisted drug should be treated as hazardous. Check the SDS from the manufacturer or the DPI. You may also check with other institutions that might be using the same drug. If any of the documents mention carcinogenicity, genotoxicity, teratogenicity (Section 13 in the DPI), or reproductive or developmental toxicity (Section 8), or if the DPI contains safe-handling warnings (Section 16), then use the precautions stipulated in the Alert. If the drug meets one or more of the criteria for hazardous drugs in the NIOSH definition, handle it as hazardous."
- How to Generate Your Own List of Hazardous Drugs, NIOSH Hazardous Drug List 2016, page 5.

NIOSH Hazardous Drug List 2018

- Anticipated to be released in September, 2018
- NIOSH carries out a hazard identification on each drug on the basis of the NIOSH criteria for a hazardous drug. No attempt has been made to perform risk assessments on each drug or to propose exposure limits.

Phases of HDs Handling Cycle

- Receiving
- Storage
- Preparation
- Transport
- Administration
- Waste (but not specifically addressed in USP <800>)

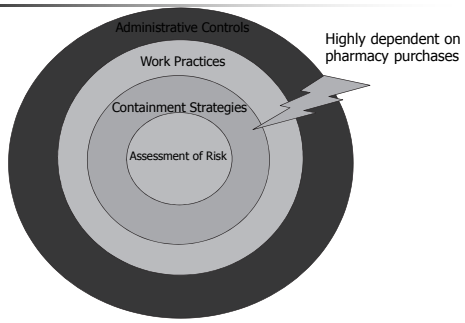
Risk Assessment: NIOSH HD List Table 5 Personal Protective Equipment & Engineering Controls

Formulation	Activity	Double chemo-therapy gloves	Protective gown	Eye/face protection	Respiratory protection	Ventilated engineering control
All types of hazardous drugs	Receiving, unpacking, and placing in storage	no (single glove can be used, unless spills occur)	yes, when spills and leaks occur	no	yes, when spills and leaks occur	no
Intact tablet or capsule	Administration from unit-dose package	no (single glove can be used)	no	no	no	N/A
Tablets or capsules	Cutting, crushing, or manipulating tablets or cap-sules; handling uncoated tablets	yes	yes	no	yes, if not done in a control device	yes[†]
	Administration	no (single glove can be used)	no	yes, if vomit or potential to spit up[‡]	no	N/A

Containment Strategies vs Work Practices vs Administrative Rules

- Containment Strategies (CS)
  - Examples: Closed system transfer device, sealed plastic transfer bags
- Work Practices (WP)
  - Examples: Prohibiting food, chewing gum or tobacco, applying cosmetics, and storing food in areas where HDs are used
- Administrative Rules (AR)
  - Examples: Purchase HDs in vials instead of ampules when possible; purchasing unit dose or unit-of-use dosage forms including liquids to avoid manipulation/compounding

Role of Pharmacy Buyers in the Process



Impact of Drug Shortages

- Need to purchase vials instead of ampules
- Need to compound in-house instead of unit-of-use sterile products
- Need to substitute non-formulary HD product

Containment Strategy Example

- Bendamustine (Table1): Which product do you purchase: TREANDA or BENDEKA?
- Do not use Treanda Injection if you intend to use a closed system transfer device (CSTD), adapters and syringes containing polycarbonate or acrylonitrile-butadiene-styrene (AABS) PRIOR TO dilution in the infusion bag. If using a syringe to withdraw and transfer Treanda Injection from the vial into the infusion bag, only use a polypropylene syringe with a metal needle and polypropylene hub to withdraw and transfer Treanda Injection into the infusion bag. However, after dilution of Treanda Injection into the infusion bag, devices that contain polycarbonate or ABS, including infusion sets, may be used.*

*https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=39d53698-57fa-7c99-fc5b-f52a55684826#i4i_section_id_addec93d-3933-0c44-e82f-582d22d32b54

