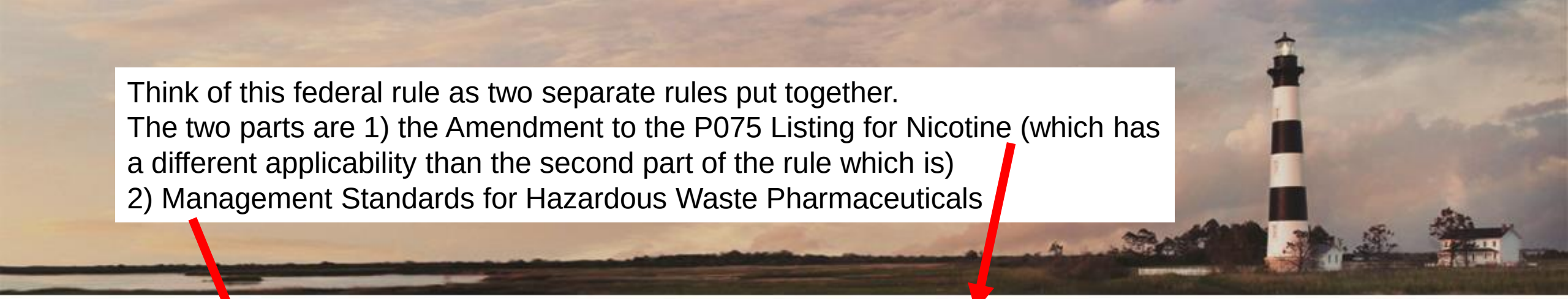
Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Final Rule

Updated 8/6/2021



Think of this federal rule as two separate rules put together.
The two parts are 1) the Amendment to the P075 Listing for Nicotine (which has a different applicability than the second part of the rule which is)
2) Management Standards for Hazardous Waste Pharmaceuticals

Amendment to the P075 Listing for Nicotine and Management Standards for Hazardous Waste Pharmaceuticals (a.k.a. Subpart P)

Questions about Hazardous Waste Pharmaceuticals?

Question: Who do I contact if I have questions about the management standards for hazardous waste pharmaceuticals?

Answer: Contact your local Hazardous Waste Section Inspector. Click on this link for a map showing the Inspector region and contact information:

https://files.nc.gov/ncdeq/Waste+Management/DWM/HW/Compliance/Compliance_Map_by_Inspector.pdf

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Acronyms and Abbreviations Used

A few abbreviations/acronyms will be used in this presentation:

- HW = Hazardous Waste
- HWS = Hazardous Waste Section
- EPA = Environmental Protection Agency
- VSQG = Very Small Quantity Generator
- SQG = Small Quantity Generator
- LQG = Large Quantity Generator
- CAA = Central Accumulation Area
- SAA = Satellite Accumulation Area
- RCRA = Resource Conservation and Recovery Act

Hazardous Waste Generator Guidance

NC Hazardous Waste Section Guidance Documents:

https://deq.nc.gov/about/divisions/waste-management/hw/technical-assistance-education-guidance/documents

"Hazardous Waste Generator "
"Hazardous Waste Pharmaceuticals"
"Aerosol Cans"
"Universal Waste"
"Used Oil"

Disclaimer

- This presentation was created to be an overview and is not all inclusive of all of the hazardous waste rules and requirements.
- This presentation should only be used as guidance.

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

- Effective on the federal level August 21, 2019
- Two parts of the Rule were effective in North Carolina at the same time as the federal rule effective date (August 21, 2019):
  - Amendment of the nicotine listing (40 CFR 261.33)
    - This is applicable to all facilities and independent of whether the facility is a healthcare or reverse distributor
  - Prohibition on sewering of hazardous waste pharmaceuticals
  - More on both of these provisions in upcoming slides

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

- North Carolina adopted federal provisions with no additions or amendments
- Federal provisions were incorporated by reference in the state Hazardous Waste Management Rules 15A NCAC 13A .0106, .0107, .0109 through .0113, and .0119
- Management Standards for Hazardous Waste Pharmaceuticals (40 CFR 266 Subpart P)
  - Effective in North Carolina on July 1, 2020
- Remember the two provisions (mentioned on previous slide) were in effect in North Carolina August 21, 2019

Management Standards for Hazardous Waste Pharmaceuticals

For more information on the federal rule (including FAQs and history):

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

Direct Link to Frequent Questions:

https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and

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Amendment to the P075 Listing for Nicotine

Amendment to the P075 Listing for Nicotine

- Effective in North Carolina on August 21, 2019
- The P075 listing for nicotine is amended such that FDA-approved over-the-counter nicotine replacement therapies are no longer included under the P075 listing as an acute hazardous waste
  - This includes nicotine patches, gums and lozenges
- Nicotine patches, gums and lozenges can be discarded as nonhazardous waste in North Carolina (as long as they have not been mixed with hazardous waste)

≠ P075

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What was the P075 listing and how did it change?

P075 Listing in 40 CFR 261.33(e) **prior** to August 21, 2019:

Hazardous waste No.	Chemical abstracts No.	Substance
P075	154-11-5	Nicotine, & salts
P075	154-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts

What was the P075 listing and how did it change?

P075 Listing in 40 CFR 261.33(e) **effective August 21, 2019**:

Hazardous waste No.	Chemical abstracts No.	Substance
P075	154-11-5	Nicotine, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).
P075	154-11-5	Pyridine, 3-(1-methyl-2-pyrrolidinyl)-, (S)-, & salts (this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies).

Nicotine is still listed as P075

- Nicotine continues to be a listed, acute hazardous waste with the hazardous waste code P075
  - Other unused formulations of nicotine will still be considered P075 when discarded, including
  - E-liquids/e-juices from e-cigarette manufacturing
  - Legacy pesticides containing nicotine
  - Nicotine used in research and manufacturing

: P075

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Management Standards for Hazardous Waste Pharmaceuticals

Management Standards for Hazardous Waste Pharmaceuticals
40 CFR 266 Subpart P

- Applies to hazardous waste pharmaceuticals generated at a healthcare facility and reverse distributors
- Does not apply to manufacturing of pharmaceuticals (***but does apply to a nurse's office/clinic at the facility***)
- Requirements are found in 40 CFR 266 Subpart P ("Subpart P")
  - Considered to be more stringent… so not optional unless facility is VSQG when counting TOTAL hazardous waste generated at facility
  - The sewer prohibition is mandatory (even if facility is VSQG)

Applicability Summary

Are you a healthcare facility or reverse distributor?
(Also applies if only a portion of the site is a healthcare facility)

Do you generate pharmaceutical waste?

Is it a hazardous waste?

Sewer Prohibition Applies
Effective Aug. 21, 2019

Determine whether
Subpart P applies

Applicability Summary

Are you a healthcare facility or reverse distributor?
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Subpart P applies

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What is a Healthcare Facility? Briefly Summarized

"Lawfully authorized" to:

1) Provide healthcare
2) Distribute, sell, or dispense pharmaceuticals

Examples:

- Hospitals
- Pharmacies
- Physician's Offices
- Long-term Care Facilities
- Wholesale Distributors

Does NOT include:

- Pharmaceutical Manufacturers
- Reverse Distributors

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What is a Healthcare Facility?
40 CFR 266.500

Healthcare facility means any person that is lawfully authorized to:

- Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body.
- Distribute, sell, or dispense pharmaceuticals, including OTC pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

Examples of Healthcare Facilities

- Hospitals
- Psychiatric Hospitals
- Ambulatory Surgical Centers
- Health Clinics
- Physicians Offices
- Optical & Dental Providers
- Chiropractors
- Long-term Care Facilities
- Ambulance Services
- Pharmacies (including mail-order)
- Retailers of OTC Medications
- Veterinary Clinics/ Hospitals
- Wholesale Distributors
- Third-party Logistics Providers that serve as Forward Distributors
- Military Medical Logistics Facilities

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What is a Healthcare Facility?
40 CFR 266.500

- A healthcare facility may be part of a site ("co-located" at a site) so these provisions could apply to a manufacturing (or other) site that has a healthcare component (e.g., nurse's office, clinic, a room with a first aid kit).
  - Source: EPA's response to rulemaking comments (page 144-145)
- Subpart P may apply to any hazardous waste pharmaceuticals generated from employee blood monitoring or from administration of vaccines.
- Tips:
  - Track inventory and ensure any hazardous waste pharmaceuticals are legitimately used for intended purpose so it won't have to be disposed.
  - Carefully evaluate any events that can cause a portion of the site to be considered a healthcare facility.

What is a Reverse Distributor?
40 CFR 266.500

Reverse distributor means any person that:

- Receives and accumulates **prescription pharmaceuticals** that are **potentially creditable** hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit.
- Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

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Applicability Summary

Are you a healthcare facility or reverse distributor?
(Also applies if only a portion of the site is a healthcare facility)

Do you generate pharmaceutical waste?

Is it a hazardous waste?

Sewer Prohibition Applies
Effective Aug. 21, 2019

Determine whether
Subpart P applies

What is a Pharmaceutical?
40 CFR 266.500

Pharmaceutical:

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

Examples of Pharmaceuticals

- Dietary Supplements
- Prescription Drugs
- OTC Drugs
- Homeopathic Drugs
- Compounded Drugs
- Investigational Drugs
- Pharmaceuticals Remaining in Containers
- Personal Protective Equipment (contaminated)
- Clean-up Materials from Pharmaceutical Spills

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Over the Counter Products with "Drug Facts" are a Pharmaceutical

The preamble (page 5842, bottom of left column) of the federal Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine Final Rule (84 FR 5842, February 22, 2019) at the below link states the following:

https://www.govinfo.gov/content/pkg/FR-2019-02-22/pdf/2019-01298.pdf

"The final definition of pharmaceutical includes both prescription drugs, as defined by 21 CFR 203.3(y) and [over the counter] OTC drugs. As previously mentioned, commenters pointed out that the same chemical may have a pharmaceutical and non-pharmaceutical use. If an OTC product is required by the FDA to include "Drug Facts" on the label, it would be considered a pharmaceutical for the purposes of this rule. In rare cases, some items that are OTC pharmaceuticals may not be labeled appropriately with a "Drug Facts" label. It is the Agency's understanding, however, that all OTC drugs must contain a Drug Facts label. Therefore, if an item meets the criteria to be considered a pharmaceutical under Subpart P but is not labeled with Drug Facts, it should still be managed as a pharmaceutical."

