

Breaking New Ground: EPA's Final Hazardous Waste Pharmaceuticals Rule

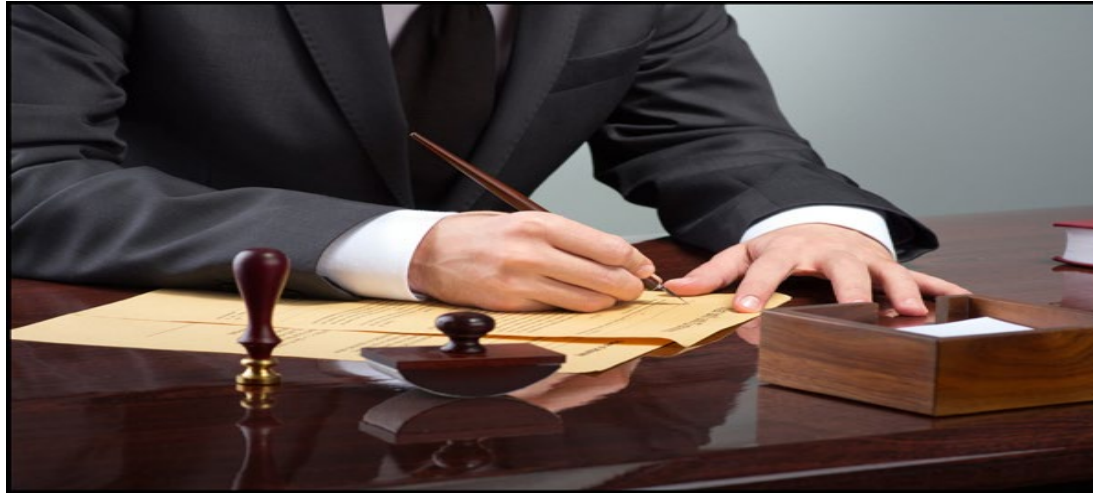
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Objectives

- Focus on the impact of the EPA's new rule on hazardous waste pharmaceuticals generated in hospitals and related settings
- Compare and contrast the new regulations with current EPA and Cal DTSC regulations
- Symbol illustrates potential point of discussion 
- Explore the relationship of the new EPA Rule and the DEA's Drug Disposal Rule of 2014
- Introduce the concept of hazardous drugs from an OSHA perspective and describe how the pending USP <800> requirements facing healthcare facilities on December 1, 2019 add another layer of complexity to operationalizing both environmental and OSHA regulations

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

- Prepublication edition released December 11, 2018
- Official publication in the Federal Register February 22, 2019
- Largest change in the proposed management of hazardous waste pharmaceuticals since RCRA regulations were finalized in 1980
- Only the second sector-specific rulemaking with Academic Labs being the first in 2008*
- Applicable in federally managed states and territories six months from publication in the Federal Register (Iowa, Alaska, Puerto Rico)
- Sewer prohibition of hazardous waste pharmaceuticals nation-wide six months from publication in the Federal Register
- All other states must adopt stricter aspects; may choose not to adopt less strict aspects

* Dec. 1, 2008 262 subpart K Alternative Requirements for Hazardous Waste Determination and Accumulation of Unwanted Material for Laboratories Owned by Eligible Academic Entities

WHY Part 266 Subpart P?


- Healthcare entities differ from pharmaceutical industry
 - Determination at point of generation by healthcare workers is difficult
 - Waste stream categorization and accuracy is challenging
 - Volume of pharmaceuticals is large and changing continuously
 - Number of individuals (healthcare workers) involved is also large
- Hazardous waste pharmaceuticals are different from hazardous waste
 - Potential for diversion
 - Street value
- Therefore, management of hazardous waste pharmaceuticals at Healthcare (HC) Facilities and Reverse Distributors (RD) are now addressed appropriately in Part 266 subpart P (not Part 262)

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
- 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

EPA's Response

40 CFR Part 266 Subpart P Management Standards for Hazardous Waste Pharmaceuticals

- Mandated for all current LQGs and SQGs; VSQGs may participate voluntarily (not applicable in California) 
- EPA has created “sector-specific” standards for the management of hazardous waste pharmaceuticals for:
 - Healthcare facilities/pharmacies, and
 - Pharmaceutical reverse distributors
- Defines regulatory status of potentially creditable outdated pharmaceuticals
- Addresses LQG status due to P-listed hazardous waste
- Exempts hazardous waste pharmaceuticals that are also a controlled substance (intersection of EPA and DEA regulations)
- New definitions of “empty” depending on dosage form
- Prohibits sewerage of hazardous waste pharmaceuticals

Healthcare Facilities Experience Difficulties Complying with Hazardous Waste Regulations (Subtitle C) as Evidenced By:

