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

PUBLIC WEBINARS PRESENTED BY EPA

FEBRUARY & MARCH 2019

Introduction to Part 266 Subpart P
1. Goals of the Pharmaceuticals Rule

2. Effective Dates & State Adoption

3. Amendment of the Nicotine Listing

4. Reverse Distribution and Reverse Logistics

5. Part 266 Subpart P Overview

   - Definitions
   - Applicability
   - Healthcare Facility Standards
   - VSQG Healthcare Facilities
   - Sewer Ban

   - DEA Controlled Substances
   - Empty Containers
   - Shipping
   - 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 THE PHARMACEUTICALS RULE

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
- Provide regulatory relief to healthcare facilities that are strictly regulated as large quantity generators even when generating small amounts of nicotine replacement therapies
EFFECTIVE DATES & STATE ADOPTION

SECTION II
EFFECTIVE DATE - AMENDMENT TO NICOTINE LISTING

- The effective date will be August 21, 2019
- The amendment to the nicotine listing is effective 6 months after publication in the Federal Register in:
  - Non-authorized states: Iowa, Alaska, Indian Country
  - US Territories (except Guam)
- Once effective, the amendment to the nicotine listing applies to any generator of waste OTC NRTs; it is not limited to healthcare facilities and reverse distributors
In authorized states, the amendment to the nicotine listing is effective only after the state adopts the amendment.

The amendment to the nicotine listing is considered LESS stringent, therefore:

- Authorized states are NOT required to adopt the amendment to the nicotine listing.
- Authorized states do NOT have a deadline to adopt the amendment to the nicotine listing.
The effective date will be August 21, 2019

Subpart P is effective 6 months after publication the Federal Register in:

- Non-authorized states: Iowa, Alaska,
- Indian Country
- US Territories (except Guam)
In authorized states, Subpart P is effective only after the state adopts Subpart P

Subpart P is considered MORE stringent; therefore authorized states are required to adopt it

- Promotes stakeholders’ request for national consistency

State adoption deadlines:

- Authorized states have until July 1, 2021 to adopt Subpart P
- Authorized states that require a statutory amendment, have until July 1, 2022 to adopt Subpart P
EFFECTIVE DATE – SEWER PROHIBITION

- The prohibition on sewering hazardous waste pharmaceuticals is promulgated under the authority of Hazardous and Solid Waste Amendments (HSWA)

- The sewer prohibition is effective in ALL states 6 months after publication in the Federal Register, regardless of whether the state
  - Is authorized, or
  - Has adopted Subpart P

- The effective date of the sewer prohibition will be August 21, 2019 for ALL states
EFFECTIVE DATES & STATE ADOPTION TIMELINE

- **Feb 22 2019**
  - FR publication 84 FR 5816
  - Nicotine amendment effective in non-authorized states
  - Subpart P effective in non-authorized states
  - Sewer ban effective in ALL states

- **August 21 2019**
  - •

- **July 2020**
  - •

- **July 1 2021**
  - Authorized states must adopt Subpart P

- **July 1 2022**
  - Authorized states that require a statutory amendment must adopt Subpart P
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

= P075
REVERSE DISTRIBUTION & LOGISTICS

SECTION IV
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 of Unsold Retail Items & Non-Rx Pharms

Reasonable Expectation of Use/Reuse or Reclamation

Donate
Sell
Recycle
Repair

Healthcare Facility

No Reasonable Expectation of Use/Reuse or Reclamation

HW TSDF
Non-Compliant Disposal
Sewer
# REVERSE LOGISTICS POLICY: THEN AND NOW

<table>
<thead>
<tr>
<th>THEN</th>
<th>NOW</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>May 16, 1991 memo</strong></td>
<td><strong>Pharmaceuticals Final Rule</strong></td>
</tr>
<tr>
<td>…to the extent that the materials involved are unused commercial chemical products with a <em>reasonable expectation</em> of being recycled in some way when returned, the materials are not considered as wastes…</td>
<td>Nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a <em>reasonable expectation</em> of being legitimately use/reused (e.g., lawfully redistributed for their intended purpose) of reclaimed</td>
</tr>
</tbody>
</table>

RCRA Online #11606

also see § 266.501(g)(2)
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

* 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
## REVERSE DISTRIBUTION vs REVERSE LOGISTICS

