The New Hazardous Waste Pharmaceuticals Rule: Bane or Blessing?

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1

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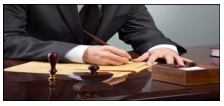

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2

3

TODAY IS THE DAY!

For certain aspects of the EPA's hazardous waste pharmaceuticals rule to take effect…..

4

No Hazardous Waste Drugs Down the Drain!

5

Objectives

1) Describe the Top Ten Take-aways from the New Hazardous Waste Pharmaceuticals Rule and how it will impact current practices at your facility
2) Describe the relationship between the new EPA Rule and the DEA's Drug Disposal Rule of 2014
3) Distinguish between a hazardous drug described by NIOSH and a hazardous waste pharmaceutical defined by EPA
4) Prioritize compliance efforts between USP <800> and EPA's new HWP Rule

6

A World of Acronyms Defined

- EPA: Environmental Protection Agency
- RCRA: Resource Conservation and Recovery Act: defines hazardous chemical waste, including some pharmaceuticals; enforced by EPA
- DEA: Drug Enforcement Administration
- CSA: Controlled Substances Act, defines drugs of abuse, enforced by DEA
- OSHA: Occupational Safety and Health Administration:
- NIOSH: National Institutes of Occupational Safety and Health, research arm of OSHA
- USP <800>: United States Pharmacopeia, General Chapter <800> Hazardous Drugs: Handling in Healthcare Settings

7

Defining "Hazardous"

- **EPA Hazardous Waste:** meets one of the definitions of hazardous waste federally or at the state level: P or U listed, characteristic of toxicity, ignitability, corrosivity, reactivity; must be a waste
- 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 (NIOSH 2019 List anticipated in December)
- 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

8

EPA's Final Rule Tackles these Issues

- Defining LQG status of healthcare facilities on acutely hazardous waste generation (> 1 kg per month), P-listed pharmaceuticals responsible for this volume of generation were mainly warfarin and nicotine
- Recognition that original RCRA regulations were designed for manufacturing and heavy industry, not healthcare
- Confusion around the intersection of EPA and DEA regulations – a few drugs are both controlled substances and hazardous pharmaceutical waste

9

EPA's Final Rule Tackles these Issues *(continued)*

- Management of "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

10

EPA's Final Rulemaking: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

- Largest change in the proposed management of hazardous waste pharmaceuticals since RCRA regulations were finalized in 1980
- Applicable in federally managed states August 21, 2019 (Iowa, Alaska, Puerto Rico, Indian Country, territories except Guam)
- Sewer prohibition of hazardous waste pharmaceuticals nation-wide August 21, 2019 ***(TODAY!)***
- All other states must adopt stricter aspects; may choose not to adopt less strict aspects

11

Quick Review of HWPs Under RCRA

- **P-listed pharmaceuticals (acutely hazardous)**
  - Sole active ingredient; unused; empty containers
  - 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

12

Examples of P-Listed Pharmaceutical Waste

- Arsenic trioxide P012
- Nicotine P075
- Physostigmine Salicylate P188
- Warfarin >0.3% P001

Items in red specifically addressed in the new regs

- Excluded from RCRA federally & in most states
  - Epinephrine salts P042
  - Nitroglycerin (weak) P081
  - Phentermine salts (CIV) P046

13

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

14

Characteristic of Toxicity

- Fails the Toxicity Characteristic Leaching Procedure (TCLP)
- Concentrated selenium and chromium usually fail the TCLP
- Examples of potentially toxic pharmaceutical ingredients:
  - Chromium D007
  - m-Cresol D024
  - Mercury (Thimerosal) D009
  - Selenium D010
  - Silver D011

15

Examples of 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®

16

Characteristics of Ignitability

- Aqueous solution containing 24% alcohol or more by volume and flash point < 140°F
  - Rubbing alcohol, hand sanitizers
  - Topical preparations: e.g. clindamycin, ethyl chloride
  - Some injections: e.g. paclitaxel
- Non-aqueous solutions with flash points < 140°F
- Oxidizers: e.g. Silver nitrate sticks (unused)
- Flammable aerosols e.g. Kenalog® aerosol spray
- Hazardous waste code D001

17

Chemotherapy Agents: Many Are Not Regulated Under RCRA

Only seven (7) active chemotherapy agents are regulated by RCRA

- Arsenic trioxide P012
- Chlorambucil U035
- Cyclophosphamide U058
- Daunomycin U059
- Melphalan U150
- Mitomycin C U010
- Streptozotocin U206

Over 100 chemotherapy agents are not regulated by EPA

Manage "bulk" chemotherapy as a hazardous waste as a best management practice.

