



Department of
**Environmental
Conservation**

Pharmaceuticals Rule

DEC Information

2020

Areas of Discussion

1. Sewer Ban
2. Amendment to the Listing of P075 for Nicotine
3. Overall Pharmaceutical Rule EPA Subpart P

Sewer Ban

Goes into effect on August 21, 2019 throughout US regardless of state adoption. (HSWA authority)

40 CFR 266.505 prohibits sewerage of hazardous waste pharmaceuticals.

Ban applies to all defined healthcare facilities and reverse distributors including CESQGs.

Amendment of P075 Definition

Listing for nicotine and pyridine adds a parenthetical;
“this listing does not include patches, gums and lozenges that are FDA-approved over-the-counter nicotine replacement therapies.”

Pharms Rule: Nicotine Listing

Nicotine P075 Listing		
No Longer Part of Listing	Still Included in the Listing, Regulated as Pharmaceuticals*	Still Included in Listing
<p>FDA-approved over-the counter nicotine replacement therapies (OTC NRTs)</p> <ul style="list-style-type: none"> • Nicotine Patches • Nicotine Gums • Nicotine Lozenges 	<ul style="list-style-type: none"> • Prescription nicotine (e.g., nasal spray, inhaler) • E-liquids packaged for retail use in ENDS • Finished product ENDS, including components & parts sealed in final packaging intended for consumer use <p>(ENDS means Electronic Nicotine Delivery System) *If generated by a health care facility</p>	<ul style="list-style-type: none"> • E-liquids used by manufacturers of tobacco products • E-liquids sold or distributed for further manufacturing, mixing or packaging into a finished e-delivery system • Legacy pesticides containing nicotine • Nicotine used in research and manufacturing • Other unused formulations

Reverse Logistics

Preamble to the Rule: EPA uses the preamble to the pharmacy rule to define their interpretation of Reverse Logistics.

Reverse Logistics is not a part of Subpart P nor this rulemaking and will not be addressed in this discussion.

40 CFR 266 Subpart P Pharmaceutical Rule

PART 266 Subpart P—Hazardous Waste Pharmaceuticals

266.500 - Definitions for this subpart.

266.501 - Applicability.

266.502 - Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

266.503 - Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

266.504 - Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

266.505 - Prohibition of sewerage hazardous waste pharmaceuticals.

266.506 - Conditional exemption for hazardous waste pharmaceuticals that are also controlled substances and household hazardous waste pharmaceuticals collected in a take-back event or program.

266.508 - Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

266.509 - Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

266.510 - Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.



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

Definition of Pharmaceutical

- *Pharmaceutical* is a drug for use by humans or other animals and 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
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Pharmaceutical does NOT include:

- Dental amalgam
- Sharps
- Medical waste



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
- 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