- Healthcare facilities are not managing hazardous waste pharmaceuticals in compliance with current regulations
- Healthcare facilities are sending hazardous waste pharmaceuticals to reverse distributors that are obviously not potentially creditable
- Healthcare facilities are disposing hazardous pharmaceutical waste into drainage systems (other states)

Broad Definition of Pharmaceutical

- Drug or dietary supplement for use by humans or animals
- Any electronic nicotine delivery system
- Any liquid nicotine (e-liquid) packaged for retail sale for use in an electronic nicotine delivery system
- Prescription drugs, over-the-counter (OTC) drugs, homeopathic drugs, compounded drugs, investigational new drugs, pharmaceuticals remaining in non-empty containers, personal protective equipment contaminated with pharmaceuticals, clean-up material from spills of pharmaceuticals

Definition of Healthcare Facility

- Provide preventative, diagnostic, therapeutic, rehab, maintenance or palliative care
- Distribute, sell, or dispense pharmaceuticals including OTCs, dietary supplements, homeopathic drugs or Rx drugs
- Wholesale distributors, 3rd party forward logistics providers, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgery centers, health clinics, physicians' offices, optical, dental, chiropractors, LTCFs, ambulance services, pharmacies, long term care pharmacies, mail-order pharmacies, veterinary clinics/hospitals
- Includes internet and mail-order pharmacies
- NOT INCLUDED: pharma manufacturers, reverse distributors, reverse logistics centers

Applicable to Long Term Care Facilities

- Includes facilities in which managing and administering of medications is done by appropriate personnel
- Does not include group homes and independent living communities
- Hazardous waste no longer excluded as household hazardous waste federally



Benefits of Operating under the Proposed Subpart P Regulations



- Hazardous pharmaceutical waste generation does not apply to generator status
- Hazardous waste that is not pharmaceutical waste is still regulated under 40 CFR 262
- No monthly tracking of P-listed and other hazardous waste pharmaceuticals
- Satellite accumulation area (SAA) and central accumulation area (CAA) regulations will not apply
- No biennial reporting requirements
- Encourages management of all pharmaceutical waste as hazardous waste
- EPA reduction in training requirements and documentation

Notification of Participation in subpart P

- Currently registered healthcare facilities: must notify using Site Identification Form (8700-12) either on its Biennial Report, if required, or within 60 days of the effective date of this subpart (varies by state)
- New registrant must notify the EPA Regional Administrator using Form 8700-12. Not required to fill out waste codes for HWPs. Notify either on Biennial Report or within 60 days of rule becoming effective.

Which Pharmaceuticals Will Be Included in Subpart P?



- Only those already considered to be a RCRA hazardous waste
- California Non-RCRA Hazardous Waste managed under the Medical Waste Management Act not impacted by the Rule *unless a HCF decides to manage all pharm waste as hazardous waste*
- The proposed rule will change how current hazardous waste pharmaceuticals are managed
- EPA sought comment on how to evaluate additional pharmaceuticals for inclusion into the regulations but that will be a separate rulemaking process in the future
- *EPA would prefer that facilities manage all pharmaceutical waste as hazardous waste* BUT has not done a cost analysis which would demonstrate costs would be significantly higher, especially given some of the new proposed requirements

Sewer Prohibition for all Hazardous Waste Pharmaceuticals (HWPs)

- Sewering of HWPs will be PROHIBITED
 - All healthcare facilities (VSQG (fka CESQG), SQG, LQG)
 - Pharmaceutical Reverse Distributors
 - Sewer ban reinforces and highlights EPA's policy against flushing pharmaceuticals
 - DEA no longer allows sewerage as a means of destroying controlled substances
 - Several federal agencies educating consumers to stop flushing pharmaceuticals
- HSWA Provision: effective in all states upon the effective date for the rule, six months after publication in the Federal Register
 - (HSWA provisions - elements of the Federal RCRA program that are implemented pursuant to the Hazardous and Solid Waste Amendments of 1984.)

Generator Status Not Determined by HW Pharmaceuticals



- HW pharmaceuticals are not included in determining generator status, therefore there is no SQG or LQG status for HW pharmaceuticals
- All HW pharmaceuticals are managed the same
 - Generators don't have to keep track of monthly generated amounts for HW
 - Generators don't have to accumulate acutely HW and non-acutely HW separately
 - Decreases episodic generation
 - It's no longer a disincentive to manage all pharmaceutical waste as hazardous waste pharmaceutical
 - Total accumulation time 1 year, no Biennial Report unless LQG for other HW, fewer training requirements and documentation

Requirements of Operating under the Proposed Subpart P Regulations

- One time notification as healthcare facility
 - EPA Form 8700-12 with Biennial Report or within 60 days of effective date
 - Not required to list waste codes for hazardous waste pharmaceuticals on notification
 - Must keep a copy of notification as long as generating waste under this rule
- Must perform waste categorization
 - Waste codes not required if all pharm waste managed as hazardous BUT must still sort incompatible waste
- Performance-based training for healthcare workers
- Total one year accumulation time
- Must keep container closed when not in use
- Must label container “Hazardous Waste Pharmaceuticals”
- Hazardous waste transporter required
- Manifesting required but no individual waste codes
- “PHARMS” in Box 13 of manifest



