Part 3. Hazardous Waste Regulations as Related to Hospitals and Pharmaceutical Wastes

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Webinar Series Objectives

- **Define the problem! What's Broken?** Discuss common non-compliance problems found in complying with the Hazardous Waste Regulations. Identify the variety of waste streams generated in Virginia hospitals **(Part 1)**
- **Understand the baseline regulations** for accurately identifying and managing the hazardous wastes hospitals and other healthcare facilities may generate. **(Part 2)**
- **Understand the regulations for complying with the Hazardous Waste Pharmaceuticals rule (Part 3)**
- Make you aware of changes to the **regulated medical waste regulations (Part 4)**
- **Discuss Best Management Practices** hospitals and other healthcare facilities can undertake to improve compliance and the do's and don'ts for managing hazardous waste safely (**Part 5**)

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Important Acronyms

HCF – Healthcare Facility
HW – Hazardous Waste
HWP – Hazardous Waste Pharmaceuticals
RD – Reverse Distributors
CS – Controlled Substances
RMW – Regulated Medical Waste
DEA – Drug Enforcement Administration
NRT – Nicotine Replacement Therapies
RCRA – Resource Conservation and Recovery Act

Objectives of this Session

1. Summarize Hazardous Waste Pharmaceuticals Rule

2. Identify basic approaches to implementation of the rule

3. Compare management of hazardous waste pharms under RCRA and then under Subpart P

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Background

- HWPs were previously regulated under the hazardous waste regulations when generated, treated, transported, stored or disposed, and **HCFs should have already been complying with RCRA!**
- HW regulations were difficult to apply to the healthcare industry
- EPA (and Virginia) had allowed pharmaceutical products to be sent for reverse distribution with the presumption that these products would be used, reused or reclaimed & the RD would not be used as a waste management service

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What does EPA's HW Pharmaceuticals Rule Do?

- Provides regulations that better fit the healthcare industry
- Eliminates intentional sewering of HWPs
- Eliminates dual regulation by EPA/DEA for controlled substances
- Clarifies how RCRA applies to reverse logistics & reverse distribution
- Re-evaluates the regulation of nicotine replacement therapies
- Defines an "empty container" with a variety of medical use containers

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What do Facilities need to know?

- You must know your HW generator status prior to Subpart P
- Once you start managing under the subpart, the weight of your HW pharmaceuticals no longer counts toward your generator status
- It starts in the pharmacy: know your HWPs
- Set up containers and procedures for generation, pick up, and disposal
- **You need to create a system that works for your facility**

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Healthcare Facilities Include:

Hospitals

Ambulatory surgical centers

Physicians' offices

Chiropractors

Pharmacies

Mail-order pharmacies

Military medical logistics facilities

Retailers of pharmaceuticals

Psychiatric hospitals

Health clinics

Optical and dental providers

Long-term care facilities

Long-term care pharmacies

Veterinary clinics & hospitals

Ambulance services

Wholesale distributors

Note: Facilities which are included in healthcare facilities of concern is as established by EPA. Other organizations may include different types of healthcare facilities in their definition

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Definitions – Healthcare Facility (HCF)

Does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers

Definitions – Reverse Distributor (RD)

- Any person that receives & accumulates prescription pharmaceuticals that are potentially creditable HWP for the purpose of facilitating or verifying manufacturer credit
- Any person, including forward distributors, third-party logistics providers, & pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit

What are the differences between a RD and RL?

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Definitions - Pharmaceutical

- Any drug or dietary supplement for use by humans or other animals;
- Any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or
- Any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials)

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Definitions - Pharmaceutical

Includes, but is not limited to:

- Dietary supplements
- Prescription drugs
- Over-the-counter drugs
- Homeopathic drugs
- Compounded drugs
- Investigational new drugs

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Definitions - Pharmaceutical

Includes, but is not limited to:

- Pharmaceuticals remaining in non-empty containers
- Personal Protective Equipment (PPE) contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals
- Electronic nicotine delivery systems (ENDS) e.g., e-cigarettes, vaping pens
- Nicotine e-liquid/e-juice packaged for retail sale for use in ENDS e.g., pre-filled cartridges or vials

Definitions - Pharmaceutical

Does NOT include:

- Dental Amalgam
- Sharps
- Medical Waste

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Definitions – Hazardous Waste Pharmaceutical (HWP)

- A pharmaceutical that is a solid waste, and
- Exhibits one or more characteristics of hazardous waste, or
- Is a listed hazardous waste

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Definitions – Hazardous Waste Pharmaceutical (HWP)

- A pharmaceutical is not a solid waste and therefore not a HWP, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed
- An OTC pharmaceutical, dietary supplement, or homeopathic drugs is not a solid waste, and therefore not a HWP, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed

Potentially Creditable HWP

- Means a *prescription (Rx)* HWP that has a reasonable expectation to receive manufacturer credit and is:
  - In original manufacturer packaging (except for recalls)
  - Undispensed
  - Unexpired, or less than one year expired

The term *does not* include evaluated HWP or nonprescription pharmaceuticals

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Healthcare Facility Requirements Managing Potentially Creditable HWP