<table>
<thead>
<tr>
<th>Reverse Distribution</th>
<th>Reverse Logistics</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rx pharmaceuticals</td>
<td></td>
</tr>
<tr>
<td>No redistribution occurs</td>
<td></td>
</tr>
<tr>
<td>Rx pharmaceuticals sent to reverse distributors are solid waste at the healthcare facility</td>
<td></td>
</tr>
<tr>
<td>In Part 266 Subpart P, which is</td>
<td></td>
</tr>
<tr>
<td>• Effective in non-authorized states 6 months after publication</td>
<td></td>
</tr>
<tr>
<td>• Effective in authorized states when state adopts Subpart P</td>
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</tr>
</tbody>
</table>
## REVERSE DISTRIBUTION vs REVERSE LOGISTICS

<table>
<thead>
<tr>
<th>Reverse Distribution</th>
<th>Reverse Logistics</th>
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<tbody>
<tr>
<td>Rx pharmaceuticals</td>
<td>Non-Rx pharmaceuticals</td>
</tr>
<tr>
<td></td>
<td>• e.g., OTCs &amp; dietary supplements</td>
</tr>
<tr>
<td></td>
<td>All other unsold retail items</td>
</tr>
<tr>
<td>No redistribution occurs</td>
<td>Redistribution sometimes occurs via:</td>
</tr>
<tr>
<td></td>
<td>• Donation</td>
</tr>
<tr>
<td></td>
<td>• Liquidation (secondary market)</td>
</tr>
<tr>
<td>Rx pharmaceuticals sent to reverse distributors <strong>are solid waste</strong> at the healthcare facility</td>
<td>Non-Rx pharmaceuticals and other unsold retail items sent to reverse logistics <strong>are not solid waste</strong> IF there is a reasonable expectation of legitimate use/reuse or reclamation</td>
</tr>
<tr>
<td>In Part 266 Subpart P, which is</td>
<td>Newly codified in Part 266 Subpart P. But affirms existing policy</td>
</tr>
<tr>
<td>• Effective in non-authorized states 6 months after publication</td>
<td>• Effective immediately federally</td>
</tr>
<tr>
<td>• Effective in authorized states when state adopts Subpart P</td>
<td>• Check with your state</td>
</tr>
</tbody>
</table>
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
  - Long-term care facility
- Reverse distributor
Pharmaceutical means

- any drug or dietary supplement for use by humans or other animals
- any electronic nicotine delivery system (ENDS)
  - 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
Pharmaceutical 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
Hazardous Waste Pharmaceutical means

- A pharmaceutical that is a solid waste, as defined in § 261.2, and
  - Exhibits one or more characteristics or
  - Is listed
- A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed
- An over-the-counter pharmaceutical, dietary supplement, or homeopathic drugs is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed
TYPES OF HAZ WASTE PHARMACEUTICALS

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

Healthcare Facility

1st Reverse Distributor

2nd Reverse Distributor

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
2. Potentially Creditable

Healthcare Facility
1. Non-Creditable

2nd Reverse Distributor
3. Evaluated

3rd Reverse Distributor
3. Evaluated
DEFINITION OF HEALTHCARE FACILITY

*Healthcare Facility* means any person that is lawfully authorized to

(1) 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; or

(2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals
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
- Veterinary clinics & hospitals
- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers
§ 266.500

DEFINITION OF LONG-TERM CARE FACILITY

Long-term Care Facility means

- A licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility
DEFINITION OF LONG-TERM CARE FACILITY

Long-term Care Facility includes, but is not limited to:

- Hospice facilities
- Nursing facilities
- Skilled nursing facilities
- Nursing and skilled nursing care portions of continuing care retirement communities

Long-term Care Facility does NOT include:

- Group homes
- Independent living communities
- Assisted living facilities
- Independent and assisted living portions of continuing care retirement communities
DEFINITION OF REVERSE DISTRIBUTOR

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.
<table>
<thead>
<tr>
<th></th>
<th>Standards for Healthcare Facilities</th>
<th>Standards for Reverse Distributors</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Potentially Creditable</td>
<td>Potentially Creditable</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping to a reverse distributor</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Non-Creditable</td>
<td>Evaluated</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Shipping to a TSDF</td>
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</tr>
</tbody>
</table>
PART 266 SUBPART P APPLICABILITY

