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

PUBLIC WEBINAR PRESENTED BY EPA

APRIL 2019

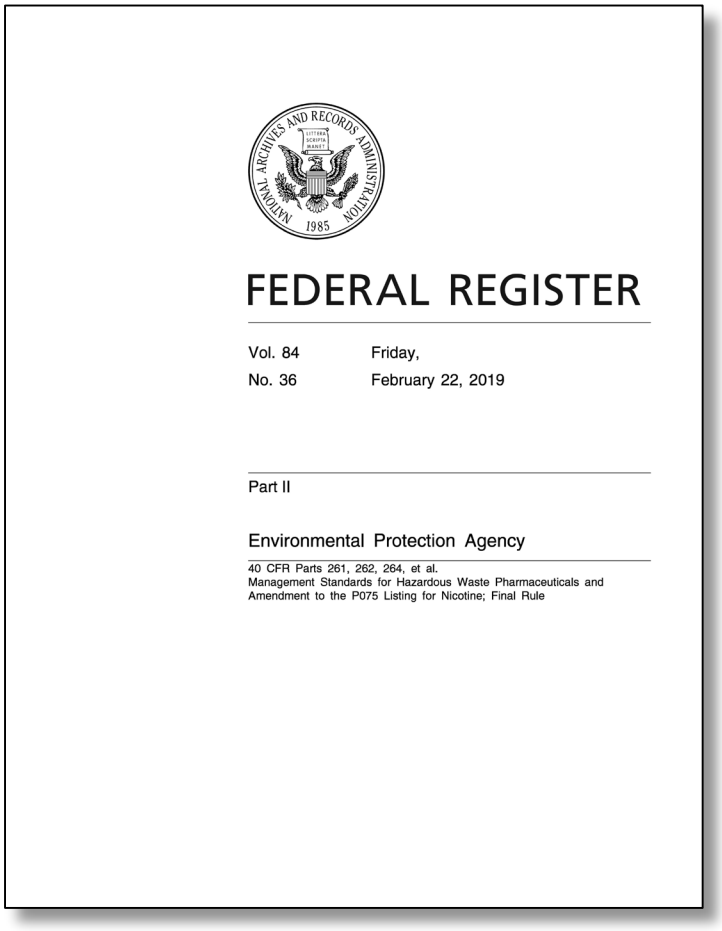
Introduction to Part 266 Subpart P

OUTLINE

1. Goals & Overview of the Pharmaceuticals Final Rule
2. Effective Dates & State Adoption
3. Amendment of the Nicotine Listing
4. Reverse Distribution and Reverse Logistics
5. Part 266 Subpart P Overview
   - Definitions
   - Applicability
   - Healthcare Facility Standards
   - VSQG Healthcare Facilities
   - Sewer Ban
   - DEA Controlled Substances
   - Empty Containers
   - Shipping
   - Reverse Distributor Standards

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
  - State adoption deadlines



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

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

EFFECTIVE DATES & STATE ADOPTION

SECTION II

EFFECTIVE DATE - AMENDMENT TO NICOTINE LISTING

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

STATE ADOPTION - NICOTINE AMENDMENT

- In authorized states, the amendment to the nicotine listing is effective only after the state adopts the amendment
- The amendment to the nicotine listing is considered LESS stringent, therefore:
  - Authorized states are NOT required to adopt the amendment to the nicotine listing
  - Authorized states do NOT have a deadline to adopt the amendment to the nicotine listing

EFFECTIVE DATE - PART 266 SUBPART P

- The effective date will be August 21, 2019
- Subpart P is effective 6 months after publication the Federal Register in:
  - Non-authorized states: Iowa, Alaska,
  - Indian Country
  - US Territories (except Guam)

§ 271.21(e)

STATE ADOPTION - PART 266 SUBPART P

- In authorized states, Subpart P is effective only after the state adopts Subpart P
- Subpart P is considered MORE stringent; therefore authorized states are required to adopt it
  - Promotes stakeholders' request for national consistency
- State adoption deadlines:
  - Authorized states have until July 1, 2021 to adopt Subpart P
  - Authorized states that require a statutory amendment, have until July 1, 2022 to adopt Subpart P

STATE ADOPTION DEADLINES

2021

July 1

2022

July 1

EFFECTIVE DATE – SEWER PROHIBITION

- The prohibition on sewering hazardous waste pharmaceuticals is promulgated under the authority of Hazardous and Solid Waste Amendments (HSWA)
- The sewer prohibition is effective in ALL states 6 months after publication in the Federal Register, regardless of whether the state
  - Is authorized, or
  - Has adopted Subpart P
- The effective date of the sewer prohibition will be August 21, 2019 for ALL states
- Applies to all healthcare facilities and reverse distributors