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
- Must determine and manage incompatibility
- Non-creditable hazardous and non-hazardous waste pharmaceuticals may be stored together
- Non-creditable HWP's prohibited from being combusted must be accumulated in separate containers and labeled with all applicable hazardous waste codes
 - E.g. arsenic trioxide (P012)

Conditional Exemptions for HWPs that are also DEA Controlled Substances

- Must be managed in accordance with DEA regulations
- Must be incinerated by one of five types of permitted combustors or destroyed by method publicly approved in writing by DEA to meet the non-retrievable standard
- Ignitable DEA controlled substances already prohibited from sewer disposal by the Clean Water Act regulations*
- Neither inventory nor “wastage” of DEA controlled substances that are hazardous wastes can be sewerered

* 40 CFR 403.5(b)(1) Specific prohibitions. In addition, the following pollutants shall not be introduced into a POTW: (1) Pollutants which create a fire or explosion hazard in the POTW, including, but not limited to, waste streams with a closed cup flashpoint of less than 140 degrees Fahrenheit or 60 degrees Centigrade using the test methods specified in 40 CFR 261.21;

EPA and DEA Intersection: Controlled Substances that are also HW Pharmaceuticals



- Examples of the very few CS that are HWPs
 - Diazepam 5mg/ml injection (D001)
 - Fentanyl sublingual spray (D001)
 - Testosterone gel (D001)
 - Chloral hydrate (U034)
- Authorized registrant who collects CS from the ultimate user and that are commingled with HW pharmaceuticals are exempt as household waste for that activity
- Long term care facilities with DEA-compliant on-site consumer collection kiosks are exempt from the hazardous waste rules for that activity, which is considered to be household hazardous waste

Conditional Exemptions for Household Waste Pharmaceuticals

- Household waste pharmaceuticals collected in a take-back event or program or DEA-approved kiosk
- Cannot be sewerred
- 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
- 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
- Does not include “other solid waste incinerators” (OSWIs), human and pet crematoriums

Change in Status of Nicotine P075



- Exemption from P075 as a hazardous waste: FDA-approved Over-the-Counter (OTC) replacement therapy in the form of lozenge, gum, or patch
 - Noted in 261.33, Discarded commercial chemical products, etc., not in subpart P
- Not exempt: Rx nicotine, e-cigarettes, e-liquids
- No exemption for a particular nicotine concentration
- Will not become effective in states authorized for the RCRA program until states have adopted the exemption.

Management of Residues (266.507)

Stock Bottles



- Stock bottle, dispensing bottle, vial, or ampule not to exceed 1 liter or 10,000 pills or a unit-dose container or delivery device 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
- Significantly impacts disposal of the following empty containers:
 - Warfarin tablets (P001) stock bottles and blisterpaks
 - Arsenic trioxide (Trisenox) (P012) 10 ml single dose vial
 - Physostigmine salicylate (P188) 1mg/ml, 2 ml ampule
 - Nicotine Nasal Spray (P075) (Nicotrol NS) 10 mg/ml nasal soln 10ml

Management of Residues (266.507)

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 material recommended

Management of Residues (266.507)

RCRA Empty: IV Bags, inhalers, aerosols, nebulizers, ointments gels creams

- Pharmaceuticals have been fully administered to a patient
- If not fully administered and NOT acute HW:
 - 261.7 (b)(1)(i) All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, and aspirating, *and*
 - 261.7 (b)(1)(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 HW, must be managed as a HW

Changes in Satellite and Central Accumulation Areas



- No longer necessary to maintain formal satellite and central accumulation storage for hazardous waste pharmaceuticals
- May continue to do so
- Containers must be marked with the words “Hazardous Waste Pharmaceuticals” during accumulation
- Must ship a hazardous waste pharmaceutical within 365 days of accumulation as a waste (266.502(f))
 - May mark the container with the date accumulation began
 - May maintain an inventory system that identifies dates first accumulated
 - May identify in the accumulation area the earliest date that a HWP became a hazardous waste

Land Disposal Restrictions (LDRs) for Non-creditable Hazardous Waste Pharmaceuticals

- Non-creditable HWPs are subject to the LDRs of 40 CFR part 268.8(a)
- Healthcare facilities not required to identify the hazardous waste codes on the LDR notification
- Healthcare facilities are required to segregate HWPs unsuitable for incineration into separate containers and label them with the appropriate hazardous waste codes (266.502(d)(4))
- Organic hazardous waste pharmaceuticals (other than arsenic trioxide) may all be incinerated at RCRA-permitted or interim status hazardous waste combustors.
- EPA open to considering alternative treatment standards for HWPs in the future

