HAZARDOUS WASTE PHARMACEUTICALS FINAL RULE
NEW JERSEY HAZARDOUS WASTE TRAINING
OCTOBER 9, 2019

Nicotine Listing Amendment & Part 266 Subpart P
3 MODULES

1. Overview of the Final Rule/Q&A Session
   - break –

2. Notification & Reporting/Q&A Session
   - lunch –

3. Hot Topics/Q&A Session
   - Nicotine Listing Amendment
   - Applicability & Counting
OVERVIEW OF FINAL RULE

MODULE 1
MODULE 1 - 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
   - Shipping
   - VSQG Healthcare Facilities
   - 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
GOALS & OVERVIEW OF THE PHARMACEUTICALS RULE

SECTION I
The Hazardous Waste Pharmaceuticals Final Rule has three components:

1. Part 266 Subpart P
2. Reverse Distribution and Reverse Logistics Policy
3. Amendment of the Nicotine Listing
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
  - GOAL: to create regulations that are a better fit for the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors
How the hazardous waste pharmaceuticals are regulated under Part 266 Subpart P depends on two things:

1. Who is managing the hazardous waste pharmaceuticals
   - Healthcare facility
   - Reverse distributor

2. Where the hazardous waste pharmaceuticals are headed
   - Directly to a TSDF
   - Indirectly to a TSDF, via a reverse distributor to obtain manufacturer credit
EFFECTIVE DATES & STATE ADOPTION

SECTION II
The effective date of Subpart P and the nicotine amendment was August 21, 2019 in:

- Non-authorized States: Iowa & Alaska
- Indian Country
- US Territories (except Guam)

Subpart P and nicotine amendment are NOT effective in authorized states until state adopts the new rules.

Sewer ban was effective everywhere on August 21, 2019 (HSWA provision)
Subpart P is considered more stringent
- Authorized states MUST adopt Subpart P
- NJ has adopted Subpart P
- Several other states already have

Nicotine amendment is considered less stringent
- Authorized states are NOT required to adopt the nicotine amendment
- NJ has adopted the nicotine amendment
- Several other states have also already adopted the nicotine amendment
STATE ADOPTION MAPS

- We are tracking state adoption separately for
  - Part 266 Subpart P
  - Nicotine amendment in Part 261
STATE ADOPTION OF PART 266 SUBPART P

Effective in:
Indian Country
4 Territories
8 States

As of Sept 6, 2019
STATE ADOPTION OF NICOTINE AMENDMENT

Effective in:
Indian Country
4 Territories
10 States

As of Sept 6, 2019
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 IS STILL LISTED AS P075

- 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
NICOTINE LISTING AMENDMENT

- We will repeat this info and expand upon it during the afternoon session
- Be ready for a quiz after lunch!
REVERSE DISTRIBUTION & LOGISTICS

SECTION IV
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 of Unsold Retail Items & Non-Rx Pharms

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>
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<tbody>
<tr>
<td>May 16, 1991 memo</td>
<td><strong>Pharmaceuticals Final Rule</strong></td>
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<tr>
<td>…to the extent that the materials involved are unused commercial chemical products with a <strong>reasonable expectation</strong> 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 <strong>reasonable expectation</strong> of being legitimately use/reused (e.g., lawfully redistributed for their intended purpose) of reclaimed also see § 266.501(g)(2)</td>
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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

Potentially Creditable Pharmaceuticals*

Non-creditable Pharmaceuticals+

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
### REVERSE DISTRIBUTION v REVERSE LOGISTICS

<table>
<thead>
<tr>
<th>Reverse Distribution</th>
<th>Reverse Logistics</th>
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<tbody>
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<tr>
<td>• Effective in authorized states when state adopts Subpart P</td>
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## REVERSE DISTRIBUTION v REVERSE LOGISTICS

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<td>• e.g., OTCs &amp; dietary supplements</td>
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<td></td>
<td>All other unsold retail items</td>
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<tr>
<td>No redistribution occurs</td>
<td>Redistribution sometimes occurs via:</td>
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<td></td>
<td>• Donation</td>
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<td></td>
<td>• Liquidation (secondary market)</td>
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<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>
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<td>Newly codified in Part 266 Subpart P with respect to pharmaceuticals. But affirms existing policy</td>
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<td>• Effective immediately federally</td>
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<td>• Check with your state</td>
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PART 266 SUBPART P

SECTION V
What type of waste is being managed:

- Pharmaceutical
- Hazardous waste pharmaceutical
  - Non-creditable hazardous waste pharmaceutical
  - Potentially creditable hazardous waste pharmaceutical
  - Evaluated hazardous waste pharmaceutical
- Household waste pharmaceutical
- Non-hazardous waste pharmaceutical
- Non-pharmaceutical hazardous waste
Who is managing the waste

- Healthcare facility
  - Long-term care facility
- Reverse distributor
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

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

Ist Reverse Distributor

2nd Reverse Distributor

Healthcare Facility

HW TSDF

2. Potentially Creditable

3. Potentially Creditable
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
- Reveres logistics centers

Ambulance services
- Pharmacies
- Long-term care pharmacies
- Mail-order pharmacies
- Retailers of pharmaceuticals (includes vape shops)
- Veterinary clinics & hospitals
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></th>
<th>Standards for Healthcare Facilities</th>
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<tr>
<td>Shipping to a reverse distributor</td>
<td>Non-Creditable</td>
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<td>Shipping to a TSDF</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
  - If healthcare facility generates above VSQG amounts of hazardous waste
- All reverse distributors

Part 266 Subpart P is both waste-specific and sector-specific.
<table>
<thead>
<tr>
<th>Healthcare facilities &amp; reverse distributors</th>
<th>Hazardous Waste Pharmaceuticals</th>
<th>Other Hazardous Wastes</th>
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<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>
</tr>
<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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<td>• Part 273 (universal waste)</td>
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</table>
PART 266 SUBPART P APPLICABILITY

- 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 considered solid waste because they are legitimately used/reused or reclaimed

2. OTC pharmaceuticals, dietary supplements or homeopathic drugs that are not considered 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

Ist 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

2nd Reverse Distributor

Healthcare Facility

HW TSDF
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)

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

Not Solid Waste

1st Reverse Logistics Center

Healthcare Facility

Non-creditable

Part 266
Subpart P
(new)

2nd Reverse Logistics Center

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
REVERSE DISTRIBUTION
NON-RX HW PHARMACEUTICALS GOING THROUGH RD?

- EPA has become aware of two scenarios where nonprescription hazardous waste pharmaceuticals are sent to reverse distributors:
  - Retail facilities keep some nonprescription pharmaceuticals (e.g., sudafed) behind the counter and everything behind the counter is managed together and sent to a reverse distributor even though they are not prescription pharmaceuticals
  - Some healthcare facilities (e.g., hospitals, clinics, etc.) only have contracts with reverse distributors, not with reverse logistics centers
- We are developing a Q&A on the topic for our website
If a healthcare facility sends a nonprescription pharmaceutical to a reverse distributor, EPA considers this over-management as hazardous waste.

The nonprescription pharmaceuticals going to a reverse distributor must be managed as potentially creditable hazardous waste pharmaceuticals:

- Have reasonable expectation of receiving manufacturer credit
- In original manufacturer packaging
- Undispensed
- Unexpired or less than 1-yr past expiration
Under Subpart P, there are no:
- Satellite accumulation areas (SAAs)
- Central accumulation areas (CAAs)

At healthcare facilities it can be difficult to accumulate hazardous waste pharmaceuticals “at or near the point of generation” as is required by the SAA regulations.

Healthcare facilities can bring hazardous waste pharmaceuticals to a central accumulation area, but are not required to...
HEALTHCARE FACILITY STANDARDS

- Standards that apply to the healthcare facility
  - Notification
  - Training
  - Hazardous waste determination

- Other standards apply to the waste and differ depending on the type of hazardous waste pharmaceuticals

  **Non-creditable hazardous waste pharmaceuticals**
  - destined for TSDF directly
  - regulations resemble Universal Waste but adds shipping requirements

  **Potentially creditable hazardous waste pharmaceuticals**
  - destined indirectly to a TSDF via reverse distributor
  - regulations only for shipping

§§ 266.502 and 266.503
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
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
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

§§ 266.502 and 266.503
### Container Standards
- Security
- Compatibility

### Labeling
- "Hazardous Waste Pharmaceuticals"
- No hazardous waste codes required

### Maximum Accumulation Time
One year

### Over-managing non-hazardous pharmaceuticals & commingling with hazardous pharmaceuticals
Allowed

### Include hazardous waste pharmaceuticals on BR
No
<table>
<thead>
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<td></td>
<td><strong>Non-Creditable</strong></td>
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<tr>
<td>On-site accumulation</td>
<td>• UW-like standards</td>
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</table>
SHIPMENTS OF HW PHARMACEUTICALS