- Hazardous Waste Determination Required
- Prohibition on sending regular HW to RD
- Biennial reporting not required for HWP only
- Respond to spills
- Recordkeeping requirements
- Shipping requirements
- Acceptance of HWP from off-site Very Small Quantity Generators

Healthcare Facility Requirements Managing Potentially-Creditable HWP

Recordkeeping (shipments to RD)

- Shipping papers prepared by HCF must be in accordance with DOT hazmat regs, if applicable.
- RD will send confirmation of delivery to HCF
- Retain for 3 years
- All records must be readily available upon request by an inspector
- Retention extended automatically during any unresolved enforcement action or as requested by the DEQ

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Healthcare Facility Requirements Managing Potentially-Creditable HWP

Shipping Requirements

- Transportation must comply with all applicable DOT hazmat regs
- If delivery confirmation is not received within 35 calendar days from the date that the shipment was sent, HCF must contact the carrier & RD to report & determine the status
- Exports must comply with applicable sections of 40 CFR part 262 subpart H, except the manifesting requirement of § 262.83(c), in addition to the two bullets above
- Imports must comply with 40 CFR § 266.509 – once they enter the US, they are subject to all applicable requirements of Subpart P

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Definitions – Non-Creditable HWP

- A *prescription* HWP with no reasonable expectation of being eligible for manufacturer credit
- A *nonprescription* HWP with no reasonable expectation of legitimate use/reuse or reclamation
- Includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by HCFs, residues of pharmaceuticals remaining in empty containers, contaminated PPE, floor sweepings, & clean-up material from the spills of pharmaceuticals

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Definitions – Non-Creditable HWP

Non-creditable HWP

- Dispensed and/or not in original packaging
- More than one year expired
- Non-prescription or OTC pharms
- Investigational drugs
- Drug samples
- Residues of pharmaceuticals in containers
- Contaminated PPE
- Floor Sweepings
- Clean-up material from pharm spills

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Definitions – Evaluated HWP

Means a *prescription* HWP that:

- Has been evaluated by a RD in accordance with Subpart P and
- Will not be sent to another RD for further evaluation or verification of manufacture credit

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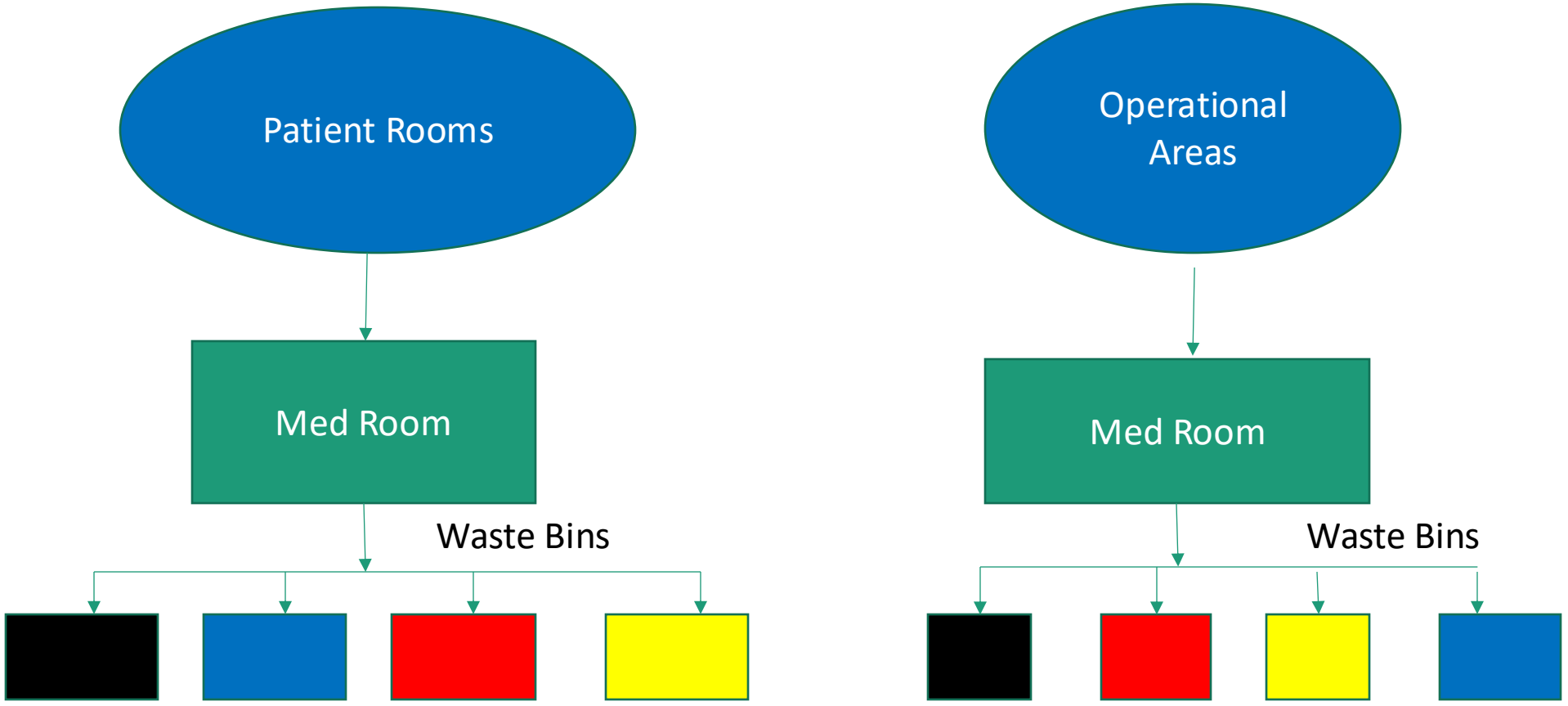
Questions so far?

