Hazardous Drugs & Waste Update: NIOSH, USP, EPA, PPE

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Learning Objectives

- Compare and contrast the NIOSH Hazardous Drug List 2020 with the 2016 version
- Describe an approach for updating current system to comply with the 2020 List
- Discuss the integration of the 2020 List into current USP <800> Assessment of Risk Process

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Learning Objectives *(continued)*

- Outline current disposal processes for personal protective equipment (PPE) based on USP <800> requirements
- Describe a process to update pharmaceutical waste management practices to comply with your state's current rule status

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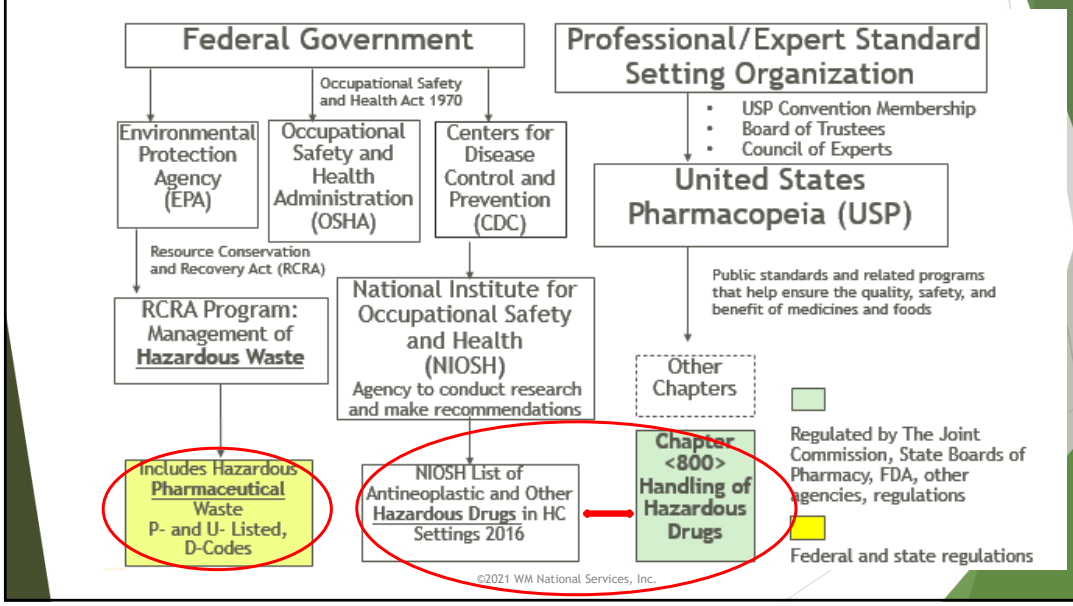
A Quick Review of the Hazardous Landscape



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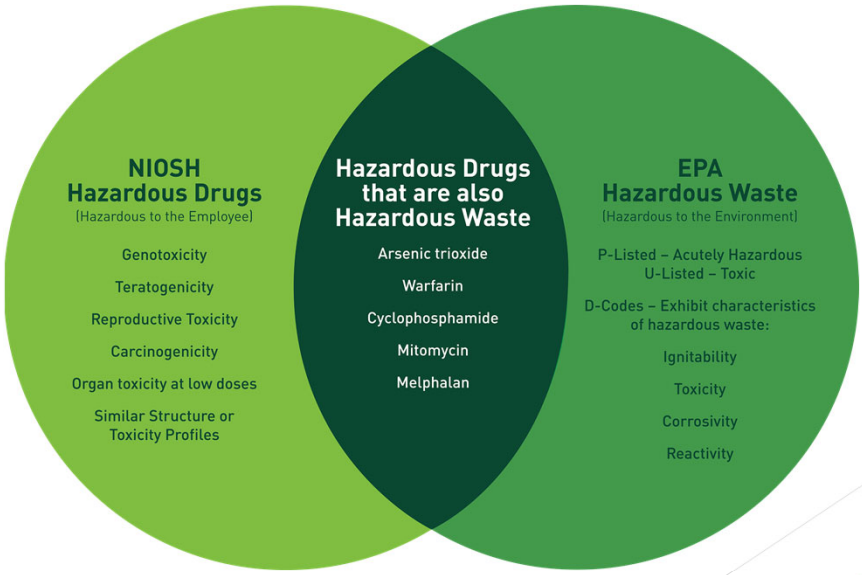
Hazardous Drugs vs Hazardous Waste



