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

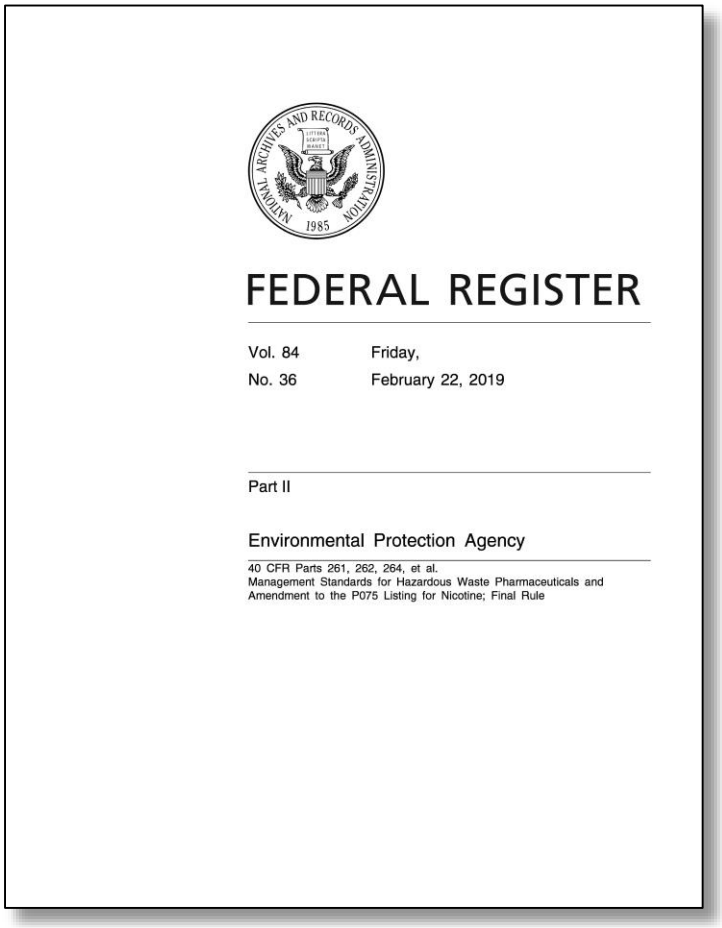
MODULE 1

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

FEDERAL REGISTER PUBLICATION

- The final rule was published in the Federal Register on February 22, 2019
- 84 FR 5816
- FR publication date drives
  - Effective dates



FEDERAL REGISTER

Vol. 84 Friday,
No. 36 February 22, 2019

Part II

Environmental Protection Agency

40 CFR Parts 261, 262, 264, et al.
Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine; Final Rule

GOALS & OVERVIEW OF THE PHARMACEUTICALS RULE

SECTION I

PHARMACEUTICALS FINAL RULE

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

Part 266 Subpart P

- 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)

Subpart P & Reverse Logistics Policy

- Provide regulatory clarity and national consistency on how RCRA applies to reverse distribution and reverse logistics

Part 261

- 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

FRAMEWORK OF PART 266 SUBPART P

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

EFFECTIVE DATES

- 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)

STATE ADOPTION

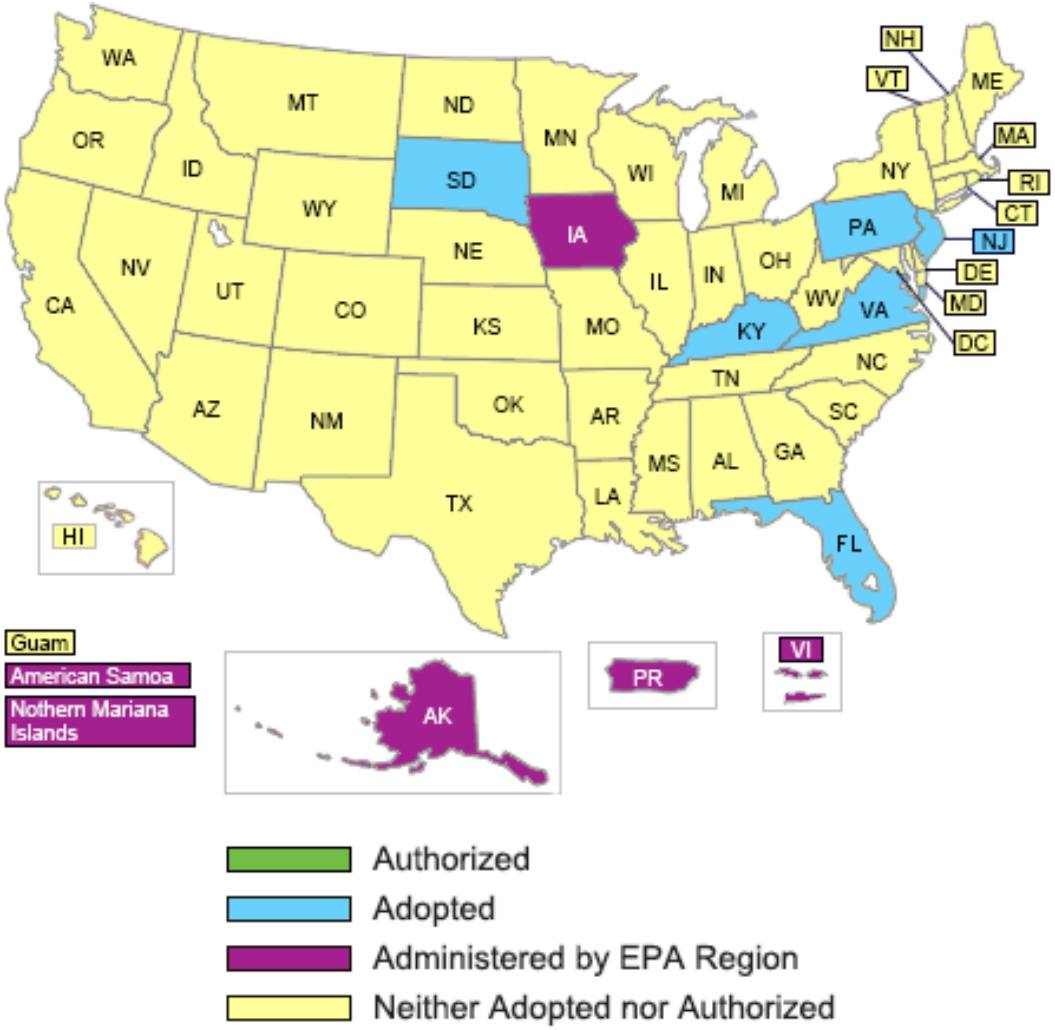
- Subpart P is considered more stringent
  - Authorized states MUST adopt Subpart P
  - NJ has adopted Subpart P
  - Several other states already have
- Nicotine amendment is considered less stringent
  - Authorized states are NOT required to adopt the nicotine amendment
  - NJ has adopted the nicotine 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
- https://www.epa.gov/hwgenerators/where-are-management-standards-hazardous-waste-pharmaceuticals-and-amendment-p075