Non-creditable & evaluated hazardous waste pharmaceuticals

- Both must be sent to a TSDF
- Both must sent with manifest and via 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)
    - "PHARMS" is in the regulations, but proving difficult to implement because it is six characters as opposed to the typical four for federal code
    - EPA is in the process of developing guidance that will allow the use of "PHRM" instead
  - Evaluated: reverse distributor must list all hazardous waste codes on manifest

§§ 266.508 & 266.509
SHIPMENTS OF HW PHARMACEUTICALS

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

§§ 266.508 & 266.509
## SUMMARY MATRIX OF PART 266 SUBPART P

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<td>• Common carrier</td>
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<td>• Manifest (waste codes)</td>
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<tr>
<td></td>
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</tr>
</tbody>
</table>
Healthcare facilities that are VSQGs are not subject to Subpart P, except the:

- Sewer prohibition
- New empty container provisions

Healthcare facilities that are VSQGs can choose to:

- Opt into Part 266 Subpart P and comply with all its provisions OR
- Continue to operate under § 262.14 and use none/any/all of the four optional provisions in § 266.504
  - Using the optional provisions does not constitute “opting in” and does not require notification
4 OPTIONAL PROVISIONS FOR VSQG HCFS

1. A VSQG healthcare facility can continue to send potentially creditable hazardous waste pharmaceuticals to a reverse distributor
   - Under 262.14, VSQGs can send hazardous waste to a list of specified types of facilities
   - We added reverse distributors to the list of types of facilities to which healthcare facilities can send hazardous waste
     - VSQGs can send only potentially creditable hazardous waste pharmaceuticals to a reverse distributor
     - VSQGs can not send other hazardous waste to a reverse distributor
4 OPTIONAL PROVISIONS FOR VSQG HCFS

2. A VSQG healthcare facility can send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided the receiving healthcare facility is following the conditions in:

- Subpart P off-site consolidation OR
- Generator Improvements Rule off-site consolidation
2. OFF-SITE CONSOLIDATION (CONTINUED)

- Some VSQG healthcare facilities prefer to return their hazardous waste pharmaceuticals to their supplier for disposal.
- EPA also prefers the practice because it diverts hazardous waste pharmaceuticals from the municipal waste stream into hazardous waste management.
- Previously, the regulations did not allow a VSQG to send its hazardous waste off-site to another generator.
- Off-site consolidation creates the regulatory mechanism to allow VSQGs to manage their hazardous waste in an environmentally preferable way.

§ 266.504(b)
2. SUBPART P OFF-SITE CONSOLIDATION

- The off-site consolidation in Subpart P was designed to accommodate existing practices in two common situations:
  1. Small off-post clinics that are near a larger base
  2. Long-term care facilities that are supplied by long-term care pharmacies

- Off-site consolidation is not limited to these two situations; it may be used in other situations provided the conditions are met.

- The receiving healthcare facility is not considered a reverse distributor; the receiving healthcare facility:
  - Is not facilitating manufacturer credit
  - Is facilitating improved management of the hazardous waste pharmaceuticals
  - May send the potentially creditable hazardous waste pharmaceuticals to a reverse distributor for manufacturer credit

§ 266.504(b)
The receiving healthcare facility must:

- Be under the control of the same person as the VSQG healthcare facility sending the hazardous waste pharmaceuticals OR be the pharmaceutical supplier to the VSQG healthcare facility
- Operate under Subpart P for its own hazardous waste pharmaceuticals
- Manage the hazardous waste pharmaceuticals it receives from off-site under Subpart P
- Keep records for 3 years of the shipments of hazardous waste pharmaceuticals that it receives from off-site

Receiving healthcare facility does not have to be an LQG
2. GIR OFF-SITE CONSOLIDATION

- The VSQG healthcare facility and the receiving LQG healthcare facility must be under the control of the same person.
- The VSQG healthcare facility must mark its containers of hazardous waste with:
  - The words “hazardous waste”
  - An indication of the hazards of the contents
- The receiving healthcare facility must:
  - Be an LQG
  - Operate under Subpart P for its own hazardous waste pharmaceuticals
  - Manage the hazardous waste pharmaceuticals it receives from off site under Subpart P
  - Notify EPA 30 days prior to receiving 1st shipment
  - Keep records for 3 years of the shipments of hazardous waste pharmaceuticals that it receives from off-site with specified information
# COMPARING OFF-SITE CONSOLIDATION