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Isopropyl Alcohol Used to Clean Wounds that is labeled with "Drug Facts" is a Pharmaceutical

Question: Isopropyl alcohol is used at healthcare facilities to both clean wounds and to clean instruments and surfaces. When is it considered a pharmaceutical?

Answer: When isopropyl alcohol is used to clean wounds, it is labeled with “Drug Facts.” If an over-the-counter product, such as isopropyl alcohol, is required by the Food and Drug Administration to include “Drug Facts” on the label, it would be considered a pharmaceutical and, if it is a hazardous waste, it would have to be managed under 40 CFR 266 Subpart P when discarded by healthcare facilities. For other uses, such as cleaning instruments and surfaces, isopropyl alcohol would not be labeled with “Drug Facts” and would be a non-pharmaceutical hazardous waste that would have to be managed under 40 CFR 262 when discarded.

EPA’s frequent questions website for Subpart P at this link: https://www.epa.gov/hwgenerators/frequent-questions-about-management-standards-hazardous-waste-pharmaceuticals-and#b1

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Applicability Summary

Are you a healthcare facility or reverse distributor?
(Also applies if only a portion of the site is a healthcare facility)

Do you generate pharmaceutical waste?

Is it a hazardous waste?

Sewer Prohibition Applies
Effective Aug. 21, 2019

Determine whether
Subpart P applies

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What is a Non-pharmaceutical Hazardous Waste?
40 CFR 266.500

Non-pharmaceutical hazardous waste is <u>not a pharmaceutical</u> (as defined in 40 CFR 266.500), but is:

- A solid waste as defined in 40 CFR 261.2 that is
  - A listed hazardous waste in 40 CFR 261 Subpart D and/or
  - Exhibits one or more characteristic identified in 40 CFR part 261 Subpart C

- Examples of non-pharmaceutical hazardous waste generated at a healthcare facility:
  - Laboratory waste (e.g., tissue processing wastes, solvents, expired lab chemicals)
  - Maintenance waste (paint, solvents, etc.)

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What is a Hazardous Waste Pharmaceutical?
40 CFR 266.500

A pharmaceutical that is a solid waste (per 40 CFR 261.2), and

- Exhibits one or more characteristic (40 CFR 261 Subpart C) and/or
  - Ignitable, corrosive, reactive, and/or toxic
- Is a listed hazardous waste (40 CFR 261 Subpart D)
  - F, K, P, and U lists

- A pharmaceutical is not a solid waste if it is legitimately used/reused or reclaimed.
- OTC pharmaceuticals are not solid wastes if it has a reasonable expectation of being legitimately used/reused or reclaimed.

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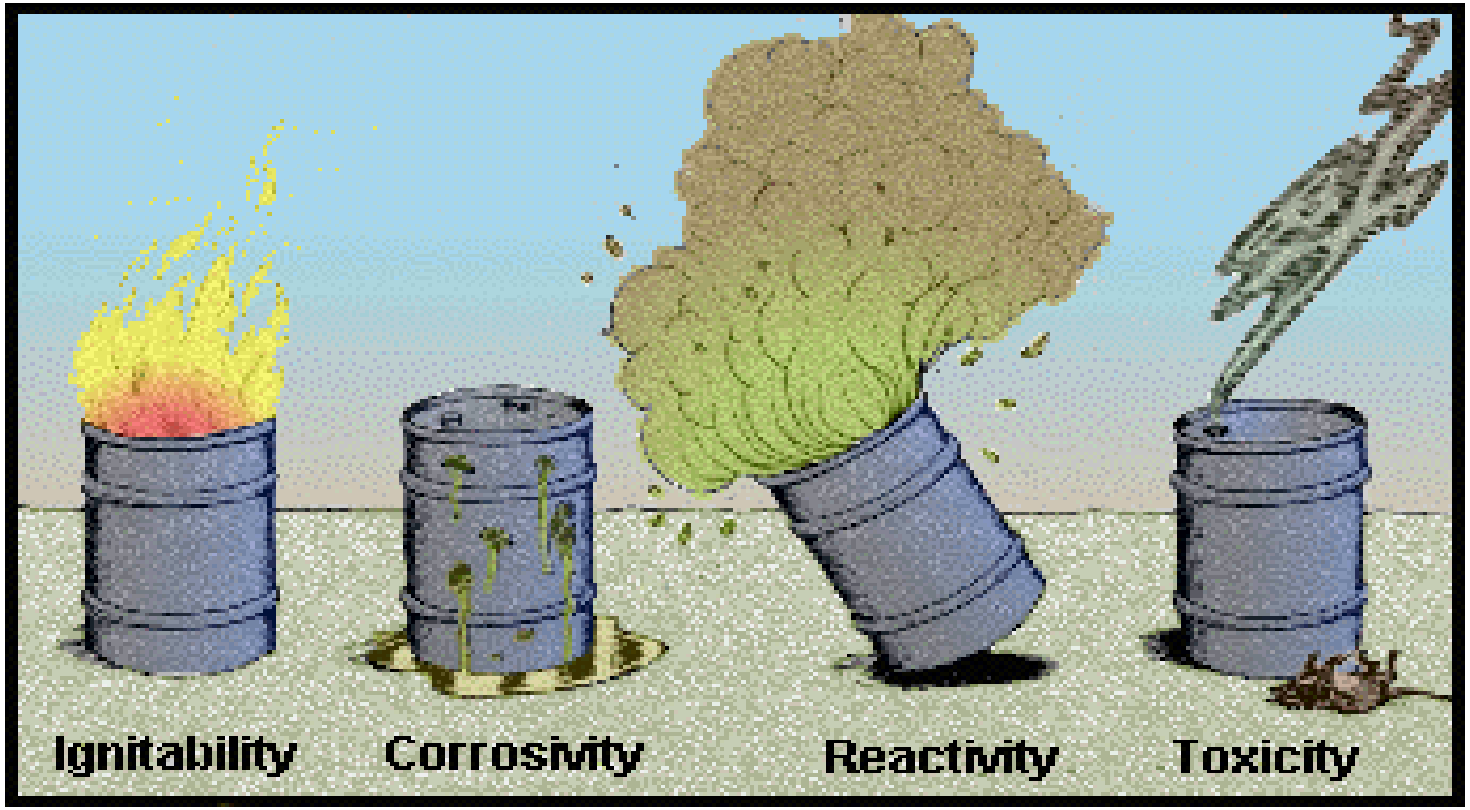
What is a "Characteristic" Hazardous Waste?

40 CFR 261 Subpart C



Ignitability – D001
40 CFR 261.21

A solid waste exhibits the characteristic of ignitability if a representative sample of the waste has any of the following properties:

- It is a liquid (other than a solution containing <24% alcohol by volume and at least 50% water by weight) and has a flash point of < 140 degrees F
- It is not a liquid and capable under standard temperature and pressure of causing fire by friction, absorption of moisture …burns vigorously and creates a hazard
- It is an ignitable compressed gas
- It is an oxidizer

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Examples of Ignitable Wastes in a Healthcare Facility

- Alcohol
- Alprostadil
- Aluminum Chloride Solution
- Ammonia inhalants
- Amyl nitrite
- Aerosols
- Androgel-Testosterone Gel
- Benzoyl peroxide
- Benzoin
- Beamethasone
- Calcipotriene
- Collondion
- Dexamethasone
- Dimethyl Sulfoxide
- Fluocinonide Solution
- Hurricaine Gel
- Mastisol
- Podofilox Gel
- Podocon
- Prednisone
- Ritonavir Solution
- Tacrolimus
- Tacrolimus
- Ciclopirox Solution
- Clindamycin Solution
- Clobetasol Propionate
- Bronchial dilators
- Erythromycin topical solution
- Merthiolate tincture
- Mouthwash (alcohol content >24%)
- Silver nitrate (oxidizer)
- Some cough medicines

Waste Code: D001

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Corrosivity – D002
40 CFR 261.22

A solid waste exhibits the characteristic of corrosivity if a representative sample of the waste has either of the following properties:

- It is aqueous and has a pH is $\leq$ 2 or $\geq$ 12.5
- It is a liquid and corrodes steel at a rate >0.25 in/yr.

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Examples of Corrosive Wastes in a Healthcare Facility

- Glacial acetic acid
- Carbolic acid
- Potassium hydroxide
- Sodium hydroxide

Waste Code: D002

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Reactivity – D003
40 CFR 261.23

A solid waste exhibits the characteristic of reactivity if a representative sample of the waste has any of the following properties:

- It is normally unstable and readily undergoes violent change w/o detonating
- It reacts violently with water
- It forms potentially explosive mixtures with water
- When mixed with water, it generates toxic gases, vapors, or fumes in a quantity sufficient to present a danger to human health/environment
- It is a cyanide or sulfide bearing waste that can generate toxic gases
- Capable of detonation or explosion
- It is a forbidden explosive defined in DOT regulations

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Examples of Reactive Wastes in a Healthcare Facility

- Some nitroglycerin formulations
  - Medical formulations determined not to be reactive (66 FR 27286; May 16, 2001 and EPA RCRA Online (RO) Document 14654) *See slide 43*
- Clinatest
  - Used to determine presence of reducing agents (such as glucose) in urine
- Ethylene oxide (sterilant)
- Dry picric acid (component of Bouin's Solution– tissue preservative)

Waste Code: D003

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Toxicity – D004 through D040
40 CFR 261.24

- Measured by performing Toxicity Characteristic Leaching Procedure (TCLP) and
- Comparing result to the list of 40 contaminants with concentration limits listed in 40 CFR 261.24

Examples:

Contaminant	Maximum concentration
Lead	5.0 mg/l
Cadmium	1.0 mg/l
Mercury	0.2 mg/l
Benzene	0.5 mg/l
Silver	5.0 mg/l

- If the TCLP test result equals or exceeds the concentration limit for a contaminant, it is considered hazardous waste for toxicity.