STATE ADOPTION OF PART 266 SUBPART P

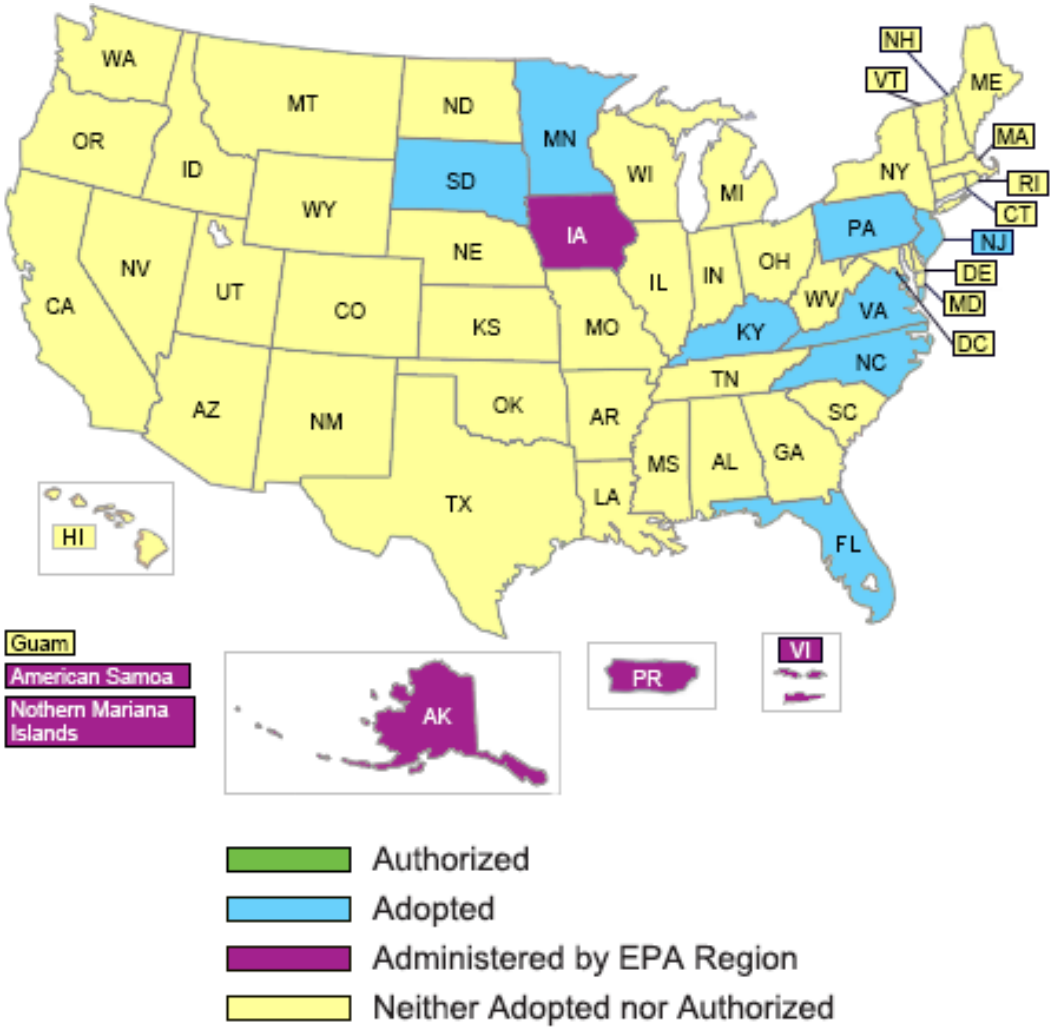
<u>Effective in:</u>
Indian Country
4 Territories
8 States