<table>
<thead>
<tr>
<th>Subpart P Off-site Consolidation</th>
<th>GIR Off-site Consolidation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Can be used by VSQG healthcare facilities <em>only</em> for hazardous waste pharmaceuticals</td>
<td>Can be used by VSQG healthcare facilities for <em>both</em> hazardous waste pharmaceuticals AND non-pharmaceutical hazardous waste</td>
</tr>
<tr>
<td>Fewer conditions</td>
<td>More conditions</td>
</tr>
</tbody>
</table>
| Receiving healthcare facility must be:  
  • operating under Subpart P  
  • under the control of the same person as the VSQG, or  
  • the supplier of the pharmaceuticals | Receiving healthcare facility must be:  
  • operating under Subpart P  
  • under the control of the same person as the VSQG |
| Receiving healthcare facility does not have to be an LQG | Receiving healthcare facility must be an LQG |
| Voluntary provision but all conditions must be followed if used | Voluntary provision but all conditions must be followed if used |
4 OPTIONAL PROVISIONS FOR VSQG HCFS

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

- Retail stores with pharmacies that are already DEA registrants can amend their DEA registration to become “collectors”
- Retail DEA collectors can put take-back collection receptacles (kiosks) in their store and/or at an LTCF
- Under DEA regulations, the collected pharmaceuticals have to be destroyed to a “non-retrievable” standard
- LTCFs that are VSQGs and that have an on-site collection receptacle, can dispose of their hazardous waste pharmaceuticals in the receptacle
- DEA collection receptacles can be used for controlled substances that are from the ultimate user only (i.e., patient)
- DEA collection receptacles can NOT be used for disposing of inventory of controlled substances from the LTCF or retail store
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 was effective in ALL states on August 21, 2019, regardless of whether state is authorized or has adopted Subpart P
Q1: EPA says they strongly discourage sewering of any pharmaceuticals by any entity. Are there any exceptions to this recommendation?
Q1: EPA says they strongly discourage sewering of any pharmaceuticals by any entity. Are there any exceptions to this recommendation?

A: The sewer ban applies to all hazardous waste pharmaceuticals at healthcare facilities and reverse distributors. Beyond the regulatory ban, EPA strongly discourages sewering of any pharmaceutical by any entity – with few exceptions:

- Sterile water, saline, lactated ringers (saline + electrolytes), etc.
- Households with drugs on FDA’s “flush list” – if the household
  - Has pets or small children
  - Does not have access to take-back receptacles or mail-back envelopes
Q2: DEA does not allow the sewering of excess inventory of controlled substances, but DEA does allow the sewering of “pharmaceutical wastage” of controlled substances. Does EPA allow the sewering of pharmaceutical wastage of hazardous waste pharmaceuticals?
Q2: DEA does not allow the sewering of excess inventory of controlled substances, but DEA does allow the sewering of “pharmaceutical wastage” of controlled substances. Does EPA allow the sewering of pharmaceutical wastage of hazardous waste pharmaceuticals?

A: No. All hazardous waste pharmaceuticals at healthcare facilities and reverse distributors are prohibited from being sewered, including:

- Pharmaceutical wastage
- Hazardous waste pharmaceuticals that are also DEA controlled substances
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

§ 266.506
<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>
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 REGULATIONS

- 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

§§ 261.7 & 266.507
## EMPTY CONTAINER STANDARDS

<table>
<thead>
<tr>
<th></th>
<th><strong>“RCRA EMPTY”</strong></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>
<td></td>
</tr>
<tr>
<td>Syringes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV Bags</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Other Containers</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

### “RCRA EMPTY”

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<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>Non-acute HW Pharms</strong></th>
<th><strong>Acute HW Pharms</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Stock/Dispensing Bottles</strong> &amp; Unit-dose containers</td>
<td>Remove contents</td>
<td>Remove contents</td>
</tr>
<tr>
<td><strong>Syringes</strong></td>
<td>Fully depress plunger</td>
<td>Fully depress plunger</td>
</tr>
<tr>
<td><strong>IV Bags</strong></td>
<td>Fully administer contents or § 261.7(b)(1)</td>
<td>Fully administer contents</td>
</tr>
<tr>
<td><strong>Other Containers</strong></td>
<td></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></th>
<th>Non-acute HW Pharms</th>
<th>Acute HW Pharms*</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Stock/Dispensing Bottles</strong>&lt;br&gt;(1 liter or 10,000 pills)&lt;br&gt;&amp; Unit-dose containers</td>
<td>Remove contents</td>
<td>Remove contents</td>
</tr>
<tr>
<td><strong>Syringes</strong></td>
<td>Fully depress plunger</td>
<td>Fully depress plunger</td>
</tr>
<tr>
<td><strong>IV Bags</strong></td>
<td>Fully administer contents or § 261.7(b)(1)</td>
<td>Fully administer contents</td>
</tr>
<tr>
<td><strong>Other Containers</strong></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*
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
A reverse distributor must inventory and evaluate each potentially creditable hazardous waste pharmaceutical within 30 days of 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

$$30 \text{ days evaluation} + 180 \text{ days accumulation} = 210 \text{ days total per RD}$$
FLOW OF HW PHARMACEUTICALS