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Examples Wastes with Toxicity Characteristic in a Healthcare Facility

Contain mercury:

- Blephamide
- Neo/Poly/HC
- Neo/Poly/Gra
- Flurbiprofen
- Merthiolate
- Mercury Nitrate
- Mercury Iodide
- Mercurochrome
- Thimerosal

Contain m-cresol:

- Insulin
- Forteo
- Levemir

Contain other heavy metals:

- Chromium
- Thermazene
- Silver Sulfadiazene

Waste Codes: D004 – D040

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What is "Listed" Hazardous Waste?
40 CFR 261 Subpart D

Four separate lists of hazardous waste

- Manufacturing process wastes:
  - F-list: Non-specific sources (40 CFR 261.31)
  - K-list: Specific sources (40 CFR 261.32)
- Unused commercial chemical products, off-specification material, container residues, spill residues (40 CFR 261.33)
  - P-list: Acutely hazardous waste chemicals
  - U-list: Toxic chemicals

Approximately 30 products listed on the P and U lists with pharmaceutical uses

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What is "Listed" Hazardous Waste?
40 CFR 261 Subpart D

- If a solid waste meets a listing description (in 40 CFR 261 Subpart D), it is a listed hazardous waste
- To determine whether the waste meets a listing description, the generator must review each list in 40 CFR 261 Subpart D
- Compare the waste/process to the narrative description in the regulation
- And determine whether or not the waste is listed
- A listing determination cannot be made through testing – only through knowledge of the waste and the process generating the waste

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Examples of P-listed Wastes at a Healthcare Facility

• Arsenic Trioxide	P012
• Epinephrine (Adrenaline)	P042
• Nicotine	P075*
• Nitroglycerine	P081**
• Physostigmine	P204
• Physostigmine Salicylate	P188
• Sodium Azide	P105
• Strychnine	P108
• Warfarin >.3%	P001

* Does not include FDA approved OTC nicotine replacement therapies (gums, patches, lozenges)

** Does not include medicinal formulations of nitroglycerin

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Nitroglycerin

Nitroglycerin in finished dosage forms (tablets, capsules, patches) is excluded from the P081 listing due to "ICR-only" rule (40 CFR 261.3(g)(1))

- ICR-only means waste is listed solely for a characteristic of
    - "I" for ignitability, "C" for corrosivity, or "R" for reactivity
- ICR-only rule means if the waste does not exhibit that characteristic, it is not regulated as a hazardous waste
- Federal Register (FR) Volume 66, page 27286, published May 16, 2001:

  https://www.govinfo.gov/content/pkg/FR-2001-05-16/pdf/01-11411.pdf
- EPA RCRA Online (RO) Document 14654:

  https://rcrapublic.epa.gov/files/14654.pdf

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Epinephrine

P042 listing (Epinephrine) does not apply to Epinephrine salts

- EPA RO Document 14788: https://rcrapublic.epa.gov/files/14788.pdf
  - EPA clarified that epinephrine salts are not included in the epinephrine P042 hazardous waste listing.
  - Therefore, epinephrine salts and all delivery devices which contacted them would be hazardous only if they exhibited one or more hazardous waste characteristic.

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Epinephrine

Epinephrine residue in a used syringe is not P042 listed hazardous waste

- EPA RO Document 13718: https://rcrapublic.epa.gov/files/13718.pdf
- P-listing applies to unused discarded commercial chemical products
- Epinephrine residue in syringe that was administered is used for intended purpose and does not meet definition of commercial chemical product
- Even if not P-listed, unused portion could still be characteristic hazardous waste

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Epinephrine

Epinephrine (as well as any other P or U listed) residue left in the syringe after the contents of the have been delivered by syringe are not a listed hazardous waste

- EPA guidance RO14788: https://rcrapublic.epa.gov/files/14788.pdf

  (from slide 44) indicates that epinephrine residue administered with a syringe is not P-listed and extends to other P- and U- listed waste delivered by syringe

  - The guidance includes "delivery devices" but does not extend to IV bags

- See slide 92 for new standards for residues of hazardous waste pharmaceuticals in empty containers (also known as "RCRA Empty" standards)

  - Also see 40 CFR 261.7 and 266.507

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Examples of U-listed Wastes at a Healthcare Facility

- Acetone U002
- Chloroform U044
- Diethylstilbestrol U089
- Formaldehyde U122
- Hexachlorophene U132
- Lindane U129
- Mercury U151
- Paraldehyde U182
- Phenacetin U187
- Phenol U188
- Reserpine U200
- Resorcinol U201
- Selenium sulfide U205
- Warfarin <.3%, (Coumadin) U248

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Using an SDS when Making a Waste Determination

A Safety Data Sheet (SDS) often provides useful information about flash point and pH so they may sometimes be used to make ignitability and corrosivity characteristic waste determinations, but be careful using an SDS when making a toxicity characteristic waste determination.

- OSHA regs do not require manufacturers to identify constituents present in material at concentrations below:
    - For noncarcinogen: 1% (10,000 ppm)
    - For carcinogen: 0.1% (1000 ppm)
- The product may contain toxicity characteristic constituents above RCRA regulatory levels even when not identified on the SDS.

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Trace and Bulk Wastes

- No RCRA hazardous waste regulatory definition/distinction between "trace" and "bulk" wastes
- RCRA hazardous waste only recognizes requirements for P- and U-listed waste
- NCDEQ, Solid Waste Section (15A NCAC 13B .1201(14)) defines trace chemotherapy waste:
  - "Trace chemotherapy waste" means medical waste containing no more than three percent by weight of a medical drug used for chemotherapy, but is not a radioactive waste.
  - Trace chemotherapy waste includes gowns, gloves, wipes, and other handling, preparation, administration, cleaning, and decontamination items used in association with chemotherapy.

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Trace and Bulk Wastes Correlation with RCRA Hazardous Waste

- Trace Waste: Items which are RCRA empty but have held any chemotherapy/cytotoxic/antineoplastic waste or have been potentially exposed to chemotherapy/cytotoxic/antineoplastic
  - RCRA Empty (vials, syringes, IV bags, tubing)
  - Containers
  - PPE not contaminated with P-listed waste
- Bulk Waste: Waste managed as hazardous waste
  - U-Listed (not empty)
  - P-Listed (e.g., Arsenic Trioxide)
  - Non-RCRA Hazardous (best practice treat as HW, e.g., NIOSH Hazardous Drugs)

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Chemotherapy Agents: Many Are Not Regulated by RCRA Hazardous Waste

- Over 100 chemotherapy agents not regulated as a hazardous waste

- Examples:
  - Alkylating agents: Cisplatin, Thiotepa
  - Antimetabolites: Fluorouracil, Methotrexate
  - Hormonal (antiandrogen): Lupron® (leuprolide)
  - Hormonal (antiestrogen): Tamoxifen
  - Mitotic Inhibitor: Taxol® (paclitaxol)

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Listed Chemotherapy Drugs that are U and P-listed Wastes

Chlorambucil	U035
Cyclophosphamide	U058
Daunomycin	U059
Diethystilbestrol	U089
Melphalan	U150
Mitomycin C	U010
Streptozotocin	U206
Uracil Mustard	U237
Arsenic Trioxide	P012

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Example Chemotherapy Agents by Brand Name

Brand Name	Chemical Name	Waste Code
Alkeran ®	Melphalan	U150
Cerubidine ®	Daunomycin	U059
CTX ®	Cyclophosphamide	U058
Cytotoxan ®	Cyclophosphamide	U058
Daunorubicin ®	Daunomycin	U059
DaunoXome ®	Daunomycin	U059
DES®	Diethystilbestrol	U089
Leukeran ®	Chlorambucil	U035
Liposomal Daunorubicin ®	Daunomycin	U059
L-PAM ®	Melphalan	U150
Mitomycin ®	Mitomycin C	U010
Mutamycin ®	Mitomycin C	U010
Neosar®	Cyclophosphamide	U058
Procytox ®	Cyclophosphamide	U058
Rubidomycin ®	Daunomycin	U059
Streptozocin ®	Streptozotocin	U206
Stilphostrol ®	Diethystilbestrol	U089
Trisenox ®	Arsenic Trioxide	P012
Zanosar ®	Streptozotocin	U206

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Other Common Chemotherapy Agents

- Bevacizumab (Avastin) Non-RCRA Hazardous
- Carmustine (Bicnu) Non-RCRA Hazardous
- Irinotecan Hydrochloride (Campostar) Non-RCRA Hazardous
- Doxorubicin Hydrochloride (Doxil) Non-RCRA Hazardous
- Oxaliplatin (Eloxatin) Non-RCRA Hazardous

- Used in cancer research/treatment (not been FDA-approved for general use):
  - Ethyl Carbamate U238
  - Azaserine U015
  - 3-Methylcholanthrene U157

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Some Chemotherapy Drugs May Also Be Ignitable

- Liquid, containing 24% alcohol by volume and at least 50 % water by weight and has a flash point<140° F
- Example: Paclitaxel Injection contains 49.7% ethanol
- Dispose also as ignitable hazardous waste

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NIOSH Hazardous Drugs vs. RCRA Hazardous Waste

- Only some NIOSH Hazardous Drugs are also RCRA Hazardous Waste

- However, to minimize the exposure to hazardous drugs in health care settings, USP800 set standards for hazardous drugs to be managed/disposed of like they are RCRA hazardous waste