Definition of Reverse Distributor

Reverse Distributor (RD) 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



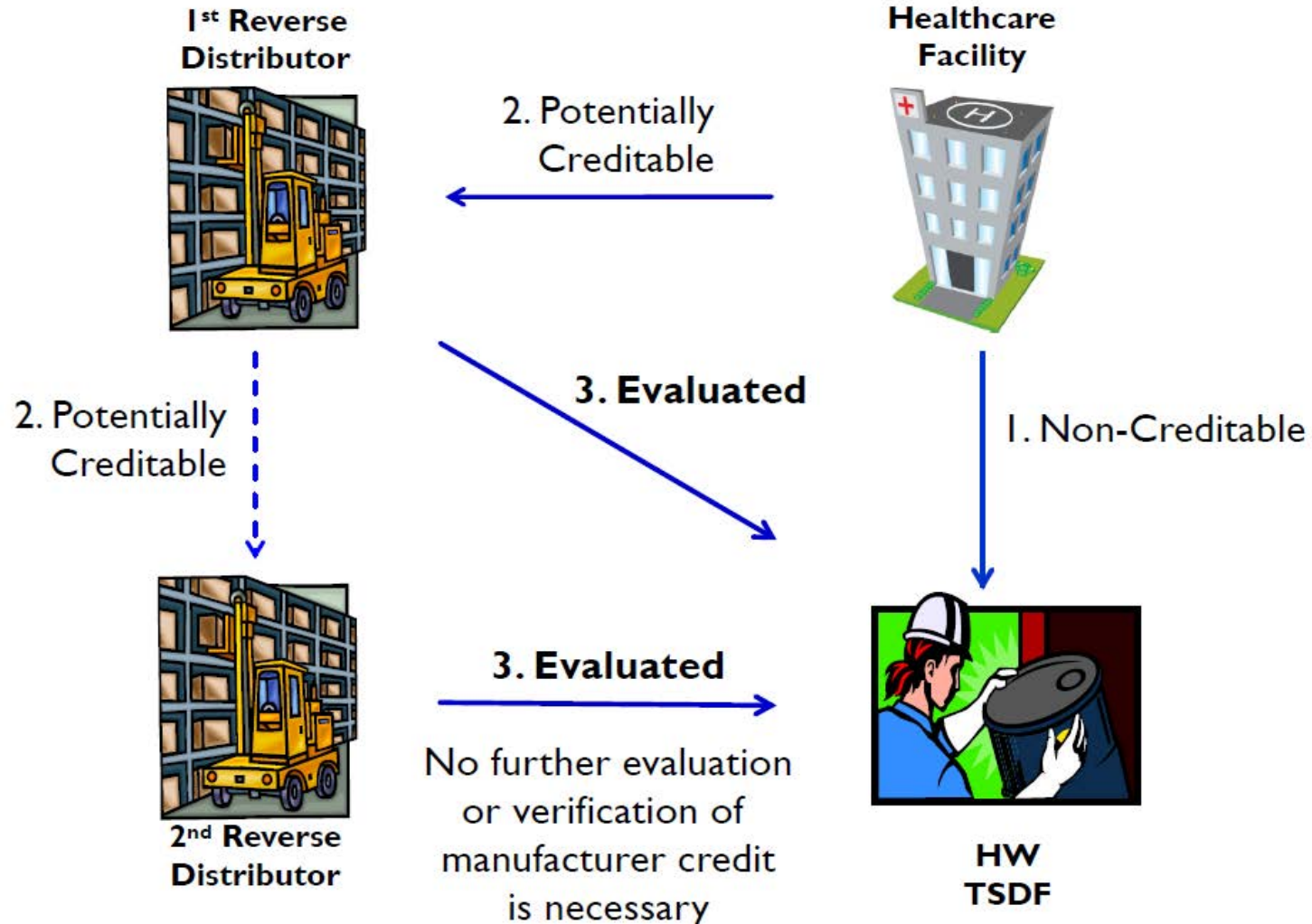
Types of HW Pharmaceuticals

There are 3 types of *Hazardous Waste Pharmaceuticals*:

- Non-creditable hazardous waste pharmaceutical (TSDF)
- Potentially creditable hazardous waste pharmaceutical (Reverse Distributor)
- Evaluated hazardous waste pharmaceutical (TSDF)



3 Types of HW Pharmaceuticals



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



Controlled Substances and Household hazardous wastes

- Conditional exemptions for hazardous wastes that are also controlled substances; and household waste pharmaceuticals collected at a take-back event or program
- Avoids dual regulation;
- Destroyed by a method approved by DEA in writing to meet their non-retrievable standard; or in one of 5 types of permitted combustion units;
- These wastes don't count towards generator category.



Conditional Exemption

Includes:

- Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration (DEA) in 21 CFR part 1308, and
- Household waste pharmaceuticals collected in a take-back event or program, including those that are collected by an authorized collector registered with the DEA that commingles the household waste pharmaceuticals with controlled substances from an ultimate user.