- Part 266 Subpart P is considered more stringent, and therefore is NOT optional

- Hazardous waste pharmaceuticals must be managed under Part 266 Subpart P by:
  - Healthcare facilities that generate above VSQG amounts of hazardous waste
  - All reverse distributors

- 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 and reverse distributors

- Healthcare facilities and reverse distributors are still subject to
  - Part 262 for the management of non-pharmaceutical hazardous wastes
  - Part 273 for the management of universal wastes,
  - Other Parts, as applicable
Once subject to Part 266 Subpart P

- There are NO generator categories under Part 266 Subpart P
- All healthcare facilities are regulated the same for their hazardous waste pharmaceuticals
- All reverse distributors are regulated the same for their hazardous waste pharmaceuticals
- Healthcare facilities & RDs operating under Subpart P do not have to
  - Keep track of how much hazardous waste pharmaceuticals they generate per month
  - Segregate the acute and non-acute hazardous waste pharmaceuticals

Provides an incentive to over-manage non-hazardous pharmaceuticals as hazardous, without having to worry about bumping up generator category & incurring additional regulations
The following are NOT subject to RCRA regulation:

1. Pharmaceuticals that are not solid waste because they are legitimately used/reused or reclaimed
2. 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
3. Recalled pharmaceuticals*
4. Pharmaceuticals under preservation order, or during an investigation or judicial proceeding*
5. Investigational new drugs*
6. Household waste pharmaceuticals
   - Healthcare facilities that are DEA registrants & collectors of household pharmaceuticals (i.e., takebacks) must comply with conditions in § 266.506

* Become subject to Subpart P when decision is made to discard
Applicability for Rx HW Pharmaceuticals

1. Non-creditable

2. Potentially Creditable

3. Evaluated

Healthcare Facility

HW TSDF
Applicability for Rx HW Pharmaceuticals

1. Non-creditable Part 266 Subpart P

2. Potentially Creditable Part 266 Subpart P

3. Evaluated Part 266 Subpart P

Healthcare Facility

HW TSDF

1st Reverse Distributor

2nd Reverse Distributor

2. Potentially Creditable Part 266 Subpart P
Applicability for Non-Rx HW Pharmaceuticals (e.g., OTCs)

Healthcare Facility

Non-creditable

*Part 266 Subpart P (new)*

HW TSDF
Applicability for Non-Rx HW Pharmaceuticals (e.g., OTCs)

1st Reverse Logistics Center

Not Solid Waste

IF there is a reasonable expectation of use/reuse or reclamation (status quo)

2nd Reverse Logistics Center

Healthcare Facility

Non-creditable

Part 266
Subpart P
(new)

HW TSDF
Applicability for Non-Rx HW Pharmaceuticals (e.g., OTCs)

1st Reverse Logistics Center

Not Solid Waste

IF there is a reasonable expectation of use/reuse or reclamation (status quo)

2nd Reverse Logistics Center

Part 262 (status quo)

Healthcare Facility

Non-creditable Part 266 Subpart P (new)

HW TSDF
HEALTHCARE FACILITY STANDARDS

- **Notification:** all healthcare facilities must submit a one-time notification that they are operating under Subpart P (using Site ID Form: 8700-12)
  - Facilities that are not required to submit a biennial report for their other hazardous waste must notify within 60 days of the rule going into effect
    - Non-authorized states: notifications will be due in October, 2019
  - Facilities that are required to submit a biennial report may notify on their normal biennial reporting cycle
    - Non-authorized states: notifications will be due with March 1, 2020

- **Training:** all personnel managing non-creditable hazardous waste pharmaceuticals must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies

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§§ 266.502 and 266.503
HEALTHCARE FACILITY STANDARDS

- **Hazardous Waste Determinations**: healthcare facilities must determine whether a waste pharmaceutical is a hazardous waste pharmaceutical
  - Applies to both potentially creditable and non-creditable waste pharmaceuticals
  - Exception: If a healthcare facility manages all of its waste pharmaceuticals as hazardous, individual hazardous waste determinations are not necessary