Sources of Pharmaceutical Waste



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Refresh: what makes a waste hazardous

Pharmaceuticals are typically hazardous because they are:

- Flammable or an oxidizer
- Toxic (most HWPs fall under this category)
- Corrosive

*just like any hazardous waste, you can't put non-compatible pharms together in a container. The pharmacy should be identifying any pharms that need to be separated and making a procedure to collect them separately.

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Examples of the Most Common P- and U-Listed Drugs

Name of Drug	Medical Use	Hazardous Waste Code
Arsenic trioxide	Antineoplastic	P012
Dalfampridine (4-aminopyridine)	Multiple sclerosis	P008
Nicotine	Replacement therapy	P075
Physostigmine salicylate	Glaucoma	P188
Warfarin >0.3%	Blood thinner	P001
Chloral hydrate (CIV)	Sedative	U034
Cyclophosphamide	Antineoplastic	U058
Daunomycin	Antineoplastic	U059
Lindane	Lice, scabies	U129
Melphalan	Antineoplastic	U150
Mitomycin C	Antineoplastic	U010
Selenium sulfide	Anti-fungal, dandruff	U205
Streptozotocin	Antineoplastic	U206

Source: 10 – Step Blueprint for Managing Pharmaceutical Waste in US Healthcare Facilities, 2022 Edition, page 7.

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Examples of D001 Ignitable Hazardous Wastes at HCFs

Ignitable Properties	Ignitable Drug Formulations
Aqueous drug formulation containing 24% or more alcohol by volume and having a flashpoint of less than 140º F or 60º C.	> Erythromycin Gel 2% > Texacort Solution 1% > Taxol Injection
Liquid drug formulations, other than aqueous solutions containing less than 24 % alcohol, with a flashpoint of less than 140 º F or 60 º C	> Flexible collodion used as a base in wart removers is not an aqueous solution and has a flashpoint = 45 degrees C
Oxidizers or materials that readily supply oxygen to a reaction in the absence of air as defined by the DOT.	> Bulk chemicals found in the compounding section of the pharmacy such as potassium permanganate
Flammable aerosol propellants meeting the DOT definition of compressed gas	> Primatene aerosol

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Corrosive Hazardous Waste: what to look out for in hospitals

- Any waste with a pH ≤2 (highly acidic) or ≥12.5 (highly basic) exhibits the characteristic of corrosivity and must be managed as a hazardous waste
- Generation of corrosive pharmaceutical wastes is generally limited to compounding chemicals in the pharmacy
- Desorb waste generated in the laboratory is a common corrosive HW
- Compounding chemicals include strong acids, such as glacial acetic acid and strong bases, such as sodium hydroxide

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Examples of toxic chemicals of concern found at hospitals

Ingredient	Waste Code	Regulatory Level (mg/L)	Drug formulations containing this ingredient
Arsenic	D004	5	Arsenic trioxide (also P-listed)
Barium	D005	100	Barium sulfate (used in radiology)
Cadmium	D006	1	Multiple mineral preparations
Chloroform	D022	6	No longer commonly used
Chromium	D007	5	Multiple mineral preparations
Lindane	D013	.4	Treatment of lice, scabies (also U-listed)
M-cresol	D024	200	Preservative in human insulin
Mercury	D009	.2	Vaccines with thimerosal, eye and ear preparations
Selenium	D010	1.0	Dandruff shampoo, multiple mineral preparations
Silver	D011	5	Silver sulfadiazine cream (topical antibiotic)

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Non Creditable HWP to Separate During Accumulation

RCRA does not allow incineration of metal-bearing waste with low organic content; it is considered impermissible dilution. Most pharmaceuticals with heavy metals have enough organic content (>1%) to allow them to be incinerated to meet the treatment standards, such as

- Multi-dose vaccines with thimerosal
- and Selenium shampoos

However, arsenic trioxide must be separated during accumulation to prevent it from being incinerated as it does not have enough organic content to be incinerated to hazardous waste treatment standards.

The container that the arsenic trioxide is in does not count toward determining the organic content.

