

HAZARDOUS WASTE PHARMACEUTICALS FINAL RULE

ASTSWMO JOINT HAZARDOUS WASTE & MATERIALS MANAGEMENT MEETING
AUGUST 13, 2019

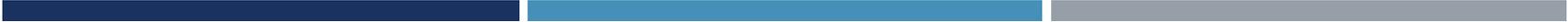
RULE REFRESHER & 5 “HIGH INTEREST” ISSUES

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OUTLINE

- I. Quick Refresher on Pharmaceuticals Final Rule
- II. Five “High Interest” Issues
 1. Amendment of the Nicotine Listing
 2. Reverse Distribution & Reverse Logistics
 3. Part 266 Subpart P: Sewer Ban
 4. Part 266 Subpart P: Applicability & Counting
 5. Part 266 Subpart P: Optional Provisions for VSQGs
- III. Next Steps



I. REFRESHER ON PHARMS FINAL RULE

THE PHARMACEUTICALS FINAL RULE IN 7 SLIDES



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 a better fit for the management of hazardous waste pharmaceuticals at healthcare facilities and reverse distributors

WASTE SPECIFIC & SECTOR SPECIFIC RULE

	Hazardous Waste Pharmaceuticals	Other Hazardous Wastes
Healthcare facilities & reverse distributors	Part 266 Subpart P	<ul style="list-style-type: none"> • Part 262 (e.g., lab waste) • Part 273 (universal waste) • Part 279 (used oil) • Etc.
Other facilities (e.g., farms/ranches, reverse logistics centers, manufacturers)	Part 262	<ul style="list-style-type: none"> • Part 262 • Part 273 (universal waste) • Part 279 (used oil) • Etc.

TYPES OF HAZ WASTE PHARMACEUTICALS

There are 3 types of *Hazardous Waste Pharmaceuticals*:

1. Non-creditable hazardous waste pharmaceutical
2. Potentially creditable hazardous waste pharmaceutical
3. Evaluated hazardous waste pharmaceutical

3 Types of HW Pharmaceuticals

Healthcare Facility



HW
TSDF

- I. Non-Creditable**
- Broken or leaking
 - Repackaged
 - Dispensed
 - Expired > 1 yr
 - Investigational new drugs
 - Contaminated PPE
 - Floor sweepings
 - Clean-up material
 - **Manifest/HW transporter required**
 - **No waste codes**
 - **PHARMS code instead**

3 Types of HW Pharmaceuticals

1st Reverse Distributor



2. Potentially Creditable



2nd Reverse Distributor

2. Potentially Creditable

- Original manufacturer packaging (except recalls)
- Undispensed
- Unexpired or less than 1-yr past expiration
- **Manifest NOT required**
- **Common Carrier allowed (e.g., FedEx, UPS)**
- **Tracking Required**