- Maximum transfers allowed between RDs
- After evaluation, 180 days accumulation 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”
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>
## 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>On-site accumulation</td>
<td>Potentially Creditible</td>
</tr>
<tr>
<td>Evaluate w/in 30 days</td>
<td></td>
</tr>
<tr>
<td>Shipping to a reverse distributor</td>
<td>Evaluated</td>
</tr>
<tr>
<td>• LQG-like standards</td>
<td></td>
</tr>
<tr>
<td>• 180 days after evaluation</td>
<td></td>
</tr>
<tr>
<td>Shipping to a TSDF</td>
<td></td>
</tr>
</tbody>
</table>
## 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><strong>Potentially Creditable</strong></td>
<td><strong>Potentially Creditable</strong></td>
</tr>
</tbody>
</table>
| On-site accumulation | • No standards  
• No time limit  
| Evaluate w/in 30 days |
| Shipping to a reverse distributor | • Confirmation of delivery  
• Common carrier  
| • Confirmation of delivery  
• Common carrier |
| **Non-Creditable** | **Evaluated** |
| On-site accumulation | • UW-like standards  
• 1 year maximum  
| • LQG-like standards  
• 180 days after evaluation |
| Shipping to a TSDF | • Manifest (PHARMS/PHRM)  
• HW transporter  
| • Manifest (waste codes)  
• HW transporter |
1. Notification
2. Manifest
3. Biennial Report
Healthcare facilities and reverse distributors must submit a one-time notification that they are operating under Subpart P, even if they already have an EPA ID.

- 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.
  - In NJ: notifications will be due on October 20, 2019.
- Facilities that are required to submit a biennial report may notify on their normal biennial reporting cycle.
  - In NJ: notifications will be due with March 1, 2020 BR.
Updated 8700-12
New Box 11D

<table>
<thead>
<tr>
<th>EPA ID Number</th>
<th>OMB# 2050-0024; Expires 05/31/2020</th>
</tr>
</thead>
</table>

### D. Pharmaceutical Activities

<table>
<thead>
<tr>
<th>Y</th>
<th>N</th>
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<tbody>
<tr>
<td></td>
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</table>

1. Operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals—if “Yes”, mark only one. Note: See the item-by-item instructions for definitions of healthcare facility and reverse distributor.

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
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<tbody>
<tr>
<td>Y</td>
<td>N</td>
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<td></td>
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</table>

   a. Healthcare Facility

<p>| | |</p>
<table>
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<th></th>
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</tr>
</thead>
<tbody>
<tr>
<td>Y</td>
<td>N</td>
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</tr>
</tbody>
</table>

   b. Reverse Distributor

2. Withdrawing from operating under 40 CFR 266 Subpart P for the management of hazardous waste pharmaceuticals. Note: You may only withdraw if you are a healthcare facility that is no longer an LQG or SQG.
Healthcare facilities that send hazardous waste pharmaceuticals directly to a TSDF (i.e., non-creditable hazardous waste pharmaceuticals)
- Must use a hazardous waste transporter
- Must use hazardous waste manifest
- Must use “PHARMS” (or "PHRM") code in Item 13 of manifest
  - Hazardous waste codes are allowed but not required
PHARMS CODE – IMPLEMENTATION

- PHARMS/PHRM code is for manifesting purposes only - it is not a waste code in the traditional sense
  - There is no new listing under Part 261
  - There is no new LDR standard
  - Using the code does not trigger permit mods for TSDFs accepting the manifested waste
PHARMS CODE – IMPLEMENTATION

- PHARMS code was developed for e-manifest
  - It has too many characters for paper manifest which is still widely in use in healthcare sector
  - Some state and industry data systems cannot accommodate six character codes
  - We plan to replace PHARMS with PHRM
BIENNIAL REPORTING UNDER SUBPART P

- **Healthcare facilities** are not required to include hazardous waste pharmaceuticals on their Biennial Report.
- **Reverse distributors** must include hazardous waste pharmaceuticals on their Biennial Report.
  - Include only the hazardous waste pharmaceuticals going to a TSDF (i.e., evaluated hazardous waste pharmaceuticals).
  - Do not include the hazardous waste pharmaceuticals going to another reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals).
- Continue to use GM Form.
- Use new G76 Source Code.
New Jersey has opted into using myRCRAid for notifications and Biennial Reporting