Other Wastes Specific to Hospitals

Bulk Chemotherapy Waste is typically managed as hazardous waste in black bins, whether or not it meets the definition of RCRA hazardous waste

Bulk chemotherapy waste can include:

- Items that once contained chemotherapy agents and that don't qualify as "RCRA empty"
- Other types of bulk waste include materials used to clean up chemo spills and visibly contaminated personal protective equipment (PPE)
- Many facilities treat bulk chemotherapy waste similar to hazardous waste pharmaceuticals (i.e., all are collected in a single hazardous waste container)

Other Wastes Specific to Hospitals

Trace Chemotherapy Waste

Trace chemo is typically managed in yellow bins which is incinerated at a hospital, medical and infectious waste incinerator (HMIWIs). DEQ recommends against autoclaving

- Empty vials
- Empty syringes
- Empty IV bags
- Wipes
- PPE, such as gloves and gowns

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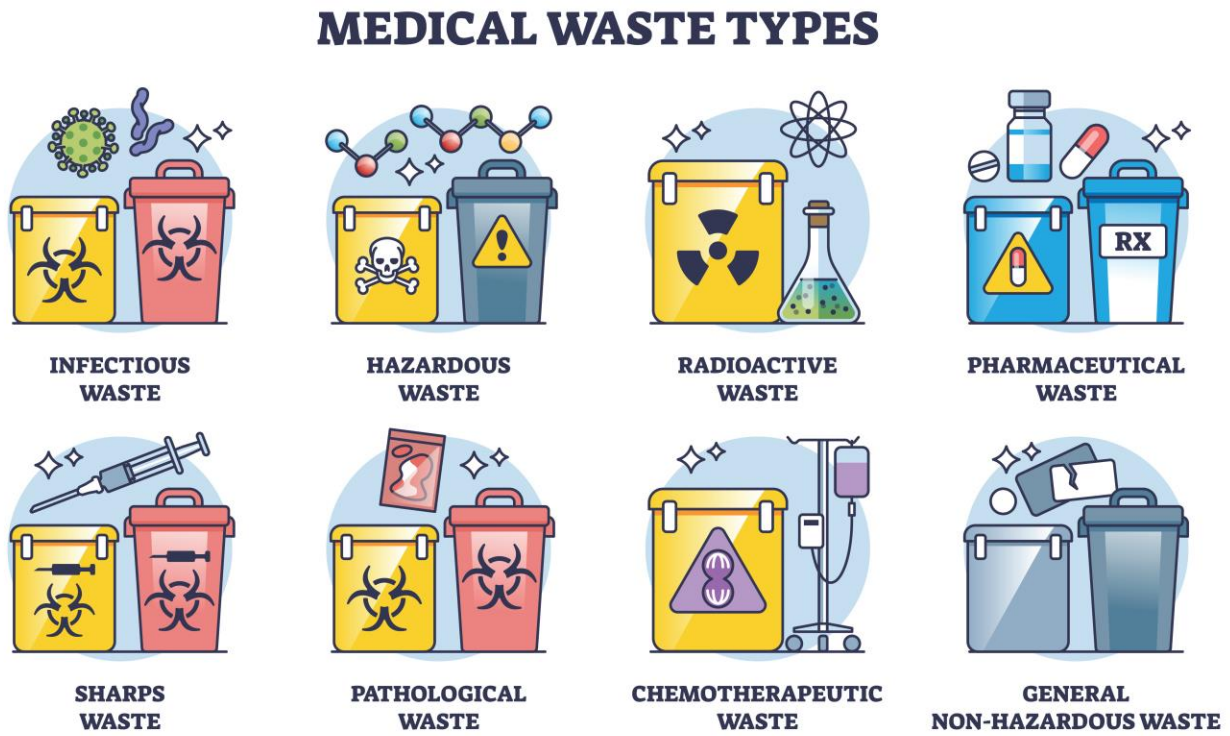
Wastes Specific to Healthcare Facilities

No hazardous waste at an HCF should be managed in the same containers as regulated medical waste!!!



Other Wastes Specific to Healthcare Facilities

- Regulated Medical Waste (RMW)
- Virginia has RMW Regulations (9VAC20-60-120) dictating management of these wastes provided they are not hazardous wastes
- This will be discussed in detail next week (Part 4)

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Other Wastes Specific to Healthcare Facilities

RMW: Sharps

Sharps waste means needles, scalpels, knives, syringes with attached needles, Pasteur pipettes and similar items having a point or sharp edge or that are likely to break during transportation and result in a point or sharp edge

Common medical materials treated as sharps waste are:

- Hypodermic Needles
- Disposable Scalpels and Blades
- Contaminated Glass and Some Plastics

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Amendment of the P075 Nicotine Listing

- FDA-approved OTC nicotine replacement therapies (NRTs) will no longer be included
- EPA concluded that FDA-approved OTC nicotine patches, gums and lozenges do not meet the regulatory criteria for acute HW
- FDA-approved OTC nicotine patches, gums and lozenges can now be discarded as non-hazardous solid waste

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What is still considered P075?