As of Sept 6, 2019

STATE ADOPTION OF NICOTINE AMENDMENT

<u>Effective in:</u>
Indian Country
4 Territories
10 States



As of Sept 6, 2019

AMENDMENT OF NICOTINE LISTING

SECTION III

NICOTINE LISTING AMENDMENT

- 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

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

REVERSE DISTRIBUTION vs REVERSE LOGISTICS

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

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

- **REVERSE LOGISTICS** of
  - Nonprescription pharmaceuticals (e.g., OTCs, supplements, etc.)
  - All other unsold retail items

REVERSE LOGISTICS
NON-RX HW PHARMACEUTICALS & OTHER UNSOLD RETAIL ITEMS

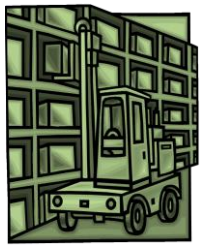
- Commenters noted that reverse logistics centers are designed to
  - evaluate unsold retail items including nonprescription pharmaceuticals
  - analyze secondary markets, and
  - assess the suitability of the unsold retail items for reuse in those secondary markets
- The final rule reaffirms & codifies 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

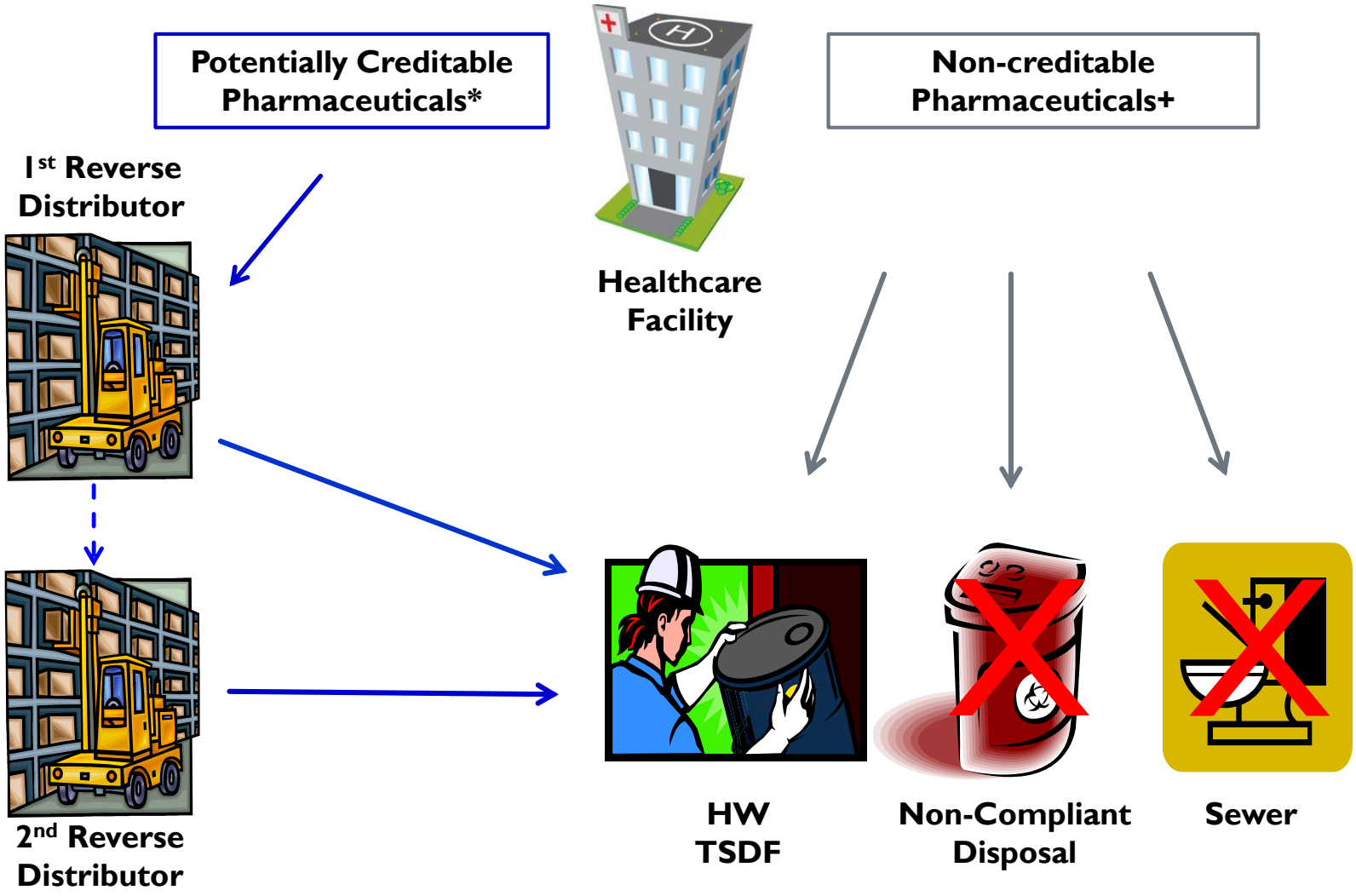
REVERSE LOGISTICS POLICY: THEN AND NOW

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

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 are solid waste at the healthcare facility	
In Part 266 Subpart P, which is • 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 • e.g., OTCs & dietary supplements All other unsold retail items
No redistribution occurs	Redistribution sometimes occurs via: • 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 • Effective in non-authorized states August 21, 2019 • Effective in authorized states when state adopts Subpart P	Newly codified in Part 266 Subpart P with respect to pharmaceuticals. But affirms existing policy • Effective immediately federally • Check with your state