- **Commingling**: healthcare facilities may accumulate both their hazardous and non-hazardous waste pharmaceuticals in the same container
  - Potentially creditable: hazardous + non-hazardous
  - Non-creditable: hazardous + non-hazardous

§§ 266.502 and 266.503
HEALTHCARE FACILITY MANAGEMENT STANDARDS

Non-creditable hazardous waste pharmaceuticals:

- **Labeling:**
  - Accumulation containers must be labeled with the words “Hazardous Waste Pharmaceuticals”
  - No hazardous waste codes or other labeling requirements

- **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
## HEALTHCARE FACILITY STANDARDS

<table>
<thead>
<tr>
<th></th>
<th>Non-creditable HW Pharms</th>
<th>Potentially Creditable HW Pharms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling</td>
<td>✓</td>
<td>None</td>
</tr>
<tr>
<td>Container Standards</td>
<td>✓</td>
<td>None</td>
</tr>
<tr>
<td>Maximum Accumulation Time</td>
<td>✓</td>
<td>None</td>
</tr>
<tr>
<td>Hazardous waste determinations*</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Over-managing non-hazardous pharmaceuticals &amp; commingling with hazardous waste pharmaceuticals</td>
<td>Allowed</td>
<td>Allowed</td>
</tr>
<tr>
<td>Include hazardous waste pharmaceuticals on BR</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

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

§ 266.500
<table>
<thead>
<tr>
<th>Standards for Healthcare Facilities</th>
<th>Standards for Reverse Distributors</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Potentially Creditable</strong></td>
<td></td>
</tr>
</tbody>
</table>
|On-site accumulation              | • No standards  
• No time limit                   |
|Shipping to a reverse distributor |                                  |

|**Non-Creditable**                |                                  |
|On-site accumulation              | • UW-like standards  
• 1 year maximum                  |
|Shipping to a TSDF                |                                  |
Healthcare facilities that are VSQGs are not subject to Part 266 Subpart P (except the sewer prohibition) but can
- Opt into Subpart P and comply with all its provisions OR
- Use the optional provisions of Part 266 Subpart P:
  1. A VSQG healthcare facility can continue to send potentially creditable hazardous waste pharmaceuticals to a reverse distributor
  2. A VSQG healthcare facility can send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided the receiving healthcare facility is
     - Operating under Part 266 Subpart P and meets certain conditions, or
     - An LQG operating under Part 262 and meets the conditions for off-site consolidation
Options for VSQG HealthCare Facilities

3. A long-term care facility that is a VSQG can dispose of its hazardous waste pharmaceuticals in an on-site collection receptacle that complies with DEA regulations.
   - Note that DEA collection receptacles can only be used for controlled substances that are from the ultimate user.

4. A long-term care facility with 20 beds or fewer will be presumed to be a VSQG and not subject to Part 266 Subpart P, except the sewer prohibition.
   - Note that long-term care facilities with >20 beds may also be VSQGs.
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 sewering of any pharmaceuticals by any entity
- REMEMBER: The sewer prohibition will be effective in ALL states 6 months after publication
There are a handful of RCRA hazardous wastes that are also DEA controlled substances

Two new conditional exemptions for healthcare facilities and reverse distributors for:

1. RCRA hazardous wastes that are also DEA controlled substances
2. Household waste pharmaceuticals collected in DEA authorized collection receptacles (kiosks)
# HW THAT ARE ALSO DEA CONTROLLED SUBSTANCES

<table>
<thead>
<tr>
<th>Name of Drug</th>
<th>Other Name(s)</th>
<th>Medical Uses</th>
<th>RCRA HW Code</th>
<th>DEA CS Schedule</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chloral/Chloral hydrate</td>
<td>Acetaldehyde, trichloro; Aquachloral Noctec, Somnote, Supprettes</td>
<td>Sedative</td>
<td>U034 Toxic</td>
<td>IV</td>
</tr>
<tr>
<td>Fentanyl sublingual spray</td>
<td>Subsys</td>
<td>Analgesic</td>
<td>D001 ignitable</td>
<td>II</td>
</tr>
<tr>
<td>Phenobarbital</td>
<td>Bellergal-S Donnatal Luminal</td>
<td>Anticonvulsant</td>
<td>D001 ignitable</td>
<td>IV</td>
</tr>
<tr>
<td>Testosterone gels/solutions</td>
<td>Androgel Axiron Fortesta, Testim</td>
<td>Hormone</td>
<td>D001 ignitable</td>
<td>III</td>
</tr>
<tr>
<td>Valium injectable/gel</td>
<td>Diazepam Diastat</td>
<td>Anti-anxiety</td>
<td>D001 ignitable</td>
<td>IV</td>
</tr>
</tbody>
</table>
DEA CONTROLLED SUBSTANCES

