



# **NEW EPA MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS**

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February 19, 2019

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Marty Stempniak

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# RESOURCE CONSERVATION AND RECOVERY ACT (RCRA)

Enacted by Congress in 1976

## Goals:

- Protecting human health and the natural environment from the potential hazards of waste disposal.
- Energy conservation and natural resources.
- Reducing the amount of waste generated through source reduction & recycling
- Ensuring the management of waste in an environmentally sound manner.
- RCRA gives EPA the authority to control hazardous waste from the "cradle to grave"...from the generation, transportation, treatment, storage and disposal.



## The RCRA program is a joint federal and state endeavor

- Environmental Protection Agency (EPA) issues the requirements (i.e. 40 CFR Parts 260-269) and all states with “delegated authority” (authorized states) must promulgate, implement and enforce the regulations. (can modify to be more stringent than EPA)
- 2 States (Iowa, Alaska) are non-authorized states ...have chosen to automatically follow EPA regulations without modification.
- In 2019 RCRA is most widely known for the regulations promulgated under it that set standards for the generation, transportation, treatment, storage and disposal of hazardous waste in the U.S. (“cradle to grave”).

Prior RCRA regulations (Part 262) do not adequately take into effect the management complexities of hazardous waste pharmaceuticals (HWPP's) generated in healthcare facilities (HCF's)

- EPA has created: 40 CFR part **266 Subpart P** to address those complexities
- Titled: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine
- 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

## EFFECTIVE DATE

- Effective 6 months after publication in the Federal Register in:
  - Non-authorized states: Iowa, Alaska,
  - Indian Country
  - US Territories (except Guam)

\*\*The effective date will be August 21, 2019

EFFECTIVE DATE

2019

August 21

## STATE ADOPTION - PART 266 SUBPART P

- In authorized states, (i.e., New York) 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 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
  - **EXCEPTION: Sewering Ban – Effective August 21, 2019**  
**ALL STATES**

### STATE ADOPTION DEADLINES

2021

July 1

2022

July 1

## EPA ESTIMATES

- EPA estimates that the final rule will reduce the amount of hazardous waste pharmaceuticals entering waterways by between 1,644 and 2,300 tons annually thereby
- reducing the presence of pharmaceutical chemicals in surface and drinking waters as has been documented by a growing body of studies.
- EPA also maintains that the streamlined management standards and regulatory relief regarding certain nicotine-containing products will result in annualized cost savings of between \$19.5 and \$22.96 million



# 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 sewerage 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

## PART 266 SUBPART P – TERMS DEFINED

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

# DEFINITION OF PHARMACEUTICAL

*Pharmaceutical* includes, but is not limited to:

- Dietary supplements
- Prescription drugs
- Over-the-counter drugs
- Homeopathic drugs
- Compounded drugs
- Investigational new drugs
- Pharmaceuticals remaining in non-empty containers
- PPE contaminated with pharmaceuticals
- Clean-up material from spills of pharmaceuticals

- 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

## DEFINITION OF SOLID WASTE

§ 261.2

- A solid waste is any discarded material that is not excluded under the regulations that implement RCRA.
- Is not limited to wastes that are physically solid. Many solid wastes are liquid, semi-solid, or gaseous material.
- A material is considered “discarded” once the facility has decided to discard it, and must be managed appropriately at that point in time.
- A material that is legitimately going to be used, reused or reclaimed is not discarded and is not a solid waste.

## DEFINITION OF HAZ WASTE PHARMACEUTICAL

*Hazardous Waste Pharmaceutical* means

- A pharmaceutical that is a solid waste,  
and
- Exhibits one or more **characteristics**  
or
- Is listed ( P List, U List)

### Characteristic Waste

- Ignitable, Corrosive, Toxic, Reactive
- EPA waste code starts with D

## ▶ P-Listed

- ▶ Acutely hazardous ([Doses < 50mg/kg can kill](#))
- ▶ Sole active ingredient
- ▶ EPA waste code starts with P

## ▶ U-Listed

- ▶ Non-acutely hazardous
- ▶ Sole active ingredient
- ▶ EPA waste code starts with U



## Common P & U-listed pharmaceuticals used in the Healthcare facility setting are:

1. **P042 – Epinephrine**
2. **P075 – Nicotine, & salts**
3. **P081 – Nitroglycerine (R)**
4. **P204 – Physostigmine**
5. **P188 – Physostigmine salicylate**
6. **P001 – Warfarin**
7. **P012 – Arsenic Trioxide**