Pharmacy Buyer Alert

- Evaluate ancillary purchases that impact hazardous drug handling
- Personal protective equipment
  - Gloves: ASTM standard for chemo gloves (D 6978-05)
  - Coated gowns (no ASTM standard) but ASHP/NIOSH recommendation
  - Additional PPE as warranted
- Closed system transfer devices: FDA product code ONB specifically created for "closed antineoplastic and HD reconstitution and transfer system"

Labeling and Messaging

- Hazardous Drug labeling
- Hazardous Waste categorization for proper disposal
- PPE worn for specific HDs
- PPE worn for specific phase of HD handling cycle
  - Receiving
  - Administration
  - Disposal
- PPE disposed in appropriate containers
  - Black
  - Trace chemo
  - Trash

From Deactivation through Disinfecting: Pharmacy Buyer Alert!

- Deactivation – renders the hazardous drug (HD) inert or inactive; typically oxidizers (e.g. peroxide, sodium hypochlorite)
- Decontamination – removes the HD residue (e.g. alcohol, water, peroxide, sodium hypochlorite)
- Cleaning – removes organic and inorganic material (e.g. germicidal hypochlorite)
- Disinfecting (sterile compounding areas) – destroys microorganisms (EPA-registered disinfectant and/or sterile alcohol)
- Coordinate with Environmental Services

USP <800> Summary

- Pharmacy buyers have an integral role to play in various stages of USP <800> implementation
- Continued compliance with UPS <800> will require constant vigilance on the part of pharmacy buyers
  - New drug purchases
  - New HD designations
  - Evaluation/purchasing of ancillary items

Quick Check

Pharmacy buyers can have an important impact on USP <800> compliance in which of the following areas:

A. Ensuring that all new drugs are evaluated based on NIOSH HD criteria

B. Evaluate impact of non-standard dosage forms due to drug shortages

C. Evaluate ancillary purchases such as CSTDs, PPE

D. All of the above!

D

Take a breath….

Current EPA Changes and Coming Attractions

- EPA Hazardous Waste Generator Improvements Rule in effect federally as of May 30, 2017
  - States in the process of adopting
- e-Manifest System required as of July 1, 2018
- New EPA Hazardous Pharm Waste Rule anticipated October, 2018
  - Federal adoption most likely six months later; states will have one to two years to adopt
  - Sewer prohibition of hazardous waste pharms immediately upon publication

Proposed EPA Management Standards for Hazardous Waste Pharmaceuticals

- Largest change in the proposed management of hazardous waste pharmaceuticals RCRA regulations were finalized in 1980

EPA's New Rule Tackles These Issues

- LQG status of many healthcare facilities is based primarily on hazardous waste pharmaceutical generation
- Recognition that original RCRA regulations were designed for manufacturing and heavy industry, not healthcare
- Intersection of EPA and DEA regulations – a few drugs are both controlled substances and hazardous pharmaceutical waste
- Need to manage "empty" containers of P-listed drugs such as warfarin and nicotine as a hazardous waste
- Sewering of hazardous waste pharmaceuticals
- Reverse distribution of outdated hazardous waste pharmaceuticals returned for credit

EPA's Creative Solution: 40 CFR Part 266 Subpart P

- EPA has developed "sector-specific" standards for the management of hazardous waste pharmaceuticals for:
  - 1. Healthcare facilities/pharmacies
  - 2. Pharmaceutical reverse distributors
- Potentially creditable hazardous waste pharmaceuticals: those that are eligible to send to a reverse distributor for potential credit
- Non-creditable hazardous waste pharmaceuticals: must be managed as hazardous waste at the facility

Which Pharmaceuticals Will Be Covered by the Proposed Rule?

- Only those already considered to be a hazardous waste
- EPA sought comment on how to evaluate additional pharms for inclusion but that will be a separate rulemaking process in the future

What Problems is EPA Addressing?