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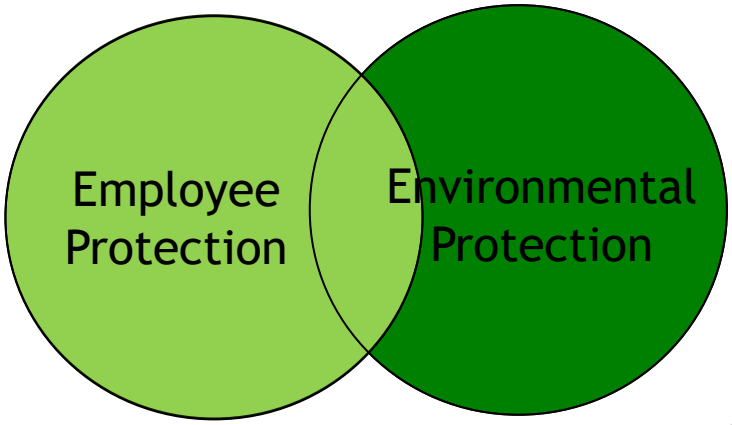
Employee Protection vs Environmental Protection



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The NIOSH Hazardous Drugs Lists: 2016, 2020, and beyond…

- TO DATE: The NIOSH Hazardous Drug List 2016 is the official list
- The NIOSH Hazardous Drug 2020 is in final revision
- The NIOSH Hazardous Drug List 2020 ONLY reviews drugs up through 2015
- SO, Pharmacy Buyers have an opportunity to assist in identifying hazardous drugs as they are purchased, especially new drugs

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Does the NIOSH List Define the Risk?

- No, the NIOSH list identifies the hazard
- The organization must evaluate the risk of exposure based on the activities during each of stage of handling:
  - Receiving
  - Storage
  - Compounding
  - Transferring
  - Administering
  - Disposal and Spill Clean-up

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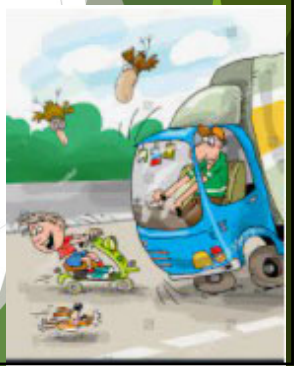
Hazard vs Risk

- A hazard has the potential to cause harm
  - A busy street
  - A sharp knife
  - Matches
- Risk is the likelihood of a hazard causing harm
  - Walking down the middle of a very busy street
  - Running with a sharp knife
  - Allowing children access to the matches unsupervised



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Quick Check

All of the following drugs are on the NIOSH Hazardous Drug List 2016. Which combination of hazard and risk is the highest?

- A warfarin tablet in a blisterpak
- Cyclophosphamide IV compounded in pharmacy
- Faulty port of daunomycin IV bag in infusion center
- Chemotherapy drugs in segregated ziplock bags from wholesaler

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The 2016 NIOSH List

- Three primary tables:
  - Table 1: antineoplastic drugs, including those with manufacturer's safe-handling guidance (MSHG)
  - Table 2: Non-antineoplastic drugs that meet one or more of the NIOSH criteria for a hazardous drug; includes those with MSHG
  - Table 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

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The NIOSH 2020 DRAFT To Date…

- THREE documents:
  - DRAFT NIOSH Procedures for Developing the NIOSH List of Hazardous Drugs in Healthcare Settings
  - **DRAFT Managing Hazardous Drug Exposures: Information for Healthcare Settings**
  - **DRAFT NIOSH List of Hazardous Drugs in Healthcare Settings, 2020 (DRAFT 2020 NIOSH List)**

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DRAFT NIOSH List of Hazardous Drugs in Healthcare Settings, 2020: Table 1

- Drugs that contain MSHI (manufacturer's special handling information) in the package insert
- And/or drugs that meet the NIOSH definition of hazardous drug AND are classified by the NTP as "known to be a human carcinogen" and/or classified by the IARC as "carcinogenic" or probably carcinogenic"
  - NTP: National Toxicology Program, 14th Report on Carcinogens
  - IARC: International Agency for Research on Cancer

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DRAFT NIOSH List of Hazardous Drugs in Healthcare Settings, 2020 Table 1 cont.