18

What are the Top Ten Take-Aways of the New Rule?

19

#1: What is 40 CFR 266 subpart P and Why is it Important?

- It is only the second time in the history of RCRA that EPA has carved out an industry-specific regulation. The first time was for academic labs in 2008.
- Due to the very different nature of healthcare, EPA has created a specific subpart to address healthcare facilities and reverse distributors.

20

#2: Who Does the Rule Apply To?

- Healthcare facilities that are large (LQG) or small (SQG) hazardous waste generators,
  - Hospitals, clinics, retail pharmacies, long term care facilities, and many other related practices
  - Very small quantity generators (VSQG, fka Conditionally Exempt Small Quantity) may participate but are not obligated to.
  - Reverse distributors who manage outdated Rx drugs for credit

21

#3: Sewer Prohibition for all Hazardous Waste Pharmaceuticals (HWPS)

- Sewering of HW Pharmaceuticals are PROHIBITED nationally *TODAY!*
  - All healthcare facilities (VSQG (fka CESQG), SQG, LQG)
  - Pharmaceutical Reverse Distributors
  - Sewer ban reinforces and highlights EPA's policy against flushing pharmaceuticals
- HSWA Provision (Hazardous and Solid Waste Amendments, 1984): **effective in all states August 21, 2019**

22

#4: When Does the Rest of the Rule Apply?

- Federally August 21, 2019: Iowa, Alaska, Puerto Rico, and all territories except Guam. All other states must adopt the rule which can take 1 to 2 years.
- New Jersey, Pennsylvania, and Kentucky have declared they will adopt the new regulations in their entirety on or about August 21, 2019.
- North Carolina will adopt the nicotine exemption immediately.
- Check with your state for an update on their adoption schedule.
- Monitor for adoption of the less stringent aspects of the rule.

23

#5: Will HWPs Still Need to be Counted Towards Generator Status under Subpart P?

- No, this is one of the major benefits of the new rule. They only need to be counted initially to determine if the facility must comply with subpart P.
- At the time of the determination of generator status, any outdated HWPs must also be counted.
- If the initial determination meets the LQG or SQG quantity requirements, the organization must participate in 40 CFR 266 subpart P.

24

HWPs Will No Longer Count Towards Generator Status Under Subpart P

- HWPs will not be included in determining generator status, therefore there is no SQG or LQG status for HWPs
- All HWPs are managed the same
  - No tracking of monthly generated amounts for HWPs
  - No separation of P-listed HWPs
  - Decreases episodic generation
  - No longer a disincentive to manage all pharmaceutical waste as hazardous waste pharmaceuticals
  - Total accumulation time 1 year

25

Hazardous Waste Determinations

- Must determine if the pharmaceutical waste is a hazardous waste
  - If all non-creditable hazardous waste pharmaceuticals are managed as hazardous waste, do not need to determine waste codes
- Must keep records of waste determinations for at least 3 years from the date the waste was last sent to a TSDF
  - If all non-creditable non-hazardous waste pharmaceuticals are managed as hazardous waste, not required to keep documentation of hazardous waste determination

26

Hazardous Waste Determinations *(continued)*

- Must determine and manage incompatibility
- Non-creditable hazardous and non-hazardous waste pharmaceuticals may be stored together
- Non-creditable HWPs prohibited from being combusted must be accumulated in separate containers and labeled with all applicable hazardous waste codes
  - E.g. arsenic trioxide (P012)
  - Mark container as "Hazardous Waste Pharmaceuticals"

27

What About Other Hazardous Waste?