- Healthcare facilities are not managing hazardous waste pharmaceuticals (HWPs) in compliance with current regulations
- Healthcare facilities are sending HWPs to reverse distributors that are obviously not potentially creditable
- Healthcare facilities are disposing of HWPs into the sewer system

Exemption of Certain Containers with P-Listed Residues

- Residues in unit-dose containers and dispensing stock bottles and vials that contained P-listed drugs would be exempt from RCRA (warfarin/nicotine)
  - Packets, cups, wrappers blister packs, unit-dose delivery devices
  - Stock bottles and vials up to 1 liter or 1000 tablets/capsules
- If all contents are removed (fully dispensed), will be considered "RCRA empty"
- Container may be disposed as non-hazardous IF original packaging is destroyed to prevent diversion e.g. crushed
- Dispensed syringes would be exempt if used to administer the drug to a patient and placed in a sharps container that is managed appropriately.

More Stringent Management of other Containers with Residues

- All other containers that held listed or characteristic pharmaceuticals must be managed as hazardous waste
  - IV bags and tubing
  - Inhalers
  - Aerosols
  - Nebulizers
  - Tubes of creams, gels, or ointments
- Much stricter than current definition of "empty" for most hazardous wastes
- Will considerably increase amount of hazardous waste generated

Benefits of Operating under the Proposed Subpart P Regulations

- Hazardous pharmaceutical waste generation does not apply to generator status
- No monthly tracking of P-listed and other HWPs
- Satellite accumulations area (SAA) and central accumulations area (CAA) regulations will not apply
- No biennial reporting requirements (Large Quantity Generators)
- Encourages management of all pharmaceutical waste as hazardous waste
- Reduced training requirements

Change in Status of Expired Pharmaceuticals

- Currently, EPA considers potentially creditable expired pharmaceuticals to be a "product" at the hospital
- Under the new rule, expired pharms would become a "waste" on the date of expiration
- Expired pharms must be counted towards waste generation initially to determine generator status
- Once a facility notifies EPA under new Subpart P, no longer need to county expired drugs towards generator status

State Implications

- Proposed rule is more stringent than existing federal standards
- States with authorized RCRA programs must adopt the stricter amendments
- States may also retain any stricter elements of their programs
- No state will be able to manage HWPs under Universal Waste Rules – FL and MI must change their rules

When Will the New Federal Regulations Take Effect?

- Most recent update for publication of the final rule is October, 2018
- Once final rule is published, may take effect six months later federally (Iowa/Alaska)
- States will have a period of time to adopt
- A ban on sewering of HWPs will probably take effect immediately upon publication

Conclusion: Stay Tuned!

- USP<800> has center stage but stay aware of EPA changes
- Review pharmacy journals for helpful hints and summary articles
- Pharmacy buyers will continue to play an increasing role in ensuring compliance with hazardous drug and hazardous waste management

Selected USP <800> References

- Safe Handling of Hazardous Drugs: Reviewing Standards for Worker Protection. Luci A. Power, MS, RPh. & Martha Polovich, PhD, RN, AOCN. Pharmacy Practice News January 2018. https://www.pharmacypracticenews.com/Review-Articles/Article/01-18/Safe-Handling-of-Hazardous-Drugs-/46654
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General References

NIOSH Hazardous Drug List 2016

- https://www.cdc.gov/niosh/docs/2016-161/
- https://www.cdc.gov/niosh/topics/hazdrug/default.html

OSHA Technical Manual

- https://www.osha.gov/SLTC/hazardousdrugs/controlling_occex_hazardousdrugs.html#mgmt

ASHP Guidance on Handling Hazardous Drugs

- https://www.ashp.org/-/media/assets/policy-guidelines/docs/guidelines/handling-hazardous-drugs.ashx

DEA Drug Disposal Rule and Industry Clarification Letter:

- https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf
- http://www.aha.org/advocacy-issues/letter/2014/141006-let-disposal.pdf
- https://www.deadiversion.usdoj.gov/drug_disposal/dear_registrant_disposal.pdf

Proposed EPA Hazardous Waste Pharmaceutical Rule

- https://www.epa.gov/hwgenerators/proposed-rule-management-standards-hazardous-waste-pharmaceuticals

EPA Hazardous Waste Generator Improvements Rule

- https://www.epa.gov/hwgenerators/final-rule-hazardous-waste-generator-improvements

Questions?

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