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

- 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
  - 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
NEW EMPTY CONTAINER STANDARDS

- 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
- Can be used to determine whether a healthcare facility is subject to Part 266 Subpart P
- 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

§§ 261.7 & 266.507

### “RCRA EMPTY”

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

*No triple rinsing of containers with acute hazardous waste pharmaceuticals*
**EMPTY CONTAINER STANDARDS**

<table>
<thead>
<tr>
<th></th>
<th><strong>“RCRA EMPTY”</strong></th>
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<td></td>
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<tr>
<td>Stock/Dispensing Bottles (1 liter or 10,000 pills) &amp; Unit-dose containers</td>
<td>Remove contents</td>
</tr>
<tr>
<td>Syringes</td>
<td>Fully depress plunger</td>
</tr>
<tr>
<td>IV Bags</td>
<td></td>
</tr>
<tr>
<td>Other Containers</td>
<td></td>
</tr>
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*No triple rinsing of containers with acute hazardous waste pharmaceuticals*
## EMPTY CONTAINER STANDARDS

<table>
<thead>
<tr>
<th>Stock/Dispensing Bottles &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>

| Other Containers | |
|------------------||

*No triple rinsing of containers with acute hazardous waste pharmaceuticals*
## EMPTY CONTAINER STANDARDS

### “RCRA EMPTY”

<table>
<thead>
<tr>
<th></th>
<th>Non-acute HW Pharms</th>
<th>Acute HW Pharms*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Stock/Dispensing Bottles (1 liter or 10,000 pills) &amp; Unit-dose containers</td>
<td>Remove contents</td>
<td>Remove contents</td>
</tr>
<tr>
<td>Syringes</td>
<td>Fully depress plunger</td>
<td>Fully depress plunger</td>
</tr>
<tr>
<td>IV Bags</td>
<td>Fully administer contents or § 261.7(b)(1)</td>
<td>Fully administer contents</td>
</tr>
<tr>
<td>Other Containers</td>
<td>§ 261.7(b)(1) or (2)</td>
<td>Can not be RCRA empty</td>
</tr>
</tbody>
</table>

*No triple rinsing of containers with acute hazardous waste pharmaceuticals*
SHIPMENTS OF HW PHARMACEUTICALS

- 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

- Non-creditable & evaluated 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 a TSDF
## SUMMARY MATRIX OF PART 266 SUBPART P

<table>
<thead>
<tr>
<th>Standards for Healthcare Facilities</th>
<th>Standards for Reverse Distributors</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially Creditable</td>
<td>Potentially Creditable</td>
</tr>
</tbody>
</table>

| On-site accumulation                |                                      |
|-------------------------------------|                                      |

| Shipping to a reverse distributor   | • Confirmation of delivery            |
|                                     | • Common carrier                      |
|                                     | • Confirmation of delivery            |
|                                     | • Common carrier                      |

<table>
<thead>
<tr>
<th>Non-Creditable</th>
<th>Evaluated</th>
</tr>
</thead>
</table>

| On-site accumulation                |                                      |
|-------------------------------------|                                      |

| Shipping to a TSDF                 | • Manifest (PHARMS)                  |
|                                     | • HW transporter                     |
|                                     | • Manifest (waste codes)             |
|                                     | • HW transporter                     |
REVERSE DISTRIBUTOR STANDARDS

- 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
FLOW OF HW PHARMACEUTICALS

- Maximum transfers allowed between RDs
- 180 days after evaluation allowed at each RD

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

HCF/Pharmacy

HW TSDF
As long as manufacturer’s credit is being determined/verified, and pharmaceuticals are destined for an RD, they are still considered “Potentially Creditable HW Pharmaceuticals”
Once manufacturer’s credit has been determined/verified, and pharmaceuticals are destined for a TSDF, they are considered “Evaluated HW Pharmaceuticals”
A reverse distributor must inventory and evaluate each potentially creditable hazardous waste pharmaceutical within 30 days or arrival to determine if it is destined for:

- Another reverse distributor (still considered “potentially creditable HW pharmaceutical”) or
- A permitted/interim status TSDF (considered “evaluated hazardous waste pharmaceutical”)

Accumulation on-site at reverse distributor:

- 180 days maximum accumulation time after evaluation

\[
30 \text{ days evaluation} + 180 \text{ days accumulation} = 210 \text{ days total per RD}
\]
REVERSE DISTRIBUTOR STANDARDS

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

- **Evaluated** hazardous waste pharmaceuticals:
  - 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
  - Containers must be in good condition and managed to prevent leaks
  - Hazardous waste codes prior to transport off-site
  - Included on Biennial Report
### REVERSE DISTRIBUTOR STANDARDS

<table>
<thead>
<tr>
<th></th>
<th>Potentially Creditable HW Pharms</th>
<th>Evaluated HW Pharms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Labeling</td>
<td>None</td>
<td>✓</td>
</tr>
<tr>
<td>Container Standards</td>
<td>None</td>
<td>✓</td>
</tr>
<tr>
<td>Accumulation Area</td>
<td>None</td>
<td>✓</td>
</tr>
<tr>
<td>Maximum Evaluation or Accumulation Time</td>
<td>✓</td>
<td>✓</td>
</tr>
<tr>
<td>Include hazardous waste pharmaceuticals on BR</td>
<td>No</td>
<td>✓</td>
</tr>
</tbody>
</table>

§ 266.510
<table>
<thead>
<tr>
<th>On-site accumulation</th>
<th>Standards for Healthcare Facilities</th>
<th>Standards for Reverse Distributors</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Potentially Creditable</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>Evaluate w/in 30 days</td>
<td></td>
</tr>
<tr>
<td>Shipping to a reverse distributor</td>
<td></td>
<td>Evaluated</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• LQG-like standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 180 days after evaluation</td>
<td></td>
</tr>
<tr>
<td>Shipping to a TSDF</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Standards for Healthcare Facilities</td>
<td>Standards for Reverse Distributors</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>-----------------------------------</td>
<td></td>
</tr>
<tr>
<td><strong>Potentially Creditable</strong></td>
<td><strong>Potentially Creditable</strong></td>
<td></td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• No standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• No time limit</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Evaluate w/in 30 days</td>
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</tr>
<tr>
<td>Shipping to a reverse distributor</td>
<td>• Confirmation of delivery</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Common carrier</td>
<td></td>
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<tr>
<td></td>
<td>• Common carrier</td>
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</tr>
<tr>
<td><strong>Non-Creditable</strong></td>
<td><strong>Evaluated</strong></td>
<td></td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• UW-like standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 1 year maximum</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• LQG-like standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• 180 days after evaluation</td>
<td></td>
</tr>
<tr>
<td>Shipping to a TSDF</td>
<td>• Manifest (PHARMS)</td>
<td></td>
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<tr>
<td></td>
<td>• HW transporter</td>
<td></td>
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<tr>
<td></td>
<td>• Manifest (waste codes)</td>
<td></td>
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<td></td>
<td>• HW transporter</td>
<td></td>
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</tbody>
</table>
REMINDERS & WRAP-UP

SECTION VI
## EFFECTIVE DATES & STATE ADOPTION TABLE

<table>
<thead>
<tr>
<th>Nicotine Exemption</th>
<th>Less Stringent</th>
<th>More Stringent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sewer Ban</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subpart P</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

| Non-authorized states (IA, AK) territories & Indian Country | August 21, 2019* | August 21, 2019* | August 21, 2019* |
| Authorized States & territories no legislative session required | • Effective when state adopts  
• State adoption not required | August 21, 2019* | • Effective when state adopts  
• July 1, 2021+ |
| Authorized States & territories legislative session required | • Effective when state adopts  
• State adoption not required | August 21, 2019* | • Effective when state adopts  
• July 1, 2022+ |

*effective date  
+state adoption deadline
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- Jessica Young [Young.Jessica@epa.gov]