HAZARDOUS WASTE PHARMACEUTICALS & AMENDMENT TO THE NICOTINE LISTING (P075) FINAL RULE

ASTSWMO MID-YEAR MEETING

MAY 1, 2019

30-Minute Introduction to Part 266 Subpart P
OUTLINE

1. Goals & Overview
2. Effective Dates & State Adoption
3. Amendment of the Nicotine Listing
4. Reverse Distribution and Reverse Logistics
5. Part 266 Subpart P Provisions
   - Definitions
   - Applicability
   - Healthcare Facility Standards
   - Shipping
   - Sewer Ban
   - DEA Controlled Substances
   - Empty Containers
   - Reverse Distributor Standards
The final rule was published in the Federal Register on February 22, 2019

84 FR 5816

FR publication date drives
- Effective dates
- State adoption deadlines
GOALS OF PHARMACEUTICALS RULE & OVERVIEW OF SUBPART P

SECTION I
GOALS OF THE PHARMACEUTICALS RULE

- Create regulations that are a better fit for the healthcare sector for the management of hazardous waste pharmaceuticals
- Eliminate the intentional sewering of hazardous waste pharmaceuticals
- Reduce overlapping regulations (e.g., DEA, FDA)
- Provide regulatory clarity and national consistency on how RCRA applies to reverse distribution and reverse logistics
- Reevaluate whether nicotine replacement therapies should be regulated as acute hazardous waste
OVERVIEW OF PART 266 SUBPART P

- Subpart P is a waste-specific and sector-specific final rule
  - for the management of hazardous waste pharmaceuticals
  - at healthcare facilities and reverse distributors
- These hazardous wastes and this sector are already regulated under RCRA
- We are not newly applying RCRA regulations to hazardous waste pharmaceuticals at healthcare facilities and reverse distributors
- We are changing HOW they are regulated under RCRA moving forward
<table>
<thead>
<tr>
<th>Healthcare facilities &amp; reverse distributors</th>
<th>Hazardous Waste Pharmaceuticals</th>
<th>Other Hazardous Wastes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Part 266 Subpart P</td>
<td></td>
<td>• Part 262 (e.g., lab waste)</td>
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<td>• Part 273 (universal waste)</td>
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<td>• Part 279 (used oil)</td>
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<td>• Etc.</td>
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<tr>
<td>Other facilities (e.g., farms/ranches, reverse logistics centers, manufacturers)</td>
<td>Part 262</td>
<td>• Part 262</td>
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<tr>
<td></td>
<td></td>
<td>• Part 273 (universal waste)</td>
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<td>• Part 279 (used oil)</td>
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<td>• Etc.</td>
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</tbody>
</table>
Part 266 Subpart P is considered more stringent, and therefore is NOT optional for:

- States to adopt
- Healthcare facilities and reverse distributors

Hazardous waste pharmaceuticals must be managed under Part 266 Subpart P by:

- All healthcare facilities that generate above VSQG amounts of hazardous waste
- All reverse distributors
EFFECTIVE DATES & STATE ADOPTION

SECTION II
All parts of the rule are effective on August 21, 2019, but only in:
- Non-authorized states (Iowa, Alaska), Indian Country, US Territories (except Guam)

Sewer prohibition (in Part 266 Subpart P)
- Effective in **ALL** states on August 21, 2019 (HWSA authority)
- Applies to **ALL** healthcare facilities and reverse distributors

The rest of Part 266 Subpart P
- Not effective in authorized states until state adopts
- More stringent - all authorized states must adopt
- Authorized states must adopt by July 1, 2021 or 2022
  - States that require a legislative session get an extra year

Nicotine Amendment (in Part 261)
- Not effective in authorized states until state adopts
- Less stringent – authorized states are not required to adopt
- No deadline to adopt
AMENDMENT OF NICOTINE LISTING

SECTION III
The P075 listing for nicotine is being amended such that FDA-approved over-the-counter nicotine replacement therapies will no longer be included under the P075 listing for hazardous waste.

- EPA has concluded that nicotine patches, gums and lozenges do not meet the regulatory criteria for acute hazardous waste.
- Nicotine patches, gums and lozenges can be discarded as non-hazardous waste.
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 in e-cigarettes, cartridges, or vials
- Prescription nicotine (e.g., nasal spray, inhaler)
- Legacy pesticides containing nicotine
- Nicotine used in research and manufacturing
REVERSE DISTRIBUTION  vs REVERSE LOGISTICS

We have adopted the terminology suggested by a significant number of commenters that distinguishes between:

- **REVERSE DISTRIBUTION** of
  - Prescription (Rx) pharmaceuticals and

- **REVERSE LOGISTICS** of
  - Nonprescription pharmaceuticals (e.g., OTCs, supplements, etc.)
  - All other unsold retail items
Commenters noted that reverse logistics centers are designed to:
- evaluate unsold retail items including nonprescription pharmaceuticals
- analyze secondary markets, and
- assess the suitability of the unsold retail items for reuse in those secondary markets

The final rule reaffirms & codifies EPA’s long standing policy that nonprescription pharmaceuticals (e.g., OTCs) that are sent through reverse logistics are not wastes at the healthcare or retail facility IF they have a *reasonable expectation* of being lawfully used/reused for their intended purpose or reclaimed.