Reporting Requirements for Healthcare Facilities (HCFs)

- Non-creditable hazardous waste pharmaceuticals not required to be reported on Biennial Report
- HCFs must submit an exception report if they have not received a signed copy of the manifest from the TSDF within 60 days of the initial shipment
- EPA may require additional reports

HCF Recordkeeping Requirements

- Signed copy of hazardous waste manifest from transporter
- Copy of exception report if needed
- Records must be readily available upon request by an inspector but may be centrally located
- Must retain documentation of hazardous waste determination for 3 years from date of last shipment
- **Requirement to retain documentation of hazardous waste determinations for 3 years is waived if all non-creditable waste pharmaceuticals are managed as hazardous waste under subpart P (266.502(j)(3))**
- Timeframes may be extended during enforcement actions



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

Prescription (Rx) Hazardous Waste Pharmaceuticals (HWP) versus OTC HWPs

- Expired/unwanted Rx drugs become a **solid waste** at the healthcare facility
 - Must be managed either as a hazardous waste or sent to a “pharmaceutical reverse distributor” if potentially creditable
- Expired/unwanted OTC drugs remain a **product** at the healthcare facility if sent to a “reverse logistics center” and evaluated for legitimate use/reuse or reclamation



Determining the Fate of Outdated/ Unwanted Prescription and OTC Drugs

- Must first determine if the outdated/unwanted drug designates as a hazardous waste
- IF all pharmaceutical waste, including outdated Rx drugs, is to be managed as hazardous waste under subpart P, do not need to make a hazardous waste determination
- If outdated hazardous waste Rx is not potentially creditable, must be managed as hazardous waste at the facility
- If outdated/unwanted OTC drug does NOT have a reasonable expectation of being legitimately used/reused or reclaimed must be managed as a hazardous waste at the facility
- Do not contribute to generator status



Outdated/Unwanted OTCs May Remain a Product



- OTC (over-the-counter) drugs that are outdated or unwanted remain a product if there is a reasonable expectation of being legitimately used/reused, or reclaimed
- Reused implies being lawfully redistributed for its intended purpose
- Hospitals do not normally contract with Reverse Logistics Centers - Can outdated OTCs ever be sent to a RX Reverse Distributor?
- Question posed to EPA - may consider some modifications

Non-creditable Prescription & OTC Hazardous Waste Pharmaceuticals

- Non-creditable Rx HWP:
 - Not in the manufacturer's original container
 - Partially administered for patient care
 - More than 12 months past expiration date
- Non-creditable OTC HWP:
 - No reasonable expectation to be legitimately used/reused or reclaimed
- Free samples, residues, contaminate PPE, floor sweepings, spill clean-up materials
 - Must be shipped on a hazardous waste manifest to a TSDF
 - Must comply with DOT pre-transport requirements
 - Hazardous waste codes not required unless lab packs of certain specific metals
 - "PHARMS" must be entered in Item 13