Pharmaceuticals Still Used in Healthcare that Are DEA Controlled Substances & RCRA Hazardous Wastes

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral; chloral hydrate	Acetaldehyde, trichloro-; Aquachloral, Noctec, Somnote, Supprettes	Sedative	U034 toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal,	Anticonvulsant	D001 ignitable	IV	Ignitable due to alcohol content
Testosterone gels	Androgel, Axiron, Fortesta, Testim	Hormone	D001 ignitable	III	Ignitable due to gel base
Valium injectable	Diazepam, Diastat	Anti-anxiety	D001 ignitable	IV	Ignitable due to alcohol content

DEA Controlled Substances & RCRA Hazardous Wastes Pharmaceuticals that Are Not in Common Use

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Paraldehyde	1,3,5-Trioxane, 2,4,6-trimethyl-; Paral	Anticonvulsant	U182 toxic	IV	No longer in common use
Paregoric	camphorated tincture of opium	Analgesic, expectorant, antidiarrheal	D001 ignitable	III	No longer in common use
Opium Tincture	Laudanum	Analgesic, antidiarrheal	D001 ignitable	II	No longer in common use



Conditions of the Exemption

- Managed in compliance with the sewer prohibition of § 266.505 and
- Collected, stored, transported, and disposed of in compliance with all applicable DEA regulations; and
- Destroyed by a method that DEA has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

Conditional Exemption

Combustion options:

- A permitted large municipal waste combustor;
- A permitted small municipal waste combustor;
- A permitted hospital, medical and infectious waste incinerator;
- A permitted commercial and industrial solid waste incinerator;
or
- A permitted hazardous waste combustor.



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



Options for VSQG Healthcare Facilities Cont.

3. A long term care facility which is a VSQG can dispose of its hazardous waste pharmaceuticals in an on-site collection receptacle that complies with DEA regulations
 - Note: DEC 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 Subpart P, except the sewer prohibition.
 - Note: long-term care facilities with >20 beds may also be VSQGs

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



Stock, Dispensing & Unit-Dose Containers

A stock bottle, dispensing bottle, vial, or ampule (not to exceed 1 liter or 10,000 pills); or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device) is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals have been removed using the ***practices commonly employed*** to remove materials from that type of container.



Syringes

Empty: if the contents have been removed *by fully depressing the plunger of the syringe*.

Not empty: the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.



Intravenous (IV) Bags

- Considered empty and the residues are not regulated as hazardous waste if the pharmaceuticals in the IV bag have been fully administered to a patient.
- If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1).



Other Containers, Including Delivery Devices

Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in § 261.7(b)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.



Shipments of HW Pharmaceuticals

Non-Creditable & Evaluated Hazardous Waste Pharmaceuticals

- Both must be sent to a TSDF
- Both must be sent with manifest and Part 364 authorized hazardous waste transporter
- Non-creditable: healthcare facility must use “PHARMS” or “PHRM” 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

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



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

$$\begin{array}{rcccl} 30 \text{ days} & + & 180 \text{ days} & = & 210 \text{ days} \\ \text{evaluation} & & \text{accumulation} & & \text{total per RD} \end{array}$$

Reverse Distributor Standards

- Potentially Creditable hazardous waste pharmaceuticals
 - No specific container or labeling standards
 - Might not be included on Annual Report
- Evaluated hazardous waste pharmaceuticals
 - Must designate an on-site accumulation area and conduct weekly inspections
 - Containers must be in good condition and managed to prevent leaks
 - Hazardous waste codes apply prior to offsite shipment
 - Included on Annual Report



Effective Dates

- Sewering ban – effective throughout US on effective date of regulations (August 21, 2019).
- Other more stringent provisions –

Enforceable by EPA on July 1, 2021 (it's complicated because EPA rule sets up the new mandatory Subpart P, but alternative requirements are not as strict as the ordinary hazardous waste regulations)

Less stringent provisions – effective when adopted by NYS by regulation, policy or enforcement discretion.

