Hazardous Waste Pharmaceuticals & Amendment to the Nicotine (P075) Listing – Reverse Distributors

Delaware Department of Natural Resources and Environmental Control
Division of Waste and Hazardous Substances
Compliance and Permitting Section
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DELAWARE DEPARTMENT OF
NATURAL RESOURCES AND
ENVIRONMENTAL CONTROL

Background

- Historically, hazardous waste pharmaceuticals were fully regulated as hazardous wastes and required healthcare facilities to send all hazardous waste pharmaceuticals to a permitted hazardous waste treatment, storage, or disposal facility
- Hazardous waste regulations were difficult to apply to the healthcare industry
- EPA and Delaware had previously allowed unwanted pharmaceuticals to be sent for reverse distribution with the presumption the pharmaceuticals would be used, reused, or reclaimed and the reverse distributor was not acting as a waste management service

Background

- EPA determined that in almost all cases, hazardous waste pharmaceuticals were being disposed by the reverse distributor (i.e., there was no use or reuse). As such, the hazardous waste pharmaceuticals were a waste at the individual healthcare facility because there was no legitimate expectation they would be used or reused by the reverse distributor

- Because of this, EPA and state inspectors identified numerous potential violations at healthcare facilities

- Key take-away: Healthcare facilities have always been subject to hazardous waste regulation. This rule is simply tailoring regulations to the healthcare industry.

Acronyms

- RCRA – Resource Conservation and Recovery Act
- EPA – Environmental Protection Agency
- DEA – Drug Enforcement Agency
- FDA – Food and Drug Administration
- LQG – Large Quantity Generator
- SQG – Small Quantity Generator
- VSQG – Very Small Quantity Generator
- TSD – Treatment, Storage, or Disposal
- OTC – Over-the-Counter
- NRT – Nicotine Replacement Therapy
- POTW – Publicly Owned Treatment Works (wastewater treatment plant)

Goals of the Final Rule

- Provide regulations that are tailored to the healthcare industry
- Eliminate intentional sewering of hazardous waste pharmaceuticals
- Eliminate dual regulation of hazardous waste pharmaceuticals by EPA/DEA/FDA and associated state agencies
- Clarify how RCRA applies to reverse logistics and reverse distribution
- Re-evaluate the regulation of nicotine replacement therapies

Reverse Distribution vs. Reverse Logistics

- EPA addressed the final part of its Retail Strategy in the Pharmaceutical Rule

- Preamble language specifically provides guidance on reverse logistics
  - Differentiates reverse distribution and reverse logistics
  - Guidance on reverse logistics applies to all retail goods, not just pharmaceuticals

Reverse Distribution vs. Reverse Logistics

Reverse Distribution	Reverse Logistics
Prescription pharmaceuticals	Non-prescription pharmaceuticals • e.g., over-the-counter pharmaceuticals and dietary supplements All other unsold retail items
No redistribution occurs	Redistribution occurs via: • Donation • Liquidation (secondary market)
Items are solid waste at the healthcare facility	Items are not a solid waste IF there is a reasonable expectation of legitimate use/reuse or reclamation
Addressed in Part 266, Subpart P	Newly codified in Part 266, Subpart P, but affirms EPA's existing policy

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)
- Any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (*e.g.*, pre-filled cartridges or vials).




Definitions: Pharmaceutical

Includes, but is not limited to:

- Dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act
- Prescription drugs, as defined by 21 CFR 203.3(y)
- Over-the-counter drugs
- Homeopathic drugs
- Compounded drugs
- Investigational new drugs
- Pharmaceuticals remaining in non-empty containers

Definitions: Pharmaceutical

Includes, but is not limited to:

- Personal protective equipment contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals
- Electronic nicotine delivery systems (e.g., e-cigarettes, vaping pens)
- Nicotine e-liquid/e-juice packaged for retail sale in use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials)