- Organizations must continue to identify, document, and manage all other hazardous wastes appropriately.
- Generator status will be determined by the amounts of non-HWP hazardous waste being generated and accumulated, e.g.:
  - Maintenance
  - Lab
  - Construction/Demolition

28

#6: Will Nicotine and Warfarin Packaging be Exempt from Disposal as HW?

- Yes, but for different reasons.
  - Warfarin packaging will be exempt due to changes in the definition of "empty."
  - Certain OTC nicotine packaging will be exempt because nicotine in certain dosage forms will be excluded as a hazardous waste.
    - 261.33(e) will exempt ***OTC nicotine lozenges, gums, and patches***, which includes the packaging.
    - Unused nicotine lozenges, gums, and patches should be managed as nonhazardous pharmaceutical waste as a Best Management Practice.

29

Are All Nicotine Dosage Forms Exempted?

- Exemption from P075 as a hazardous waste: FDA-approved Over-the-Counter (OTC) replacement therapy in the form of lozenge, gum, or patch
- Not exempt: Rx nicotine replacement therapy (NRT), e-cigarettes, nicotine e-liquids
- No exemption for a particular nicotine concentration
- Exemption will not become effective in states authorized for the RCRA program until states have adopted the exemption

30

Quick Check

Which of the following are accurate descriptions of the impact of the new regulations that impact hazardous pharmaceutical waste management? T or F?

A. It is very common for EPA to carve out a specific industry for regulation.

FALSE: Only the second time in history.

B. No hazardous waste pharmaceuticals can be drained disposed after today, August 21, 2019, anywhere in the U.S.

TRUE: This regulation is promulgated under the HWSA regulations and applies immediately in all states.

31

Quick Check *(continued)*

C. All nicotine in finished dosage forms is exempt federally from P075 and therefore not a hazardous waste when discarded.

FALSE: Only OTC nicotine gums, lozenges, and patches are exempt.

D. The new rule is considered to be stricter so all states must adopt it.

TRUE: The rule in general is stricter although some aspects are less strict and states do not need to adopt those aspects.

32

#7: How Will Other "Empty" Containers Be Managed?

- Stock bottle, dispensing bottle, vial, or ampule not to exceed 1 liter or 10,000 pills or a unit-dose container or delivery device is empty when:
  - Drugs have been removed using practices commonly employed for that type of container
  - No triple rinsing needed for P-listed HWPs
  - No measuring of contents needed for other HWPs

33

Management of Residues in Syringes

- Syringes
  - Empty when contents have been removed by fully depressing the plunger
  - If not empty and has a needle attached, must be managed as a "dual" hazardous/biohazardous waste
- Three methods for becoming "empty"
  - Administration to patient
  - Injecting contents into an IV or other delivery system
  - Emptying remaining contents into a hazardous waste collection container
    - Absorbent/adsorbent material recommended to avoid free liquids

34

Management of Residues: IV Bags

- The container is "RCRA-empty" if:
  - U-listed or characteristic hazardous waste - fully administer the contents or no more than 3% by weight remains
  - P-listed - fully administer the contents. No triple rinsing allowed or required.
    - E.g. a fully used IV bag of arsenic trioxide can be disposed as trace chemotherapy (yellow) rather than as a hazardous waste (black)

35

Management of Residues: Inhalers, Aerosols, Nebulizers, Ointments, Gels, Creams

- Pharmaceuticals have been fully administered to a patient and NOT P-listed
- If not fully administered and NOT P-listed:
  - (i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, *and*
  - (iii)(A) No more than 3 percent by weight of the total capacity of the container remains in the container
- If not fully administered or P-listed HWP, must be managed as a HWP

36

#8: What About Hazardous Waste Controlled Substances?