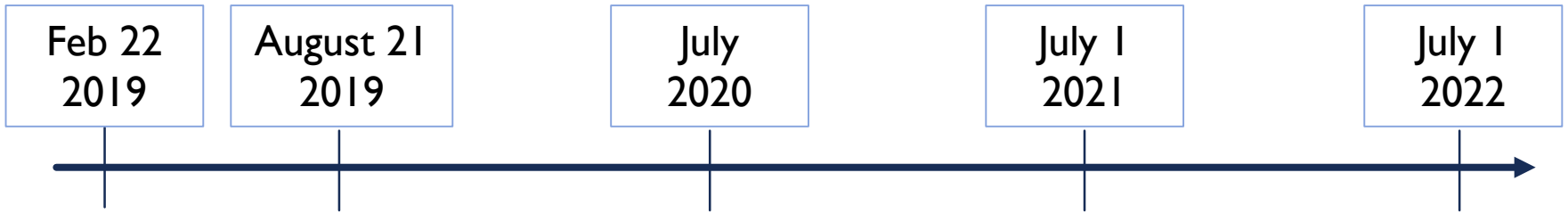
EFFECTIVE DATE

2019

August 21

FOR ALL STATES

EFFECTIVE DATES & STATE ADOPTION
TIMELINE



FR publication 84 FR 5816

- Nicotine amendment effective in non-authorized states
- Subpart P effective in non-authorized states
- Sewer ban effective in ALL states