Possible State Changes

- DEC is considering to require all healthcare facilities to notify within 60 days of adoption of the rule and not allow the notification as part of an annual report (DEC requirement vs biannual under EPA).
- DEC is considering to prohibit the incineration of HW pharmaceuticals containing mercury, even those with <1 percent total organic carbon. (IX. E. 3. of rule preamble)

Possible State Changes Cont.

- Creditable HW pharms, do not become HW until they are evaluated, so the point of generation moves to the Reverse Distributor or manufacturer. DEC plans to assess regulatory fees at that point of generation. However, Non-Creditable HW pharmaceuticals are HW at the HCF. EPA however proposes to not have them reported on the Annual report. Because DEC must account for all HW in Regulatory Fees and Special Assessments, we would continue to require that they be included on the annual report. If a HCF chooses to also handle non-creditable **non-HW** pharmaceuticals under Subpart P, DEC needs to be able to distinguish these in the annual report from non-creditable **HW** pharmaceuticals.

Possible State Changes Cont.

- EPA recommends that aerosols and liquids be put in sealed plastic bags, containers or other management practices during accumulation to reduce the risk of spills and releases. DEC is considering adopting this condition as a requirement. (XI. C. 1. d. of rule preamble)
- EPA doesn't require labelling of potentially creditable hazardous waste when being accumulated. EPA clearly says that states may be more stringent. DEC is considering requiring a label with words like "Creditable Waste" or some other means to identify the materials, while not identifying them as pharmaceuticals. EPA chose to not require labels because of possible diversion of waste identified as pharmaceuticals. (XI. C. 1. d. of rule preamble)

Possible State Changes Cont.

- DEC is considering to require LTC pharmacies to notify that they will be receiving from LTCF VSQGs similar to the Generator Improvements Rule VSQG consolidation to LQG requirement.
- EPA's shipping requirements for creditable HW Pharmaceuticals under Subpart P, does not include provisions for shipments which do not arrive in a timely manner or are undelivered that necessitate notification to EPA. DEC is considering adding this requirement.
- The performance-based closure standard for Reverse Distributors do not contain all of the notification requirements for closure found in the Generator Improvements Rule. DEC is considering adding this requirement. (XVII. C. 1. g. of rule preamble)

Possible State Changes Cont.

- The rule does not require an accumulation date on the containers of evaluated hazardous waste pharmaceuticals. The preamble states that states may require the accumulation start date. DEC intends to include this requirement. (XVII C. 3. d. of rule preamble)
- EPA did not define the term “business relation” in relation to the HCF consolidation of a LTCF VSQG to a LTC pharmacy. DEC is considering not including this term as part of this requirement.



Possible State Changes Cont.

The rule will require at 266.508(a)(1)(iii)(C), that lab packs of HW pharms which contain metals D0(04,05,06,07,08,10 and 11) must be marked with the appropriate waste codes. DEC is considering requiring a LDR form for these specific lab packs so the disposal facility knows of the implications of the metals. (XVI. A. 3. of rule preamble)

- *approximately 6 pharmaceuticals have numerical LDR treatment standards;*
- *one pharmaceutical containing metals (P012 – arsenic trioxide) can't be adequately treated by incineration.*



How to Comment

Submit **written** comments:

- Email: HWregs@dec.ny.gov (Include "Comments on Regulatory Initiatives" in the subject line of the email) or
- Mail: Michelle Ching; Division of Materials Management; NYSDEC; 625 Broadway, Albany, NY 12233-7256



Further Assistance

- Email: HWRegs@dec.ny.gov
- Phone: (518) 402-8651

On DEC's website:

<https://www.dec.ny.gov/regulations/117108.html>

Additional Resources

The regulation and other links:

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

Complete archive of the March 4 CLU-IN webinar - *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the Hazardous Waste Listing for Nicotine*: https://clu-in.org/conf/tio/HazWastePharmaceuticals_030419/

NYS DEC Hazardous Waste Pharmaceuticals Rulemaking webpage: <https://www.dec.ny.gov/regulations/117211.html>