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USP 800 vs. RCRA

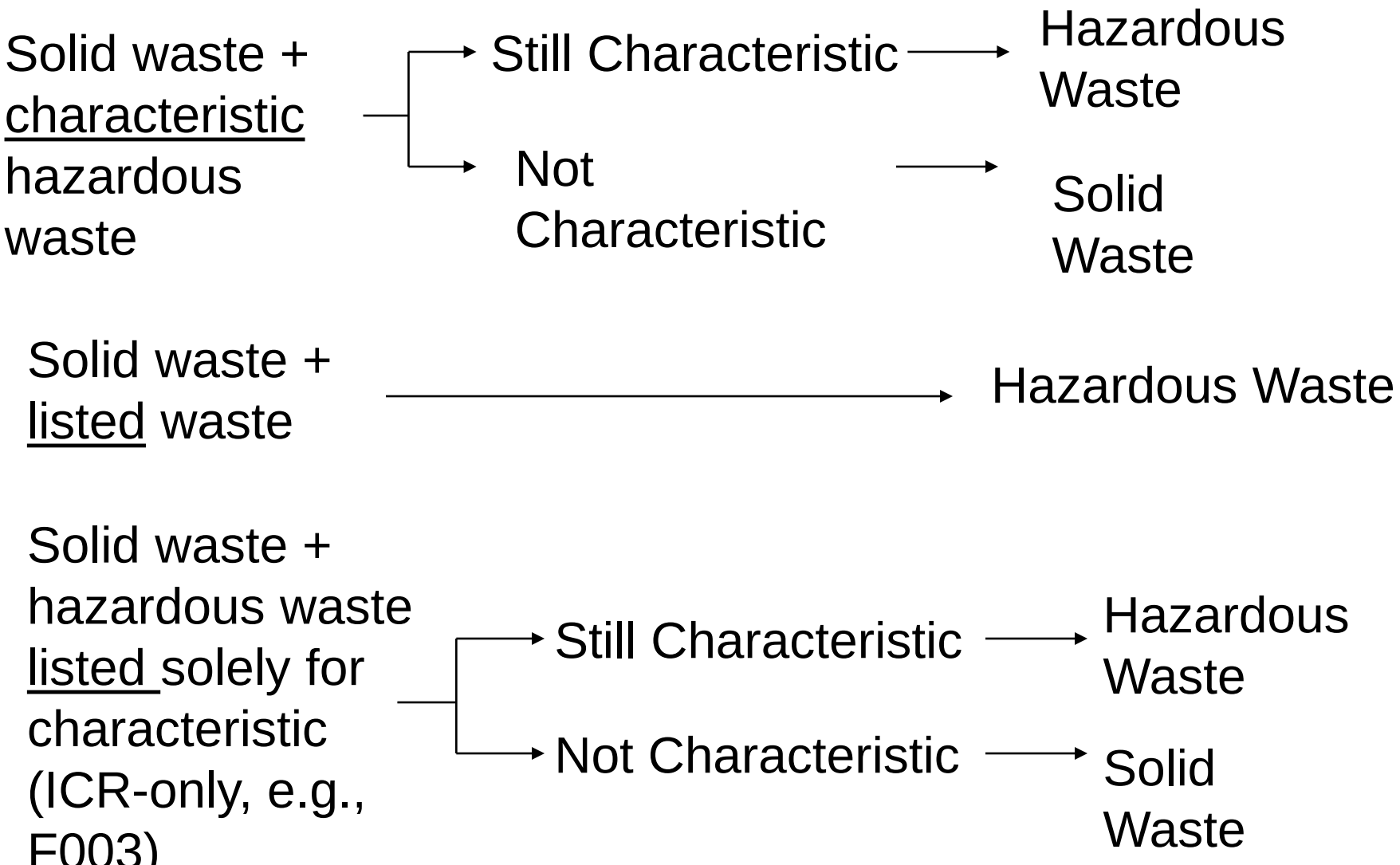
Description of Process/Requirement	USP 800	RCRA Hazardous Waste
General Applicability	Hazardous Drugs (HD)	Hazardous Wastes (HW)
Specific Applicability	- NIOSH list of antineoplastic and other hazardous drugs in USP800 that pose hazard to health care workers. - Specifically: carcinogens, teratogens, reproductive toxicity, Organ toxicity, Genotoxicity, Chemical structure and toxicity that mimic existing drugs that are hazardous. - It is NOT the EPA hazardous materials list which includes materials hazardous to the environment. - Agents not on the NIOSH list (e.g. antibiotics, some hazardous materials) that may need special handling. - The majority of the NIOSH hazardous drugs do not meet the definition of a RCRA hazardous waste.	Materials that are a solid waste (40 CFR 261.2) that have one or more hazardous characteristics (40 CFR 261 Subpart C; ignitable, corrosive, reactive, toxic) and/or are listed in 40 CFR 261 Subpart D. Some of the NIOSH Hazardous Drugs also meet the definition of hazardous waste when disposed but hazardous waste definition extends beyond the NIOSH Hazardous Drugs list.
Purpose	To protect the health care worker by implementing processes for personal protective equipment, engineering controls, and work practices intended to minimize the exposure to hazardous drugs in health care settings.	To protect human health and the environment from exposure to hazardous waste.
Development/ Oversight	Developed by the USP Compounding Expert Committee with the assistance of the USP Compounding with Hazardous Drugs Expert Panel and government liaisons from the U.S. Food and Drug Administration (FDA) and the U.S. Centers for Disease Control and Prevention (CDC), including NIOSH.	- The Resource Conservation and Recovery Act (RCRA) gives EPA the authority to control hazardous waste from the "cradle-to-grave." This includes the generation, transportation, treatment, storage, and disposal of hazardous waste. Federal regulatory requirements 40 CFR 260 through 279. - North Carolina has been authorized to implement the state hazardous waste management program in lieu of EPA. State regulatory oversight (adoption of federal regulations by reference) 15A NCAC 13A with additional state requirements. State hazardous waste law is found in NCGS 130A-290 through 130A-310.12
Enforcement	- EPA/NCDEQ regulate the generation, transportation, treatment, storage, and disposal of hazardous drugs that are hazardous waste. - NIOSH and CDC may not be actual federal regulations but can be incorporated in state or local law or hospital policies - Joint Commission considers proper disposal of hazardous medication waste as part of their Environment of Care standards - FDA gives guidance - State and federal government can enforce USP	EPA and NCDEQ, Hazardous Waste Section

What is not considered Hazardous Waste?

These are not hazardous waste unless they have been mixed with hazardous waste:

- Medical Waste
  - Link to the NCDEQ, Solid Waste Section website for information about medical waste: https://deq.nc.gov/about/divisions/waste-management/medical-waste
- Biohazards
- Radioactive Material/Waste
- Household Hazardous Waste
- Asbestos
- PCBs

Mixtures


Solid waste + characteristic hazardous waste
Still Characteristic
Hazardous Waste
Not Characteristic
Solid Waste
Solid waste + listed waste
Hazardous Waste
Solid waste + hazardous waste listed solely for characteristic (ICR-only, e.g., F003)
Still Characteristic
Hazardous Waste
Not Characteristic
Solid Waste

Ensure ALL Hazardous Waste is Counted

- Laboratories
- Nursing units
- Nuclear Medicine areas
- Operating rooms
- X-rays units
- Dental clinics
- Pharmacy
- Morgue
- Maintenance areas
- Construction areas
- Laundry
- Vehicle maintenance
- Grounds keeping
- Patient rooms
- Other Areas?

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HW Pharmaceutical Management

- Hazardous waste pharmaceutical should NOT be placed in red sharps containers
  - Biohazardous waste/infectious waste


MEDS

Applicability Summary

Are you a healthcare facility or reverse distributor?
(Also applies if only a portion of the site is a healthcare facility)

Do you generate pharmaceutical waste?

Is it a hazardous waste?

Sewer Prohibition Applies
Effective Aug. 21, 2019

Determine whether
Subpart P applies

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Hazardous Waste Pharmaceuticals Sewer Prohibition

Sewer Prohibition

- Hazardous waste pharmaceuticals may not be sewered (e.g., no disposal down the drain and no flushing)
- The sewer prohibition applies to:
  - All healthcare facilities, including healthcare facilities that are VSQGs
  - All reverse distributors
  - Hazardous wastes that are DEA controlled substances are also subject to the sewer prohibition
- EPA strongly discourages sewering of any pharmaceuticals by any entity
- The sewer prohibition was effective in ALL states on August 21, 2019

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Sewer Prohibition - Frequent Question

Question: Does the sewer prohibition apply to non-hazardous waste pharmaceuticals?

Answer: Technically, the sewer prohibition (described at 40 CFR 266.505) only applies to hazardous waste pharmaceuticals, but EPA encourages facilities to restrict non-hazardous waste pharmaceuticals from being sewered.

Items that EPA has indicated are okay to sewer are Lactated Ringer's Solution or Saline Solution when no hazardous waste pharmaceuticals have been added to them.

Drug Enforcement Agency (DEA) Controlled Substances and Hazardous Waste Pharmaceuticals

Hazardous Wastes that are DEA Controlled Substances

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA Controlled Substance Schedule
Chloral/ Chloral hydrate	Acetaldehyde, trichloro; Aquachloral, Noctec, Somnote, Supprettes	Sedative	U034 Toxic	IV
Fentanyl Sublingual spray	Subsys	Analgesic	D001 Ignitable	II
Phenobarbital	Bellergal-S Donnatal Luminal	Anticonvulsant	D001 Ignitable	IV
Testosterone Gels/solutions	Androgel Axiron Fortesta, Testim	Hormone	D001 Ignitable	III
Valium Injectable/gel	Diazepam Diastat	Anti-anxiety	D001 Ignitable	IV

DEA Controlled Substances Exemption from RCRA
40 CFR 266.506

Hazardous waste pharmaceuticals that are also DEA Controlled Substances are exempt from RCRA requirements provided the following conditions are met:

- Not sewered, and
- Managed in compliance with DEA regulations, and
- Destroyed by a method that the DEA has publicly deemed in writing to meet their non-retrievable standard, or
- Combusted at one of the following types of permitted facilities (see specifics at 40 CFR 266.506(b)(3))
    - Large or small municipal waste combustor (MWC)
    - Hospital, medical and infectious waste incinerator (HMIWI)
    - Commercial and industrial waste incinerator (CISWI) or
    - Hazardous waste combustor

Applies only to healthcare facilities notifying and operating under Subpart P.

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Sewer Prohibition and DEA Controlled Substances

- DEA controlled substances that are ***product inventory*** may <u>not</u> be sewered
  - Must be made non-retrievable (per DEA) and sewering does not make them non-retrievable

- (Based on DEA 2014 letter) DEA controlled substances that have been prescribed for immediate administration and not fully consumed during the process are considered ***<u>pharmaceutical wastage</u>***
  - DEA controlled substances that are pharmaceutical wastage (**<u>except for the 5 that are RCRA hazardous wastes</u>**) may be sewered because they do not need to meet non-retrievable standard.

- The 5 DEA/RCRA controlled substances (regardless of whether they are DEA product inventory or wastage) may **<u>not</u>** be sewered.

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Sewer Prohibition and Non-Controlled Substances

- RCRA hazardous waste pharmaceuticals (excludes any controlled substances discussed on the previous slide) may not be sewered
- Non-hazardous waste pharmaceuticals (excludes any controlled substances)
  - EPA *encourages* these not be sewered.

