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

PUBLIC WEBINAR PRESENTED BY EPA APRIL 2019

Introduction to Part 266 Subpart P
OUTLINE

1. Goals & Overview of the Pharmaceuticals Final 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 & OVERVIEW 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
- Reevaluate whether nicotine replacement therapies should be regulated as acute hazardous waste

Part 266
Subpart P

Subpart P & Reverse Logistics Policy

Part 261
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
EFFECTIVE DATES & STATE ADOPTION

SECTION II
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 in 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.
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.

Applies to all healthcare facilities and reverse distributors.
EFFECTIVE DATES & STATE ADOPTION TIMELINE

- **FR publication** 84 FR 5816
- **Feb 22 2019**
  - 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
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

Healthcare Facility

No Reasonable Expectation of Use/Reuse or Reclamation

Reverse Logistics Center

Donate  Sell  Recycle  Repair

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 also see § 266.501(g)(2)</td>
</tr>
</tbody>
</table>

RCRA Online #11606
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

1st Reverse Distributor

2nd Reverse Distributor

Potentially Creditable Pharmaceuticals*

Non-creditable Pharmaceuticals+

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
## REVERSE DISTRIBUTION v 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</td>
<td></td>
</tr>
<tr>
<td>August 21, 2019</td>
<td></td>
</tr>
<tr>
<td>• Effective in authorized states when state adopts Subpart P</td>
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</tbody>
</table>
## 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>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 are solid waste at the healthcare facility</td>
<td>Non-Rx pharmaceuticals and other unsold retail items sent to reverse logistics are not solid waste 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></td>
</tr>
<tr>
<td>• Effective in non-authorized states August 21, 2019</td>
<td></td>
</tr>
<tr>
<td>• Effective in authorized states when state adopts Subpart P</td>
<td>Newly codified in Part 266 Subpart P. But affirms existing policy</td>
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<tr>
<td></td>
<td>• Effective immediately federally</td>
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<tr>
<td></td>
<td>• Check with your state</td>
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</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**
- **Household waste pharmaceutical**
- **Non-hazardous waste pharmaceutical**
- **Non-pharmaceutical hazardous waste**
DEFINITION OF PHARMACEUTICAL

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

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
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
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

I. 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
   - HW TSDF

2. Potentially Creditable
   - 1st Reverse Distributor
   - Healthcare Facility
   - 2nd Reverse Distributor

- Original manufacturer packaging (except recalls)
- Undispensed
- Unexpired or less than 1-yr past expiration
3 Types of HWV 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

*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:

- Pharmaceutical manufacturers
- Reverse distributors
- Revers logistics centers
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
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.
## 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>
<tr>
<td>On-site accumulation</td>
<td></td>
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<tr>
<td>Shipping to a reverse distributor</td>
<td></td>
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<tr>
<td></td>
<td>Non-Creditable</td>
</tr>
<tr>
<td></td>
<td>Evaluated</td>
</tr>
<tr>
<td>On-site accumulation</td>
<td></td>
</tr>
<tr>
<td>Shipping to a TSDF</td>
<td></td>
</tr>
</tbody>
</table>
PART 266 SUBPART P APPLICABILITY

- 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
    - If healthcare facility generates above VSQG amounts of hazardous waste
  - All reverse distributors

- Part 266 Subpart P is both waste-specific and sector-specific
## WASTE SPECIFIC & SECTOR SPECIFIC RULE

<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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<tr>
<td></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></td>
<td>• Etc.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Other facilities (e.g., farms/ranches, reverse logistics centers, manufacturers)</th>
<th>Part 262</th>
<th>• Part 262</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>• Part 273 (universal waste)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Part 279 (used oil)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• Etc.</td>
</tr>
</tbody>
</table>
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

1st Reverse Distributor

2nd Reverse Distributor

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

1st Reverse Distributor

Healthcare Facility

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

1\textsuperscript{st} Reverse Logistics Center

\textbf{Not Solid Waste}

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

2\textsuperscript{nd} Reverse Logistics Center

\textbf{Healthcare Facility}

Non-creditable
\textbf{Part 266 Subpart P (new)}

\textbf{HW TSDF}
Applicability for Non-Rx HW Pharmaceuticals (e.g., OTCs)

1st Reverse Logistics Center

Healthcare Facility

Not Solid Waste

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

Part 262 (status quo)

Non-creditable Part 266 Subpart P (new)

2nd Reverse Logistics Center

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 20, 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 BR

- **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
**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

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**HEALTHCARE FACILITY STANDARDS**

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**§§ 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 limit:** 1 year

Potentially creditable hazardous waste pharmaceuticals:

- **No labeling, containers standards or accumulation time**
### § 266.500

#### 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*
## SUMMARY MATRIX OF PART 266 SUBPART P

<table>
<thead>
<tr>
<th>Standards for Healthcare Facilities</th>
<th>Standards for Reverse Distributors</th>
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<tbody>
<tr>
<td><strong>Potentially Creditable</strong></td>
<td></td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• No standards</td>
</tr>
<tr>
<td></td>
<td>• No time limit</td>
</tr>
<tr>
<td>Shipping to a reverse distributor</td>
<td></td>
</tr>
<tr>
<td><strong>Non-Creditable</strong></td>
<td></td>
</tr>
<tr>
<td>On-site accumulation</td>
<td>• UW-like standards</td>
</tr>
<tr>
<td></td>
<td>• 1 year maximum</td>
</tr>
<tr>
<td>Shipping to a TSDF</td>
<td></td>
</tr>
</tbody>
</table>
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 facility, provided the receiving facility is either
     - A healthcare facility 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
Optional provisions only for VSQG long-term care 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
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 on August 21, 2019
Two new conditional exemptions for healthcare facilities and reverse distributors for:

1. The handful of RCRA hazardous wastes that are also DEA controlled substances (see next page)

2. Household waste pharmaceuticals that are collected in DEA authorized collection receptacles (kiosks)
   - Retail pharmacies and hospitals that are already DEA registrants, can amend their DEA registration to become “collectors” of household pharmaceuticals
   - Collectors can install kiosks for permanent take-backs of household pharmaceuticals
   - Under DEA regulations, the collected household pharmaceuticals have to be destroyed to a “non-retrievable” standard
## 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, Suprettes</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>
In both cases, the hazardous waste pharmaceuticals are exempt from RCRA, provided they meet the following conditions:

- 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 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

<table>
<thead>
<tr>
<th></th>
<th>“RCRA EMPTY”</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Non-acute HW Pharms</td>
</tr>
<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></td>
</tr>
<tr>
<td>IV Bags</td>
<td></td>
</tr>
<tr>
<td>Other Containers</td>
<td></td>
</tr>
</tbody>
</table>

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

### §§ 261.7 & 266.507

<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></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>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Non-acute HW Pharms</strong></td>
</tr>
<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>Fully administer contents or § 261.7(b)(1)</td>
</tr>
<tr>
<td>Other Containers</td>
<td></td>
</tr>
</tbody>
</table>

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

### “RCRA EMPTY”

<table>
<thead>
<tr>
<th>Stock/Dispensing Bottles (1 liter or 10,000 pills) &amp; Unit-dose containers</th>
<th>Non-acute HW Pharm</th>
<th>Acute HW Pharm*</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
SHIPMENTS OF HW PHARMACEUTICALS

- Non-creditable & evaluated hazardous waste pharmaceuticals
  - Both must be sent to a TSDF
  - Both must sent with manifest and hazardous waste transporter
    - Non-creditable: healthcare facility must use “PHARMS” code on manifest in item 13 (other hazardous waste codes are allowed but not required)
    - Evaluated: reverse distributor must list all hazardous waste codes on manifest

- 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
    - 35 days from date the shipment was sent
    - Electronic delivery confirmation that common carriers use will typically be sufficient
<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>
<tr>
<td><strong>On-site accumulation</strong></td>
<td><strong>Non-Creditable</strong></td>
</tr>
<tr>
<td><strong>Shipping to a reverse distributor</strong></td>
<td><strong>Evaluated</strong></td>
</tr>
<tr>
<td>• Confirmation of delivery</td>
<td>• Manifest (waste codes)</td>
</tr>
<tr>
<td>• Common carrier</td>
<td>• HW transporter</td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>On-site accumulation</strong></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Shipping to a TSDF</strong></td>
<td>• Manifest (PHARMS)</td>
</tr>
<tr>
<td></td>
<td>• HW transporter</td>
</tr>
</tbody>
</table>
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

HCF/Pharmacy

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

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

\[
\text{30 days evaluation} + \text{180 days accumulation} = \text{210 days total per RD}
\]
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
## § 266.510

### REVERSE DISTRIBUTOR STANDARDS

<table>
<thead>
<tr>
<th>Standards</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>
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</tbody>
</table>
### SUMMARY MATRIX OF PART 266 SUBPART P

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

SECTION VI
## EFFECTIVE DATES & STATE ADOPTION TABLE

<table>
<thead>
<tr>
<th>Non-authorized states (IA, AK) territories &amp; Indian Country</th>
<th>Less Stringent</th>
<th>More Stringent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Exemption</td>
<td>August 21, 2019*</td>
<td>August 21, 2019*</td>
</tr>
</tbody>
</table>
| 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
CONTACT INFORMATION

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- Narendra Chaudhari Chaudhari.Narendra@epa.gov
- Jessica Young Young.Jessica@epa.gov