PART 266 SUBPART P

SECTION V

§ 266.500

PART 266 SUBPART P – NEW TERMS DEFINED

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

§ 266.500

PART 266 SUBPART P – NEW TERMS DEFINED

Who is managing the waste

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

§ 266.500

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
- 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

Pharmaceutical does NOT include:

- Dental amalgam
- Sharps
- Medical waste

§ 266.500

DEFINITION OF HAZ WASTE PHARMACEUTICAL

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

§ 266.500

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

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

3 Types of HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable

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

Healthcare Facility

2. Potentially Creditable

1. Non-Creditable

2nd Reverse Distributor

HW TSDF

3 Types of HW Pharmaceuticals

1st Reverse Distributor

Healthcare Facility

2. Potentially Creditable

3. Evaluated

1. Non-Creditable

2. Potentially Creditable

2nd Reverse Distributor

3. Evaluated

No further evaluation or verification of manufacturer credit is necessary

HW TSDF

§ 266.500

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

Healthcare Facility does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reveres logistics centers

§ 266.500

DEFINITION OF LONG-TERM CARE FACILITY

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

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

Long-term Care Facility does NOT include:

- Group homes
- Independent living communities
- Assisted living facilities
- Independent and assisted living portions of continuing care retirement communities

§ 266.500

DEFINITION OF REVERSE DISTRIBUTOR

Reverse Distributor means

- Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit
- Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor

SUMMARY MATRIX OF PART 266 SUBPART P

	Standards for Healthcare Facilities	Standards for Reverse Distributors
	Potentially Creditable	**Potentially Creditable**
On-site accumulation		
Shipping to a reverse distributor		
	Non-Creditable	**Evaluated**
On-site accumulation		
Shipping to a TSDF		

§ 266.501

PART 266 SUBPART P APPLICABILITY

- Part 266 Subpart P is considered more stringent, and therefore is NOT optional for
  - States to adopt
  - Healthcare facilities and reverse distributors
- Hazardous waste pharmaceuticals must be managed under Part 266 Subpart P by:
  - All healthcare facilities
    - If healthcare facility generates above VSQG amounts of hazardous waste
  - All reverse distributors
- Part 266 Subpart P is both waste-specific and sector-specific

WASTE SPECIFIC & SECTOR SPECIFIC RULE

	Hazardous Waste Pharmaceuticals	Other Hazardous Wastes
Healthcare facilities & reverse distributors	Part 266 Subpart P	• 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	• Part 262 • Part 273 (universal waste) • Part 279 (used oil) • Etc.