- Many of these drugs are cytotoxic (toxic to living cells)
- The majority are hazardous to males or females who are actively trying to conceive
- Women who are pregnant or may become pregnant
- Women who are breast feeding
- Not all drugs in Table 1 are antineoplastic drugs

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DRAFT NIOSH List of Hazardous Drugs in Healthcare Settings, 2020 Table 2

- Drugs that meet the NIOSH definition of a hazardous drug but are not drugs that have MSHI or the NPT or IARC classifications
- Exhibit one or more of the types of toxicity described in the NIOSH definition of a hazardous drug
- May be classified as IARC possibly carcinogenic, NTP reasonably anticipated to be a human carcinogen, or not classified
- Some may be a reproductive hazard

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Summary of the Two Tables

- Include the Drug Name
- The AHFS Classification (American Hospital Formulary Service)
- Supplemental Information
  - Which criteria they meet
  - Black box warnings
  - Additional reproductive information

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Changes to the Placement of Drugs on the List

- Documented in a separate table
- Drugs removed from the list
- Drugs moved to a different table

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Summary of Changes

Table 1: antineoplastic drugs, including MSHI (includes only reproductive hazard)

Table 2: Non-antineoplastic drugs that meet 1 or more NIOSH criteria, including MSHG

Table 3: Non-antineoplastic drugs that primarily have adverse reproductive effects

Table 1: MSHI , NTP human carcinogen, IARC carcinogenic or probably carcinogenic

Table 2: No MSHI, may be IARC possibly carcinogenic, NTP reasonably anticipated to be carcinogen

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Items to Note

- Placement in a specific table ***did not and does not in and of itself signify greater or lesser hazard***
- The tables are no longer organized around the ASHP "antineoplastic" category
- The USP <800> definition of antineoplastic drug will change slightly when the NIOSH 2020 list is finalized and will include fewer drugs

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USP <800> Clarification of "Antineoplastic"

- "For the purpose of this chapter, the term antineoplastic only refers to antineoplastic drugs included in Table 1 of **THE MOST CURRENT NIOSH LIST.**" (Upper case and bold added…)….
- This Revision Bulletin will not result in any changes for entities implementing the 2016 NIOSH List."
- https://www.uspnf.com/sites/default/files/usp_pdf/EN/USPNF/revisions/gc-800-rb-notice-20200626.pdf

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On-going review

- **"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 and employers should consider creating a facility-specific hazardous drug list."**

*NIOSH List of Hazardous Drugs in Healthcare Settings, 2020, page 6.

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On-Going Review *(continued)*

- Drugs reviewed between January 2014 and December 2015
  - Recently approved drugs that include MSHI are added to the list immediately and posted on the NIOSH website
- All new drugs over the past five years must be evaluated at the facility level
  - NIOSH list is therefore the **minimal Hazardous Drug list**

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Role for Pharmacy Buyers: Keeping an Eye on HD Dosage Forms

- Purchase unit dose rather than bulk tablets/capsules when available
- Purchase film-coated tablets when available
- Purchase unit-dose solutions and suspensions when available
- Purchase pre-loaded syringes rather than vials

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DRAFT Managing Hazardous Drug Exposures: Information for Healthcare Settings (FKA Table 5)

- Provides relatively detailed information and suggestions for managing exposure risk to hazardous drugs in healthcare settings

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DRAFT Managing Hazardous Drug Exposures: Information for Healthcare Settings (FKA Table 5) - *continued*