More information to come on how to use myRCRAid……
HOT TOPICS

MODULE 3
1. Nicotine Listing Amendment
2. Applicability & Counting
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
Forms of nicotine that are **exempt from P075 listing:**

- FDA-approved OTC NRTs (patches, gums & lozenges)
### NICOTINE UNDER THE PHARMACEUTICALS RULE

**Forms of nicotine that are **exempt** from P075 listing:**
- FDA-approved OTC NRTs (patches, gums & lozenges)

**Forms of P075 nicotine that are **pharmaceuticals** are regulated under Part 266 Subpart P:**
- Prescription nicotine (i.e., inhaler, nasal spray)
- E-liquids packaged for retail use in ENDS (e.g., pre-filled liquid cartridges & vials sealed in final packaging that is sold or distributed to consumers)
- Finished product ENDS, including components & parts sealed in final packaging intended for consumer use (e.g., e-cigarettes or vaping pens)
NICOTINE UNDER THE PHARMACEUTICALS RULE

Forms of nicotine that are **exempt from P075 listing**:
- FDA-approved OTC NRTs (patches, gums & lozenges)

Forms of P075 nicotine that are **pharmaceuticals** are regulated under Part 266 Subpart P:
- Prescription nicotine (i.e., inhaler, nasal spray)
- E-liquids packaged for retail use in ENDS (e.g., pre-filled liquid cartridges & vials sealed in final packaging that is sold or distributed to consumers)
- Finished product ENDS, including components & parts sealed in final packaging intended for consumer use (e.g., e-cigarettes or vaping pens)

Forms of P075 nicotine that are **NOT pharmaceuticals** are regulated under Part 262:
- E-liquids used by manufacturers of tobacco products
- E-liquids sold or distributed for further manufacturing, mixing, or packaging into a finished electronic delivery system
- Legacy pesticides containing nicotine
- Nicotine used in research and manufacturing
Q1: Does the nicotine exemption for OTC NRTs apply to manufacturers?
Q1: Does the nicotine exemption for OTC NRTs apply to manufacturers?

A: Yes. The nicotine exemption for OTC NRTs applies to any generator of the discarded products. The listing for P075 under Part 261 has been amended. Therefore, the nicotine exemption for OTC NRTs is not limited to healthcare facilities and reverse distributors operating under Subpart P.
Q2: Do OTC Nicotine Replacement Therapies kept behind the pharmacy counter qualify for the nicotine exemption?
Q2: Do FDA-approved OTC nicotine replacement therapies kept behind the pharmacy counter qualify for the nicotine exemption?

A: Yes. The nicotine exemption applies to all FDA-approved OTC nicotine replacement therapies, regardless of where they are located within a healthcare facility, or if they are prescribed. Because it modifies the P075 listing in part 261, the nicotine exemption applies to all generators, not just healthcare facilities and reverse distributors.
Q3: Do VSQG healthcare facilities have to opt into subpart P to take advantage of the nicotine amendment?
Q3: Do VSQG healthcare facilities have to opt into subpart P to take advantage of the nicotine amendment?

A: No. The nicotine amendment was finalized at the same time as subpart P, but it is not part of subpart P. The nicotine exemption applies to all generators of FDA-approved OTC nicotine replacement therapy waste, not just healthcare facilities and reverse distributors.
Q4: Can I use the nicotine amendment in New Jersey?
Q4: Can I use the nicotine amendment in New Jersey?

A: Yes. New Jersey has adopted the nicotine listing amendment. Note that if the nicotine waste goes outside of the state to a state that has not adopted the amendment, the waste may be regulated as a hazardous waste.

In other authorized states, the amendment must be adopted before generators can utilize it. Because it is considered less stringent, authorized states are not required to adopt it.