§ 266.501

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

§ 266.501

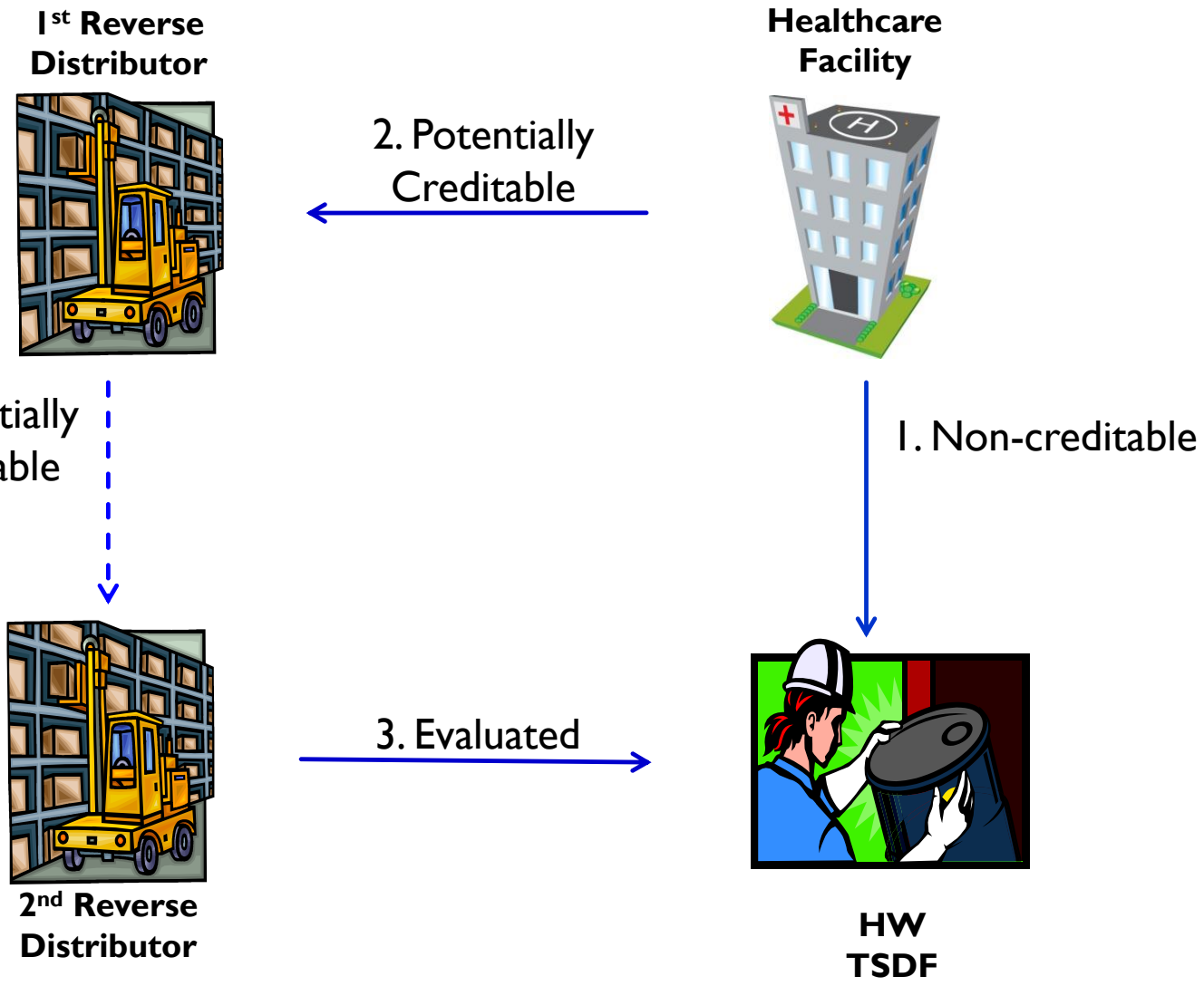
PART 266 SUBPART P APPLICABILITY

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



Applicability for Rx HW Pharmaceuticals

1st Reverse Distributor

2. Potentially Creditable
Part 266 Subpart P

Healthcare Facility

2. Potentially Creditable
Part 266 Subpart P

1. Non-creditable
Part 266 Subpart P

2nd Reverse Distributor

3. Evaluated
Part 266 Subpart P

HW TSDF

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

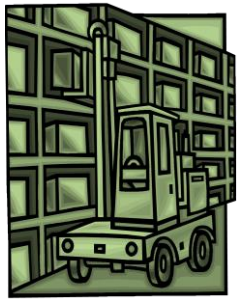
Healthcare Facility

Non-creditable
Part 266 Subpart P (new)

HW TSDF

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

1st Reverse Logistics Center



Not Solid Waste

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

Healthcare Facility

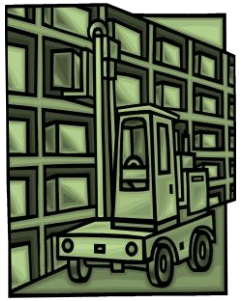
Non-creditable ***Part 266 Subpart P (new)***

2nd Reverse Logistics Center

HW TSDF

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

1st Reverse Logistics Center



Healthcare Facility

Not Solid Waste

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

Non-creditable ***Part 266 Subpart P (new)***

2nd Reverse Logistics Center

Part 262 ***(status quo)***

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

REVERSE DISTRIBUTION
NON-RX HW PHARMACEUTICALS GOING THROUGH RD?

- 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

HEALTHCARE FACILITY STANDARDS

- 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

§§ 266.502 and 266.503

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

  <u>Non-creditable hazardous waste pharmaceuticals</u>
  - destined for TSDF directly
  - regulations resemble Universal Waste but adds shipping requirements

  <u>Potentially creditable hazardous waste pharmaceuticals</u>
  - 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

§§ 266.502 and 266.503

HEALTHCARE FACILITY STANDARDS

- Hazardous Waste Determinations: healthcare facilities must determine whether a waste pharmaceutical is a hazardous waste pharmaceutical
  - Applies to both potentially creditable and non-creditable waste pharmaceuticals
  - Exception: If a healthcare facility manages all of its waste pharmaceuticals as hazardous, individual hazardous waste determinations are not necessary
- Commingling: healthcare facilities may accumulate both their hazardous and non-hazardous waste pharmaceuticals in the same container
  - Potentially creditable: hazardous + non-hazardous
  - Non-creditable: hazardous + non-hazardous

§§ 266.502 and 266.503

HEALTHCARE FACILITY MANAGEMENT STANDARDS

Non-creditable hazardous waste pharmaceuticals:

- Labeling:
  - Accumulation containers must be labeled with the words "Hazardous Waste Pharmaceuticals"
  - No hazardous waste codes or other labeling requirements
- Container Standards:
  - Structurally sound, will not react with contents (i.e., compatible)
  - Remain closed and secured in a manner that prevents unauthorized access to its contents
- Accumulation time limit: 1 year

Potentially creditable hazardous waste pharmaceuticals:

- No labeling, containers standards or accumulation time

§ 266.500

HEALTHCARE FACILITY STANDARDS

	Non-creditable HW Pharms	Potentially Creditable HW Pharms
Container Standards	• Security • Compatibility	None
Labeling	• "Hazardous Waste Pharmaceuticals" • No hazardous waste codes required	None
Maximum Accumulation Time	One year	None
Over-managing non-hazardous pharmaceuticals & commingling with hazardous pharmaceuticals	Allowed	Allowed
Include hazardous waste pharmaceuticals on BR	No	No

SUMMARY MATRIX OF PART 266 SUBPART P

	Standards for Healthcare Facilities	Standards for Reverse Distributors
	Potentially Creditable	
On-site accumulation	• No standards • No time limit	
Shipping to a reverse distributor		
	Non-Creditable	
On-site accumulation	• UW-like standards • 1 year maximum	
Shipping to a TSDF		

§§ 266.508 & 266.509

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

SUMMARY MATRIX OF PART 266 SUBPART P

	Standards for Healthcare Facilities	Standards for Reverse Distributors
	Potentially Creditable	**Potentially Creditable**
On-site accumulation		
Shipping to a reverse distributor	• Confirmation of delivery • Common carrier	• Confirmation of delivery • Common carrier
	Non-Creditable	**Evaluated**
On-site accumulation		
Shipping to a TSDF	• Manifest (PHARMS/PHRM) • HW transporter	• Manifest (waste codes) • HW transporter

§ 266.504

SUBPART P & VSQG HEALTHCARE FACILITIES

- 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

§ 266.504(a)

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

§ 266.504(b)

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

§ 266.504(b)

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)

2. SUBPART P OFF-SITE CONSOLIDATION (CONTINUED)

- 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

§ 266.504(b)

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

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: • 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

§ 266.504(c)

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

§ 266.504(d)

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

§ 266.505

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

SEWER BAN FAQS

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

SEWER BAN FAQS

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

SEWER BAN FAQS

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?