Definitions: Pharmaceutical

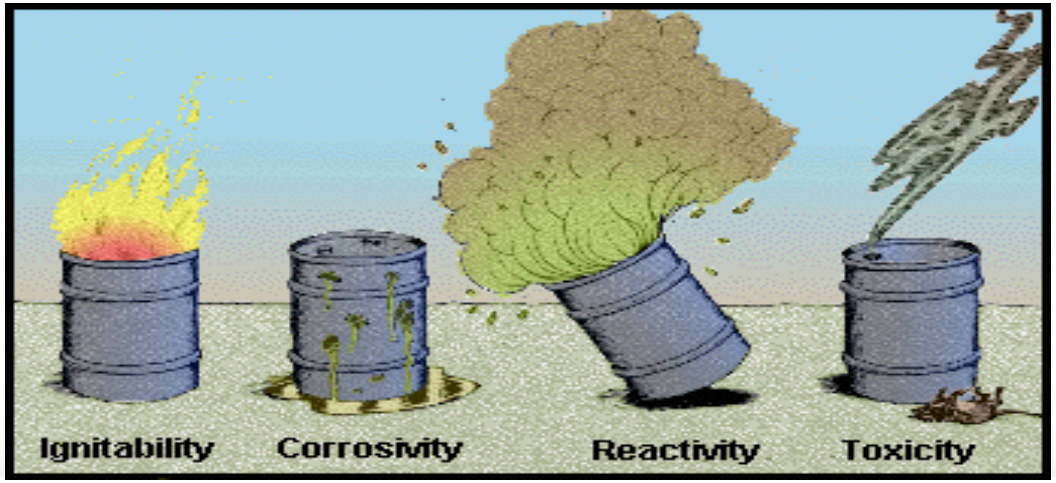
Does NOT include:

- Dental amalgam
- Sharps
- Infectious waste

Definitions: Hazardous Waste Pharmaceutical

A pharmaceutical that is a solid waste AND

- Exhibits one of more characteristics of hazardous waste OR
- Is a listed hazardous waste



Definitions: Hazardous Waste Pharmaceutical

A pharmaceutical is NOT a solid waste (and therefore not a hazardous waste pharmaceutical) if it is legitimately used, reused, or reclaimed.

Definitions: Hazardous Waste Pharmaceutical

Three types of hazardous waste pharmaceuticals

- Potentially-creditable
- Non-creditable
- Evaluated

Definitions: Potentially-Creditable Hazardous Waste Pharmaceutical

A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is:

- (1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
- (2) Undispensed; and
- (3) Unexpired or less than one year past expiration date.

Definitions: Potentially-Creditable Hazardous Waste Pharmaceutical

Does not include:

- Evaluated hazardous waste pharmaceuticals
- Nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Definitions: Non-Creditable Hazardous Waste Pharmaceutical

- A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit

OR

- A nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed.

Definitions: Non-Creditable Hazardous Waste Pharmaceutical

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
- Clean-up material from the spills of pharmaceuticals.

Definitions: Evaluated Hazardous Waste Pharmaceutical

A prescription hazardous waste pharmaceutical that:

- Has been evaluated by a reverse distributor in accordance with Part 266, Subpart P

AND

- Will not be sent to another reverse distributor for further evaluation or verification of manufacturer credit

Summary: Hazardous Waste Pharmaceutical

Potentially-Creditable	Non-Creditable	Evaluated
Prescription pharmaceutical with reasonable expectation of manufacturer credit • In original packaging • Undispensed • Unexpired or less than 1 year after expiration date	• Prescription pharmaceutical without a reasonable expectation of manufacturer credit • Nonprescription pharmaceutical without a reasonable expectation to be legitimately used/reused or reclaimed	• Prescription pharmaceutical that has been evaluated for manufacturer credit and does not need further evaluation

Definitions: Non-Hazardous Waste Pharmaceutical

A pharmaceutical that is a solid waste, but does NOT

- Exhibit one of more characteristics of hazardous waste and
- Is not a listed hazardous waste

Definitions: Non-Pharmaceutical Hazardous Waste

A hazardous waste that is listed or characteristic but does not meet the definition of a pharmaceutical.

Definitions: Reverse Distributor

- 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

What Does This Rule Do?

- Adds regulations specific to the management of hazardous waste pharmaceuticals (Part 266, Subpart P)
- Prohibits the disposal of hazardous waste pharmaceuticals down the drain (sewering ban)
- Eliminates dual regulation of hazardous waste pharmaceutical by EPA and DEA
- Maintains the household hazardous waste exemption for pharmaceuticals collected during take-back events, but ensures proper disposal
- Codifies EPA's policy on non-prescription pharmaceuticals going through reverse logistics
- Excludes certain FDA-approved over-the-counter nicotine replacement therapies (OTC NRTs) from hazardous waste regulation

Who is Subject to the Rule?

Healthcare facilities that generate hazardous waste pharmaceuticals

Facilities that generate waste OTC NRTs carrying the P075 waste code

Reverse Distributors

Who is Subject to the Rule

- This presentation focuses only on Reverse Distributors. A separate PowerPoint presentation and recorded training are available discussing healthcare facilities.