- Controlled substances that are also a hazardous waste ***will be exempted*** from the RCRA hazardous waste regulations under subpart P, assuming all DEA requirements for disposal are met.
- Neither inventory nor "wastage" of DEA controlled substances that are hazardous wastes can be sewered
- Destroyed by a method DEA has publicly deemed in writing to meet non-retrievable standard, ***OR***…
- Must be incinerated by 1 of 5 types of permitted combustors

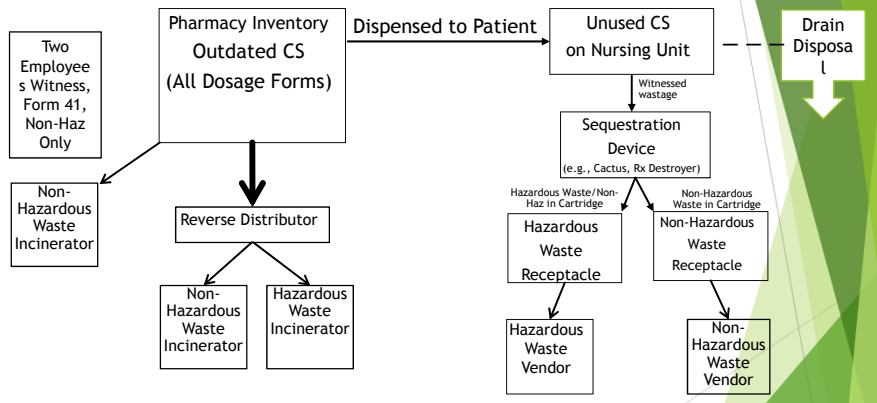
37

Hospital Decision Tree: Controlled Substance Disposal

- Is the controlled substance part of the pharmacy's inventory or dispensed/administered "wastage"?
- Pharmacy Inventory:
  - Outdated controlled substances in original containers
  - Compounded IVs that have outdated
  - Partially used multiple dose vials that are beyond use based on sterility standards
- Wastage:
  - Dispensed and partially administered IVs, multiple dose vials, refused/dropped tablets/capsules

38

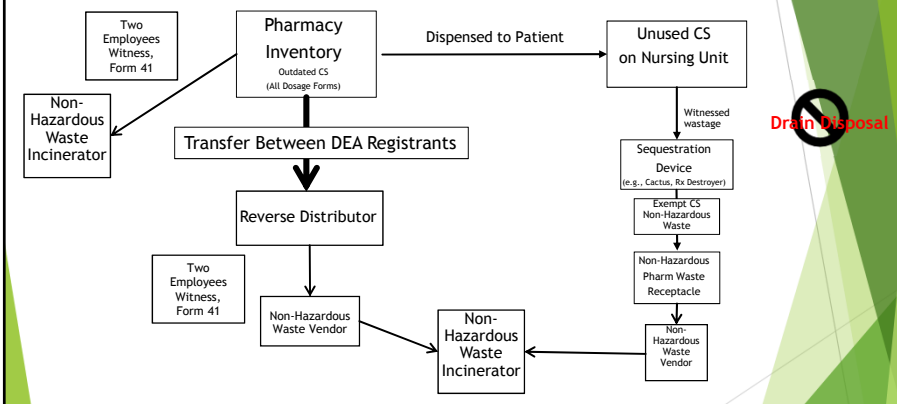
Current Controlled Substance Decision Tree



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

39

Revised Federal Controlled Substance Decision Tree Under Subpart P



* Be sure to check state regulations to ensure the controlled substance exemption is adopted

40

Operational Impact of DEA Exemption

- Disposal of controlled substance "wastage" in the nursing units should include sequestration into a device that renders the drugs "non-divertable"
  - Examples:
    - Cactus Smart Sink® (denaturation)
    - Rx Destroyer™ (activated carbon)
    - CsRx™ (activated carbon)
- Devices will no longer need to be disposed into a hazardous pharmaceutical waste container, but can be disposed as non-hazardous pharmaceutical waste by incineration
  - Cannot be disposed in the trash

41

Quick Check

A. An empty warfarin blisterpak will no longer be a hazardous waste when a state adopts the new rule.

True: empty unit-dose containers are exempt from RCRA.

B. An empty IV bag that held arsenic trioxide must still be managed as a P-listed hazardous waste

False: if the contents are fully administered to the patient, the IV bag is considered RCRA-empty nd can be disposed as trace chemotherapy

42

Quick Check *(continued)*

C. Controlled substances remaining after dispensing to the patient are considered "wastage" by DEA and out of the DEA closed loop, but must be managed in compliance with all applicable environmental rules.