SEWER BAN FAQS

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

§ 266.506

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

HW THAT ARE ALSO DEA CONTROLLED SUBSTANCES

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

§ 266.506

DEA CONTROLLED SUBSTANCES (CONTINUED)

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

§§ 261.7 & 266.507

EMPTY CONTAINERS

- New empty container standards apply to
  - Containers with hazardous waste pharmaceuticals – acute & non-acute
  - Healthcare facilities and reverse distributors subject to Part 266 Subpart P and
  - Anyone else with containers of hazardous waste pharmaceuticals
- Residues remaining in "RCRA empty" containers are not regulated as hazardous waste
- 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

	"RCRA EMPTY"	
	Non-acute HW Pharms	Acute HW Pharms*
Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit-dose containers	Remove contents	Remove contents
Syringes		
IV Bags		
Other Containers		

*No triple rinsing of containers with acute hazardous waste pharmaceuticals

§§ 261.7 & 266.507

EMPTY CONTAINER STANDARDS

	"RCRA EMPTY"	
	Non-acute HW Pharms	Acute HW Pharms*
Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit-dose containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags		
Other Containers		

*No triple rinsing of containers with acute hazardous waste pharmaceuticals

§§ 261.7 & 266.507

EMPTY CONTAINER STANDARDS

	"RCRA EMPTY"	
	Non-acute HW Pharms	Acute HW Pharms*
Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit-dose containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or § 261.7(b)(1)	Fully administer contents
Other Containers		

*No triple rinsing of containers with acute hazardous waste pharmaceuticals

§§ 261.7 & 266.507

EMPTY CONTAINER STANDARDS

	"RCRA EMPTY"	
	Non-acute HW Pharms	Acute HW Pharms*
Stock/Dispensing Bottles (1 liter or 10,000 pills) & Unit-dose containers	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or § 261.7(b)(1)	Fully administer contents
Other Containers	§ 261.7(b)(1) or (2)	Can not be RCRA empty

*No triple rinsing of containers with acute hazardous waste pharmaceuticals

§ 266.510

REVERSE DISTRIBUTOR STANDARDS

- A reverse distributor is a new type of hazardous waste management facility that can only accept hazardous waste that is "potentially creditable hazardous waste pharmaceuticals"
  - No RCRA storage permit required
  - No generator categories for reverse distributors (e.g., VSQG, SQG, LQG)
  - All reverse distributors are regulated the same for hazardous waste pharmaceuticals
- Standards are similar to LQGs, with some additions:
  - One-time notification as a reverse distributor
  - Inventory of hazardous waste pharmaceuticals
  - Security requirements

§ 266.510

REVERSE DISTRIBUTOR STANDARDS

- 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 days evaluation + 180 days accumulation = 210 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

FLOW OF HW PHARMACEUTICALS

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"**

HCF/Pharmacy

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

HW TSDF

FLOW OF HW PHARMACEUTICALS

HCF/Pharmacy

Once manufacturer's credit has been determined/verified, and pharmaceuticals are destined for a TSDF, they are considered

"Evaluated HW Pharmaceuticals"

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

HW TSDF

§ 266.510

REVERSE DISTRIBUTOR STANDARDS

- Potentially creditable hazardous waste pharmaceuticals:
  - No specific labeling or container standards
  - Not included on Biennial Report
- Evaluated hazardous waste pharmaceuticals:
  - Must designate an on-site accumulation area and conduct weekly inspections
  - LQG training for personnel handling evaluated hazardous waste pharmaceuticals
  - Label as "hazardous waste pharmaceuticals" during accumulation
  - Containers must be in good condition and managed to prevent leaks
  - Hazardous waste codes prior to transport off-site
  - Included on Biennial Report

§ 266.510

REVERSE DISTRIBUTOR STANDARDS

	Potentially Creditable HW Pharms	Evaluated HW Pharms
Labeling	None	✓
Container Standards	None	✓
Accumulation Area	None	✓
Maximum Evaluation or Accumulation Time	✓	✓
Include hazardous waste pharmaceuticals on BR	No	✓

SUMMARY MATRIX OF PART 266 SUBPART P

	Standards for Healthcare Facilities	Standards for Reverse Distributors
		Potentially Creditable
On-site accumulation		Evaluate w/in 30 days
Shipping to a reverse distributor		
		Evaluated
On-site accumulation		• LQG-like standards • 180 days after evaluation
Shipping to a TSDF		

SUMMARY MATRIX OF PART 266 SUBPART P

	Standards for Healthcare Facilities	Standards for Reverse Distributors
	Potentially Creditable	**Potentially Creditable**
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

NOTIFICATION & REPORTING

MODULE 2

MODULE 2 - OUTLINE

1. Notification
2. Manifest
3. Biennial Report

NOTIFICATION

- 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

EPA ID Number | | | | | | | | | | | | |

OMB# 2050-0024; Expires 05/31/2020

D. Pharmaceutical Activities

☐ Y ☐ N	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.
☐	a. Healthcare Facility
☐	b. Reverse Distributor
☐ Y ☐ N	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.