- Nicotine in any other form (including non-FDA approved OTC NRTs) continues to be P075 acute hazardous waste
- Other unused formulations will still be considered P075 when discarded, including:
- E-liquids/e-juices in e-cigarettes, cartridges or vials
- Prescription nicotine (e.g. nasal spray, inhaler)
- Nicotine used in research and manufacturing

E-liquids, e-juices & prescription NRTs while still meeting the listing may be managed as HWP under Subpart P of 266 when discarded

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Sewering Ban

- Effective Aug. 21, 2019, in all states including Virginia
- All HCFs, including VSQGs that operate under the hazardous waste generator regulations in lieu of Subpart P, as well as RDs, are prohibited from discharging HWP into a sewer system that passes through a publicly-owned treatment works (POTW)
- HWP must be managed properly as potentially-creditable HWP or non-creditable HWP
- HCFs & RDs remain subject to the Clean Water Act prohibitions for treatment standards & prohibited discharges

Sewering Ban

- HWPs that are subject to regulation by DEA are also subject to the sewer prohibition
- Mandatory for ALL HCFs & RDs that manage HWP
- Does not apply to non-HW pharmaceuticals but is a best management practice to not sewer ANY pharmaceuticals

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Residues of HWP in Empty Containers

- Formerly, residues of acute HWPs in containers were regulated unless the container was triple rinsed & the rinse water managed as HW
- HW Pharmaceuticals Final Rule modifies the “empty container” provisions to indicate that containers of HW Pharmaceuticals are now regulated under Subpart P

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Residues of HWP in Empty Containers

- Stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container is considered empty (and the residues not regulated as HW) if the pharmaceuticals have been removed using the practices commonly employed to remove materials from that type of container.
- Syringe is considered empty & residues not regulated as HW provided the contents have been removed by fully depressing the plunger of the syringe
  - If a syringe is not empty, place into a container & manage as non-creditable HWP & any applicable federal, state, and local requirements for sharps containers & medical waste

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Residues of HWP in Empty Containers

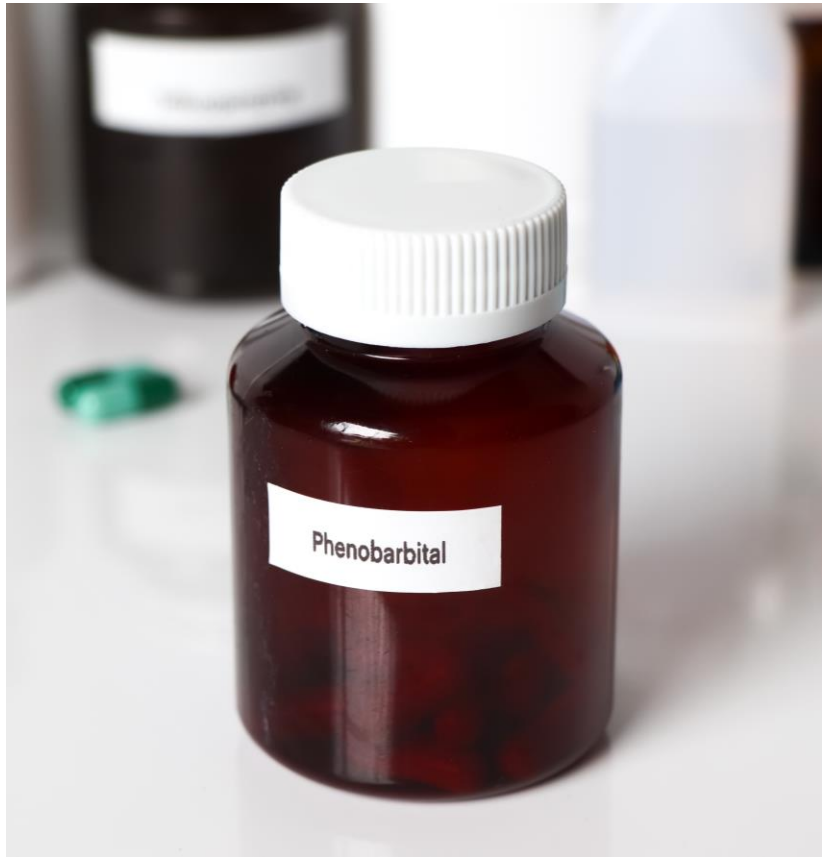
- Intravenous (IV) bag is considered empty & residues are not regulated as HW provided the pharmaceuticals have been fully administered to a patient
  - If IV bag is not empty, place into a container that is managed & disposed of as a non-creditable, unless the IV bag held non-acute HWP and is empty as defined in § 261.7(b)(1).
- HWP remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable HWP, unless the container held non-acute HWP & is empty (defined in § 261.7(b)(1) or (2))

Controlled Substances

- Controlled substances (CS) are those drugs regulated by the DEA, divided into five schedules based on potential for abuse:
  - Schedule I includes drugs that have no accepted medical use, such as heroin
  - Schedule II drugs are used medically but have high abuse potential such as morphine, and their purchase, storage and use are strictly monitored
  - Schedules III through V are drugs with decreasing abuse potential including cough suppressants and sedatives
  - HWP that are also CS regulated by the Drug Enforcement Administration (DEA)

Controlled Substances

- There are only eight HWPs that are CS:
  - Chloral; chloral hydrate;
  - Fentanyl Sublingual Spray
  - Phenobarbital
  - Testosterone Gels
  - Valium Injectable
  - Paraldehyde – no longer commonly used
  - Paregoric – no longer commonly used
  - Opium Tincture – no longer commonly used