Healthcare Facility

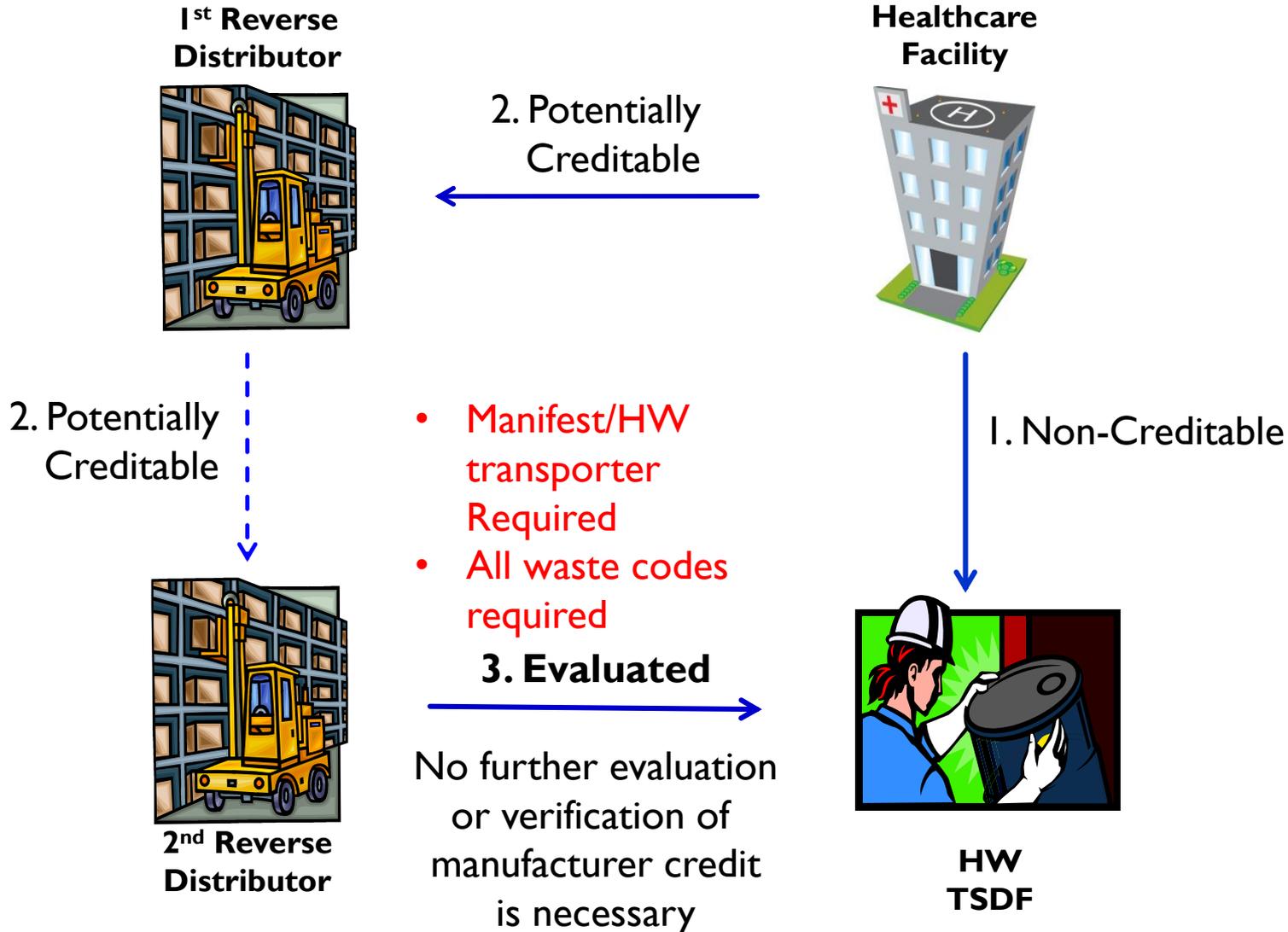


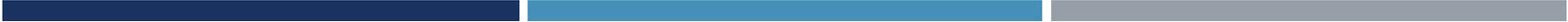
1. Non-Creditable



HW TSDF

3 Types of HW Pharmaceuticals





II. FIVE HIGH INTEREST ISSUES

I. AMENDMENT OF NICOTINE LISTING



AMENDMENT OF THE NICOTINE LISTING

- 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



≠ P075

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



= P075

3 NICOTINE FAQs

Q1: Does the nicotine exemption for OTC NRTs apply to manufacturers?

3 NICOTINE FAQs

QI: 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 26I has been amended. Therefore, the nicotine exemption for OTC NRTs is not limited to healthcare facilities and reverse distributors operating under Subpart P.

3 NICOTINE FAQs

Q2: Do OTC Nicotine Replacement Therapies kept behind the pharmacy counter qualify for the nicotine exemption?

3 NICOTINE FAQs

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 26 I, the nicotine exemption applies to all generators, not just healthcare facilities and reverse distributors.

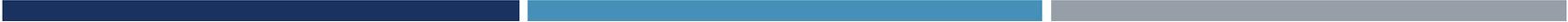
3 NICOTINE FAQs

Q3: Do VSQG healthcare facilities have to opt into subpart P to take advantage of the nicotine amendment?

3 NICOTINE FAQs

Q3: Do VSQG healthcare facilities have to opt into subpart P to take advantage of the nicotine amendment?