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Drug Disposal Units/Products

- There are many different types of units/products that claim to destroy drugs on the market.
- These units/products go by different names.
- These are just a few examples.
- For this presentation they will be referred to as "**Drug Disposal Units/Products**". They can also be known as a drug "sequestration unit."

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EPA's Management Matrix for Hazardous Waste Pharmaceuticals and DEA Controlled Substances

	RCRA HW Pharmaceutical	Non-RCRA Pharmaceutical
DEA Controlled Substance	•Drug Disposal Unit/Product Use OK (wastage only) •Conditional exemption applies •Container is not subject to Subpart P	•Drug Disposal Unit/Product Use (wastage only) •Container is not subject to Subpart P
DEA non-Controlled Substance	•Drug Disposal Unit/Product Use OK •Conditional exemption does not apply •Container is subject to Subpart P	•Drug Disposal Unit/Product Use OK •Container is not subject to Subpart P

"Conditional exemption" is the DEA Controlled Substances Exemption from RCRA described in 40 CFR 266.506 and on slide 69.

Drug Disposal Units/Products

Information from EPA:

- DEA does not recognize any drug disposal product/unit as meeting their non-retrievable standard
  - Cannot be used for product inventory (DEA terminology)
  - Can be used for pharmaceutical wastage (DEA terminology)

- Drug disposal product/unit may be used for RCRA HW Pharmaceuticals, but it does not meet land disposal treatment requirements
  - Must be sent for hazardous waste disposal (to meet land disposal restrictions)
  - May be used on-site as accumulation container, but must be managed as a HW

Drug Disposal Units/Products

Two scenarios:

- Drug disposal unit/product will be used for *everything* in the pharmacy.
  - Must assume that all types of pharmaceuticals are in the containers (DEA controlled, RCRA hazardous waste and non-hazardous waste)
  - It must be managed as both DEA Controlled substance and RCRA hazardous waste
  - Even after DEA exemption does not apply (because mixed with other RCRA HW)

- Drug disposal unit/product will be used for only DEA controlled substances. A healthcare facility opting into Subpart P and managing the container/waste under DEA requirements and meeting conditions of 40 CFR 266.506 is exempt from RCRA requirements (see slide 69).

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Drug Disposal Units/Products - Frequent Question

Slide 1 of 3

Question: If a healthcare facility puts leftover, partially administered pharmaceuticals into an on-site drug disposal unit/product (or "sequestration unit") can that unit be placed in the trash?

Answer: Not in most cases. If a drug disposal unit/product contains any hazardous waste pharmaceuticals, it cannot be disposed of in the trash.

- Drug disposal units/products are often marketed to hospitals for the collection of leftover, partially administered pharmaceuticals (what DEA refers to as "pharmaceutical wastage").
- According to DEA's "Dear Practitioner" letter from October 17, 2014, pharmaceutical wastage of DEA controlled substances does not have to be destroyed to meet the DEA's non-retrievable standard; therefore, pharmaceutical wastage of controlled substances may be placed in sequestration units.

Continued on the next slide

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Drug Disposal Units/Products - Frequent Question

Slide 2 of 3

Answer from last slide (continued)

EPA recommends that healthcare facilities take a conservative approach by assuming the likely scenario that healthcare workers will use the sequestration units to collect a combination of pharmaceutical wastage, including:

1. Regulated RCRA hazardous wastes
2. Conditionally exempt RCRA hazardous wastes that are also DEA controlled substances (see 40 CFR 266.506), and
3. DEA controlled substances.

If a healthcare facility uses the drug disposall unit/product only for collecting pharmaceutical wastage of DEA controlled substances that are not RCRA hazardous wastes, the unit may go in the trash. However, we expect that this is an unlikely scenario.

Continued on the next slide

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Drug Disposal Units/Products – Frequent Question

Slide 3 of 3

Answer from last slide (continued)

- If hazardous waste pharmaceuticals are placed in the drug disposal unit/product, the drug disposal unit/product may not be put in trash.
- Nor would the unit be eligible for the conditional exemption in 40 CFR 266.506.
- In this case, the unit would be subject to the 40 CFR part 266 Subpart P container standards during accumulation and pre-transportation.
- Furthermore, because the treatment standard under the land disposal restrictions is combustion for most hazardous waste pharmaceuticals, the unit must go to a hazardous waste combustor for treatment, and then to a hazardous waste landfill for disposal.
- For additional detail, see page 5901 of the preamble to the Hazardous Waste Pharmaceuticals Final Rule (84 FR 5816; February 22, 2019).

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Subpart P Applicability and Counting

Applicability Summary

Are you a healthcare facility or reverse distributor?
(Also applies if only a portion of the site is a healthcare facility)

Do you generate pharmaceutical waste?

Is it a hazardous waste?

Sewer Prohibition Applies
Effective Aug. 21, 2019

Determine whether
Subpart P applies

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How do you know if 40 CFR 266 Subpart P applies?

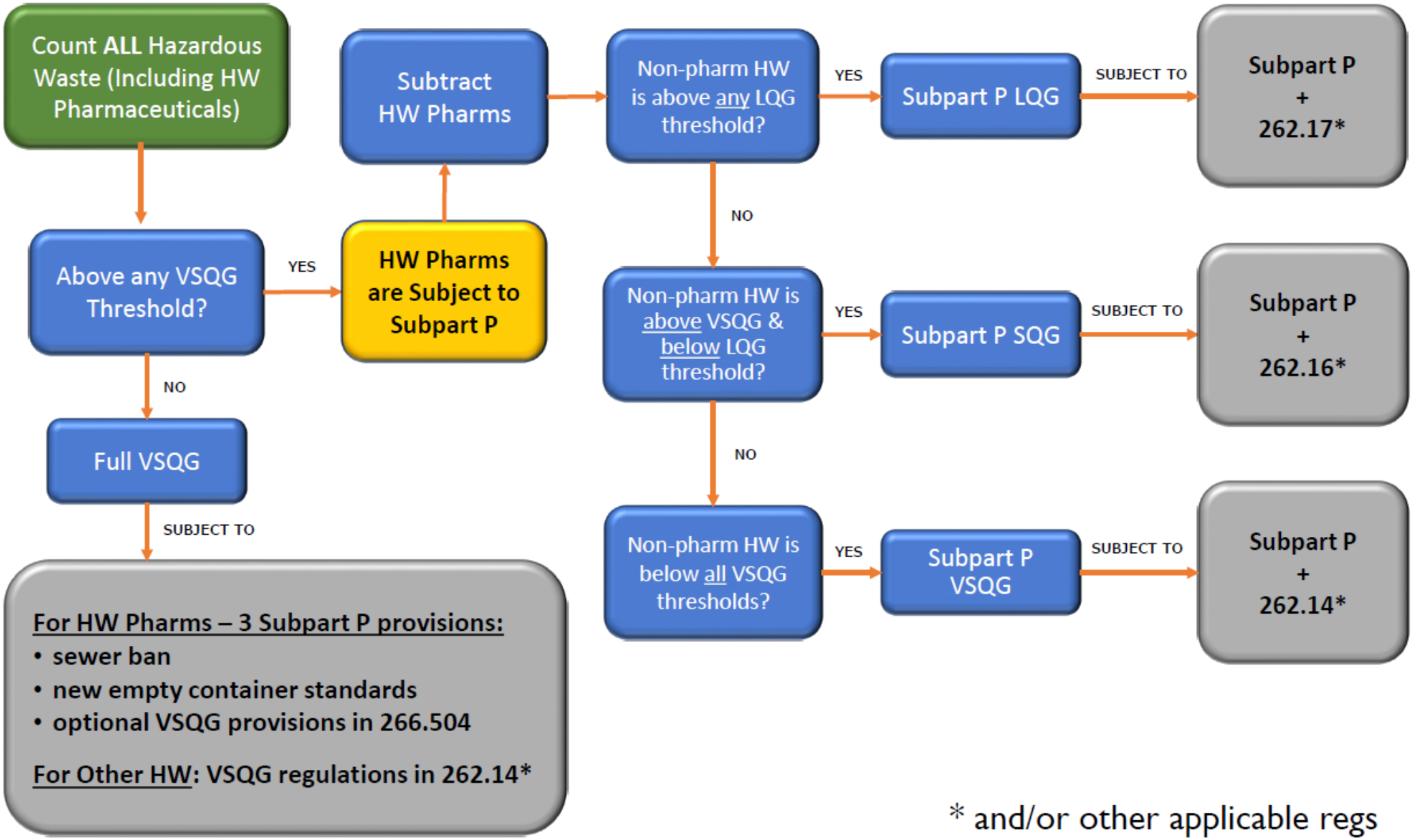
40 CFR 266 Subpart P applies to:

- Facilities (both healthcare facilities and when a portion of the facility is a healthcare facility) that generate SQG or LQG **total** amounts of hazardous waste

  Total HW at facility = HW pharmaceuticals + non-pharmaceutical HW

- All Reverse Distributors (regardless of HW generator category)
- Healthcare facilities that generate VSQG **total** amounts of HW (HW pharm + non-pharm HW) must comply with sewer prohibition, but have the option to either comply with 40 CFR 262.14 or Subpart P.

Applicability Flow Chart for Healthcare Facilities



* and/or other applicable regs

Hazardous Waste Generator Category Guidance

Category of Generator	Quantity of non-acute HW generated in a calendar month	Quantity of acute HW generated in a calendar month	Quantity of residues from a clean-up of acute HW generated in a calendar month	Maximum Accumulation Time	Maximum On-Site Waste Accumulation Amount
Very Small Quantity Generator (VSQG)	≤ 220 lbs. (100 kg)	≤ 2.2 lbs. (1 kg)	≤ 220 lbs. (100 kg)	No time limit	• 2,200 lbs. (1000 kg) non-acute HW at any time (approximately equal to five 55-gallon containers) • ≤ 2.2 lbs. (1 kg) acute HW at any time • ≤ 220 lbs. (100 kg) acute HW from a clean-up at any time
Small Quantity Generator (SQG)	> 220 lbs. (100 kg) but < 2200 lbs. (1000 kg)	≤ 2.2 lbs. (1 kg)	≤ 220 lbs. (100 kg)	180 days; 270 days if TSDF is 200 miles or more from the facility	• 13,200 lbs. (6000 kg) non-acute HW at any time (approximately equal to thirty 55-gallon containers)
Large Quantity Generator (LQG)	≥ 2,200 lbs. (1000 kg)	> 2.2 lbs. (1 kg)	> 220 lbs. (100 kg)	90 days	No quantity limit

Ensure ALL Hazardous Waste is Counted

- Laboratories
- Nursing units
- Nuclear Medicine areas
- Operating rooms
- X-rays units
- Dental clinics
- Pharmacy
- Morgue
- Maintenance areas
- Construction areas
- Laundry
- Vehicle maintenance
- Grounds keeping
- Patient rooms
- Other Areas?