In Indian Country, territories & non-authorized states, the nicotine amendment became effective on August 21, 2019.
STATE ADOPTION OF NICOTINE AMENDMENT

Effective in:
Indian Country
4 Territories
10 States

As of Sept 6, 2019
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 reverse distributors
  - All healthcare facilities that generate above VSQG amounts of hazardous waste

- VSQG healthcare facilities can choose to:
  - Opt into Part 266 Subpart P and comply with all its provisions OR
  - Use any or all of the four optional provisions in § 266.504
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
Determining whether a healthcare facility is subject to Subpart P:

1. Count all hazardous waste generated per month, including hazardous waste pharmaceuticals

2. If generating below all monthly VSQG amounts of hazardous waste:
   - $\leq 1$ kg (2.2 lbs) acute hazardous waste and
   - $\leq 100$ kg (220 lbs) non-acute hazardous waste and
   - $\leq 100$ kg (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste

3. Then:
   - Healthcare facility is not subject to Subpart P
   - Healthcare facility is a VSQG under Part 262 for ALL of its hazardous waste
Determining whether a healthcare facility is subject to Subpart P:

1. Count all hazardous waste generated per month, including hazardous waste pharmaceuticals

2. If generating above any monthly VSQG amount of hazardous waste:
   - >1 kg (2.2 lbs) acute hazardous waste or
   - >100 kg (220 lbs) non-acute hazardous waste or
   - >100 kg (220 lbs) of any residue or contaminated soil, water, or other debris resulting from the cleanup of a spill, into or on any land or water, of any acute hazardous waste

3. Then:
   - Healthcare facility is subject to Subpart P for its hazardous waste pharmaceuticals – and –
   - Healthcare facility is a VSQG/SQG/LQG under Part 262 for its other hazardous waste
Non-pharmaceutical hazardous waste remains regulated under Part 262 (or other applicable Parts).
- Under Part 262, generator status must be determined for non-pharmaceutical hazardous waste: VSQG, SQG, LQG

As a result, a healthcare facility can be:
- VSQG for all HW or
- Subject to Subpart P for hazardous waste pharmaceuticals & VSQG/SQG/LQG for other hazardous waste
<table>
<thead>
<tr>
<th>Nickname</th>
<th>Subpart P Applicability for HW Pharmaceuticals</th>
<th>Part 262 Generator Category for other HW</th>
</tr>
</thead>
<tbody>
<tr>
<td>Full VSQG</td>
<td>Sewer ban</td>
<td>VSQG</td>
</tr>
<tr>
<td></td>
<td>New empty container standards</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Optional provisions</td>
<td></td>
</tr>
<tr>
<td>Subpart P VSQG</td>
<td>All of Subpart P</td>
<td>VSQG</td>
</tr>
<tr>
<td>Subpart P SQG</td>
<td>All of Subpart P</td>
<td>SQG</td>
</tr>
<tr>
<td>Subpart P LQG</td>
<td>All of Subpart P</td>
<td>LQG</td>
</tr>
</tbody>
</table>
**Applicability Flow Chart for Healthcare Facilities**

- **Count ALL Hazardous Waste (Including HW Pharmaceuticals)**
- **Above any VSQG Threshold?**
  - **HW Pharms are Subject to Subpart P**
    - **Non-pharm HW is above any LQG threshold?**
      - **YES**
      - **Subpart P LQG**
      - **SUBJECT TO**
      - **Subpart P + 262.17**
    - **NO**
      - **Non-pharm HW is above VSQG & below LQG threshold?**
        - **YES**
        - **Subpart P SQG**
        - **SUBJECT TO**
        - **Subpart P + 262.16**
      - **NO**
        - **Non-pharm HW is below all VSQG thresholds?**
          - **YES**
          - **Subpart P VSQG**
          - **SUBJECT TO**
          - **Subpart P + 262.14**
    - **NO**
      - **Full VSQG**
- **Subtract HW Pharms**
- **For HW Pharms – 3 Subpart P provisions:**
  - sewer ban
  - new empty container standards
  - optional VSQG provisions in 266.504
- **For Other HW: VSQG regulations in 262.14**

* and/or other applicable regs
EXAMPLE

5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals
+ 200 kg of hazardous waste (not acute, not pharmaceutical)
EXAMPLE

Count ALL Hazardous Waste (Including HW Pharmaceuticals)

5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals
+ 200 kg of hazardous waste (not acute, not pharmaceutical)
EXAMPLE

Count **ALL** Hazardous Waste (Including HW Pharmaceuticals)

5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals
+ 200 kg of hazardous waste (not acute, not pharmaceutical)
= 5 kg acute hazardous waste and
225 kg non-acute hazardous waste
5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals
+ 200 kg of hazardous waste (not acute, not pharmaceutical)

= 5 kg acute hazardous waste and ABOVE 1 KG
225 kg non-acute hazardous waste ABOVE 100 KG
EXAMPLE

5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals

+ 200 kg of hazardous waste (not acute, not pharmaceutical)

= 5 kg acute hazardous waste and ABOVE 1 KG

= 225 kg non-acute hazardous waste ABOVE 100 KG
EXAMPLE

5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals
+ 200 kg of hazardous waste (not acute, not pharmaceutical)
= 200 kg non-pharmaceutical hazardous waste
EXAMPLE