Reverse Distributors

§266.510

- Typically facilities receiving hazardous waste are required to have a treatment, storage, or disposal (TSD) permit
- When a hazardous waste TSD permit is required:
  - When the conditions of Subpart P are not met
  - When manifested hazardous waste from off-site is accepted
  - When hazardous waste pharmaceuticals are treated and disposed on site
- If conditions of Subpart P are met, reverse distributors can receive potentially-creditable hazardous waste pharmaceuticals from off-site without a permit

Reverse Distributors
§266.510

- Standards for reverse distributors are similar to LQGs, with some additions:
  - One-time notification
  - Inventory of hazardous waste pharmaceuticals
  - Security requirements

Reverse Distributors

§266.510

Healthcare Facility

- Maximum transfers allowed between reverse distributors
- Each reverse distributor has 30 days to evaluate pharmaceutical
- 180 days of accumulation allowed after each evaluation at each reverse distributor

1st Reverse Distributor
(can be a manufacturer)

2nd Reverse Distributor
(can be a manufacturer)

3rd Reverse Distributor
(must be a manufacturer)

HW TSD

Reverse Distributors

§266.510

Healthcare Facility

- Provided manufacturer credit is still being determined/verified and pharmaceuticals are destined for a reverse distributor, they are still considered **potentially-creditable hazardous waste pharmaceuticals**

1st Reverse Distributor
(can be a manufacturer)

2nd Reverse Distributor
(can be a manufacturer)

3rd Reverse Distributor
(must be a manufacturer)

HW TSD

Reverse Distributors

§266.510

Healthcare Facility

- Once manufacturer credit has been determined/verified and pharmaceuticals are destined for a hazardous waste TSD, they are considered **evaluated hazardous waste pharmaceuticals**

1st Reverse Distributor
(can be a manufacturer)

2nd Reverse Distributor
(can be a manufacturer)

3rd Reverse Distributor
(must be a manufacturer)

HW TSD

Reverse Distributors
§266.510

- Notification
  - Reverse distributors must notify the Department of its Subpart P activities within 60 days of the effective date of the rule or within 60 days of becoming subject to Subpart P
- Inventory
  - Reverse distributors must maintain an inventory of all hazardous waste pharmaceuticals accumulated on site.
  - Each received pharmaceutical must be inventoried within 30 days of arrival
  - Inventory must include identify and quantity of each hazardous waste pharmaceutical

Reverse Distributors
§266.510

- Evaluate
  - Reverse distributor that is NOT a manufacturer must evaluate a potentially-creditable hazardous waste pharmaceutical within 30 days to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or a hazardous waste TSD facility
    - If the hazardous waste pharmaceutical is destined for another reverse distributor, it remains a potentially-creditable hazardous waste pharmaceutical
    - Once manufacturer credit is evaluated and it is determined the hazardous waste pharmaceutical is destined to go to a TSD, it becomes an evaluated hazardous waste pharmaceutical

Reverse Distributors
§266.510

- Evaluate
  - Reverse distributor that IS a manufacturer must evaluate a potentially-creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 days
    - Cannot be sent to another reverse distributor
    - Once manufacturer credit is evaluated and it is determined the hazardous waste pharmaceutical is destined to go to a TSD, it becomes an evaluated hazardous waste pharmaceutical

Reverse Distributors
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- Accumulation Time Limits
  - Potentially-creditable and evaluated hazardous waste pharmaceuticals can be accumulated for 180 days
  - 180 days start after the potentially-creditable hazardous waste pharmaceuticals have been evaluated (e.g., determined the need to go to another reverse distributor or be disposed)
  - Aging pharmaceuticals – unexpired pharmaceuticals that are otherwise creditable, but are awaiting their expiration date (i.e., aging in a holding morgue) can be accumulated for up to 180 days after the expiration date