The preamble to the final rule reaffirms the same policy for all unsold retail items (other than prescription pharmaceuticals).
Reverse Logistics Center

Reasonable Expectation of Use/Reuse or Reclamation

No Reasonable Expectation of Use/Reuse or Reclamation

Healthcare Facility

Donate  Sell  Recycle  Repair

HW  TSDF  Non-Compliant Disposal  Sewer
Commenters confirmed that reverse distributors receive shipments of unused/expired prescription pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these unused pharmaceuticals.

Prescription pharmaceuticals at RDs are not reused, nor resold, and are discarded.

The final rule maintains the position from the proposed rule that prescription pharmaceuticals moving through reverse distribution are wastes at the healthcare facility.

The fact that the hazardous waste pharmaceuticals have value in the form of manufacturer credit has allowed us to take a tailored and more flexible regulatory approach.

EPA developed a regulatory system that is designed with existing business practices in mind for unused/expired prescription pharmaceuticals that are sent through reverse distribution.
Reverse Distribution of Rx HW Pharmaceuticals

* Potentially Creditable Pharmaceuticals* - Unsold/unused pharmaceuticals that have a reasonable expectation of receiving credit from the manufacturer

+ Non-creditable Pharmaceuticals+ - Pharmaceuticals with no reasonable expectation of receiving credit from the manufacturer

1st Reverse Distributor

2nd Reverse Distributor

Healthcare Facility

HW TSDF

Non-Compliant Disposal

Sewer

* Unsold/unused pharmaceuticals that have a reasonable expectation of receiving credit from the manufacturer

+ Pharmaceuticals with no reasonable expectation of receiving credit from the manufacturer
PART 266 SUBPART P

SECTION V
PART 266 SUBPART P – NEW TERMS DEFINED

- *Pharmaceutical*

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

- *Healthcare facility*

- *Reverse distributor*
DEFINITION OF PHARMACEUTICAL

Pharmaceutical is a drug for use by humans or other animals and includes, but is not limited to:

- Dietary supplements
- Prescription drugs
- Over-the-counter drugs
- Homeopathic drugs
- Compounded drugs
- Investigational new drugs
- Pharmaceuticals remaining in non-empty containers
- PPE contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals

Pharmaceutical does NOT include:

- Dental amalgam
- Sharps
- Medical waste

- Electronic nicotine delivery systems (ENDS) e.g. e-cigarettes, vaping pens
- Nicotine e-liquid/e-juice packaged for retail sale for use in ENDS e.g. pre-filled cartridges or vials
There are 3 types of Hazardous Waste Pharmaceuticals:

1. Non-creditable hazardous waste pharmaceutical
2. Potentially creditable hazardous waste pharmaceutical
3. Evaluated hazardous waste pharmaceutical
3 Types of HWV Pharmaceuticals

1. **Non-Creditable**
   - Broken or leaking
   - Repackaged
   - Dispensed
   - Expired >1 yr
   - Investigational new drugs
   - Contaminated PPE
   - Floor sweepings
   - Clean-up material
3 Types of HWV Pharmaceuticals

1. Non-Creditable

2. Potentially Creditable
   - Original manufacturer packaging (except recalls)
   - Undispensed
   - Unexpired or less than 1-yr past expiration

1st Reverse Distributor

2nd Reverse Distributor

Healthcare Facility

HW TSDF
3 Types of HW Pharmaceuticals

1. **Non-Creditable**

2. **Potentially Creditable**

3. **Evaluated**
   - No further evaluation or verification of manufacturer credit is necessary

**1st Reverse Distributor**

**2nd Reverse Distributor**

**Healthcare Facility**

**HW TSDF**
DEFINITION OF HEALTHCARE FACILITY (CONTINUED)

Healthcare Facility includes, but is not limited to:

- Wholesale distributors
- Third-party logistics providers (3PLs) that serve as forward distributors
- Military medical logistics facilities
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physicians’ offices
- Optical and dental providers
- Chiropractors
- Long-term care facilities

Healthcare Facility does NOT include:

- Ambulance services
- Pharmacies
- Long-term care pharmacies
- Mail-order pharmacies
- Retailers of pharmaceuticals (includes vape shops)
- Veterinary clinics & hospitals

- Pharmaceutical manufacturers
- Reverse distributors
- Revers logistics centers
HEALTHCARE FACILITY MANAGEMENT STANDARDS