Authorized states must adopt Subpart P

Authorized states that require a statutory amendment must adopt Subpart P

AMENDMENT OF NICOTINE LISTING

SECTION III

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

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

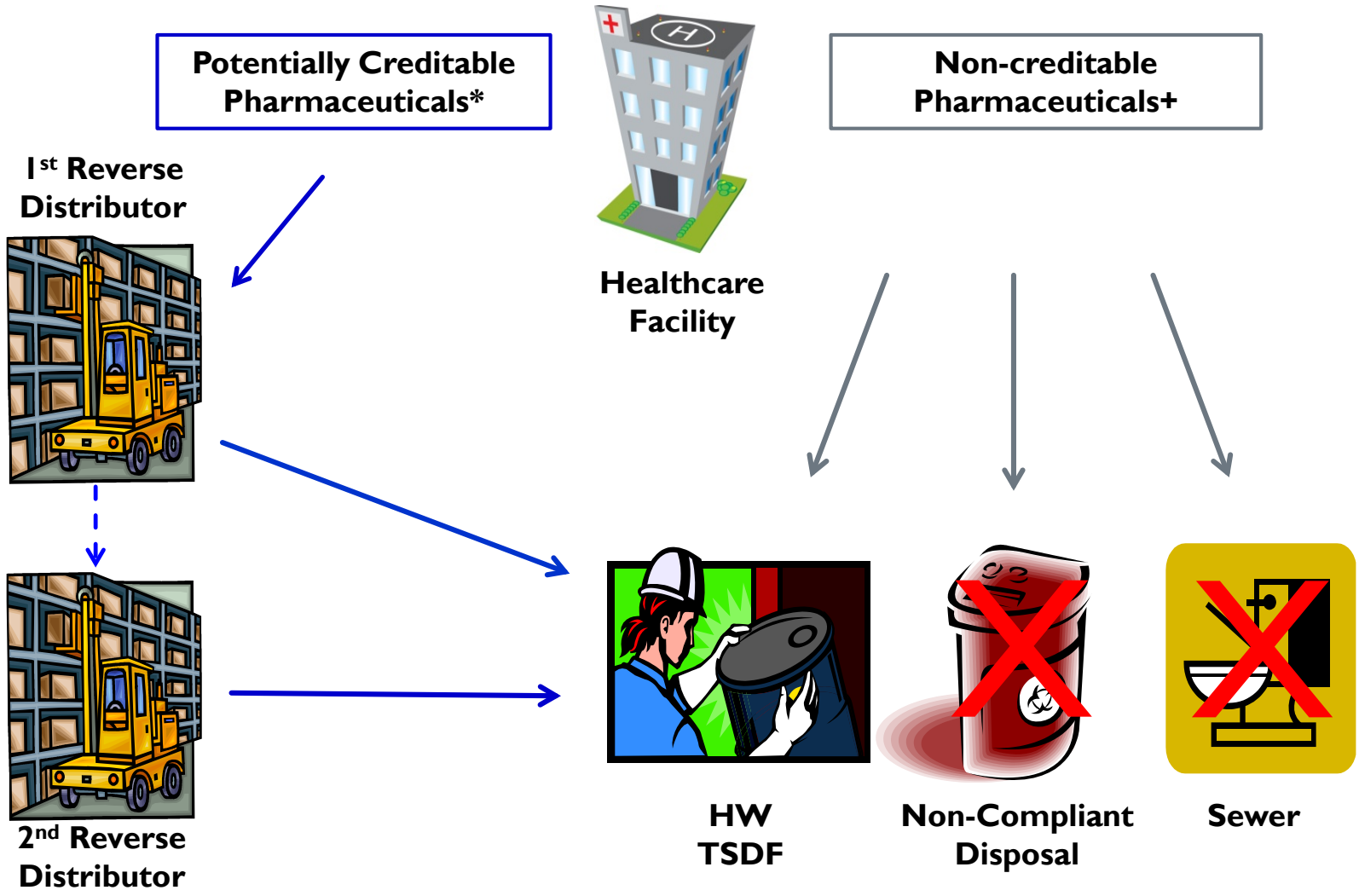
REVERSE LOGISTICS POLICY: THEN AND NOW

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. 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

- ***Pharmaceutical***
- ***Hazardous waste pharmaceutical***
  - ***Non-creditable hazardous waste pharmaceutical***
  - ***Potentially creditable hazardous waste pharmaceutical***
  - ***Evaluated hazardous waste pharmaceutical***
- ***Healthcare facility***
  - ***Long-term care facility***
- ***Reverse distributor***
- *Household waste pharmaceutical*
- *Non-hazardous waste pharmaceutical*
- *Non-pharmaceutical hazardous waste*