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Controlled Substances

- Under DEA requirements, controlled substances when disposed must be destroyed so as to be no longer retrievable
- Historically CS may have been sewered
  - Currently discouraged
  - Prohibited after Aug. 21, 2019, if the CS is a HWP

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Controlled Substances

Conditional Exemption applies to:

- HWP that is also on a CS list by DEA in 21 CFR Part 1308
- HWP collected in a take-back event or program that are collected by an authorized collector (as defined by the DEA) registered with the DEA, that commingles the HHWP with CS from an ultimate user (as defined by the DEA)

Controlled Substances

Conditions for exemption (HWP that are CS)

- Manage in compliance with the sewer prohibition
- Collect, store, transport, and dispose of in compliance with all applicable DEA regulations for CS
- Destroy by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted

Sequestration Units

*Photos were obtained through a search online

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Controlled Substances

Combustion of CS that are HWP – acceptable units

- Permitted large municipal waste combustor
- Permitted small municipal waste combustor
- Permitted hospital, medical and infectious waste incinerator
- Permitted commercial & industrial solid waste incinerator
- Permitted hazardous waste combustor

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Controlled Substances- Bottom Line

- If only CS (HW or non-HW) are placed in the container, then it is not regulated under RCRA as long as the container and contents are properly incinerated (the only disposal method accepted by the DEA)
- Sequestration units are not considered proper disposal. They are only a step in that process.

If a facility cannot be certain that no one would put any non CS wastes in the sequestration unit, it might be best to manage those units as hazardous waste pharmaceutical containers.

QUESTIONS??

Let’s talk about implementation of the rule to a healthcare facility

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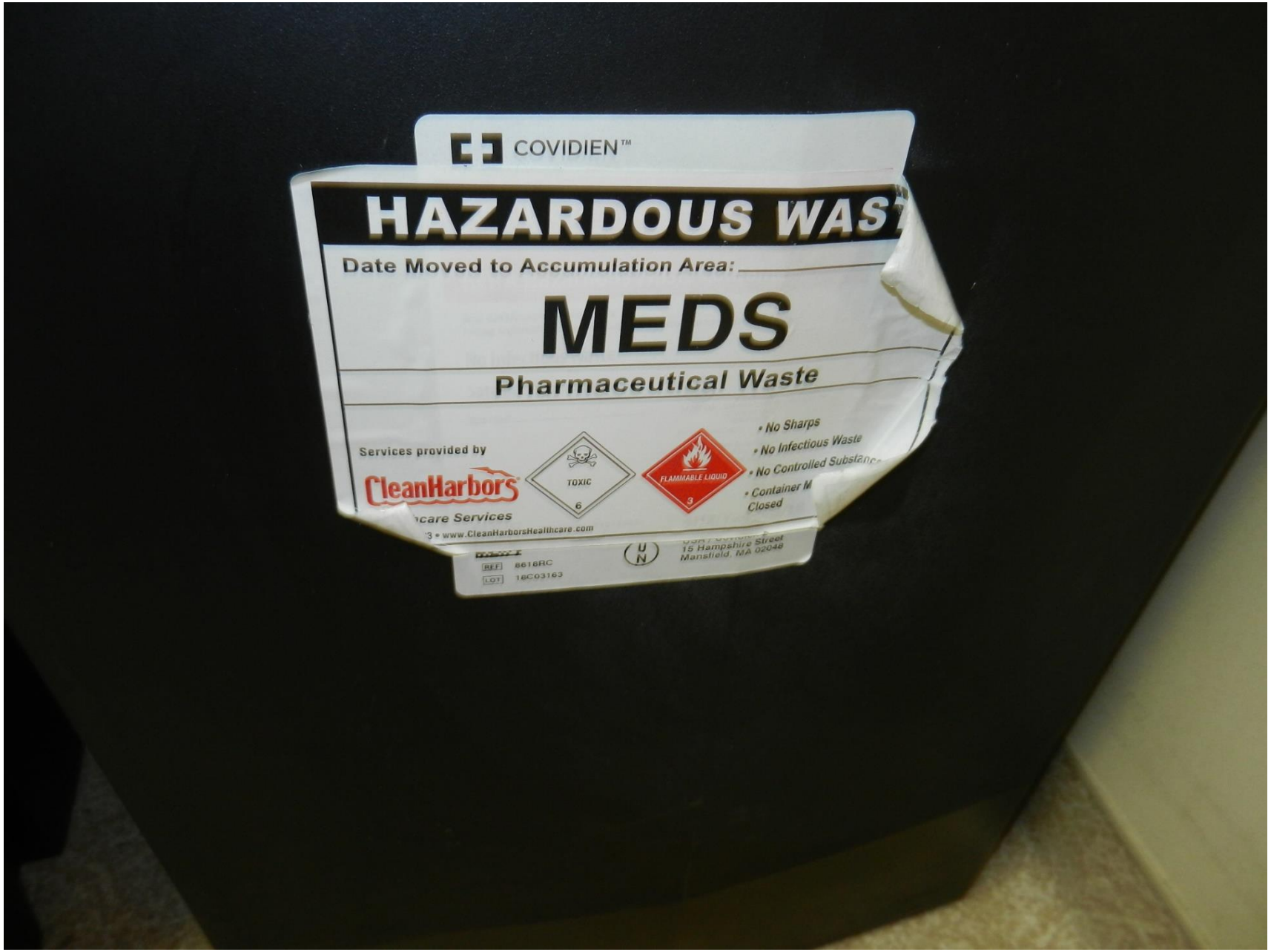
Subpart P Container Requirements