A: No. The nicotine exemption applies to all generators of FDA-approved OTC nicotine replacement therapy waste, not just healthcare facilities and reverse distributors. However, it has to be adopted by an authorized state before generators can utilize it. Because it is considered less stringent, authorized states are not required to adopt it. In non-authorized states, the nicotine amendment will be effective on August 21, 2019.



II. FIVE HIGH INTEREST ISSUES

2. REVERSE DISTRIBUTION & LOGISTICS



REVERSE DISTRIBUTION vs REVERSE LOGISTICS

We 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

REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & 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



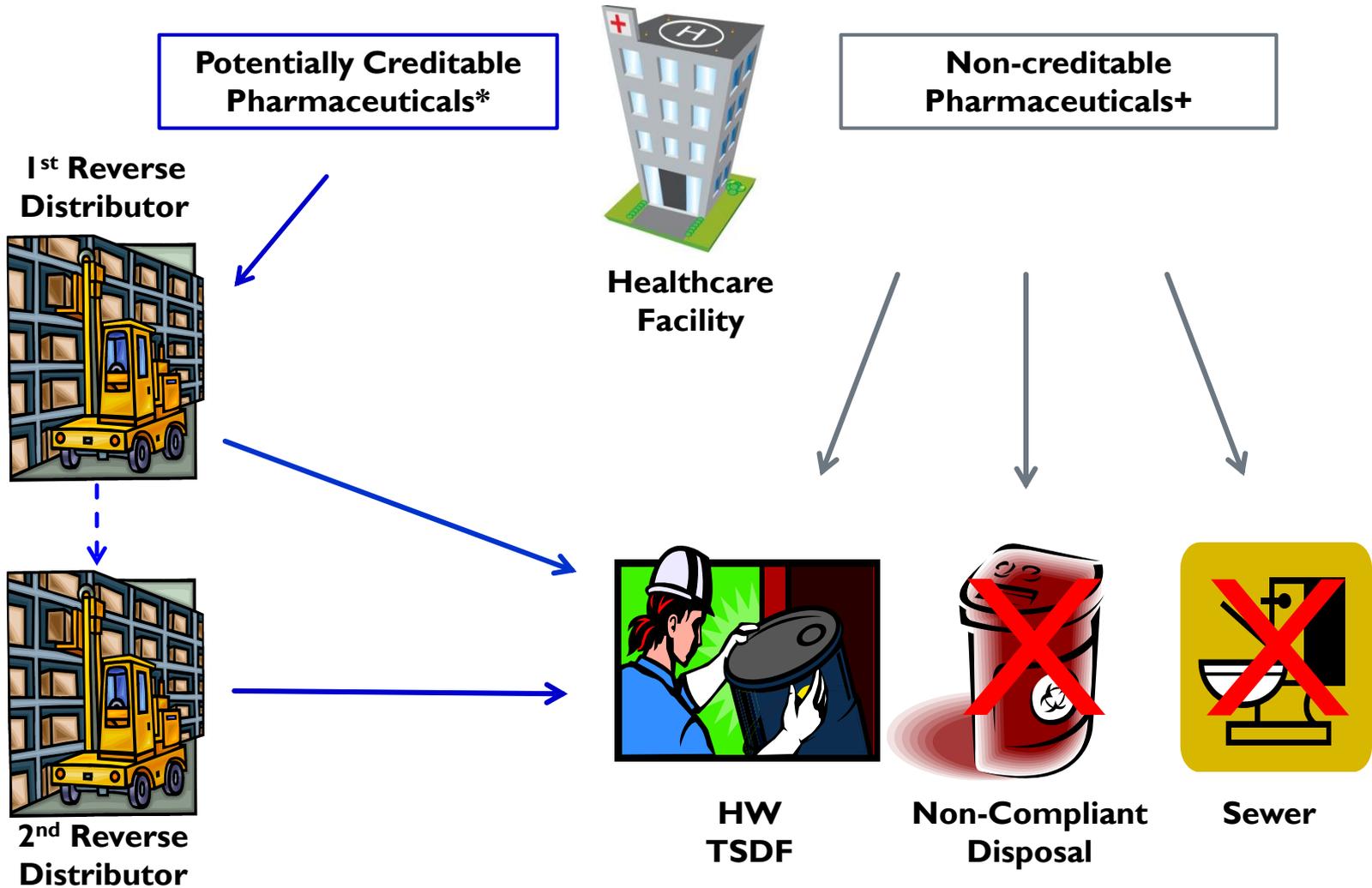
Sewer

REVERSE DISTRIBUTION

RX HW PHARMACEUTICALS

- Commenters confirmed that
 - reverse distributors receive shipments of unused/expired prescription pharmaceuticals from healthcare facilities and, on behalf of manufacturers, facilitate the process of crediting healthcare facilities for these unused pharmaceuticals
 - prescription pharmaceuticals at RDs are not reused, nor resold, and are discarded
- The final rule maintains the position from the proposed rule that prescription pharmaceuticals moving through reverse distribution are wastes at the healthcare facility
- The fact that the hazardous waste pharmaceuticals have **value** in the form of manufacturer credit has allowed us to take a tailored and more flexible regulatory approach
- EPA developed a regulatory system that is designed with existing business practices in mind for unused/expired prescription pharmaceuticals that are sent through reverse distribution

Reverse Distribution of Rx HW Pharmaceuticals



* Unsold/unused pharmaceuticals that have a reasonable expectation of receiving credit from the manufacturer
+ Pharmaceuticals with no reasonable expectation of receiving credit from the manufacturer

REVERSE DISTRIBUTION v REVERSE LOGISTICS

Reverse Distribution	Reverse Logistics
Rx pharmaceuticals	
No redistribution occurs	
Rx pharmaceuticals sent to reverse distributors <u>are solid waste</u> at the healthcare facility	
<p>In Part 266 Subpart P, which is</p> <ul style="list-style-type: none"> • Effective in non-authorized states August 21, 2019 • Effective in authorized states when state adopts Subpart P 	