Non-creditable hazardous waste pharmaceuticals:

- Labeling: “Hazardous Waste Pharmaceuticals”
- Container Standards:
  - Structurally sound, will not react with contents (i.e., compatible)
  - Remain closed and secured in a manner that prevents unauthorized access to its contents
- Accumulation time: 1 year

Potentially creditable hazardous waste pharmaceuticals:

- No labeling, containers standards or accumulation time
SHIPMENTS OF HW PHARMACEUTICALS

Non-creditable & evaluated hazardous waste pharmaceuticals
- Both must be sent to a TSDF
- Both must be sent with manifest and hazardous waste transporter

Potentially creditable hazardous waste pharmaceuticals
- Can be sent to a reverse distributor before going to a TSDF
- 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

§§ 266.508 & 266.509
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
- We strongly discourage sewerering of any pharmaceuticals by any entity
- REMEMBER: The sewer prohibition will be effective in ALL states on August 21, 2019
Two new conditional exemptions for healthcare facilities and reverse distributors

1. RCRA hazardous wastes that are also DEA controlled substances
2. Household waste pharmaceuticals collected in DEA authorized collection receptacles (kiosks)

In both cases, the hazardous waste pharmaceuticals are exempt from RCRA, provided they meet the following conditions:

- Not seweried, 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
  - Large or small municipal waste combustor (MWC)
  - Hospital, medical and infectious waste incinerator (HMIWI)
  - Commercial and industrial solid waste incinerator (CISWI) or
  - Hazardous waste combustor
EMPTY CONTAINERS

- New empty container standards apply to
  - Containers with hazardous waste pharmaceuticals – acute & non-acute
  - Healthcare facilities and reverse distributors subject to Part 266 Subpart P and
  - Anyone else with containers of hazardous waste pharmaceuticals

- Residues remaining in “RCRA empty” containers are not regulated as hazardous waste

- Four different standards for different types of containers found in a healthcare setting

- Triple rinsing of containers with acute hazardous waste pharmaceuticals is not required/allowed anymore
## Empty Container Standards

<table>
<thead>
<tr>
<th>Stock/Dispensing Bottles (1 liter or 10,000 pills) &amp; Unit-dose containers</th>
<th>Non-acute HW Pharms</th>
<th>Acute HW Pharms*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Remove contents</td>
<td>Remove contents</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Syringes</th>
<th>Fully depress plunger</th>
<th>Fully depress plunger</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>IV Bags</th>
<th>Fully administer contents or § 261.7(b)(1)</th>
<th>Fully administer contents</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Other Containers</th>
<th>§ 261.7(b)(1) or (2)</th>
<th>Can not be RCRA empty</th>
</tr>
</thead>
</table>

*No triple rinsing of containers with acute hazardous waste pharmaceuticals*
A reverse distributor is a new type of hazardous waste management facility that can only accept hazardous waste that is “potentially creditable hazardous waste pharmaceuticals”

- No RCRA storage permit required
- No generator categories for reverse distributors (e.g., VSQG, SQG, LQG)
- All reverse distributors are regulated the same for hazardous waste pharmaceuticals

Standards are similar to LQGs, with some additions:

- One-time notification as a reverse distributor
- Inventory of hazardous waste pharmaceuticals
- Security requirements
REMINDERS & WRAP-UP

SECTION VI
<table>
<thead>
<tr>
<th></th>
<th>Standards for Healthcare Facilities</th>
<th>Standards for Reverse Distributors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potentially Creditable</strong></td>
<td>• No standards</td>
<td>Evaluate w/in 30 days</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• No time limit</td>
<td></td>
</tr>
<tr>
<td><strong>Non-Creditable</strong></td>
<td>• UW-like standards</td>
<td>• LQG-like standards</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• 1 year maximum</td>
<td>• 180 days after evaluation</td>
</tr>
<tr>
<td>Shipping to a reverse distributor</td>
<td>• Confirmation of delivery</td>
<td>• Confirmation of delivery</td>
</tr>
<tr>
<td></td>
<td>• Common carrier</td>
<td>• Common carrier</td>
</tr>
<tr>
<td>Shipping to a TSDF</td>
<td>• Manifest (PHARMS)</td>
<td>• Manifest (waste codes)</td>
</tr>
<tr>
<td></td>
<td>• HW transporter</td>
<td>• HW transporter</td>
</tr>
</tbody>
</table>
EFFECTIVE DATES & STATE ADOPTION TIMELINE

- Feb 22, 2019: Nicotine amendment effective in non-authorized states
- August 21, 2019: Subpart P effective in non-authorized states
- July 1, 2021: Authorized states must adopt Subpart P
- July 1, 2022: Authorized states that require a statutory amendment must adopt Subpart P

FR publication 84 FR 5816
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