MANIFEST

- 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

MyRCRAid

- 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

MODULE 3 - OUTLINE

1. Nicotine Listing Amendment
2. Applicability & Counting

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 <u>patches, gums and lozenges</u> 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

NICOTINE UNDER THE PHARMACEUTICALS RULE

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

4 NICOTINE FAQS

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

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4 NICOTINE FAQS

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.

4 NICOTINE FAQS

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

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4 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 261, the nicotine exemption applies to all generators, not just healthcare facilities and reverse distributors.

4 NICOTINE FAQS

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

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4 NICOTINE FAQS

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.

4 NICOTINE FAQS

Q4: Can I use the nicotine amendment in New Jersey?

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4 NICOTINE FAQS

Q4: Can I use the nicotine amendment in New Jersey?

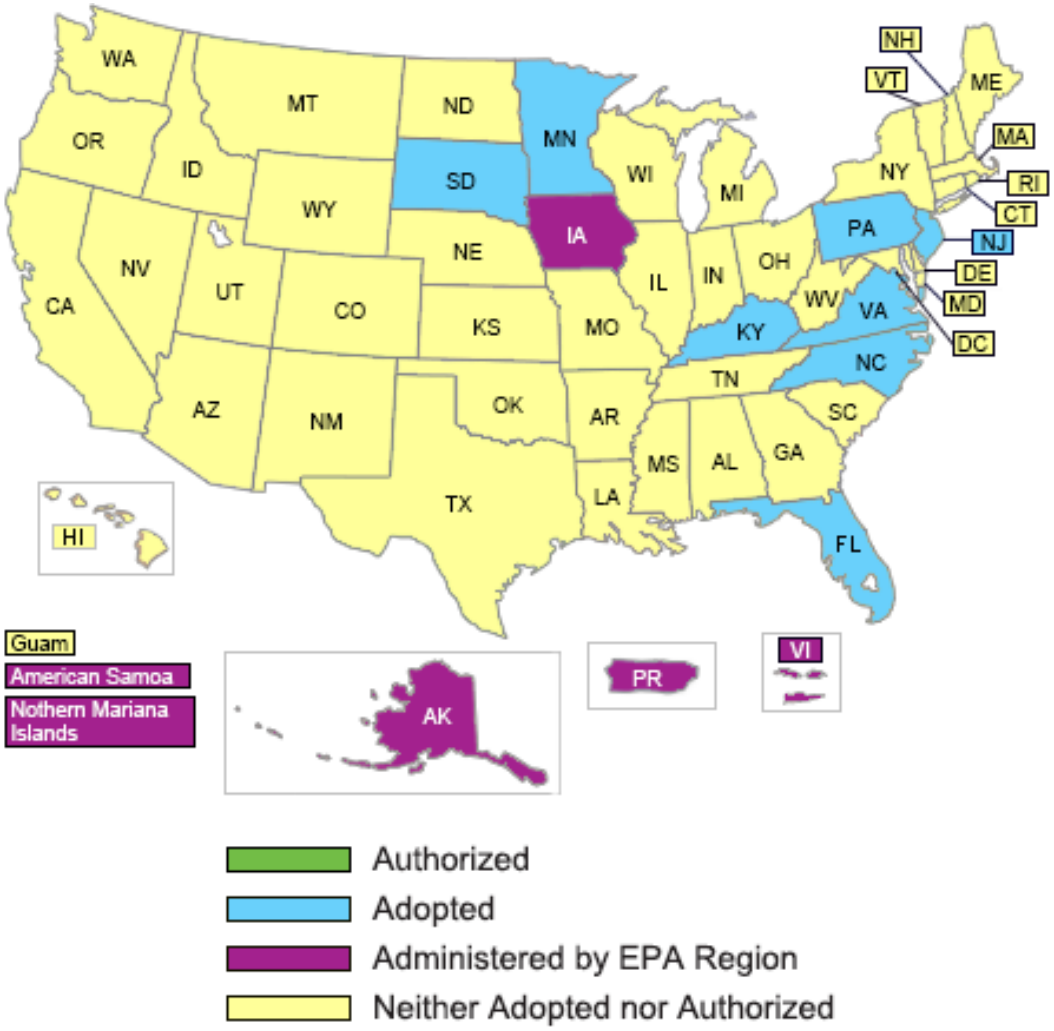
A: Yes. New Jersey has adopted the nicotine listing amendment. Note that if the nicotine waste goes outside of the state to a state that has not adopted the amendment, the waste may be regulated as a hazardous waste.