- IMPORTANT: Includes a much more detailed Table of Control Approaches (page 55) on suggested administrative controls and personal protective equipment
  - Common dosage forms
  - Receiving/transportation
  - Compounding
  - Administering
  - Disposal and Cleaning
  - Spill Clean-up

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Enforceability of USP <800>

- "General Chapter is informational and not compendially applicable because it is not referenced in General Notices, a monograph, or another applicable general chapter numbered below <1000>. (e.g. <795>, <797>)"
- "State agencies (e.g., State Boards of Pharmacy), other regulators (e.g., Occupational Safety and Health Administration), and oversight organizations (e.g., The Joint Commission) may make their own determinations regarding the applicability and enforceability for entities within their jurisdiction."

https://www.usp.org/sites/default/files/usp/document/our-work/compounding/compendial-applicability-of-usp-800.pdf

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Developing an Assessment of Risk

- Identify all drugs in the formulary that are on the current and proposed lists
- Review all drugs entered the market after 2016 that "look like" the listed hazardous drugs
- Consider the steps from receiving through storage, preparation, disposal in the pharmacy, cleaning, and transportation
- Administration must include nursing leadership

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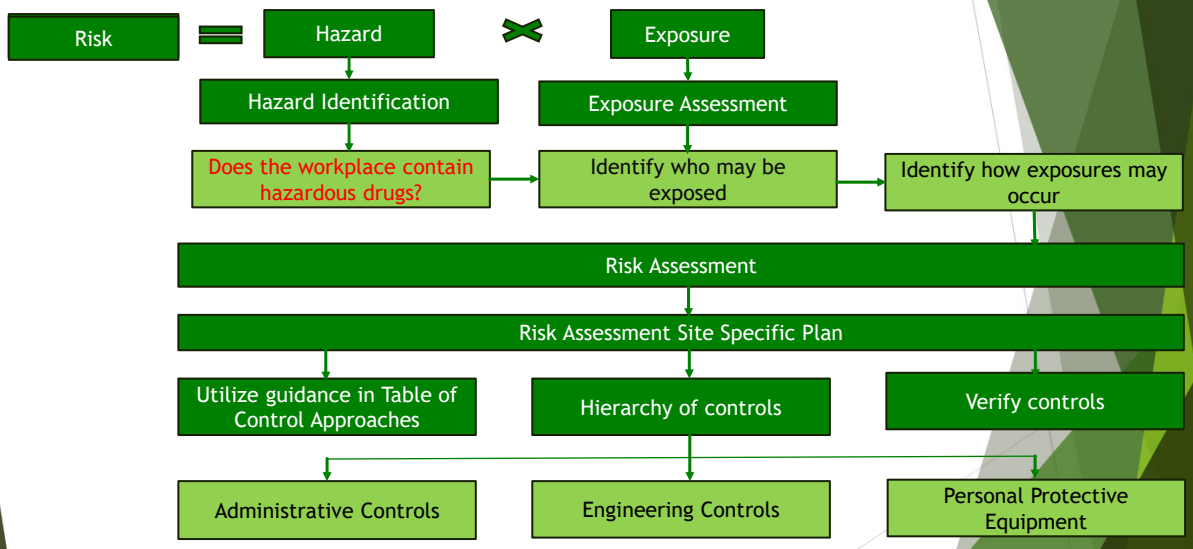
Elements of Risk Assessment



*Managing Hazardous Drug Exposures: Information for Healthcare Settings (Draft), page 23.

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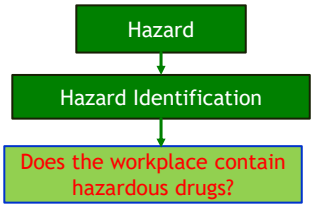

- National Drug Code (OTC and prescription products):
  - 10 digits, 3 sections (e.g. 4-4-2)
    - **Manufacturer**
    - **Product (strength, dosage form, formulation)**
    - **Package size**
  - Drug: hazardous identification per NIOSH
  - Dosage form: risk of exposure (e.g. tablets vs. liquids)