- Non-creditable HWPs must be in closed, secured containers that are not unattended or in public areas
- Must be labeled "hazardous waste pharmaceuticals"
- Must be accumulating no longer than one-year (best way to do this?)

Subpart P encourages facilities to combine all HW and non-HW pharms into one container (note: one caveat to that statement is that there are a handful of Pharms that require additional treatment and cannot be put into a container with other HW Pharms unless they are all treated with the more stringent treatment requirements)


NO SHARPS


COVIDIEN™
HAZARDOUS WAS
Date Moved to Accumulation Area:
MEDS
Pharmaceutical Waste
Services provided by
CleanHarbors
TOXIC
6
FLAMMABLE LIQUID
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• No Sharps
• No Infectious Waste
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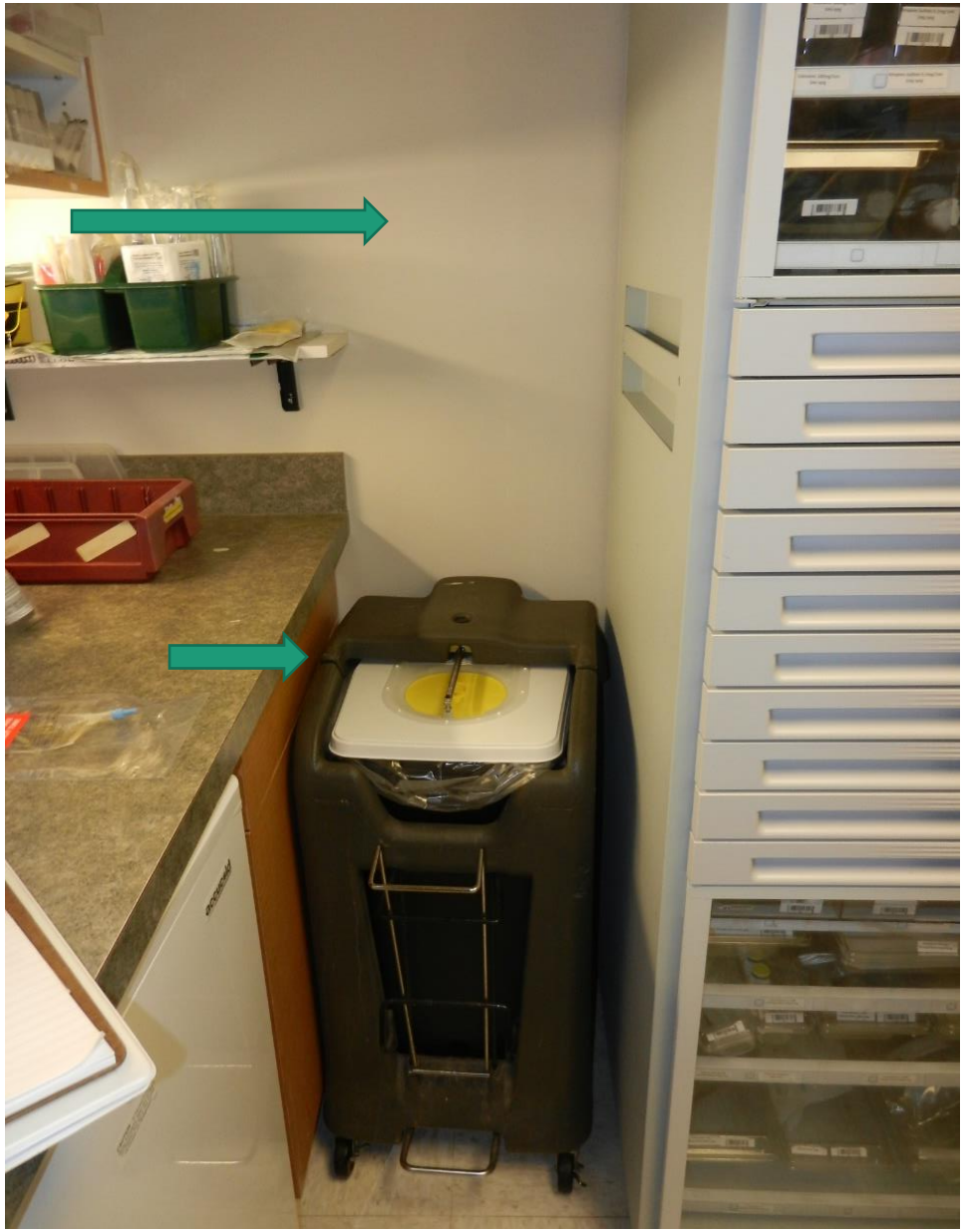