Reverse Distribution: When to Use It

Potentially Creditable Waste

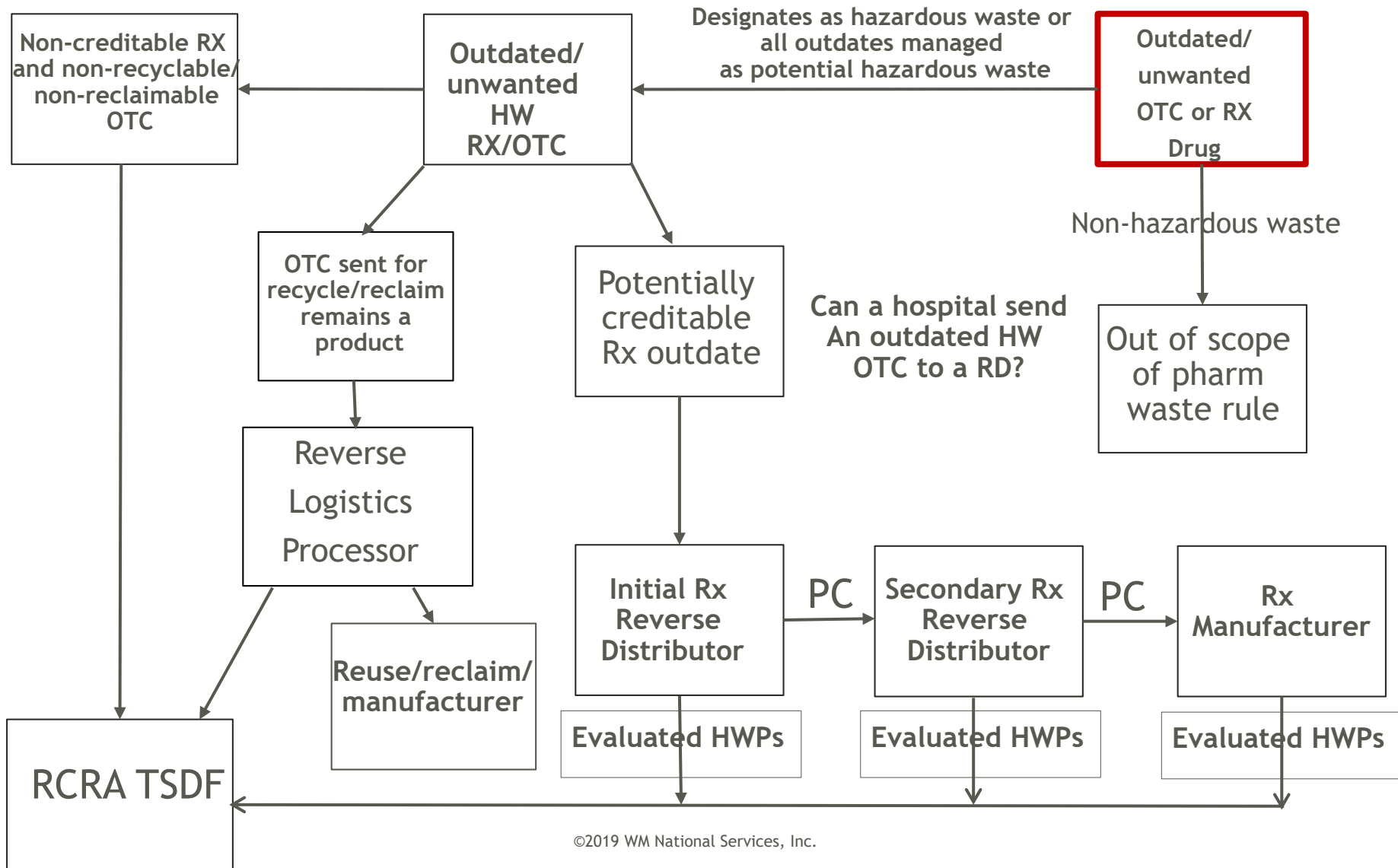


Non-creditable Waste

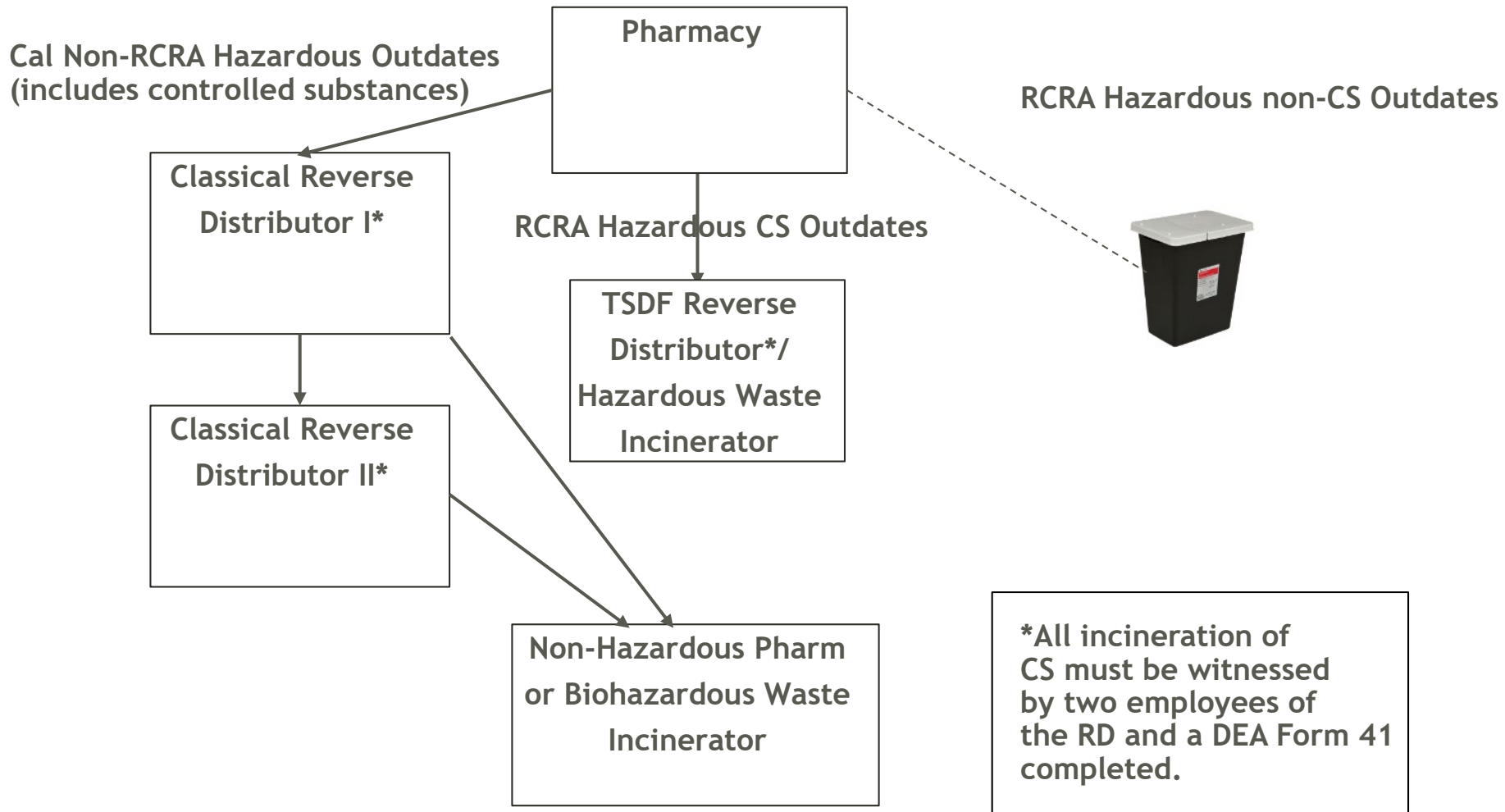


If a hazardous waste, must be managed as such. If a HWP and controlled substance in pharmacy inventory, **currently** must be sent to a TSDF reverse distributor, no credit given (Cal DTSC & DEA)

Managing Outdated HWP Rx & OTC Drugs



Current DEA and CAL EPA DTSC Required Pathways for Outdates in Pharmacy



Potentially Creditable Rx HPW (Reasonable Expectation of Credit)



- PRESCRIPTION pharmaceuticals only; not OTCs, dietary supplements
- Undispensed
- In the original manufacturer's container, including partials
- Unexpired or less than one year past expiration date
- May be sent to reverse distributor via common carrier (266.509 (a)(2))
- Delivery confirmation required within 35 days of shipment
 - No requirement to notify EPA; States may enact stricter requirements
- DOT hazard class 1-8 applies, not class 9 since no manifest is required

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 (Not applicable in Cal)
- Manages in compliance with subpart P, keeps records for 3 years
- PROHIBITED from sending hazardous waste OTHER THAN potentially creditable HWPs to a reverse distributor

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
- Must comply with DOT shipping descriptions for hazardous materials (usually ORM-D)
- 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

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.

Requirements of Reverse Distributor

- Must notify EPA of its reverse distribution activity under subpart P within 60 days of the effective date of subpart P (date will vary by state)
- Any reverse distributor that does not have an EPA ID number must obtain one within 60 days of the effective date
- Must maintain a current inventory of all potentially creditable and evaluated HWPs accumulated on site
- Must inventory each potentially creditable HWP within 30 calendar days of arrival at the facility
 - Name or NDC and quantity
 - Inventories meeting other regulatory requirements e.g. State Boards of Pharmacy, DEA, will suffice
- Must determine if still potentially creditable or evaluated HWP within 30 days of arrival
- After evaluation, may accumulate both potentially creditable and evaluated HWPs for 180 days
- Unexpired creditable HWPs may held for 180 days after they expire (known as “aging”)