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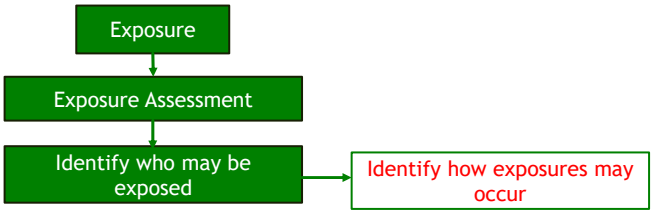

- Routes of exposure: eyes, mouth, lungs, skin, ingestion, inhalation
- All stages of handling, especially:
  - Preparation/Compounding: Risks of Exposure
  - Administration: Risks of Exposure

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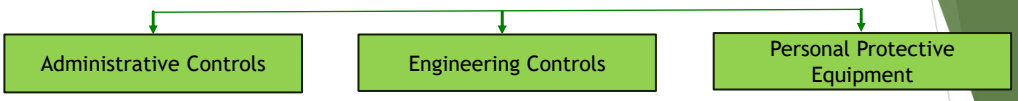

- Engineering controls (containment strategies)
  - C-PEC (Containment Primary Engineering Control)
  - C-SEC (Containment Secondary Engineering Control)
- Administrative controls
  - Rules, culture
  - Work practices (including policies and procedures (P&Ps) of PPE requirements by staff)
- PPE
  - Gloves, gowns, eye/face, respiratory

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USP <800> PPE Requirements for Each Phase of Handling HDs

- **Preparation** (compounding of sterile and non-sterile HDs): 2 pairs of ASTM standard D6978 chemo gloves; sterile outer glove for sterile compounding; gowns; head/hair/shoe covers.
- **Administration:** 2 pairs of ASTM (American Society for Testing and Materials) standard D6978 chemo gloves when administering NIOSH Table 1 antineoplastics; gowns for injectable NIOSH Table 1 antineoplastics.

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USP <800> PPE Requirements for Each Phase of Handling HDs - *continued*

- **Spill clean-up:** 2 pairs of ASTM standard D6978 chemo gloves; gown; goggles and face shield if risk of spill/splash, respiratory protection (if spill is larger than what can be contained with a spill kit).
- **Deactivate/Decontaminate**/and cleaning underneath the work surface in the C-PEC: fit-tested NIOSH-certified N95, full-facepiece, or chemical cartridge-type respirator or PAPR.

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Suggested Disposal of PPE Use in Hazardous Drug Handling

- Consider yellow trace chemotherapy container for all trace-contaminated PPE used in sterile compounding
- Consider yellow trace chemotherapy container for all trace-contaminated PPE used to handle drugs that designate as antineoplastic drugs

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Suggested Disposal of PPE Use in Hazardous Drug Handling - *continued*

- Consider trash for all trace contaminated PPE used in the management of non-antineoplastic drugs
- Use black hazardous waste container for all PPE used in spill clean-up for any drugs

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Quick Check

A. The NIOSH 2020 Hazardous Drug List identifies the hazard posed by the drug. The healthcare facility must evaluate the risk.

- *True*

B. In the Draft NIOSH 2020 Hazardous Drug List, drugs in Table One are considered to pose a higher risk than drugs in Table Two.

- *False*

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Key Takeaways

- The Assessment of Risk decisions will change slightly due to the realignment of tables into two instead of three and additional changes suggested in the Management document
- The employee protection basics remain the same
- Each NDC must be evaluated and decisions documented at least annually and with any changes in procedures

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Key Takeaways - *continued*

- New hazardous drugs should ideally have an assessment of risk completed at the P&T committee level with nursing involvement prior to purchase
- HOWEVER, pharmacy buyers will be critical in selecting appropriate dosage forms and packaging, e.g. unit dose versus bulk, to reduce employee handling risks

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Update on State Adoption of OTC Nicotine Exemption and Subpart P

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EPA's Hazardous Waste Pharmaceutical Initiatives

- EPA banned drain disposal of hazardous waste pharmaceuticals (HWPs)
  - August 21, 2019 nationwide
- EPA has also removed OTC nicotine gums, lozenges, and patches from the P-list of hazardous waste under 40 CFR 261.33(e)
  - August 21, 2019 federally (Iowa, Alaska)
  - Other states adopting over time