§ 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

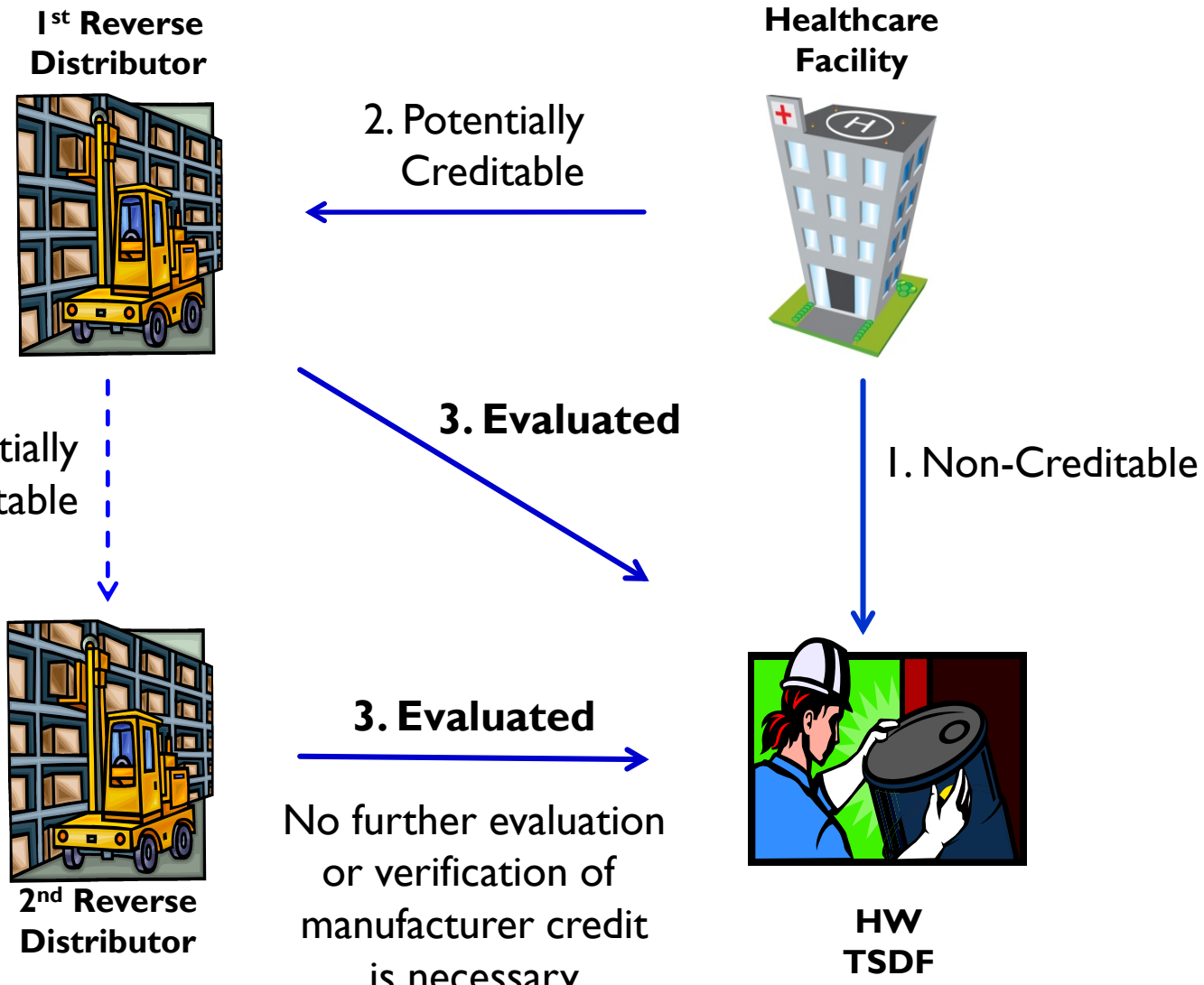
2. Potentially Creditable

1. Non-Creditable

2nd Reverse Distributor

HW TSDF

3 Types of HW Pharmaceuticals



§ 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

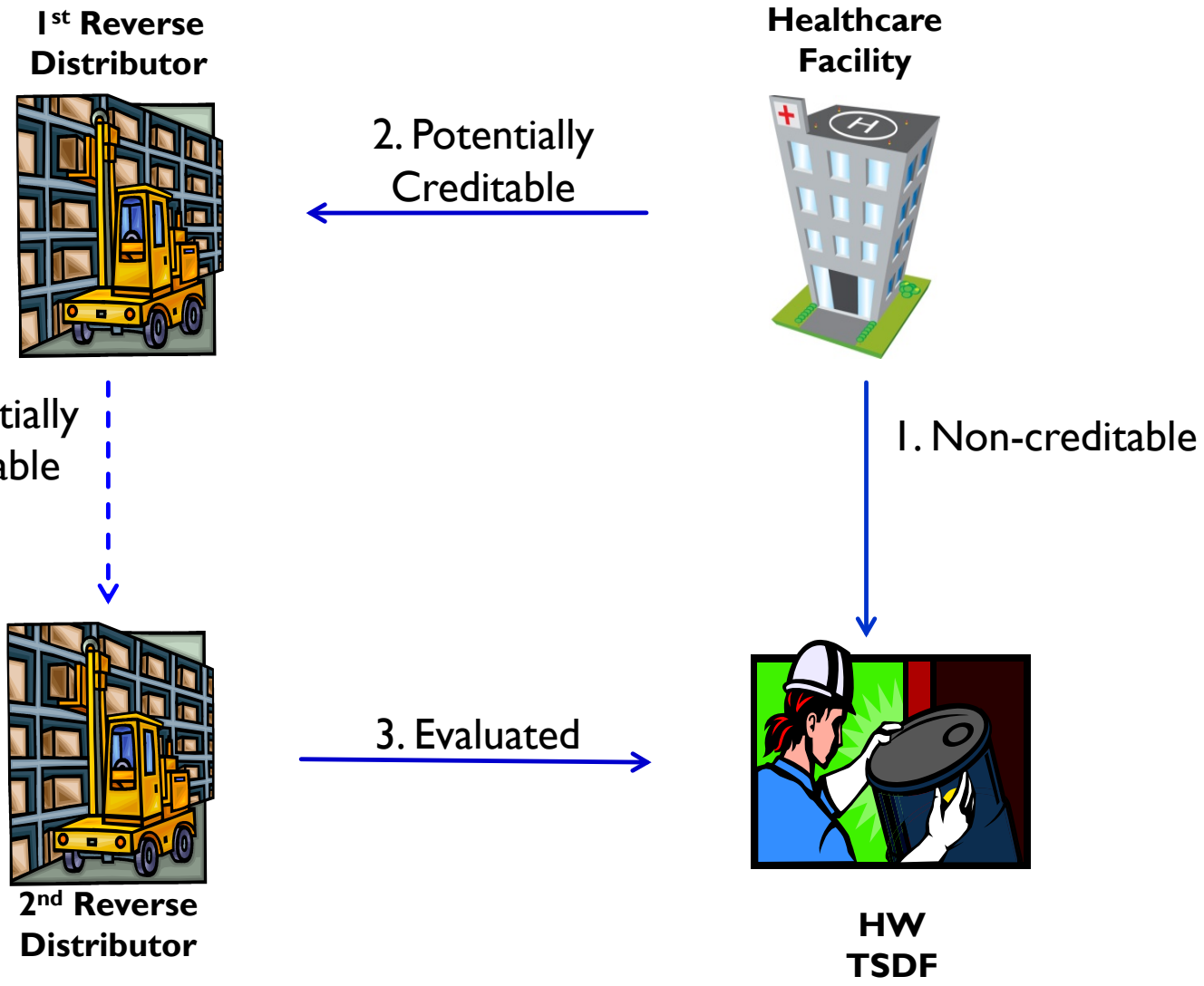
PART 266 SUBPART P APPLICABILITY

The following are NOT subject to RCRA regulation:

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

* Become subject to Subpart P when decision is made to discard

Applicability for Rx HW Pharmaceuticals



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

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

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

§§ 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
Labeling	✓	None
Container Standards	✓	None
Maximum Accumulation Time	✓	None
Hazardous waste determinations*	✓	✓
Over-managing non-hazardous pharmaceuticals & commingling with hazardous waste pharmaceuticals	Allowed	Allowed
Include hazardous waste pharmaceuticals on BR	No	No

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

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		

§ 266.504

OPTIONS FOR VSQG HEALTHCARE FACILITIES

Healthcare facilities that are VSQGs are not subject to Part 266 Subpart P (except the sewer prohibition) but can

- Opt into Subpart P and comply with all its provisions OR
- Use the optional provisions of Part 266 Subpart P:
  1. A VSQG healthcare facility can continue to send potentially creditable hazardous waste pharmaceuticals to a reverse distributor
  2. A VSQG healthcare facility can send its hazardous waste pharmaceuticals off-site to another facility, provided the receiving facility is either
     - A healthcare facility operating under Part 266 Subpart P and meets certain conditions, OR
     - An LQG operating under Part 262 and meets the conditions for off-site consolidation

§ 266.504

OPTIONS FOR VSQG HEALTHCARE FACILITIES

- Optional provisions only for VSQG long-term care facilities

3. A long-term care facility that is a VSQG can dispose of its hazardous waste pharmaceuticals in an on-site collection receptacle that complies with DEA regulations
    - Note that DEA collection receptacles can only be used for controlled substances that are from the ultimate user
4. A long-term care facility with 20 beds or fewer will be presumed to be a VSQG and not subject to Part 266 Subpart P, except the sewer prohibition
    - Note that long-term care facilities with >20 beds may also be VSQGs

§ 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 will be effective in ALL states on August 21, 2019