True: DEA does include documentation requirements but leaves disposal up to the registrant. EPA is more prescriptive for hazardous waste controlled substances, requiring incineration at this time.

D. If any hazardous waste controlled substances are administered in the nursing unit, it will be very difficult to continue drain-disposing non-hazardous controlled substances and remain in compliance with the sewer ban of HWPs.

True: it will be difficult for nurses to distinguish between HWP and non-HWP controlled substances.

43

#9: Are Any New Drugs Being Listed as Hazardous Waste?

- No, EPA mentions it is interested in doing so and asks for suggestions, however, this will be a separate rulemaking in the future
- However, since many chemotherapy drugs are not listed, dispose of these as hazardous waste as a best management practice
- EPA does encourage the management of all pharmaceutical waste as hazardous waste

44

#10: What About Outdated Rx Drugs Sent to a Reverse Distributor?

- An Rx drug ***will be considered a waste*** when it outdates at the pharmacy.
- If it is potentially creditable, as defined in the regulation, it can be sent to a reverse distributor for evaluation, following certain additional requirements.
- Under the current rule, outdated OTC hazardous waste pharmaceuticals CANNOT be sent to a reverse distributor but remain a product if potentially reusable/recyclable etc. and must be sent to a reverse logistics center.
- Stay tuned for possible change in the future regarding outdated HWP OTCs.

45

Distinction Between Reverse Distributor vs. Reverse Logistics Center

- Reverse distributor: any person that receives and accumulates *prescription (Rx)* pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals *for the purpose of facilitating or verifying manufacturer credit*.
- Includes forward distributors, third-party logistics providers, and pharmaceutical manufacturers that *process Rx pharms for credit*.
- Reverse logistics centers are not specifically defined in their role as evaluators of OTCs for possible reuse, donation, or reclamation

46

Potentially Creditable Rx HWP (Reasonable Expectation of Credit)

- PRESCRIPTION pharmaceuticals only; not OTCs, dietary supplements
- Undispensed
- In the original manufacturer's container, including partials
- Unexpired or less than 1 year past expiration date

47

Managing Potentially Creditable HWPs

- Must determine if potentially creditable pharmaceutical is a hazardous waste
- May manage potentially creditable non-hazardous pharmaceutical waste as a hazardous waste
- May accept potentially creditable HWPs from a VSQG under the same control (May not be applicable in all states)
- Manage in compliance with subpart P, keep records for 3 years
- PROHIBITED from sending hazardous waste OTHER THAN potentially creditable Rx HWPs to a reverse distributor

48

Shipping Potentially Creditable HWPs to a Reverse Distributor

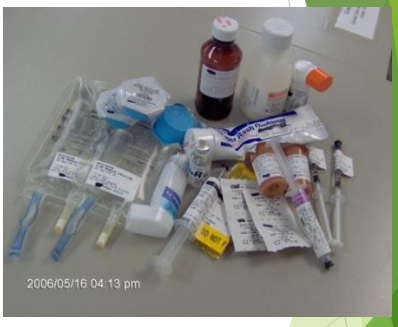
- May be from a healthcare facility to a reverse distributor or from a reverse distributor to another reverse distributor via common carrier
- Must comply with DOT shipping descriptions for hazardous materials (usually ORM-D: Other Regulated Material – Class D or Limited Quantity Label)
- Receiving reverse distributor must provide confirmation of receipt, custody and control (paper or electronic) to the shipper
- If confirmation not received ***within 35 days of shipping date***, shipper must contact carrier and RD to report and determine status of shipment
- **KNOW HOW TO ACCESS YOU RD RECORDS!**