REVERSE DISTRIBUTION v REVERSE LOGISTICS

Reverse Distribution	Reverse Logistics
Rx pharmaceuticals	Non-Rx pharmaceuticals <ul style="list-style-type: none"> e.g., OTCs & dietary supplements All other unsold retail items
No redistribution occurs	Redistribution sometimes occurs via: <ul style="list-style-type: none"> Donation Liquidation (secondary market)
Rx pharmaceuticals sent to reverse distributors <u>are solid waste</u> at the healthcare facility	Non-Rx pharmaceuticals and other unsold retail items sent to reverse logistics <u>are not solid waste</u> IF there is a reasonable expectation of legitimate use/reuse or reclamation
In Part 266 Subpart P, which is <ul style="list-style-type: none"> Effective in non-authorized states August 21, 2019 Effective in authorized states when state adopts Subpart P 	Newly codified in Part 266 Subpart P. But affirms existing policy <ul style="list-style-type: none"> Effective immediately federally Check with your state

REVERSE LOGISTICS POLICY: THEN AND NOW

THEN May 16, 1991 memo	NOW Pharmaceuticals Final Rule
<p>...to the extent that the materials involved are unused commercial chemical products with a <u>reasonable expectation</u> of being recycled in some way when returned, the materials are not considered as wastes...</p> <p>RCRA Online #11606</p>	<p>Nonprescription pharmaceuticals and other retail items that are sent through reverse logistics are not solid wastes at the retail store if they have a <u>reasonable expectation</u> of being legitimately use/reused (e.g., lawfully redistributed for their intended purpose) of reclaimed</p> <p>also see § 266.501(g)(2)</p>

REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

- Issues in the final reverse logistics policy:
 1. Ultimate disposition of the items
 2. Expired items
 3. Items subject to a “destroy disposition”
 4. Crediting process
 5. Items subject to a recall
 6. Items that are broking, damaged, or leaking

REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

I. Ultimate disposition of unsold retail items returned to the manufacturer

- Data suggests a majority of items moving through reverse logistics are returned to the manufacturer, but EPA did not receive data on the ultimate disposition of retail items that are returned to a manufacturer
- Items are not wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed

REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

2. Unsold retail items that have expired

- Some items may be returned to the manufacturer for evaluation for liquidation
- Nonprescription pharmaceuticals with “best by” dates can often be donated or liquidated past the date
- FDA occasionally allows the donation of drugs that are past the expiration date
- Items are not wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed

REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

3. Unsold retail items subject to a “destroy disposition”

- Retail items sometimes cannot be legitimately used/reused if they are subject to a “destroy disposition”
- Although these items cannot be legitimately used/reused, they are not wastes if they have a reasonable expectation of being legitimately reclaimed

The New York Times

*Burberry to Stop
Burning Clothing and
Other Goods It Can't Sell*

The New York Times

*Slashers' Work Ruins Shoes
Discarded at a Nike Store*



REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

4. Crediting process for unsold retail items

- Traditional Approach
 - Credit awarded after unsold retail items are returned to a reverse logistics center for processing
- Adjustable Rate Policy or “Swell Allowance”
 - Credit awarded up-front based on the assumption that a percentage of items will become unsalable
- Unsold retail items that received credit up-front through a “swell allowance” are not wastes if there is a reasonable expectation of being legitimately used/reused or reclaimed

REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

5. Unsold retail items subject to a recall

- FDA oversees all pharmaceutical recalls
- CPSC has authority over most other retail items
- Occasionally, other federal agencies regulate recalled retail items (e.g., National Highway Traffic Safety Administration oversees motor vehicle recalls)
- EPA is choosing not to apply RCRA regulations to recalled unsold retail items overseen by FDA or CPSC, but will evaluate other recalled unsold retail items on a case-by-case basis

REVERSE LOGISTICS

NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

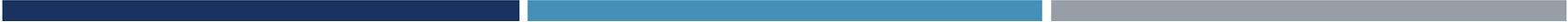
6. Unsold retail items that are broken, damaged, or leaking

- Items that are broken, damaged, or leaking cannot be sent through reverse logistics
- To go through reverse logistics, the packaging must be in good condition with no leaks or continuing or intermittent releases to the environment
- E.g., a retail item with damage to outer packaging while the inner container remains intact can go through reverse logistics if they have a reasonable expectation of being legitimately used/reused or reclaimed

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
 - Traditional healthcare facilities (e.g., hospitals, clinics, etc.) do not have contracts with reverse logistics centers
- If a healthcare facility sends a nonprescription pharmaceutical to a reverse distributor, EPA considers this over-management as hazardous waste, but the items must have reasonable expectation of receiving manufacturer credit



II. FIVE HIGH INTEREST ISSUES

3. PART 266 SUBPART P: SEWER BAN



SEWER PROHIBITION

- Hazardous waste pharmaceuticals may not be sewerred (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 also DEA controlled substances are subject to the sewer prohibition
- We strongly discourage sewerred of any pharmaceuticals by any entity
- **REMEMBER:** The sewer prohibition will be effective in ALL states on August 21, 2019

5 SEWER BAN FAQs

Q1: EPA says they strongly discourage sewerage of any pharmaceuticals by any entity. Are there any exceptions to this recommendation?

5 SEWER BAN FAQs

Q I: EPA says they strongly discourage sewerage 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 sewerage of any pharmaceutical by any entity – with few exceptions:

- Saline, lactated ringers (saline + electrolytes), etc.
- Households with pets/children and that do not have access to take-back receptacles or mail-back envelopes – but only for the few drugs on FDA’s “flush list”

5 SEWER BAN FAQS

Q2: Does the sewer ban apply to pharmaceutical manufacturers?

5 SEWER BAN FAQs

Q2: Does the sewer ban apply to pharmaceutical manufacturers?