Reporting Requirements of Reverse Distributors

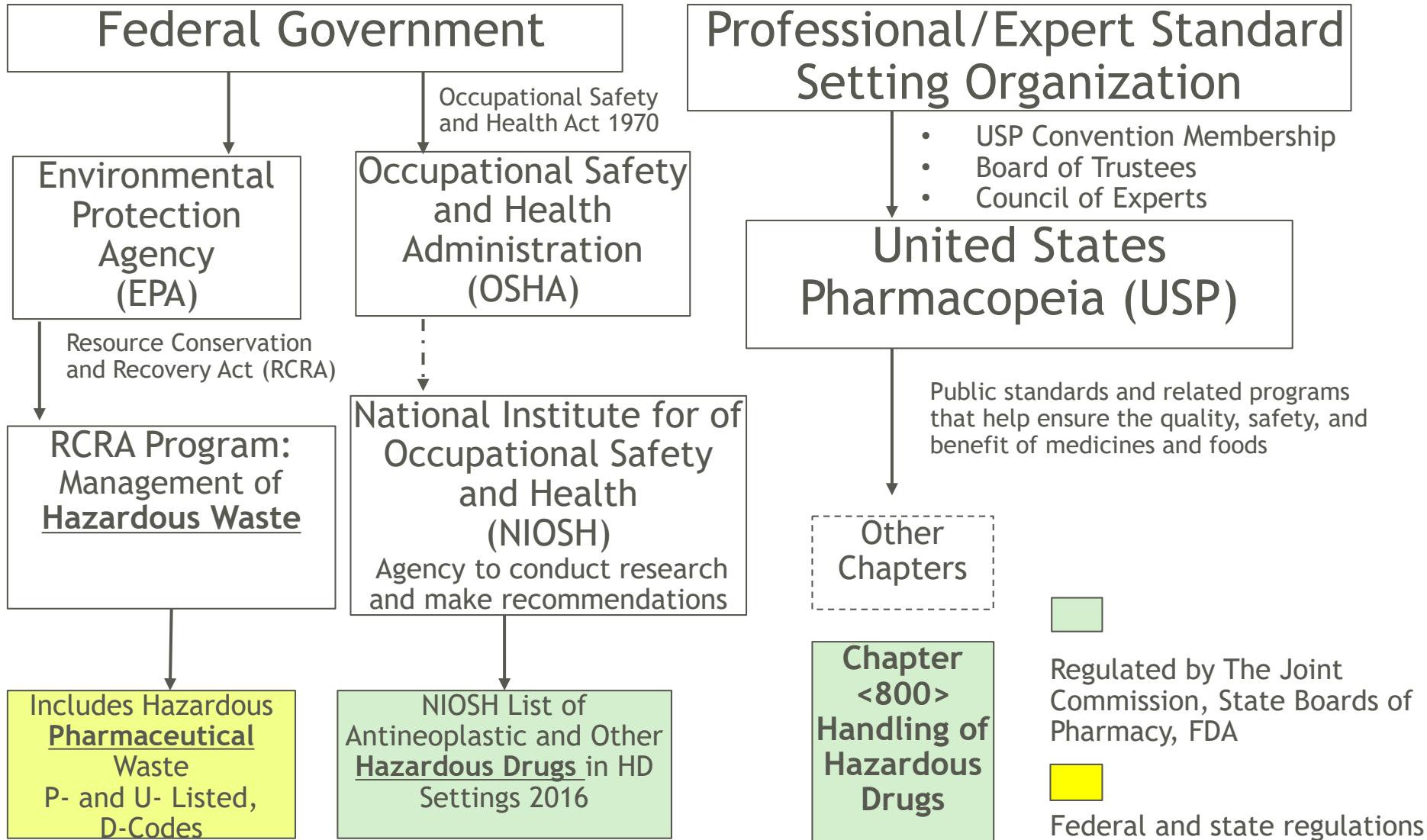
- Must submit an unauthorized waste report upon receipt of waste not in compliance with the Rule
 - **Non-creditable HWPs including drugs partially administered to patients, etc.**
 - Non-pharmaceutical hazardous waste
 - Regulated medical waste (biohazardous)
- Send copy to EPA Regional Administrator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

Evaluated Hazardous Waste Pharmaceutical

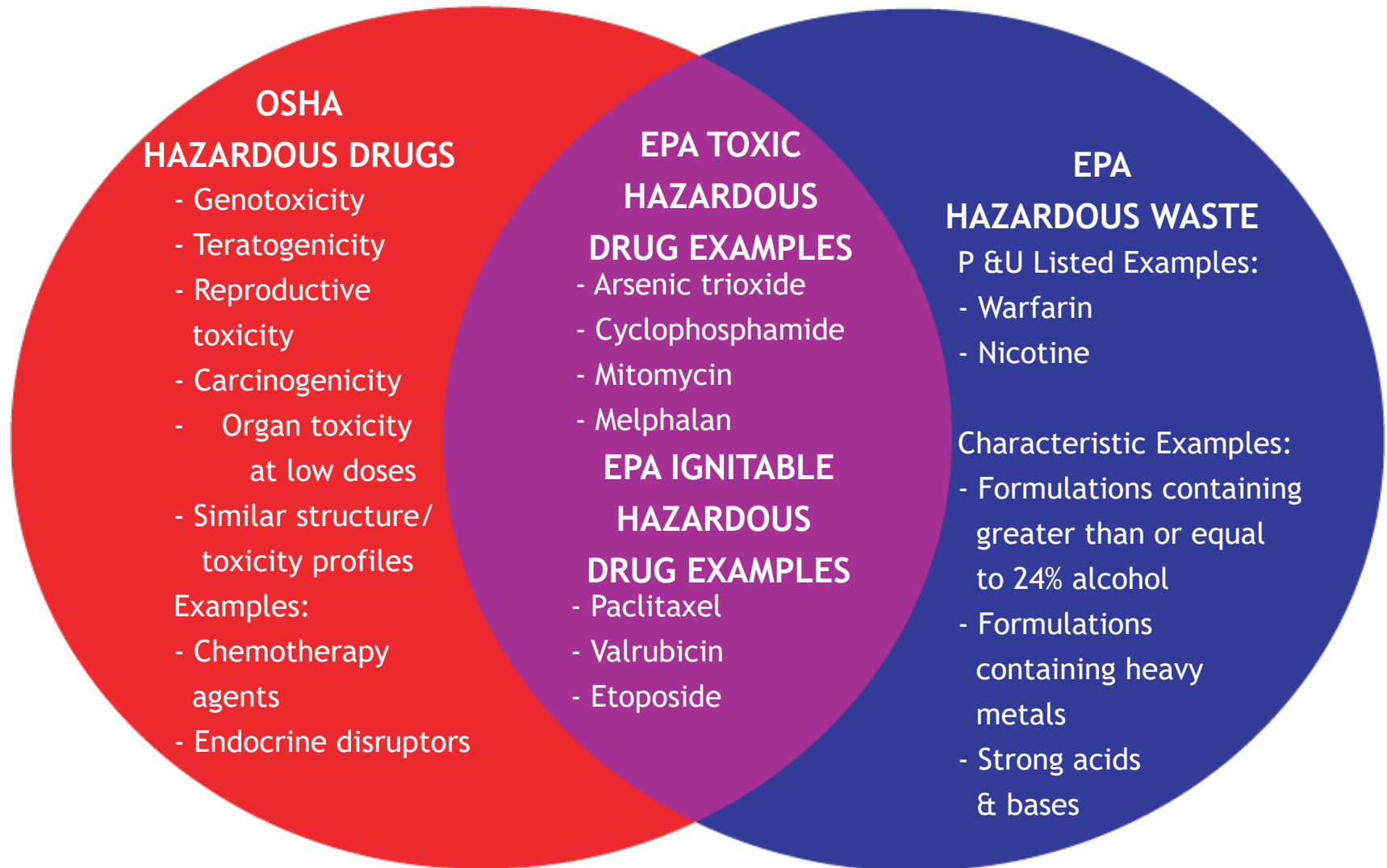
- A prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor and will not be sent to another RD for further evaluation or verification of manufacturer credit
- Must be transferred to a hazardous waste treatment, storage and disposal site (TSDF) on a Uniform Hazardous Waste Manifest.