Applicability of 40 CFR 266 Subpart P

Example for a Healthcare Facility:

Step 1: Is the <u>total</u> non-acute HW amount for the site above 220 lbs. in a calendar month?

(<u>Total</u> HW for site = HW pharmaceuticals + non-pharmaceutical HW)

- If YES, then Healthcare facility must comply with Subpart P requirements (go to next slide for STEP 2)
- If NO, then Healthcare facility must comply with sewer prohibition but has option to comply with VSQG requirements (40 CFR 262.14) or Subpart P

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Counting of HW Pharmaceuticals for Healthcare Facilities

Step 2: Once applicability of Subpart P is determined (based on total amounts of HW), the amount of HW pharmaceuticals does not need to be counted towards the generator category when managed under Subpart P (40 CFR 262.13(c)(9))

- When operating under Subpart P, the healthcare facility may subtract the amount of HW Pharmaceuticals from the total amount of HW to determine generator category
- Healthcare facilities previously operating as SQG or LQG prior to operating under Subpart P, will likely be able to reduce their HW generation category because HW generation is based only on non-pharmaceutical HW under Subpart P
- When a facility is able to downgrade their category, they are still operating under Subpart P and must meet Subpart P requirements.

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Management Standards for Hazardous Waste Pharmaceuticals

- Part 266 Subpart P is both waste-specific and sector-specific; it does NOT apply to the management of:
  - Non-pharmaceutical hazardous waste
  - Hazardous waste pharmaceuticals by facilities other than healthcare facilities (or portions of a site that meet the definition of a healthcare facility) and reverse distributors
  - Over the counter pharmaceuticals (and other unsold retail items) from healthcare facilities with reasonable expectation of legitimate use/reuse that are sent to reverse logistics center
- Healthcare facilities and reverse distributors are still subject to
  - 40 CFR 262 for the management of non-pharmaceutical hazardous wastes
  - 40 CFR 273 for the management of universal wastes,
  - Other Parts, as applicable

Management Standards for Hazardous Waste Pharmaceuticals

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  - 40 CFR 273 for the management of universal wastes,
  - Other Parts, as applicable

Reverse Logistics

EPA Memo dated October 17, 2019: https://rcrapublic.epa.gov/files/14915.pdf

- Clarifies reverse logistics applies to the entire retail sector, beyond pharmaceuticals/healthcare facilities.
- The memo strongly emphasizes that items sent through reverse logistics (from a retail store to a reverse logistics facility) are not considered a waste (at the retail store) if they have some reasonable expectation of being legitimately used/reused or reclaimed.
- Additional information about reverse logistics is in the preamble of the Management Standards for Hazardous Waste Pharmaceuticals Rule (84 FR 5816; February 22, 2019)

Reverse Logistics vs. Reverse Distribution

Reverse Logistics

- Applies to non-prescription pharmaceuticals and other unsold retail items
- Potential to be used/reused or reclaimed
- Not a RCRA solid waste (also not a hazardous waste) if there is a reasonable expectation of being legitimately used/reused or reclaimed

Reverse Distribution

- Applies to prescription pharmaceuticals
- Potential for healthcare facility to receive manufacturer's credit
- Potentially creditable hazardous waste pharmaceuticals are a solid waste and therefore a hazardous waste

Subpart P Applicability

The following are NOT subject to RCRA regulation:

- Pharmaceuticals that are not solid waste because they are legitimately used/reused or reclaimed
- OTC pharmaceuticals, dietary supplements or homeopathic drugs that are not solid waste because they have a reasonable expectation of being legitimately used/reused or reclaimed
- Recalled pharmaceuticals*
- Pharmaceuticals under preservation order, or during an investigation or judicial proceeding*
- Investigational new drugs*
- Household waste pharmaceuticals
- Healthcare facilities that are DEA registrants & collectors of household pharmaceuticals (i.e., takebacks) must comply with conditions in 40 CFR 266.506

* Become subject to Subpart P when decision is made to discard

RCRA Empty for Hazardous Waste Pharmaceutical Containers

Old Requirements for a Pharmaceutical Container to be Considered Empty

Empty U–listed & Characteristic drug containers

- All contents have been removed using normal means

  and

- No more than 1 inch or 3% by weight remains

Empty P-listed drug containers

- Triple rinsed
- Rinseate managed as HW

To reduce exposure, hospitals will dispose of container as P-listed instead of triple rinsing

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New RCRA Empty for HW Pharmaceutical Containers

40 CFR 266.507(a)

- ✓ A stock bottle,
- ✓ Dispensing bottle,
- ✓ Vial, or Ampule (not to exceed 1 liter or 10,000 pills); or
- ✓ A unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device)

Is considered empty and the residues are not regulated as HW

When: The pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

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New RCRA Empty for HW Pharmaceutical Containers

40 CFR 266.507(b)

✓ A syringe

Is considered empty and the residues are not regulated as HW

When: the contents have been removed by fully depressing the plunger of the syringe

If a syringe is not empty:

- The syringe must be placed with its remaining HW pharmaceuticals into a container
  - That is managed & disposed of as a non-creditable HW pharmaceutical
  - Meets any applicable requirements for sharps containers & medical waste

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New RCRA Empty for HW Pharmaceutical Containers

40 CFR 266.507(c)

- ✓ Intravenous (IV) bags

Are considered empty and the residues are not regulated as HW

When: the pharmaceuticals in the IV bag have been fully administered to a patient

If an IV bag is not empty:

- The IV bag must be placed with its remaining HW pharmaceuticals into a container that is managed and disposed of as a non-creditable HW pharmaceutical
  - Unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in 40 CFR 261.7(b)(1).

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New RCRA Empty for HW Pharmaceutical Containers
40 CFR 266.507(d)

✓ Other containers, including delivery devices

- HW pharmaceuticals remaining in **all other types of unused, partially administered, or fully administered containers** must be managed as non-creditable HW pharmaceuticals
- Unless the container held non-acute HW pharmaceuticals & is empty as defined in 40 CFR 261.7(b)(1) or (2).
  - This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

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Standards for Healthcare Facilities Managing ***Non-creditable and Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Categories for Hazardous Waste Pharmaceuticals in Subpart P

- Potentially Creditable HW Pharmaceuticals
  - Unused or un-administered; and
  - Unexpired or less than one year past expiration date

- Non-creditable HW Pharmaceuticals
  - Hazardous waste pharmaceutical that is not expected to be eligible for manufacturer's credit

- Evaluated HW Pharmaceuticals
  - No further evaluation or verification of manufacturer credit is necessary

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Non-creditable Hazardous Waste Pharmaceuticals
40 CFR 266.500

Non-creditable Hazardous Waste Pharmaceuticals means:

- Prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or
- Nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately use/reuse or reclaimed.
- This includes, but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

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Non-creditable Hazardous Waste Pharmaceuticals Examples

- Broken or leaking
- Repackaged
- Dispensed
- Expired greater than one year
- Investigational new drugs
- Contaminated PPE
- Floor sweepings
- Clean-up material

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Potentially Creditable Hazardous Waste Pharmaceuticals
40 CFR 266.500

Potentially Creditable Hazardous Waste Pharmaceuticals means:

- Prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is
  - In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
  - Undispensed; and
  - Unexpired or less than one year past expiration date.
- The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to over-the-counter drugs, homeopathic drugs, and dietary supplements.
- More information on slide 108

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Potentially Creditable Hazardous Waste Pharmaceuticals
Briefly Summarized

- Original manufacturer packaging (except recalls)
- Undispensed
- Unexpired or less than 1-year past expiration
- More information on slide 148

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Evaluated Hazardous Waste Pharmaceuticals
40 CFR 266.500

Evaluated Hazardous Waste Pharmaceuticals means:

- A prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with 40 CFR 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.
    - At the reverse distributor manufacturer's credit will be determined/verified
    - Then the evaluated hazardous waste pharmaceuticals are transported from the reverse distributor to a permitted hazardous waste treatment, storage and disposal facility

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3 Types of HW Pharmaceuticals

1st Reverse Distributor

Healthcare Facility

2. Potentially Creditable

3. Evaluated

2. Potentially Creditable

1. Non-Creditable

2nd Reverse Distributor

3. Evaluated

No further evaluation or verification of manufacturer credit is necessary

HW TSDF

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Overview and Comparison of Standards for Management of Hazardous Waste Pharmaceuticals at Healthcare Facilities

HEALTHCARE FACILITY STANDARDS

	Non-creditable HW Pharms	Potentially Creditable HW Pharms
Labeling	✓	None
Container Standards	✓	None
Maximum Accumulation Time	✓	None
Hazardous waste determinations*	✓	✓
Over-managing non-hazardous pharmaceuticals & commingling with hazardous waste pharmaceuticals	Allowed	Allowed
Include hazardous waste pharmaceuticals on BR	No	No

*Not required for either type if managing all pharmaceutical waste as hazardous

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Overview and Comparison of Standards for Shipping Hazardous Waste Pharmaceuticals from Healthcare Facilities

- Non-Creditable Hazardous Waste Pharmaceuticals
  - Manifest and hazardous waste transporter are required
  - When shipped by a healthcare facility, use "PHARMS" on manifest instead of hazardous waste codes
  - When shipped by a reverse distributor, use hazardous waste codes on manifest
  - Must be sent to permitted hazardous waste treatment, storage, and disposal facility
- Potentially Creditable Hazardous Waste Pharmaceuticals
  - Manifest and hazardous waste transporter are NOT required
  - Common carrier (e.g., UPS, USPS, FedEx) is acceptable
  - Shipper must receive delivery confirmation from reverse distributor
    - Electronic tracking systems will typically be sufficient

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Brief Summary of Non-Creditable Hazardous Waste Pharmaceutical Management Requirements