A: The sewer ban in the hazardous waste pharmaceuticals final rule does not apply to pharmaceutical manufacturers, unless the manufacturer is a reverse distributor. However:

- EPA strongly discourages the sewerage of any pharmaceutical by any entity
- EPA has promulgated Effluent Guidelines and Standards for Pharmaceutical Manufacturing at 40 CFR 439, which address Clean Water Act discharges of pollutants associated with this industry

5 SEWER BAN FAQs

Q3: The sewer prohibition says that healthcare facilities and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly owned treatment works (POTW). Does that mean that hazardous waste pharmaceuticals can be discharged to septic systems, privately owned treatment works and federally owned treatment works?

5 SEWER BAN FAQs

Q3: The sewer prohibition says that healthcare facilities and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly owned treatment works (POTW). Does that mean that hazardous waste pharmaceuticals can be discharged to septic systems, privately owned treatment works and federally owned treatment works?

A: No.

- Since 1980, the RCRA domestic sewage exclusion has excluded from the definition of solid waste “Any mixture of domestic sewage and other wastes that passes through a sewer system to a *publicly-owned treatment works* for treatment” (see § 261.4(a)(1)(ii))
- Only discharges of mixtures of domestic sewage and hazardous waste to *publicly-owned treatment works* were excluded from the regulatory definition of solid waste
- Discharges of hazardous waste, including hazardous waste pharmaceuticals, to septic tanks, privately owned treatment works, and federally owned treatment works are considered solid wastes and therefore not allowed

5 SEWER BAN FAQs

Q4: Who will enforce the sewer ban?

5 SEWER BAN FAQs

Q4: Who will enforce the sewer ban?

A: The sewer prohibition of Subpart P will be enforced through RCRA inspections of healthcare facilities and reverse distributors by state or federal officials. In addition:

- The Clean Water Act's NPDES pretreatment program could also potentially apply and result in enforcement of requirements of the sewer prohibition if such requirements are adopted as part of a publicly owned treatment works' approved pretreatment program
- Elements of the sewer prohibition may be reflected currently in the specific prohibitions on discharge by indirect users of POTWs in EPA's Pretreatment Regulations at 40 CFR Part 403 – e.g., for D001 and D003

5 SEWER BAN FAQs

Q5: DEA does not allow the sewerage of excess inventory of controlled substances, but DEA does allow the sewerage of “pharmaceutical wastage” of controlled substances. Does EPA allow the sewerage of pharmaceutical wastage of hazardous waste pharmaceuticals?

5 SEWER BAN FAQs

Q5: DEA does not allow the sewerage of excess inventory of controlled substances, but DEA does allow the sewerage of “pharmaceutical wastage” of controlled substances. Does EPA allow the sewerage of pharmaceutical wastage of hazardous waste pharmaceuticals?

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

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



II. FIVE HIGH INTEREST ISSUES

4. PART 266 SUBPART P: APPLICABILITY & COUNTING



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

GENERATOR CATEGORY & PHARMS RULE

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:
 - ≤ 1 kg (2.2 lbs) acute hazardous waste and
 - ≤ 100 kg (220 lbs) non-acute hazardous waste and
 - ≤ 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

GENERATOR CATEGORY & PHARMS RULE

Determining whether a healthcare facility is subject to Subpart P:

1. Count all hazardous waste generated per month, including hazardous waste pharmaceuticals
2. If generate 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 is a VSQG/SQG/LQG under Part 262 for its other hazardous waste

GENERATOR CATEGORY & PHARMS RULE

- 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

GENERATOR CATEGORY & PHARMS RULE

- 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

SCENARIOS FOR HEALTHCARE FACILITIES

Nickname	Subpart P Applicability for HW Pharmaceuticals	Part 262 Generator Category for other HW
Full VSQG	Sewer ban New empty container standards Optional provisions	VSQG
Subpart P VSQG	All of Subpart P	VSQG
Subpart P SQG	All of Subpart P	SQG
Subpart P LQG	All of Subpart P	LQG

GENERATOR CATEGORY & PHARMS RULE

Four provisions are expected to affect the amount of hazardous waste pharmaceuticals that gets counted

Decrease Amount of Hazardous Waste Pharmaceuticals	Increase Amount of Hazardous Waste Pharmaceuticals
1. Nicotine patches, gums & lozenges are not hazardous waste	3. Sewer prohibition
2. Pharmaceuticals managed under Subpart P do not count toward determining a facility's Part 262 generator category	4. Pharmaceuticals that are destined for a reverse distributor are solid waste