49

Reverse Distribution: When to Use It

Potentially Creditable Outdates

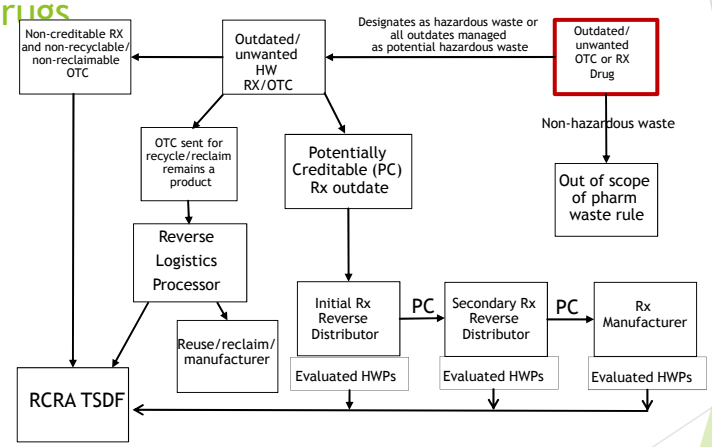
Non-creditable Waste



If a hazardous waste, must be considered to be waste at the facility and managed according to subpart P.

50

Managing Outdated HWP Rx & OTC Drugs



51

Reverse Distribution Recordkeeping Requirements for Health Care Facilities

- The following records must be kept for 3 years:
  - Confirmation of delivery to the reverse distributor
  - DOT shipping papers if applicable
  - Recommended: notice of pick-up and notice of delivery by common carrier, such as FedEx, UPS, etc., meets requirement

52

NEW! Reporting Requirements of Reverse Distributors

- Must submit an unauthorized waste report upon receipt of waste not in compliance with the Rule
  - ***Non-creditable HWPs including drugs partially administered to patients, etc.***
  - Non-pharmaceutical hazardous waste
  - Regulated medical waste (biohazardous)
- Send copy to EPA Regional Administrator within 45 days of receipt and copy to healthcare facility that shipped

53

NEW! Reporting Requirements of Reverse Distributors *(continued)*

- Report must be signed by owner, operator, or authorized representative
  - EPA ID number, name, address of reverse distributor
  - Date unauthorized waste received
  - ***EPA ID number, name, address of healthcare facility that shipped unauthorized waste***
  - Description and quantity of each unauthorized waste received
  - Method of treatment, storage, or disposal
  - Brief explanation of why the waste was unauthorized, if known

54

Conditional Exemptions for Household Waste Pharmaceuticals

- Household waste pharmaceuticals collected in a take-back event or program or DEA-approved kiosk
- Cannot be sewered
- Must be in compliance with DEA regulations
- Must be destroyed in a manner DEA has publicly deemed in writing to meet their non-retrievable standards of destruction, ***OR***…

55

Conditional Exemptions for Household Waste Pharmaceuticals (continued)

- Must be destroyed in a manner DEA has publicly deemed in writing to meet their non-retrievable standards of destruction, ***OR***…
- Incinerated at either a:
  - Permitted large or small municipal waste combustor
  - Permitted hospital, medical and infectious waste incinerator
  - Permitted commercial and industrial solid waste incinerator e.g. a waste-to-energy incinerator
  - Permitted hazardous waste incinerator

56

Quick Check

1) Which of the following outdated drugs can be sent to a reverse distributor under the new pharmaceutical waste regulation?

- A. Outdated warfarin repackaged into unit-dose blisterpaks by the pharmacy
- B. Outdated physostigmine salicylate in its original ampule
- C. Outdated Centrum Silver in its original stock bottle
- D. Silver sulfadiazine cream compounded on-site

57

Quick Check *(continued)*

2. Which of the following shipments will trigger a report to the EPA Regional Administrator and to the health care facility from the reverse distributor?