§ 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

§§ 266.508 & 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 hazardous waste transporter
    - Non-creditable: healthcare facility must use "PHARMS" code on manifest in item 13 (other hazardous waste codes are allowed but not required)
    - Evaluated: reverse distributor must list all hazardous waste codes on manifest
- Potentially creditable hazardous waste pharmaceuticals
  - Can be sent to a reverse distributor before going to a TSDF
  - Manifest and hazardous waste transporter are ***NOT*** required
  - Common carrier (e.g., UPS, USPS, FedEx) is acceptable
  - Shipper must receive delivery confirmation from reverse distributor
    - 35 days from date the shipment was sent
    - Electronic delivery confirmation that common carriers use will typically be sufficient

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) • HW transporter	• Manifest (waste codes) • HW transporter

§ 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

FLOW OF HW PHARMACEUTICALS

HCF/Pharmacy

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

1st RD can be a manufacturer

2nd RD can be a manufacturer

3rd RD must be a manufacturer

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

- A reverse distributor must inventory and evaluate each potentially creditable hazardous waste pharmaceutical within 30 days or arrival to determine if it is destined for:
  - Another reverse distributor (still considered "potentially creditable HW pharmaceutical") or
  - A permitted/interim status TSDF (considered "evaluated hazardous waste pharmaceutical")
- Accumulation on-site at reverse distributor:
  - 180 days maximum accumulation time after evaluation

30 days evaluation + 180 days accumulation = 210 days total per RD

§ 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

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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) • HW transporter	• Manifest (waste codes) • HW transporter

REMINDERS & WRAP-UP

SECTION VI

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 no legislative session required	• Effective when state adopts • State adoption not required	August 21, 2019*	• Effective when state adopts • July 1, 2021+
Authorized States & territories legislative session required	• Effective when state adopts • State adoption not required	August 21, 2019*	• Effective when state adopts • July 1, 2022+

*effective date
+state adoption deadline

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