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

<u>Effective in:</u>
Indian Country
4 Territories
10 States



As of Sept 6, 2019

§ 266.501

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

§ 266.501

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

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 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

§ 266.501

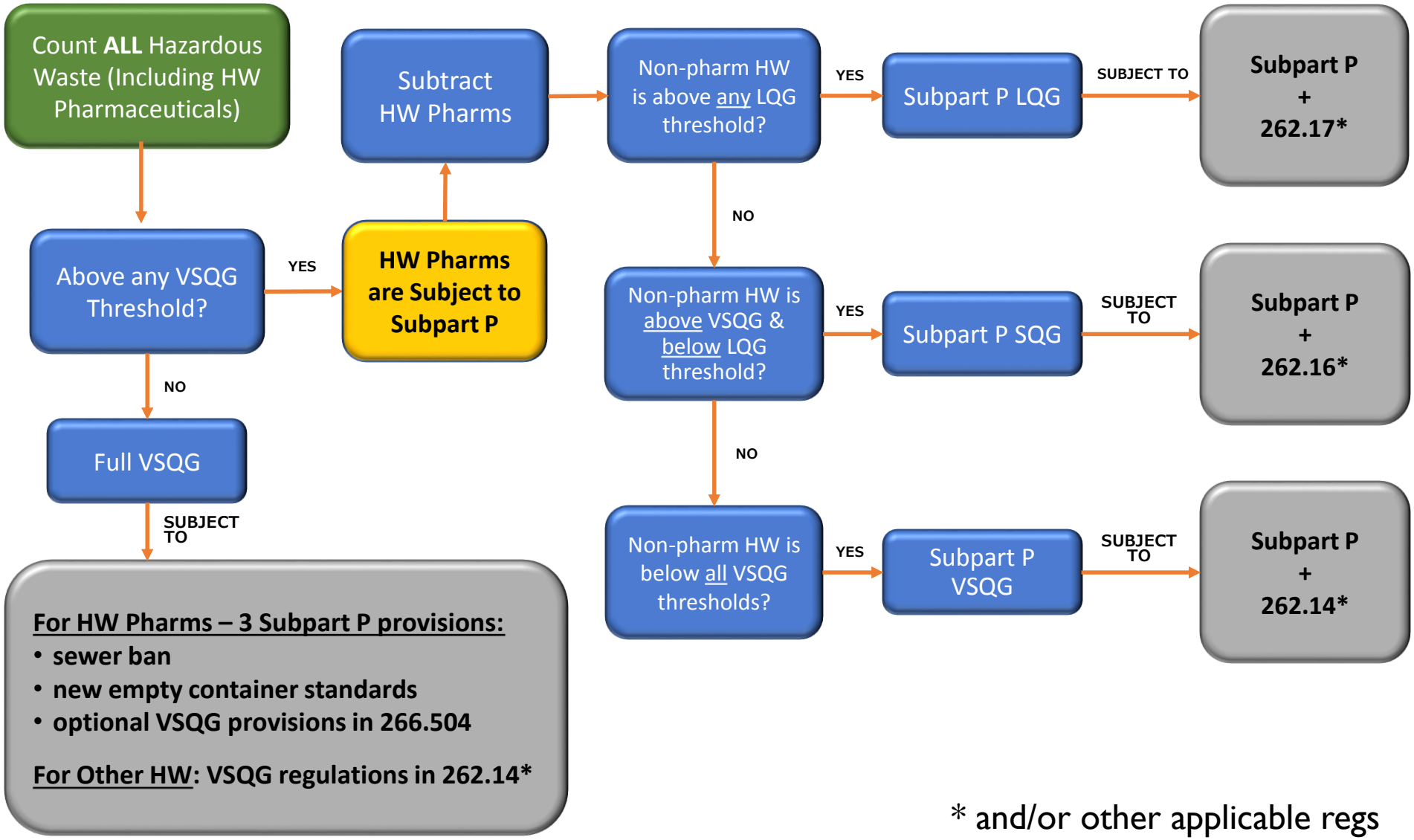
GENERATOR CATEGORY & PHARMS RULE

- 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

Applicability Flow Chart for Healthcare Facilities



* 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

EXAMPLE

Above any VSQG Threshold?

5 kg acute hazardous waste pharmaceuticals

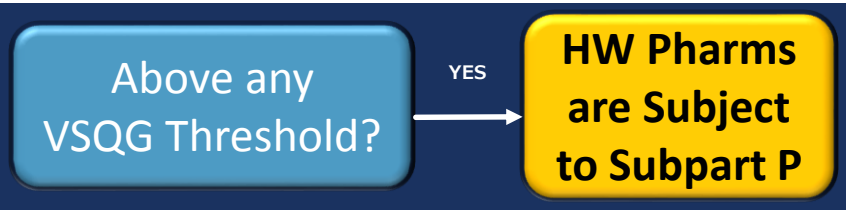
25 kg non-acute hazardous waste pharmaceuticals

\+ 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

Subtract HW Pharms

~~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

Non-pharm HW is above VSQG & below LQG threshold?

~~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

Subpart P SQG

5 kg acute hazardous waste pharmaceuticals

25 kg non-acute hazardous waste pharmaceuticals

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

Hazardous Waste Pharmaceuticals	+	Non-pharmaceutical Hazardous Waste
SUBPART P		SQG

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

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

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 sewered 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

APPLICABILITY FAQS

Q1: If an LQG such as a manufacturer or military base has an on-site clinic, is the clinic regulated under Subpart P?

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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.

APPLICABILITY FAQS

Q2: Can a healthcare facility avoid RCRA regulation by not counting its hazardous waste pharmaceuticals?

APPLICABILITY FAQS

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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

	Less Stringent	More Stringent	
	Nicotine Exemption	**Sewer Ban**	**Subpart P**
Non-authorized states (IA, AK) territories & Indian Country	August 21, 2019*	August 21, 2019*	August 21, 2019*
Authorized States & territories	• Effective when state adopts • State adoption NOT required	August 21, 2019*	• Effective when state adopts • State adoption required

*effective date

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