- Facilities must notify (electronically submitting an EPA 8700-12 in RCRAInfo) they are managing waste under Subpart P or withdrawing
  - LQGs may notify with next biennial report after being subject to Subpart P
  - SQGs must notify within 60 days of becoming subject to Subpart P
- Waste determination: must determine whether that pharmaceutical is a HW pharmaceutical
  - May choose to manage its non-HW pharmaceuticals as non-creditable HW pharmaceuticals.
- Training: thoroughly familiar with proper waste handling and emergency procedures

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Brief Summary of Non-Creditable Hazardous Waste Pharmaceutical Management Requirements

- Container standards:
  - Structurally sound, compatible with contents, no spills or leaks
  - Closed and secured to prevent unauthorized access to contents
  - Label: “Hazardous Waste Pharmaceuticals”

- Maximum accumulation time: 1 year
  - Marking/labeling the container with the date
  - Maintaining an inventory system that identifies the date
  - Placing in a specific area and identifying the earliest date

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Brief Summary of Non-Creditable Hazardous Waste Pharmaceutical Management Requirements

- Tracking of shipments through manifest maintained for 3 years
- Land disposal restrictions apply
- Meet DOT packing and shipping requirements

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Notification – 40 CFR 266.502(a)

- Healthcare facilities must notify the Hazardous Waste Section (electronically using RCRAInfo) they are managing hazardous waste pharmaceuticals under Subpart P
  - LQGs may notify with next biennial report after being subject to Subpart P
  - Any site that is not required to file a biennial report (SQG/VSQG) must notify within 60 days of becoming subject to Subpart P
- A VSQG (when counting total hazardous waste) must have an EPA ID number and notify of opting into Subpart P
- A healthcare facility that operated under Subpart P must notify the site is no longer subject to Subpart P because it is a VSQG under 40 CFR 262.14 and electing to not operate under Subpart P

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Notification – 40 CFR 266.502(a)

- Copy of the notification of operating under Subpart P must be kept on file at the site for as long as the healthcare facility is subject to Subpart P
- Copy of the notification for withdrawal from Subpart P must be kept on file at the site for three years

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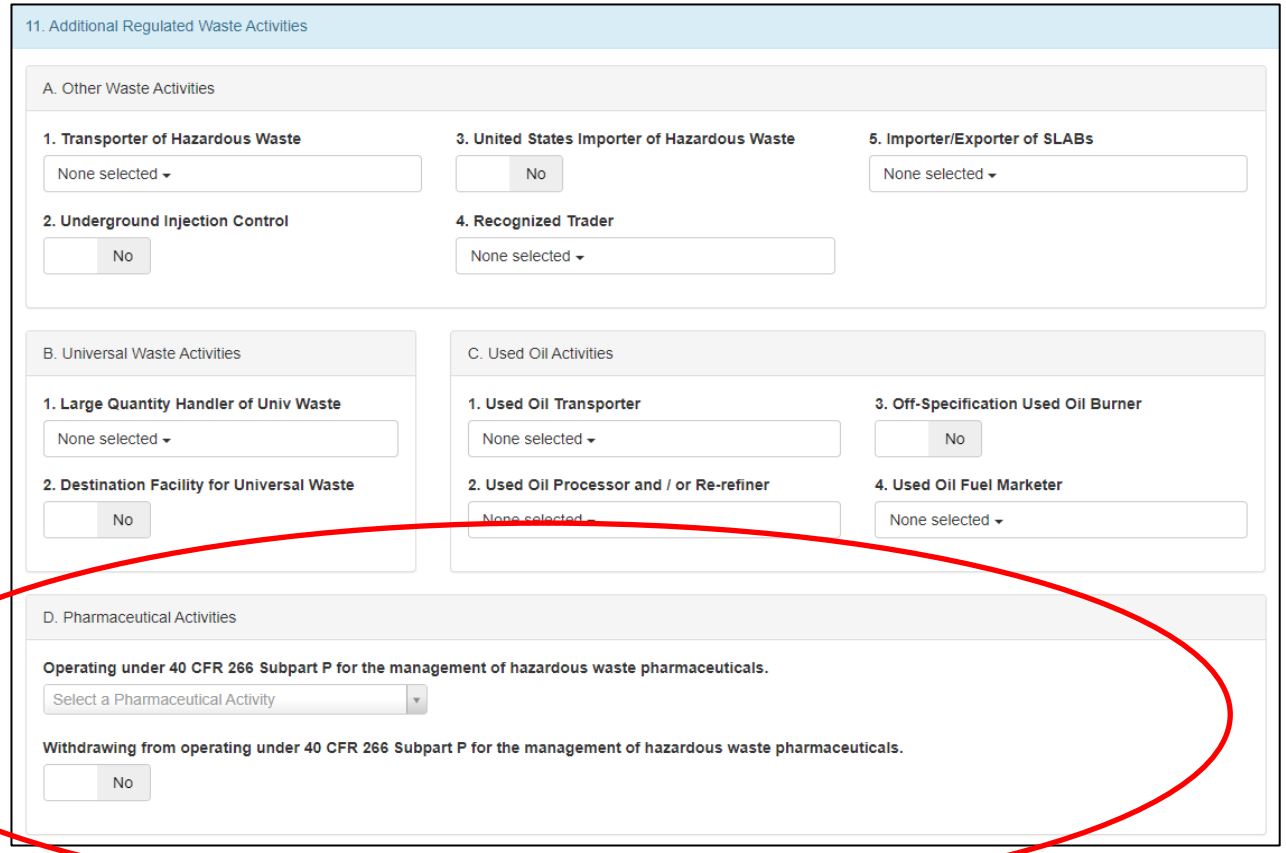
Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Notification – 40 CFR 266.502(a)
(continued)

- See the guidance document for Notification under Subpart P at this link:
  - https://deq.nc.gov/about/divisions/waste-management/hw/technical-assistance-education-guidance/documents
  - Click on the "Hazardous Waste Pharmaceutical" category



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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Training – 40 CFR 266.502(b)

- A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies

- Training is similar to the hazardous waste small quantity generator training requirements

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Waste Determination – 40 CFR 266.502(c)

- A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical
  - It exhibits one or more characteristic identified in 40 CFR 261 Subpart C and/or
  - It is listed in 40 CFR 261 Subpart D
- A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under Subpart P

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Container Standards – 40 CFR 266.502(d)(1)

- A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is:
  - Structurally sound,
  - Compatible with its contents, and
  - Lacks evidence of leakage, spillage, or damage that could cause leakage, under reasonably foreseeable conditions

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Container Standards – 40 CFR 266.502(d)(2)

- A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so it does not have the potential to:
  - Generate extreme heat or pressure, fire or explosion, or violent reaction;
  - Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;
  - Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;
  - Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or
  - Through other like means threaten human health/environment.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Container Standards – 40 CFR 266.502(d)(3)

- A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Container Standards – 40 CFR 266.502(d)(4)

- A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container.
- **EXCEPT** that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of dilution prohibition of 40 CFR 268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste codes.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Labeling – 40 CFR 266.502(e)

- A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase:

"Hazardous Waste Pharmaceuticals"

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Maximum Accumulation Time – 40 CFR 266.502(f)(1)

- A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.
  - Maximum accumulation time: 1 year

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Maximum Accumulation Time – 40 CFR 266.502(f)(2)

- A healthcare facility must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating (starting from the date it first becomes a waste).

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Maximum Accumulation Time – 40 CFR 266.502(f)(2)

- The healthcare facility may make this demonstration by any of the following methods:
  - Marking/labeling the container with the date the non-creditable hazardous waste pharmaceuticals became a waste;
  - Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;
  - Placing non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any in that area became a waste.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Land Disposal Restrictions – 40 CFR 266.502(g)

- The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR 268.
- A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with 40 CFR 268.7(a) requirements except that it is not required to identify the hazardous waste codes on the land disposal restriction notification.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Managing Rejected Shipments – 40 CFR 266.502(h)

- A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later received that shipment back as a rejected load in accordance with the manifest discrepancy provisions of 40 CFR 264.72 or 265.72 may accumulate the returned waste on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with 40 CFR 266.502(d) [Container Standards] and 266.502(e) [Labeling].

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Managing Rejected Shipments – 40 CFR 266.502(h)

Upon receipt of the returned shipment, the healthcare facility must

- Sign either:
  - Item 18c of the original manifest, if the original manifest was used for the returned shipment; or
  - Item 20 of the new manifest, if a new manifest was used for the returned shipment
- Provide the transporter a copy of the manifest
- Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility
- Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standard of 40 CFR 266.508(a)

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Reporting Requirements: Biennial Reports – 40 CFR 266.502(i)(1)

- Healthcare facilities are <u>not</u> subject to the biennial reporting requirements of 40 CFR 262.41, with respect to non-creditable hazardous waste pharmaceuticals.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Reporting Requirements: Exception Reports – 40 CFR 266.502(i)(2)(i)

- If a healthcare facility does not receive a copy of the manifest with the signature of the owner/operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit and exception report (see next slide).

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Reporting Requirements: Exception Reports – 40 CFR 266.502(i)(2)(i)

The exception report (for shipments from healthcare facility to the designated facility) are sent to the Hazardous Waste Section and consists of:

- A legible copy of the original manifest, indicating the healthcare facility has not received confirmation of delivery
- A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Reporting Requirements: Exception Reports– 40 CFR 266.502(i)(2)(ii)

- If a healthcare facility does not receive a copy of the manifest for a rejected shipment of non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner/operator of the altname facility, within 60 days of the date the waste was accepted by the initial transporter forwarding the shipment from the designated facility to the alternate facility, the healthcare facility must file an exception report (see next slide).

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Reporting Requirements: Exception Reports– 40 CFR 266.502(i)(2)(ii)

The exception report (for shipments from the designated facility to an alternate facility) are sent to the Hazardous Waste Section and consists of:

- A legible copy of the original manifest, indicating the healthcare facility has not received confirmation of delivery
- A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Reporting Requirements: Additional Reports– 40 CFR 266.502(i)(3)

- The Hazardous Waste Section may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

Currently, the Hazardous Waste Section does not have any additional reporting requirements as described in this provision.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Recordkeeping Requirements: Manifests – 40 CFR 266.502(j)(1)

- A healthcare facility must keep a copy of each manifest signed in accordance with 40 CFR 262.23(a) [manifest signed by the generator and transporter] for three years or until it receives a signed copy form the designated facility which received the non-creditable hazardous waste pharmaceuticals.
- The signed copy from the designated facility must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Recordkeeping Requirements: Exception Reports – 40 CFR 266.502(j)(2)

- A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Recordkeeping Requirements: Exception Reports – 40 CFR 266.502(j)(3)

- A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s(consistent with 40 CFR 262.11(f), for at least three years from the date the waste was last sent to on-site or off-site treatment, storage, or disposal.
- The healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Recordkeeping Requirements

- Records Retention – 40 CFR 266.502(j)(4)
  - The periods of retention referred to in 40 CFR 266.502 are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Hazardous Waste Section.