GENERATOR CATEGORY & PHARMS RULE

- I. 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

GENERATOR CATEGORY & PHARMS RULE

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

GENERATOR CATEGORY & PHARMS RULE

3. SUBPART P: Sewer prohibition

- Hazardous waste pharmaceuticals can not be sewerred and must be counted toward determining whether a healthcare facility is subject to Subpart P

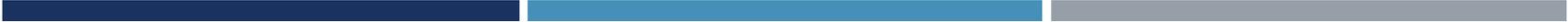
GENERATOR CATEGORY & PHARMS RULE

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

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**



II. FIVE HIGH INTEREST ISSUES

5. PART 266 SUBPART P: VSQGS



SUBPART P & VSQG HEALTHCARE FACILITIES

- Healthcare facilities that are “Subpart P VSQGs” are subject to all of provisions of Subpart P for their hazardous waste pharmaceuticals
- Healthcare facilities that are “full VSQGs,” are not subject to Subpart P, except the:
 - Sewer prohibition
 - New empty container provisions
- Healthcare facilities that are “full VSQGs” can choose to:
 - Opt into Part 266 Subpart P and comply with all its provisions OR
 - Continue to operate under Part 262 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

- I. 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

2. OFF-SITE CONSOLIDATION (CONTINUED)

- 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

2. SUBPART P OFF-SITE CONSOLIDATION (CONTINUED)

- 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 (CONTINUED)

- 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 and
 - 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
 - Manage the hazardous waste pharmaceuticals it receives from off site under Subpart P

COMPARING OFF-SITE CONSOLIDATION

Subpart P Off-site Consolidation	GIR Off-site Consolidation
Can be used by VSQG healthcare facilities only for hazardous waste pharmaceuticals	Can be used by VSQG healthcare facilities for both hazardous waste pharmaceuticals AND non-pharmaceutical hazardous waste
Fewer conditions	More conditions
Receiving healthcare facility must be: <ul style="list-style-type: none"> • 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: <ul style="list-style-type: none"> • 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 DEA registrants can amend their DEA registration to become “collectors”
 - Retail DEA collectors can put take-back collection receptacles (kiosks) in their store or at an LTCF
 - 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 OPTIONAL PROVISIONS FOR VSQG HCFS

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

TAKE HOME MESSAGES

If you remember nothing else from this presentation, remember these points:

- Nicotine amendment: only applies to FDA-approved OTC NRTs, i.e., can be discarded as non-hazardous waste
- Reverse Distribution/Reverse Logistics: Anything that does not have a reasonable expectation of receiving manufacturer credit or use/reuse or reclamation is waste at the healthcare facility
- Sewer Ban: Hazardous waste pharmaceuticals may not be sewerred (e.g., no disposal down the drain and no flushing). Sewer prohibition will be effective in ALL states on August 21, 2019
- Generator Category: Hazardous waste pharmaceuticals must be managed under Subpart P to get the benefit of not counting them toward a facility's generator category
- Healthcare Facilities that are VSQGs:
 - Subpart PVSQGs: subject to all Subpart P provisions
 - Full VSQGs: not subject to Subpart P except for sewer ban and new empty container provisions; can choose to opt into Part 266 Subpart P or continue to operate under Part 262 and use none/any/all of the four optional provisions in § 266.504



III. NEXT STEPS



PHARMACEUTICALS TEAM TO DO LIST

- Develop more written FAQs for website
 - Definitions
 - Applicability
 - Nicotine
 - Sequestration units/Drug disposal units
- Develop targeted trainings/fact sheets for specific audiences
 - VSQGs
 - Long-term care facilities
- Deliver longer-format trainings
 - New Jersey – October 9th
 - Looking to schedule more
- Continue coordinating with import/export team on implementation
- Track state adoption of Subpart P & Nicotine listing amendment
- Continue technical assistance related to pharmaceutical take-backs

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Final rule webpage: <https://www.epa.gov/hwgenerators/final-rule-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075>