- A. Receipt of regulated medical waste
- B. Receipt of non-hazardous outdated pharmaceuticals
- C. Receipt of non-pharmaceutical hazardous waste
- D. Receipt of non-creditable hazardous waste pharmaceuticals

58

Summary

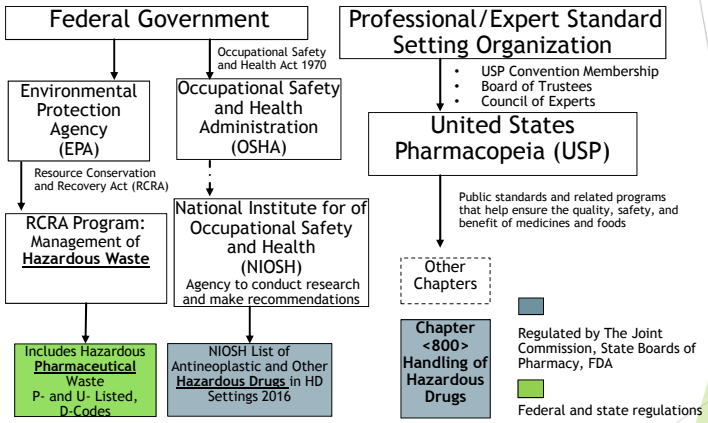
- ***No hazardous waste pharmaceuticals down the drain as of TODAY!***
- Review controlled substance disposal program in the nursing units
  - Consider a sequestration device if still drain disposing
- AK, IA, PR: your organization has either 60 days or next Biennial Report to notify EPA if you are CURRENTLY SQG or LQG; compliance expectations now however.
- NJ, PA, KY: check with your state but most likely they have adopted the entire rule and the same timeline applies.
- All others stay alert for when your state will adopt and if the less restrictive aspects are included.

59

Shifting Gears: Hazardous Drugs vs Hazardous Waste Complying with USP <800>

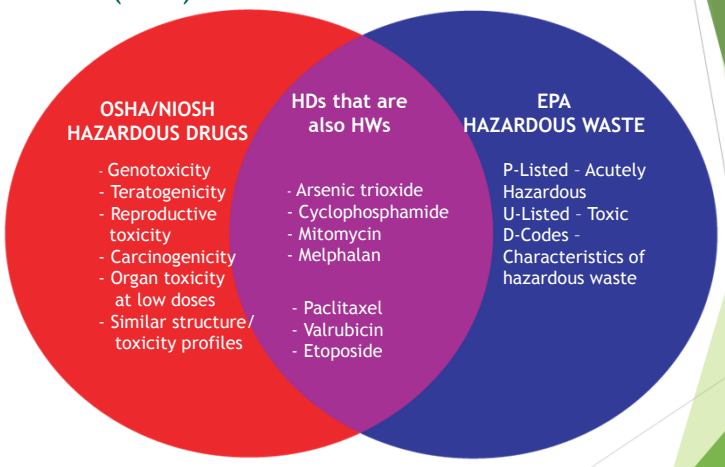
60

Relationship between: EPA, RCRA, OSHA, NIOSH, USP



61

Hazardous Drugs (HD) vs. Hazardous Waste (HW) - Where OSHA & EPA Meet



62

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

"It's not just about hazardous pharmaceutical waste anymore…"

- Confusion exists:
  - HD = HW
  - HD ≠ HW
  - HW ≠ HD

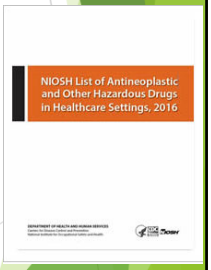
Phases of HDs Handling Cycle:

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

63

NIOSH Hazardous Drug List 2016; 2019 List Pending

- **Potential new date of release: December, 2019**
- Table One: Antineoplastic drugs (chemotherapy)
- 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 Three: Non-antineoplastic drugs that primarily have adverse reproductive effects
- Table Five: Personal Protective Equipment and Engineering Controls
- Facilities are responsible for examining all new drugs purchased regarding definitions of hazardous drugs



64

Considerations and Challenges: USP <800>

- Healthcare entities are gearing up for this change in handling HDs – Deadline is December 1, 2019
- Similar to categorization of waste; each individual drug must be assessed for risk as opposed to class of drug
- Assessment of Risk documentation should be available for any survey or inspection
- Neither RCRA nor NIOSH apply to consumers

65

Quick Check

A. There is a great deal of confusion between NIOSH hazardous drugs and EPA hazardous waste pharmaceuticals.

True

B. Hazardous drugs must be managed as hazardous waste and enforcement is by EPA and state environmental authorities.

False

66

Quick Check *(continued)*

C. If your organization is currently a Large Quantity Generator or a Small Quantity Generator of hazardous waste, you MUST participate in subpart P when your state adopts the regulation.