HAZARDOUS WASTE
MEDS
NO SHARPS


Stericycle
SYSTEM CONTAINER
INCINERATION ONLY
In-Service Date:
Stericycle
HAZARDOUS WASTE
PHARMACEUTICALS
(Sort Code BKC)
(Hazardous Waste - Satellite Accumulation Container)
Ignitable/Toxic Ex: (Alcohol, M-Cresol)
KEEP LID CLOSED
DO NOT REMOVE OR DISPENSE ITEMS FROM THIS CONTAINER
NO INFECTIOUS / BIOHAZARDOUS
(No blood or body fluids)
NO CONTROLLED SUBSTANCES
(Witness waste per policy)
NO FREE LIQUIDS
(Use sealable bag to contain liquid before placing in container)


Stericycle Nursing Only
Blood or Bodily Fluids
Needles, sharps, empty glass
Maintenance IV Solutions
Trace Chemotherapy
Controlled Medication
Black Container:
Blue Container:
No Code/ No Alert
Pharmaceutical Waste
Stericycle
CONTROLLED SUBSTANCE WASTE DISPOSAL INSTRUCTIONS
Stericycle
SYSTEM CONTAINER
INCINERATION ONLY
Stericycle
HAZARDOUS COMPATIBLE PHARMACEUTICAL WASTE
KEEP LID CLOSED
DO NOT REMOVE OR DISPOSE ITEMS FROM THIS CONTAINER
NO INFECTIOUS / BIOHAZARDOUS
NO CONTROLLED SUBSTANCES
NO FREE LIQUIDS


MEDS
NO SHARPS
24 UNIT

Other Wastes Specific to Healthcare Facilities

Aerosol Cans

- Non-Hazardous Aerosol Cans - There are many pharmaceuticals that come in aerosol cans that do not contain propellants that exhibit the ignitability or reactive characteristic. The HCF needs to determine how aerosol cans are going to be managed. Managing them with hazardous waste aerosol cans is often the simplest approach.
- Hazardous Aerosol Cans - Aerosol cans that may be reactive with flammable propellants should be managed as hazardous waste under the ignitable and reactive hazardous waste code of D001 and D003. Additional hazardous waste codes may apply to the unused contents of any partially filled cans.

Note: Aerosol cans are now part of DEQ's universal waste regulations

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RCRA Baseline vs. RCRA Pharmaceutical Waste Requirements

Regulation	RCRA Baseline	RCRA Subpart P Wastes
Generator Category	VSQG, SQG, LQG	One Category
Waste Generation	Count to determine generator category	Not required for HWPs if HCF complies with Subpart P, but counting required for non-HWPs
Waste Accumulation	Varies by generator category	One year or less without a permit or interim status
Waste Codes	Specific waste codes	One Code (PHARMS)
Satellite Accumulation Areas	Yes	N/A
Types of Waste	Characteristic, Listed	Must determine if - Non-credible HW (Disposed) -Potentially credible HW
Waste Requirements	40 CFR Part 262	40 CFR Part 266 Subpart P

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Commonalities with Non-Creditable HWPs

Regulation	RCRA Baseline	RCRA Subpart P – Non-Credible HW
HW Determinations	Yes	Yes. Non-HW Pharms not required if managed under Subpart P
Notification	Yes	Similar to Baseline Program
Container Standards and Labeling	Yes	Similar to Baseline program, **BUT**
Training	Yes	Similar to Baseline SQG program, **BUT**
Land Disposal Restrictions	Yes	Same, but waste codes simplified
Rejected Loads	Yes	Similar to Baseline Program
BR and Exception Reporting	Yes	BR not required **for Subpart P Pharmaceutical HW**
HW Manifesting	Yes	Same as Baseline program, **but waste codes simplified.**
Spill management	Yes	Similar to Baseline program, **BUT**
Pre-transport requirements	Yes	Same as Baseline program
Designation facility (TSDF)	Yes	Same as Baseline program

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Major Takeaways

- HCFs must count their pre-rule HW generation rate to determine generator status for rule applicability
- HCFs that are LQG or SQG must comply with Subpart P for HWP
- HCF cannot sewer hazardous waste pharmaceuticals after Aug. 21, 2019
- P075 Nicotine Listing no longer includes OTC NRTs
- CS, if managed correctly (and separately) under DEA rules are conditionally exempt from RCRA

Issues and Decisions (will be covered in Part 5!!)

1. Who's in charge? Are roles and responsibilities clear as to who leads and who follows? Does your hospital have a project management plan with clearly assigned tasks and deadlines?

2. Who in your organization determines if a hospital has generated a HW and HWP? Same person? Two different persons? Other?

3. What are the costs and benefits of managing all pharmaceuticals, whether HW or non-HW, under Subpart P?

4. Does your hospital have a plan/scheme for sorting and disposing of all types of HWP and non-HWPs a process exist in the hospital to determine what NIOSH drugs may also be a HWP when disposed?

5. Does hospital have process in place for what wastes to count and not count under Subpart P?

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Any Questions? Comments?

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