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EPA's Hazardous Waste Pharmaceutical Initiatives - *continued*

- 40 CFR Subpart P: EPA has added an entirely new section to the hazardous waste regulations
  - 40 CFR Subpart P Hazardous Waste Pharmaceuticals
    - August 21, 2019 federally (Iowa, Alaska)
    - Other states adopting up until July 1, 2022 depending upon if they can do so through regulation or legislation
  - Hazardous waste controlled substances exempted under specific conditions

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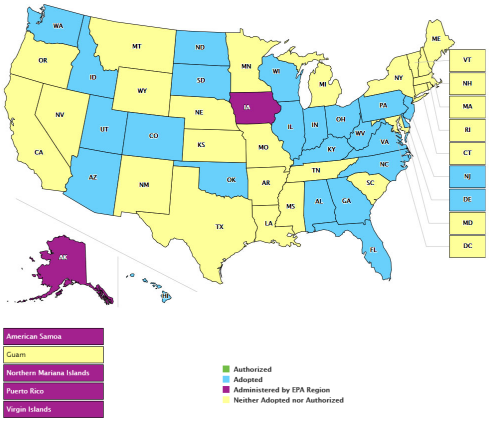
Which States Have Adopted Subpart P & The Nicotine Exclusion?



Last updated on July 6, 2021

https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075

- AK, IA, PR, VI, Indian Country, US Territories except Guam; AL, AZ, CO, DE, FL, GA, HI, ID, IL, IN, KY, NC, ND, NJ, OH, OK, PA, SC, UT, VA, SD, WA, WI, WV
- NH, CA and MD adopted only the OTC Nicotine exclusion while NY will use enforcement discretion to exclude nicotine
- MN has informally adopted the nicotine exclusion and some of the aspects of the new rule.
- Designations on map and listed states are updated as of July 6, 2021

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Sewer Prohibition for all Hazardous Waste Pharmaceuticals

- Sewering of HWPs is PROHIBITED nationally
  - All healthcare facilities
  - Pharmaceutical Reverse Distributors
  - Sewer ban reinforces and highlights EPA's policy against flushing pharmaceuticals
- **Includes hazardous waste controlled substances**
- HSWA Provision (Hazardous and Solid Waste Amendments, 1984): **effective in all states August 21, 2019**

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Who Does the Subpart P Rule Apply To?

- Healthcare facilities that are large quantity (LQG) or small quantity (SQG) hazardous waste generators
- Very small quantity generators (VSQG, fka Conditionally Exempt Small Quantity Generator) may participate but are not obligated to
- Reverse distributors who manage outdated drugs for credit

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Hazardous Waste Generator Status Definitions

Requirement	Very Small Quantity Generator	Small Quantity Generator	Large Quantity Generator
Quantity Limits	≤100 kg/month of non-acute hazardous waste and ≤ 1 kg/month of acute hazardous waste, and ≤ 100kg/month of acute spill residue or soil 40 CFR 260.10	>100 and <1,000 kg/month of non-acute hazardous waste and ≤ 1 kg/month of acute hazardous waste and ≤100 kg/month of acute spill residue or soil 40 CFR 260.10	≥1,000 kg/month or >1 kg/month of acute hazardous waste, or >100 kg/month of acute spill residue or soil. 40 CFR 260.10

Excerpted from https://www.epa.gov/hwgenerators/hazardous-waste-generator-regulatory-summary

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Will HWPs Still Count 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.
- If the initial determination meets the LQG or SQG quantity requirements, the organization must participate in 40 CFR 266 Subpart P.

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Will HWPs Still Count Towards Generator Status under Subpart P? *(continued)*

- All HWPs are managed the same
  - No tracking of monthly generated amounts of HWPs
  - No separation of P-listed HWPs
  - Decreases episodic generation possibilities
  - No longer a disincentive to manage all pharmaceutical waste as HWPs
  - Total accumulation time of ONE YEAR: recommend dating when first used

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What Are the Container Labeling Requirements Under Subpart P?