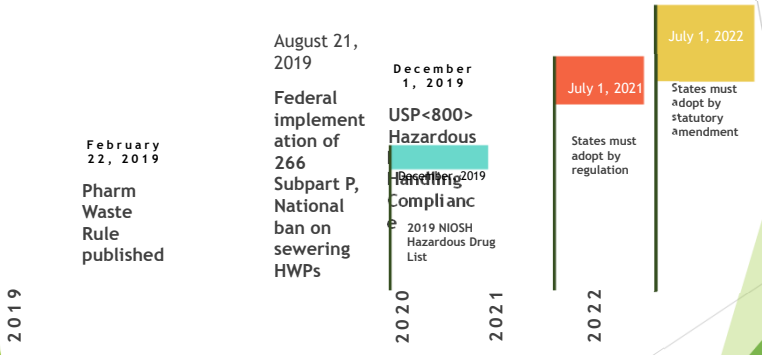
True

D. If your organization is a Very Small Quantity Generator of hazardous waste, you are not required to participate in subpart P but may choose to do so.

True

67

Hazardous Drug/Hazardous Waste Compliance Timeline



68

Prioritizing Compliance Efforts Between USP <800> and the New Pharm Waste Rule

- Review your current pharmaceutical waste program
  - Have you identified all drugs that become a hazardous waste pharmaceutical?
  - Do you as the buyer review all new drugs purchased to determine their hazardous waste status?
  - Work with pharmacy and nursing to ensure compliance with the current hazardous waste regulations as they apply to waste pharmaceuticals

69

Prioritizing Compliance Efforts Between USP <800> and the New Pharm Waste Rule *(cont.)*

- Identify all hazardous drugs using the 2016 NIOSH hazardous drug list plus those recommended by NIOSH and identified in other references as potential hazardous drugs, e.g. eFacts
  - Set up a system to review all drugs purchased for potential hazardous drug status
  - Ensure these drugs are subject to an Assessment of Risk process by dosage form
  - Stay alert for the 2019 NIOSH Hazardous Drug List in December

70

Meeting the August 21, 2019 Federal Effective Date

- Do you stock ANY hazardous waste pharmaceuticals that are controlled substances?
  - If so, determine if any controlled substances are being drain disposed and immediately begin discussions on alternative sequestration and disposal methods
- Are any other hazardous waste pharmaceuticals being drain disposed?
  - If so, immediately begin developing alternative compliance disposal methods as hazardous pharmaceutical waste

71

Meeting the August 21, 2019 Federal Effective Date (continued)

- Are you located in IA, AK, PR, Indian Country, or a US territory other than Guam?
  - If so, begin preparing to comply with all aspects of CFR Subpart P on August 21, 2019
- Are you located in NJ, PA, or KY?
  - If so, monitor your state environmental regulatory agency and prepare to comply with all aspects of the new pharm waste regulation on or near August 21, 2019 as indicated by your state
- For all other states, regularly monitor their progress towards adoption. Be alert for webinars and other educational opportunities from these agencies

72

Completing the Hazardous Drug Assessment of Risk, USP<800> by December 1, 2019

- Ensure your hazardous drug list is maintained as up-to-date as possible
- Ensure that pharmacy staff understand the difference between a hazardous drug and hazardous waste
- Identify current and potential hazardous drug shortages that could impact Assessment of Risk determinations
  - Develop alternative PPE, ventilatory controls for these situations
- Identify those hazardous drugs that will be compounded
- Evaluate various programs available in the market to assist in determining and documenting the Assessment of Risk

73

Summary

While the compliance dates we have discussed are important, it's equally important to consider the management of both hazardous drugs and hazardous pharmaceutical waste as continuous improvement processes that need constant attention and revision.

74

General References

Final 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

NIOSH Hazardous Drug List 2016 - 2019

- https://www.cdc.gov/niosh/review/peer/isi/hazdrug2018-pr.html
- 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

75

Questions?

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76