1. **U034 – Chloral hydrate**
2. **U035 – Chlorambucil**
3. **U058 – Cyclophosphamide**
4. **U059 – Daunomycin**
5. **U075 – Dichlorodifluoromethane**
6. **U089 – Diethylstilbestrol**
7. **U129 – Lindane**
8. **U150 – Melphalan**
9. **U010 – Mitomycin C**
10. **U200 – Reserpine**
11. **U201 – Resorcinol**

## Criteria and Characteristics of Hazardous Waste.....

<b>Ignitability (D001)</b>	<p>A solid waste that meets <i>any</i> of the following criteria:</p> <ol style="list-style-type: none"> <li>1. <b>A liquid that has a flash point of less than 140°F</b></li> <li>2. <b>A solid</b>, under standard temperature and pressure, <b>that can cause fire through friction, absorption of moisture, or spontaneous chemical changes</b> and burn vigorously and persistently that it creates a hazard;</li> <li>3. An ignitable <b>compressed gas</b> as defined by the Department of Transportation in 49 CFR 173.300; or,</li> <li>4. <b>An oxidizer</b> as defined by the Department of Transportation in 49 CFR 173.151</li> </ol> <p>.</p>
<b>Corrosivity (D002)</b>	<p>A solid waste that meets <i>any</i> of the following criteria:</p> <ol style="list-style-type: none"> <li>1. An <b>aqueous liquid</b> that has a <b>pH of 2 or less or 12.5 or more</b>; or,</li> <li>2. A <b>liquid</b> that corrodes steel at <b>a rate of 6.35 mm or more</b> per year as determined by the National Association of Corrosion Engineers</li> </ol>
<b>Reactivity (D003)</b>	<p>A solid waste that meets <i>any</i> of the following criteria:</p> <ol style="list-style-type: none"> <li>1. Instability and readiness to under go violent change;</li> <li>2. Violent reactions when mixed with water;</li> <li>3. Formation of potentially explosive mixtures when mixed with water;</li> <li>4. Generation of toxic fumes in quantities sufficient to present a danger to human health or the environment when mixed with water;</li> <li>5. Cyanide or sulfide waste which generate toxic fumes when exposed to acidic conditions;</li> <li>6. Ease of detonation or explosive reaction when exposed to pressure or heat;</li> <li>7. Ease of detonation or explosive decomposition or reaction at standard temperature and pressure; or,</li> <li>8. Defined as a forbidden explosive by the Department of Transport ation .</li> </ol>
<b>Toxicity (D004- D043)</b>	<p>A solid waste whose extract under the test procedure specified under 40CFR Part 261.24 contains one or more constituents at concentrations greater than those specified in the Maximum Concentration of Contaminants for the Toxicity Characteristic Table:</p>

## Examples of Characteristic Hazardous Pharmaceuticals

Humalog, Humulin R, Humulin N, Lantus,

Taxol, Atrovent, Flovent, Lindane (Kwell),

Erythromycin 2% sol & pads, Fluocinonide Sol 0.05%,

Flurbiprofen Sol 0.03%, FML S.O.P. Oint 0.1% ,

Forteo Sol 750/3ml,

Any drug with thimerosal or phenylmercuric acetate  
(vaccines, eye drops, nasal spray)

## 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

# 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

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*Healthcare Facility does NOT include:*

- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers

## DEFINITION OF LONG-TERM CARE FACILITY

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

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

*Long-term Care Facility* **does NOT** include:

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



## OTHER IMPORTANT DEFINITIONS

### 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, they are discarded

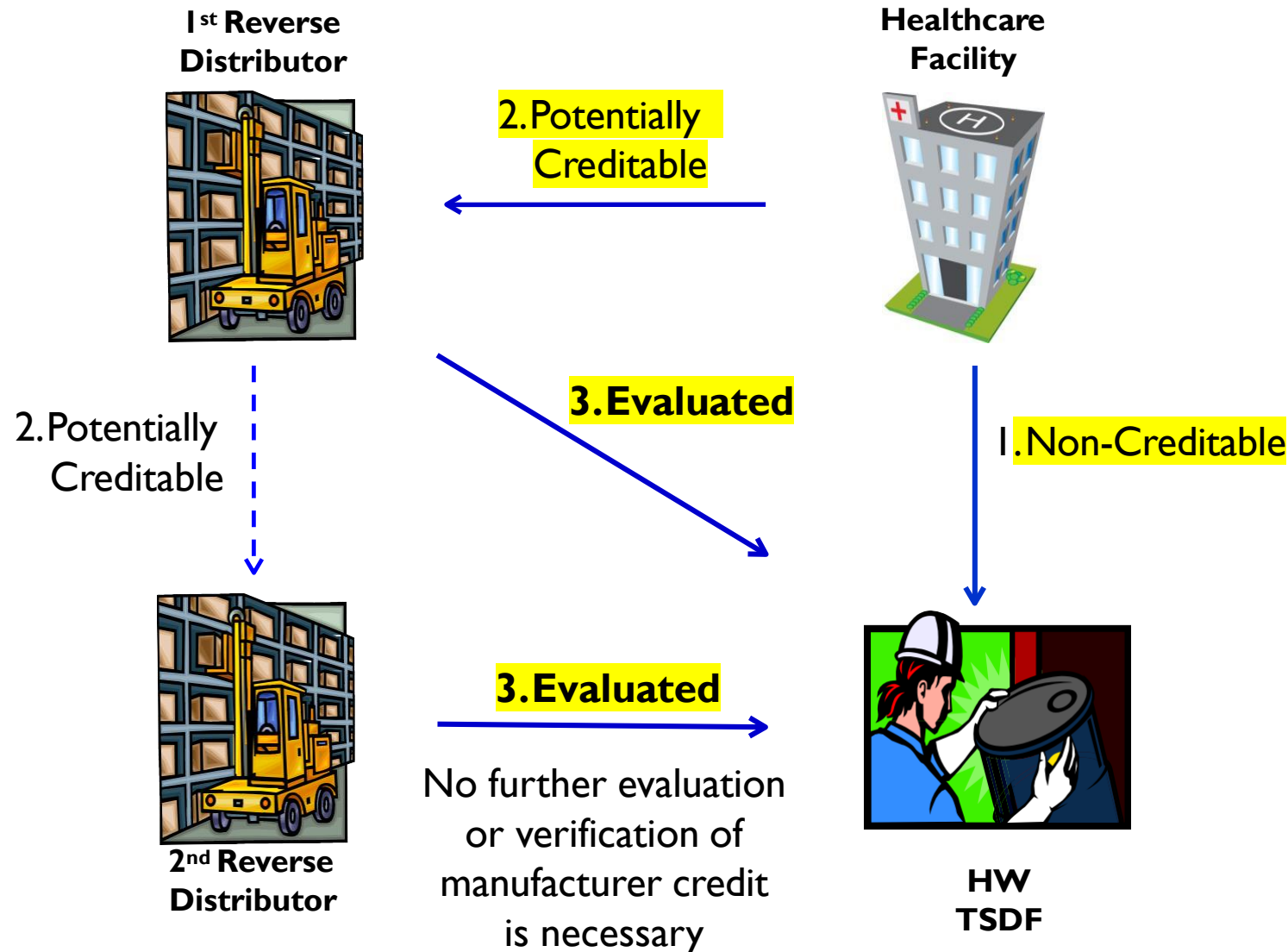
### REVERSE LOGISTIC CENTERS

- evaluate unsold retail items including nonprescription pharmaceuticals (OTCs)
- analyze secondary markets, and
- assess the suitability of the unsold retail items for reuse in those secondary markets

### TSDF (Treatment, Storage and Disposal Facility)

- Permitted facility that treats, stores, or disposes of hazardous waste

# 3 Types of HW Pharmaceuticals: Non-Creditable, Potentially Creditable, Evaluated



### 3 Types of HW Pharmaceuticals

Healthcare  
Facility



HW  
TSDF

#### I. **Non-Creditable**

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

## POTENTIALLY CREDITABLE HWP

HWP that has a reasonable expectation for manufacturer credit

OK to send Potentially Creditable HWP back to RD if:

- Undispensed (and)
- Prescription (and)
- In original manufacturer container (and)
- Less than 1 year past expiration date

# NON - CREDITABLE HAZARDOUS WASTE PHARMACEUTICAL

- HWP that has NO reasonable expectation for manufacturer credit
- CAN NOT be sent back to a reverse distributor
- A HWP that fails at least one of the Potentially Creditable HWP criteria:  
Undispensed, Rx, original packaging, < 1 year expired

Also includes non-prescription HWP's (OTCs) that do not have a reasonable expectation of legitimately being used/reused or reclaimed

Examples of non-creditable pharmaceuticals:

Samples, investigational drugs, compounding chemicals, compounded drugs

## HEALTHCARE FACILITY STANDARDS

- Notification: all healthcare facilities must submit a one-time notification that they are operating under Subpart P (using Site ID Form: 8700-12)
  - Facilities that are not required to submit a biennial report for their other hazardous waste must notify within 60 days of the rule going into effect
    - Non-authorized states: notifications will be due in October 20, 2019
  - Facilities that are required to submit a biennial report may notify on their normal biennial reporting cycle
    - Non-authorized states: notifications will be due with March 1, 2020 BR
- Training: all personnel managing non-creditable hazardous waste pharmaceuticals must be thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies



## HEALTHCARE FACILITY STANDARDS

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

## HEALTHCARE FACILITY MANAGEMENT STANDARDS

### Non-creditable hazardous waste pharmaceuticals:

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

### Potentially creditable hazardous waste pharmaceuticals:

- No labeling, container standards or accumulation time

## 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

## VSQG (Very Small Quantity Generator) ... CFR 260.1040

A generator who generates  $\leq$  to the following amounts in a calendar month:

100kg (220lb) of nonacute hazardous waste

and

1 kg (2.2 lb ) of acute hazardous waste

VSQG = 98-99% LTC Facilities (Important)

## 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, (i.e. vendor pharmacy provided the receiving facility is either**
    - **A healthcare facility (i) operating under Part 266 Subpart P(ii) is under the same control as the transferring facility or has a business relationship, (iii) manages the new wastes under Subpart P, and (iv) keeps records of the shipment for three years.**
    - An LQG operating under Part 262 and meets the conditions for off-site consolidation

## 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



## 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	D00I ignitable	II
Phenobarbital	Bellergal-S Donnatal Luminal	Anticonvulsant	D00I ignitable	IV
Testosterone gels/solutions	Androgel Axiron Fortesta, Testim	Hormone	D00I ignitable	III
Valium injectable/gel	Diazepam Diastat	Anti-anxiety	D00I ignitable	IV

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**From:** Heggen, Toril L (HEALTH)  
**Sent:** Thursday, May 23, 2019 12:05 PM  
**To:** [wlyons@pharmaconconsulting.com](mailto:wlyons@pharmaconconsulting.com)  
**Subject:** FW: narc destruction

Bill,

Here is the info I have so far.

***Consult their pharmacy consultant and discuss having the pharmacy register with the DEA as a “collector”. The registration is free. Then the pharmacy can place a medication drop box in a secure location at the facility where unwanted medications can be placed. They still need to follow record-keeping procedures including a witness and 2 signatures when something is placed in the box.***

We are working on formal procedures, once I have that training and information I will get that over to you.

## DISPOSE OF RX HERE



### ACCEPTED

Prescriptions (schedule II-V controlled and non-controlled substances),  
Prescription Ointments, Vitamins, Prescription Patches, Liquids,  
Lotions/Creams, Pet Medications, Over-the-Counter Medications

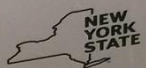


### NOT ACCEPTED

Needles, Inhalers, Aerosol Cans, Thermometers, Hydrogen Peroxide

**R<sub>x</sub>**  
**Drug Drop**

Enhancing the health, safety &  
welfare of New Yorkers



Department of  
Environmental  
Conservation

## DEA CONTROLLED SUBSTANCES (CONTINUED)

In both cases, the hazardous waste pharmaceuticals are exempt from RCRA, provided they meet the following conditions:

- Not sewerred, 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

## 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

## SHIPMENTS OF HW PHARMACEUTICALS

- Non-creditable & evaluated hazardous waste pharmaceuticals
  - Both must be sent to a TSDF
  - Both must be 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

## Exemption – Nicotine P075 – 40 CFR 261

FDA approved Over-The-Counter (OTC) Nicotine Replacement Therapies (NTR's) are exempted from the P075 listing

- The exemption only applies to patches, gums and lozenges
- The exemption does not apply to nicotine containing e-cigarettes (e.g., electronic cigarettes and vaping pens), e-liquids (packaged for retail sale) or prescription NRT's even though the EPA considers them to be pharmaceuticals
- Previously, NTR's were considered an acute hazardous waste by the EPA

**EFFECTIVE DATE: AUGUST 21, 2019** (All states as well as Sewering Ban)

## IN CLOSING

EFFECTIVE DATE: AUGUST 21, 2019 - coming quickly

- 1) START PLANNING and train applicable staff (i.e. no sewerage)
- 2) Be on Lookout for:
  - BNE formal ANNOUNCEMENTS/ PROCEDURES
  - NYS ADOPTION/ADDITIONS to 40 CFR part 266 Subpart P