- Records Availability – 40 CFR 266.502(j)(5)
  - All records must be readily available upon request by an inspector

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Response to Spills of Non-creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities - 40 CFR 266.502(k)

- A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with 40 CFR 266.502.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Accepting Non-creditable Hazardous Waste Pharmaceuticals from Off-site - 40 CFR 266.502(l)

- A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator (VSQG) under 40 CFR 262.14 without a hazardous waste permit (or interim status) provided the receiving healthcare facility specific conditions are met (see next slides).

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Accepting Non-creditable Hazardous Waste Pharmaceuticals from Off-site - 40 CFR 266.502(l)

The receiving healthcare facility:

- Must be under the control of the same person as the VSQG healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site or
  - "*Control*" for the purposes of 40 CFR 266.502, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on the behalf of a different person (as defined in NCGS 130A-290(22)) shall not be deemed to "control" such healthcare facilities.
  - "*Person*" (as defined in NCGS 130A-290(22) in lieu of 40 CFR 260.10) means an individual, corporation, company, association, partnership, unit of local government, State agency, federal agency or other legal entity.
- Have a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Accepting Non-creditable Hazardous Waste Pharmaceuticals from Off-site - 40 CFR 266.502(l)

The receiving healthcare facility also:

- Is operating under 40 CFR 266 Subpart P for the management of its non-creditable hazardous waste pharmaceuticals.
- Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with 40 CFR 266 Subpart P.
- Keeps records of the non-creditable hazardous waste pharmaceutical shipments it receives from off site for three years from the date that the shipment is received.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Shipments - 40 CFR 266.508(a)

A healthcare facility must ship non-creditable hazardous waste pharmaceuticals off site to a designated facility (such as a permitted or interim status hazardous waste treatment, storage, and disposal facility) in compliance with specific pre-transport requirements, before transporting or offering for transport off-site:

- **Packaging** – Package the waste in accordance with the appliable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR parts 173, 178 and 180.

- **Labeling** – Label each package in accordance with DOT regulations on hazardous materials under 49 CFR part 172 subpart D.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Shipments - 40 CFR 266.508(a) (*continued*)

- **Marking**
  - Mark each package of hazardous waste pharmaceuticals in accordance with the applicable DOT regulations on hazardous materials under 49 CFR part 172 subpart D;
  - Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

    "HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

    Healthcare Facility's Name and Address: _____

    Healthcare Facility's EPA Identification Number: _____

    Manifest Tracking Number: _____"

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Shipments - 40 CFR 266.508(a) (*continued*)

- **Marking (continued)**
  - Lab packs that will be incinerated in compliance with 40 CFR 268.42(c) are not required to be marked with EPA hazardous waste codes, except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA hazardous waste codes.

- **Placarding -** Placard or offer the initial transporter the appropriate placards according to DOT regulations for hazardous materials under 49 CFR part 172 subpart F.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Shipments - 40 CFR 266.508(a) (continued)

A healthcare facility must ship non-creditable hazardous waste pharmaceuticals off site to a designated facility (such as a permitted or interim status hazardous waste treatment, storage, and disposal facility) in compliance with the manifest requirements of 40 CFR part 262 Subpart B, except that:

- A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste codes) in Item 13 of EPA Form 8700-22 [manifest].
- A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word “PHARMS” in Item 13 of EPA Form 8700-22 [manifest].

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Exporting and Importing Non-Creditable Hazardous Waste Pharmaceuticals

- Exporting - 40 CFR 266.508(b)
  - A healthcare facility that exports non-creditable hazardous waste pharmaceuticals is subject to 40 CFR 262 Subpart H.
- Importing - 40 CFR 266.508(c)
  - Any person that imports non-creditable hazardous waste pharmaceuticals is subject to 40 CFR 262 Subpart H.
  - A healthcare facility may not accept imported non-creditable hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off-site.

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Standards for Healthcare Facilities Managing ***Non-creditable*** *Hazardous Waste Pharmaceuticals*

Remember that with non-creditable hazardous waste pharmaceuticals there are:

- No hazardous waste generator categories
- No satellite or central accumulation areas
- No need to segregate acute and non-acute hazardous waste

Non-creditable hazardous waste pharmaceuticals are not universal waste, but they are managed more similarly to the requirements for universal waste than those for hazardous waste.

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Brief Summary of Potentially Creditable Hazardous Waste Pharmaceutical Management Requirements

- Waste determination: must determine whether potentially creditable pharmaceutical is a HW pharmaceutical
  - May choose to manage potentially creditable non-HW pharmaceuticals as potentially creditable HW pharmaceuticals.
- Send to a pharmaceutical reverse distributor
- Tracking records must be kept 3 years
  - Must receive a confirmation of delivery
- Meet DOT packing and shipping requirements

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*Standards for Healthcare Facilities Managing **Potentially Creditable** Hazardous Waste Pharmaceuticals*

Waste Determination – 40 CFR 266.503(a)

- A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether that pharmaceutical is a potentially creditable hazardous waste pharmaceutical.
  - It exhibits one or more characteristic identified in 40 CFR 261 Subpart C and/or
  - It is listed in 40 CFR 261 Subpart D
- A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under Subpart P.

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*Standards for Healthcare Facilities Managing **Non-creditable** Hazardous Waste Pharmaceuticals*

Accepting Potentially Creditable Hazardous Waste Pharmaceuticals from Off-site - 40 CFR 266.503(b)

- A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator (VSQG) under 40 CFR 262.14 without a hazardous waste permit (or interim status) provided the receiving healthcare facility specific conditions are met (see next slides).

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Accepting Potentially Creditable Hazardous Waste Pharmaceuticals from Off-site - 40 CFR 266.503(b)

The receiving healthcare facility:

- Must be under the control of the same person as the VSQG healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off-site or
  - "*Control*" for the purposes of 40 CFR 266.502, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on the behalf of a different person (as defined in NCGS 130A-290(22)) shall not be deemed to "control" such healthcare facilities.
  - "*Person*" (as defined in NCGS 130A-290(22) in lieu of 40 CFR 260.10) means an individual, corporation, company, association, partnership, unit of local government, State agency, federal agency or other legal entity.
- Have a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG healthcare facility.

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*Standards for Healthcare Facilities Managing **Potentially Creditable** Hazardous Waste Pharmaceuticals*

Accepting Potentially Creditable Hazardous Waste Pharmaceuticals from Off-site - 40 CFR 266.503(b)

The receiving healthcare facility also:

- Is operating under 40 CFR 266 Subpart P for the management of its potentially creditable hazardous waste pharmaceuticals.
- Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with 40 CFR 266 Subpart P.
- Keeps records of the potentially creditable hazardous waste pharmaceutical shipments it receives from off site for three years from the date that the shipment is received.

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Prohibition – 40 CFR 266.503(c)

- Healthcare facilities are prohibited from sending hazardous waste other than potentially creditable hazardous waste to a reverse distributor

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Biennial Reporting – 40 CFR 266.503(d)

- Healthcare facilities are not subject to biennial reporting requirements under 40 CFR 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under Subpart P.

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Recordkeeping – 40 CFR 266.503(e)(1)

- A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment for three years from the date of shipment:

  - The confirmation of deliver; and

  - The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

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*Standards for Healthcare Facilities Managing **Potentially Creditable** Hazardous Waste Pharmaceuticals*

Recordkeeping Requirements

- Records Retention – 40 CFR 266.503(e)(2)
  - The periods of retention referred to in 40 CFR 266.503 are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the Hazardous Waste Section.

- Records Availability – 40 CFR 266.503(e)(3)
  - All records must be readily available upon request by an inspector

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Response to Spills of Potentially Creditable Hazardous Waste Pharmaceuticals at Healthcare Facilities - 40 CFR 266.503(f)

- A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with 40 CFR 266.502.

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

Shipments - 40 CFR 266.509(a)

- A healthcare facility who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off site to a reverse distributor must comply with all applicable DOT regulations in 40 CFR 171 through 180 for any potentially creditable hazardous waste pharmaceuticals that meet the definition of hazardous materials in 49 CFR 171.8

- A potentially creditable hazardous waste pharmaceutical does not require a hazardous waste manifest (and therefore is not considered a hazardous waste under DOT regulations).

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Standards for Healthcare Facilities Managing ***Potentially Creditable*** *Hazardous Waste Pharmaceuticals*

- Delivery Confirmation - 40 CFR 266.509(b)
  - Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility that initiated the shipment that the shipment arrived at its destination and is under the custody and control of the reverse distributor.

- Procedure when delivery confirmation is not received within 35 days - 40 CFR 266.509(c)
  - If a healthcare facility initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a revers distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility must contact the carrier and the reverse distributor promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

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*Standards for Healthcare Facilities Managing **Potentially Creditable** Hazardous Waste Pharmaceuticals*

Exporting and Importing Potentially Creditable Hazardous Waste Pharmaceuticals

- Exporting - 40 CFR 266.509(d)
  - A healthcare facility that exports non-creditable hazardous waste pharmaceuticals is subject to 40 CFR 262 Subpart H.
- Importing - 40 CFR 266.509(e)
  - Any person that imports non-creditable hazardous waste pharmaceuticals is subject to 40 CFR 262 Subpart H.
  - A healthcare facility may not accept imported non-creditable hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off-site.

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Questions

Questions about Hazardous Waste Pharmaceuticals?

Question: Who do I contact if I have questions about the management standards for hazardous waste pharmaceuticals?

Answer: Contact your local Hazardous Waste Section Inspector. Click on this link for a map showing the Inspector region and contact information:

https://files.nc.gov/ncdeq/Waste+Management/DWM/HW/Compliance/Compliance_Map_by_Inspector.pdf

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