Reverse Distributors
§266.510

- Accumulation Time Limits

30 days evaluation + **180 days accumulation** =

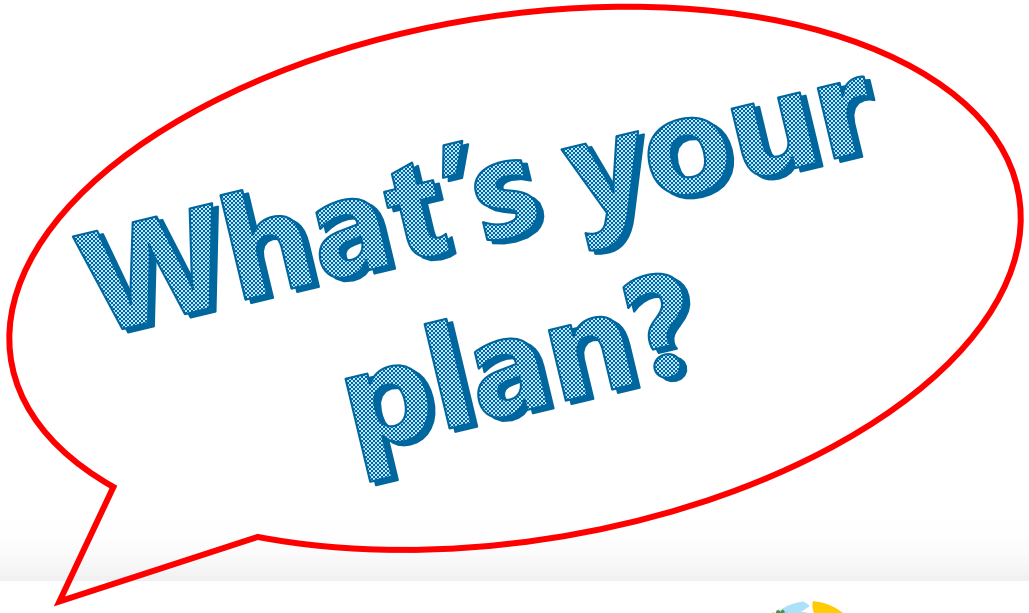
210 days total per reverse distributor

Reverse Distributors
§266.510

- Security
  - Prevent unknowing entry and minimize possibility for the unauthorized entry into the portion of the facility where hazardous waste pharmaceuticals are kept
  - Examples:
    - 24-hour continuous monitoring surveillance system
    - Artificial barrier (e.g., fence)
    - Entry controls, such as keycard access

Reverse Distributors
§266.510

- Contingency Plan and Emergency Procedures
  - Must prepare a contingency plan
  - Must comply with the same preparedness and prevention requirements applicable to LQGs (Part 262, Subpart M)



Reverse Distributors
§266.510

- Closure
  - Comply with closure standards applicable to LQGs (§262.17(a)(8)(ii) and (iii))
  - Notify DNREC 30 days prior to closure (EPA Form 8700-12)
  - Meet the closure performance standards
  - Notify DNREC within 90 days of closing the facility that the closure performance standards have been met

Reverse Distributors
§266.510

- Reporting Unauthorized Waste - §266.510(a)(9)
  - Unauthorized waste reports must be submitted to DNREC within 45 days of receipt, with a copy to the sender of the waste
    - Unauthorized waste must be managed in accordance with all applicable regulations (i.e., as fully-regulated hazardous waste if necessary)

- Recordkeeping
  - Copy of notification for as long as facility is subject to Subpart P
  - A copy of the delivery confirmation and shipping papers for each shipment of potentially-creditable hazardous waste pharmaceuticals received
  - A copy of the current inventory of hazardous waste pharmaceuticals

Reverse Distributors
§266.510

- Management of Potentially-Creditable Hazardous Waste Pharmaceuticals
  - No specific labeling or container standards
  - Not included in annual report

- Off-Site Shipments – Potentially-Creditable Hazardous Waste Pharmaceuticals
  - Ship to another reverse distributor or manufacturer within 180 days in accordance with §266.509
  - Maintain shipping records with confirmation of delivery

Reverse Distributors
§266.510

- Management of Evaluated Hazardous Waste Pharmaceuticals (§266.510(c))
  - Designate an on-site accumulation area
  - Label containers "Hazardous Waste Pharmaceuticals"
  - Ensure containers are closed, in good condition, and compatible with wastes
  - Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted (e.g., arsenic trioxide – P012) in separate containers
  - Conduct inspections at least once every 7 days
  - Provide training to personnel (same training as LQG requirements)
  - Included in annual report

Reverse Distributors
§266.510

- Off-site Shipments – Evaluated Hazardous Waste Pharmaceuticals
  - Ship off-site in accordance with §266.508(a) or (b) – on a hazardous waste manifest to a hazardous waste TSD
  - Mark all containers with hazardous waste codes (can be done through bar coding or radio frequency identification)
  - Rejected shipments managed the same as for rejected hazardous waste shipments
  - Land disposal restriction notification required

Reverse Distributors
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- Reporting – Evaluated Hazardous Waste Pharmaceuticals
  - Annual reporting (same as LQG annual report)
  - Exception report – if reverse distributor has not received a copy a signed manifest from the TSD, it must contact the TSD within 35 days and submit an exception report to DNREC within 45 days notifying the manifest has not been received.

Reverse Distributors
§266.510

- Recordkeeping – 3 years
  - Weekly inspection records (written or electronic)
  - Hazardous waste manifests
  - Exception reports
  - Personnel training records
  - All records must be readily available for a DNREC inspector. Record retention periods are automatically extended during the course of any unresolved enforcement action.

Reverse Distributors

§266.510

	Potentially-Creditable HW Pharms	Evaluated HW Pharms
Labeling	None	✓
Container Standards	None	✓
Accumulation Area	None	✓
Weekly Inspections	None	✓
Maximum Evaluation or Accumulation Time	✓	✓
Include pharmaceuticals in annual report	No	✓

Questions?

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