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

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



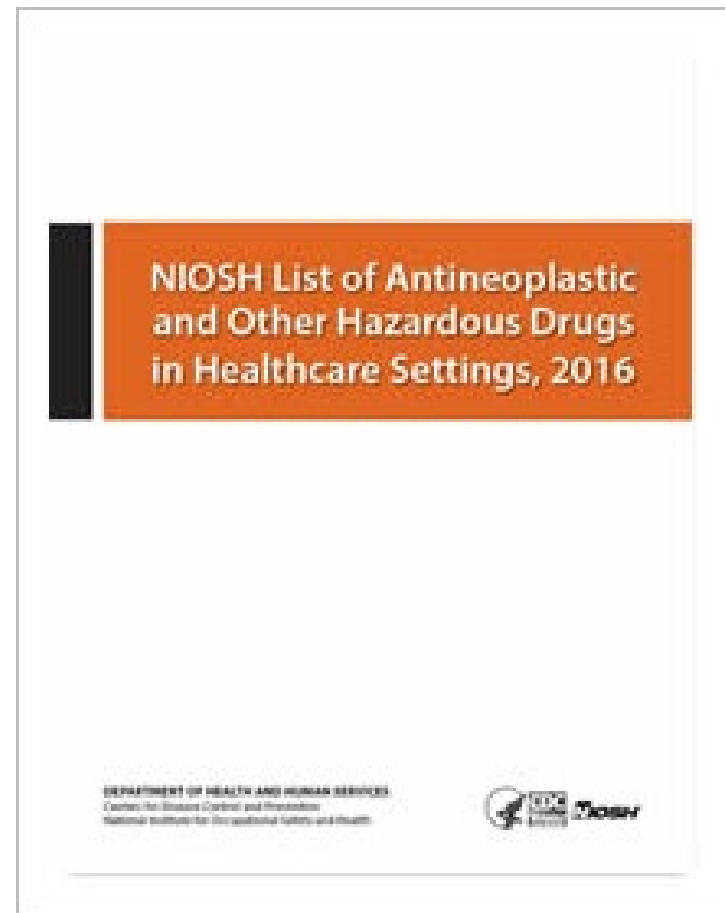
Hazardous Drugs vs. Hazardous Waste Where OSHA and EPA Meet



NIOSH Hazardous Drug List 2016

<https://www.cdc.gov/niosh/docs/2016-161/>

- 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
- Total number of drugs on the list is 217



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 \neq HW
 - HW \neq HD
- Phases of HDs Handling Cycle:
 - Receiving
 - Storage
 - Preparation
 - Transport
 - Administration
 - Waste (but not specifically addressed in USP <800>)

Considerations and Challenges: USP <800>

- Healthcare entities are gearing up for this change in handling HDs - Deadline is December 01, 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

References

Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine

- <https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>

California Version of HERC Blueprint

- <https://bacwa.org/wp-content/uploads/2008/10/CaliforniaBlueprintFinalDraft80908.pdf>

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>

Healthcare Education Resource Center ([HERC](#))

- <http://www.hercenter.org/hazmat/tenstepblueprint.pdf>

WMSS PharmEcology Services

- www.pharmecology.com

Questions?

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