- Accumulation containers must be **individually labeled "Hazardous Waste Pharmaceuticals"**
- No hazardous waste codes or other labeling required
- Containers must be sturdy, non-reactive, and **kept closed (not sealed)** when not in active use
- Containers must be secured to prevent unauthorized access
- Total accumulation time: one year

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OTC Nicotine Gums, Lozenges, and Patches Removed from the P-list of Hazardous Waste Federally – States Slowly Adopting

- 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.
- NOTE: Rx Nicotine replacement therapy is not exempt; empty packaging not exempt

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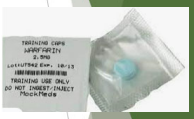
Empty Containers Exempted for Most HWPs

- 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



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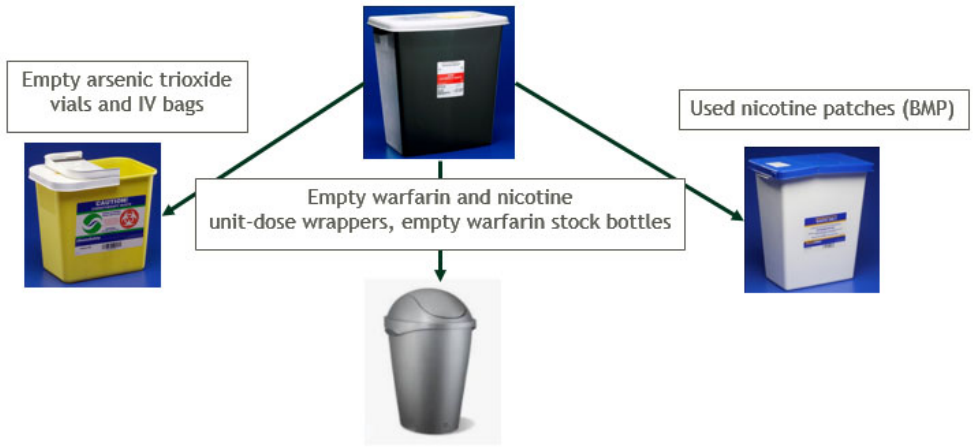
Apply the New Rule to Initiate Cost Savings



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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 and can be disposed as trace chemotherapy

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Quick Check

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

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EPA Conditions of the Controlled Substance Hazardous Waste Exemption

- 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.
- No hazardous waste controlled substances can be sewered
- Must be 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 incinerators

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Hospital Decision Tree: Controlled Substance Disposal

- Is the controlled substance part of the pharmacy's inventory or dispensed/administered "wastage"?
- **Pharmacy Inventory:**
  - Must be sent to a reverse distributor unless two employees can witness incineration
- **Wastage:**
  - Dispensed and partially administered IVs, multiple dose vials, refused/dropped tablets/capsules

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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"
- Devices where hazardous controlled substances were added will no longer need to be disposed in a hazardous pharmaceutical waste container, but can be disposed as non-hazardous pharmaceutical waste when managed through incineration
- Cannot be disposed in the trash

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Examples of Controlled Substance Sequestration Systems

Rx Destroyer™

RxCarbon™ Pad

Cactus Smart Sink®

Cs RX®

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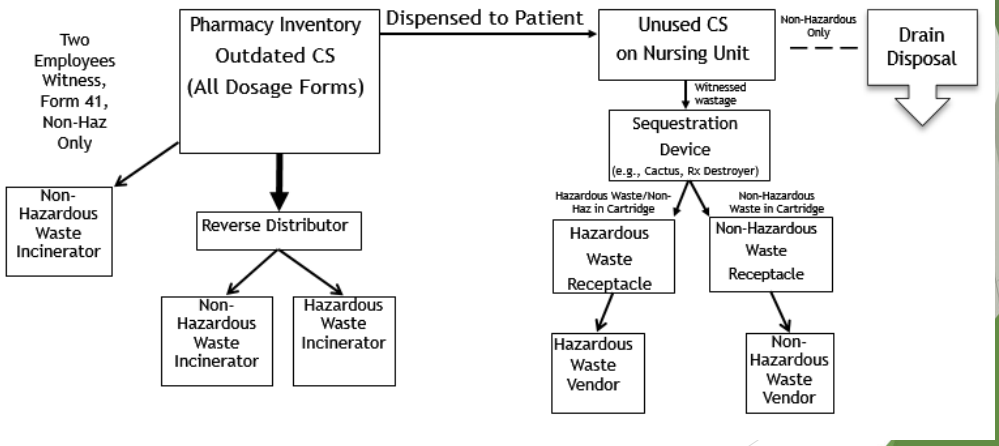
PRIOR to Subpart P - Controlled Substance Decision Tree