5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals
+ 200 kg of hazardous waste (not acute, not pharmaceutical)
= 200 kg non-pharmaceutical hazardous wastes = SQG
EXAMPLE

5 kg acute hazardous waste pharmaceuticals
25 kg non-acute hazardous waste pharmaceuticals
+ 200 kg of hazardous waste (not acute, not pharmaceutical)

Hazardous Waste + Non-pharmaceutical
Pharmaceuticals + Hazardous Waste
SUBPART P + SQG
Four provisions are expected to affect the amount of hazardous waste pharmaceuticals that gets counted.

<table>
<thead>
<tr>
<th>Decrease Amount of Hazardous Waste Pharmaceuticals</th>
<th>Increase Amount of Hazardous Waste Pharmaceuticals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Nicotine patches, gums &amp; lozenges are not hazardous waste</td>
<td>3. Sewer prohibition</td>
</tr>
<tr>
<td>2. Pharmaceuticals <strong>managed under Subpart P</strong> do not count toward determining a facility’s Part 262 generator category</td>
<td>4. Pharmaceuticals that are destined for a reverse distributor are solid waste</td>
</tr>
</tbody>
</table>
1. **PART 261**: Nicotine patches, gums & lozenges are not hazardous waste

   - Some retailers have told us that they are LQGs only because of their nicotine hazardous waste
   - Some healthcare facilities may drop down in generator category now that nicotine patches, gums and lozenges are not considered hazardous waste
   - If the healthcare facility becomes a VSQG, it is not subject to Subpart P, except the sewer ban and the new empty container standards
   - Effect of the P075 listing amendment on generator category will be limited by the fact that e-juices/e-cigs are still P075
2. **SUBPART P**: Pharmaceuticals managed under **Subpart P** do not count toward determining a facility’s Part 262 generator category

- A healthcare facility or reverse distributor only gets the benefit of not counting their hazardous waste pharmaceuticals toward its generator category when their hazardous waste pharmaceuticals are managed under Subpart P.

- Some healthcare facilities and most reverse distributors operating under Subpart P may drop down in generator category for their non-pharmaceutical hazardous waste.
3. **SUBPART P: Sewer prohibition**
   - Hazardous waste pharmaceuticals can not be sewered and must be counted toward determining whether a healthcare facility is subject to Subpart P
4. **SUBPART P**: Pharmaceuticals destined for a reverse distributor are solid waste

- Previously, pharmaceuticals destined for a reverse distributor were not considered solid waste and were not counted toward determining the RCRA regulatory status of the healthcare facility

- Under the final rule, pharmaceuticals destined for a reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals) are solid waste

- Potentially creditable hazardous waste pharmaceuticals sent to reverse distributors must be counted toward determining whether a healthcare facility is subject to Subpart P
Q1: If an LQG such as a manufacturer or military base has an on-site clinic, is the clinic regulated under Subpart P?
Q1: If an LQG such as a manufacturer or military base has an on-site clinic, is the clinic regulated under Subpart P?

A: Yes. A clinic that is co-located within a larger facility is regulated as a healthcare facility under Subpart P, assuming the larger facility is not a VSQG.
Q2: Can a healthcare facility avoid RCRA regulation by not counting its hazardous waste pharmaceuticals?
Q2: Can a healthcare facility avoid RCRA regulation by not counting its hazardous waste pharmaceuticals?

A: No. A healthcare facility only gets the benefit of not counting its hazardous waste pharmaceuticals when it is managing them under Part 266 Subpart P hazardous waste regulations.
TAKE HOME MESSAGE

If you remember nothing else from the discussion of Subpart P and generator status, remember this:

Hazardous waste pharmaceuticals must be managed under Subpart P to get the benefit of not counting them toward a facility’s generator category.
REMINDERS & WRAP-UP

The End is Nigh.....
### EFFECTIVE DATES & STATE ADOPTION TABLE

<table>
<thead>
<tr>
<th></th>
<th>Less Stringent</th>
<th>More Stringent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Nicotine Exemption</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non-authorized states (IA, AK) territories &amp; Indian Country</td>
<td>August 21, 2019*</td>
<td>August 21, 2019*</td>
</tr>
</tbody>
</table>
| Authorized States & territories | • Effective when state adopts  
• State adoption NOT required | August 21, 2019* | • Effective when state adopts  
• State adoption required |
| Sewer Ban           |                |                |
| Subpart P           |                |                |

*effective date
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