



# Intro to Managing Pharmaceutical Waste at Healthcare Facilities

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# Overview

- Overview of Pharmaceutical Rule
- Applicability
- Healthcare Facility Standards
- Reverse Distributor Standards

# Overview of Pharmaceutical Rule

- In 30 Texas Administrative Code (TAC) 335 Subchapter W
  - Rules became effective on February 3, 2022

## Contents:

- New Management of Pharmaceutical Waste at Healthcare Facilities
- Sewering ban
- New Nicotine Listing

# Nicotine Listing

- Removed FDA-approved over-the-counter nicotine replacement therapies from the P075 listing
- All other nicotine waste is still considered a hazardous waste if it meets the P075 listing
  - Nicotine e-liquids and e-cigarettes are P075 waste
- Not dependent on type of facility that generates waste

# Applicability

# Pharmaceutical Waste Rules Applicability

- Only applies to hazardous pharmaceutical waste generated at healthcare facilities
- Healthcare facilities calculate hazardous non-pharmaceutical and hazardous pharmaceutical waste generated per month
- If that number is above 220 pounds per month, must manage waste under Subchapter W

# Example Hospital

- Hospital A generates 100 pounds of hazardous waste reagents per month from lab processing
- Hospital A also generates 160 pounds of pharmaceutical hazardous waste per month
- Facility generates more than 220 pounds of hazardous waste per month, so they must operate under Subchapter W

# Low Generation Facility Options

If calculation shows they generate less than 220 pounds per month, the facility has three options:

1. Manage all waste under 30 TAC 335.53
2. Optional provisions
3. Choose to operate under Subchapter W



# Example Doctor's Office

- Doctor's Office generates 10 pounds of hazardous waste solvents per month from a remodeling of their office
- Doctor's Office also generated 40 pounds of hazardous waste pharmaceuticals per month
- Facility is not required to operate under Subchapter W and can decide which option they want to manage their waste

# Subchapter W Facilities

- Pharmaceutical waste must be managed under Subchapter W for facilities that generate more than 220 pounds per month
  - Once in Subchapter W, no generator status
  - Same requirements within Subchapter W no matter how much pharmaceutical waste generated per month
- Non pharmaceutical waste will be under 30 TAC 335.53
  - Will have generator status for non pharmaceutical waste

# Pharmaceutical Waste

- Pharmaceutical definition includes:
  - Dietary supplements
  - Prescription drugs
  - Over-the-counter drugs
  - Electronic nicotine delivery system and liquid nicotine
  - Compounded drugs
- Pharmaceutical does not include:
  - Sharps
  - Dental amalgam

# Healthcare Facility Definition

- Healthcare facility includes:
  - Hospitals, clinics, physicians' offices
  - Optical and dental providers
  - Pharmacies
  - Veterinary clinics
- Does not include:
  - Pharmaceutical manufacturers
  - Assisted living or independent living communities

# Types of Hazardous Waste Pharmaceuticals

- Non-creditable hazardous waste pharmaceutical
- Potentially creditable hazardous waste pharmaceutical
- Evaluated hazardous waste pharmaceutical

# Non-Creditable Pharmaceutical Waste

- Sent from healthcare facility to TSDF
- Determined cannot be awarded manufacturer credit
- Examples include:
  - Broken or leaking
  - Dispensed or expired
  - Contaminated PPE

# Potentially Creditable Waste

- Sent from Healthcare Facility to Reverse Distributor
- Healthcare facility could potentially receive manufacturer credit for waste
- Original manufacturer packaging, undispensed and unexpired, or less than one year past expiration

# Evaluated Pharmaceutical Waste

- Reverse Distributor to Treatment Storage and Disposal Facility (TSDF)
- Potentially Creditable hazardous waste that has been evaluated by the reverse distributor and will be sent to a TSDF
- This happens after manufacturer's credit has been determined/verified



# Empty Containers

- Empty container definitions in Subchapter W
- Residues remaining in RCRA empty containers are not hazardous waste depending on container type
- Triple rinsing with acute hazardous waste not allowed anymore

# Types of Empty Containers

- Stock/dispensing bottles
  - Remove contents = considered empty
- Syringes
  - Fully depress plunger = considered empty
- IV Bags
  - Non-acute- fully administer contents or limited residue, then considered empty
  - Acute- fully administer contents, then considered empty
- Other containers
  - Acute waste cannot be RCRA empty