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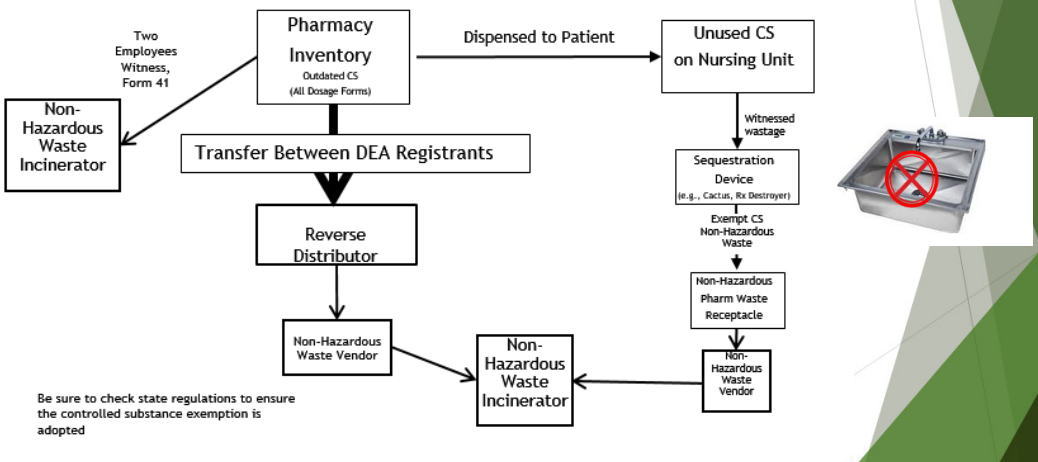
Revised Federal ControlledSubstance Decision Tree Under Subpart P



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Change in Outdated Drug Management

- Outdated drugs now considered waste at the facility when they outdate
- Segregate outdates immediately into potentially creditable (returns) and waste
- Segregate waste into hazardous and non-hazardous or all hazardous
- DO NOT wait for your returns company to do the segregation

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What Is "Potentially Creditable"?

- Undispensed
- In the original manufacturer's package
- Unexpired or less than 1 year past expiration date
- Reverse distributors MUST REPORT receipt of noncompliant waste
  - ***Non-creditable HWPs including drugs partially administered to patients, etc.***
  - Non-pharmaceutical hazardous waste
  - Regulated medical waste (biohazardous)

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Quick Check

- 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 original ampule and Centrum Silver in the original stock bottle

C. Silver sulfadiazine cream compounded on-site

D. None of the above

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Which Facilities Need to Register Under Subpart P?

- All current large and small quantity generators of hazardous waste
- Must submit or amend EPA Form 8700-12 Identification Form
- Very Small Quantity generators may register but are not required to do so
- Environmental Services Manager usually responsible

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Key Takeaways

- No hazardous waste drugs can be sewered
- OTC Nicotine gums, lozenges, and patches are exempt from hazardous waste regulations
- The definitions of "empty" have changed significantly in your favor
- Send only potentially creditable outdated HWPs to your reverse distributor
- All LQGs and SQGs must register under subpart P when your state adopts the regulation

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General References

- USP General Chapter <800> Hazardous Drugs – Handling in Healthcare Settings
  - https://www.usp.org/compounding/general-chapter-hazardous-drugs-handling-healthcare
- 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
  - https://www.cdc.gov/niosh/docs/2016-161/
  - https://www.cdc.gov/niosh/topics/hazdrug/default.html
- NIOSH Proposed Hazardous Drug List 2020
  - https://www.cdc.gov/niosh/docket/review/docket233c/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

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