# Healthcare Facility Requirements

# Pharmaceutical Notification Requirements

- If required to register because of non pharmaceutical waste, then update TCEQ by submitting Parts D and G of TCEQ 00002
- If not required to register because of non pharmaceutical waste, then submit EPA form 8700-12

# Example Hospital Notification

- Hospital A generates 100 pounds of hazardous waste reagents per month from lab processing
- Hospital A also generates 160 pounds of pharmaceutical hazardous waste per month
- Facility generates more than 220 pounds, so they must operate under Subchapter W
- Notification: Submits 8700-12

# Healthcare Facility Container Requirements

- Non-creditable
  - Labeling: “Hazardous Waste Pharmaceuticals”
  - No hazardous waste codes or other labeling requirements
  - Accumulation time limit: 1 year
- Potentially Creditable
  - No labeling, container standards, or accumulation time

# Shipments of Pharmaceutical Waste

- Non creditable
  - Must be sent to a TSDF with a registered transporter
  - Must use a manifest
- Potentially Creditable
  - Can be sent to a reverse distributor before going to TSDF
  - Manifest and registered transporter not required
  - Shipper must receive delivery confirmation from reverse distributor

# Healthcare Facility Summary Table

Requirements	Potentially Creditable	Non-creditable
<b>On-site Accumulation</b>	No standards, no time limit	One year max on storage, labeling standards
<b>Shipping</b>	Confirmation of delivery, use a common carrier	Use a manifest and hazardous waste transporter
<b>Training</b>	No	Proper waste handling and emergency procedures
<b>Waste Determination</b>	Yes	Yes



# Accepting Waste from Low Generation Facility

- Healthcare facility can accept potentially creditable waste from a low quantity healthcare facility that is under control of the same person
  - Low generation healthcare facility must generate less than 220 pounds of hazardous waste per month
- Keeps records of shipments
- Accepting healthcare facility manages the waste under Subchapter W

# Reverse Distributor Requirements

# Reverse Distributor Overview

- Reverse distributor only accepts hazardous waste that is potentially creditable pharmaceutical
- No RCRA storage permit required
- No generator categories, all reverse distributors are regulated the same
- Notify by submitting TCEQ Form 00002

# Reverse Distributor Inventory

- Reverse distributor must inventory and evaluate potentially creditable hazardous waste within 30 days:
  - Is it destined for another reverse distributor
  - Is it destined for a TSDF
- 180-day accumulation limit at reverse distributor
  - Starts after evaluation

# Potentially Creditable Storage Requirements

- Potentially creditable hazardous waste pharmaceuticals:
  - No specific labeling or container standards
  - Not included on Biennial Report

# Evaluated Pharmaceutical Requirements

- Must designate an on-site accumulation area and conduct weekly inspections
- LQG training for personnel handling evaluated hazardous waste pharmaceuticals
- Label as “hazardous waste pharmaceuticals” during accumulation
- Label with hazardous waste codes prior to transport off-site

# Evaluated Pharmaceutical Shipping Requirements

- Use a manifest with waste codes
- Use a registered transporter

# Reverse Distributor Summary Table

Requirements	Potentially Creditable	Evaluated
<b>On-site Accumulation Time</b>	Evaluate within 30 days	Ship 180 days after evaluation
<b>Shipment</b>	Confirmation of delivery, common carrier	Manifest, use hazardous waste transporter
<b>Labeling</b>	None	Yes
<b>Container Standards</b>	None	Yes
<b>Weekly Inspections</b>	None	Yes
<b>Training</b>	No	Yes



# How to Get Help

- SBLGA:
  - Hotline: 1-800-447-2827
  - [Texasenvirohelp@tceq.texas.gov](mailto:Texasenvirohelp@tceq.texas.gov)
  - [IHW Compliance Resources webpage](#)
- Technical Questions: IHW Permits
  - [IHWPer@tceq.texas.gov](mailto:IHWPer@tceq.texas.gov)
- Registration Questions: IHW Registration and Reporting
  - [wasteval@tceq.texas.gov](mailto:wasteval@tceq.texas.gov)

# Questions?

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