EPA Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine
Summary of Changes for Healthcare Facilities

The purpose of this document is to summarize EPA's Final Rule: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine. This summary is meant is intended to help members understand the rule changes and how they impact healthcare facilities and reverse distributors*. Please refer to EPA website on the final rule for specific information and details about the regulation. For questions or comments directed to ASHP, please contact PracticeAdvancement@ashp.org.

The final rule has three main provisions that will affect healthcare facilities:

- Ban on "sewering" (intentional disposal through toilets or drains) of hazardous waste pharmaceuticals.
- Over-the-counter nicotine replacement therapies are exempted from the P075 hazardous waste listing of nicotine, meaning gums, patches, and lozenges will no longer need to be handled as hazardous pharmaceutical waste.
- Subpart P changes to pharmaceutical waste generator categories and requirements.

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Executive Summary

On February 22nd, the Environmental Protection Agency's (EPA) final rule: *Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine* was published in the Federal Register. The rule takes effect on August 21st; however, some sections of the rule must be adopted by state EPAs. The EPA's goal was to create regulations that are a better fit for the healthcare sector. In general, healthcare personnel are not prepared to assume hazardous waste management responsibilities, nor is it EPA's expectation that they assume primary hazardous waste management responsibilities.

The final rule has three main provisions that will affect healthcare facilities:

- Ban on "sewering" (intentional disposal through toilets or drains) of hazardous waste pharmaceuticals.
    - This ban is *more* strict than current regulations and therefore will be automatically adopted by all states and U.S. territories.
    - **This ban is effective as of August 21, 2019 for all states and U.S. Territories.**

- Over-the-counter nicotine replacement therapies are exempted from the P075 hazardous waste listing of nicotine, meaning gums, patches, and lozenges will no longer need to be handled as hazardous pharmaceutical waste.
    - Liquid nicotine, e-cigarettes, nicotine cartridges, and nicotine used in research or manufacturing are not exempted.
    - **This change is effective as of August 21, 2019 for EPA non-authorized states and territories: Iowa, Alaska, Native American Country, and U.S. Territories.**
    - **This change is *less* strict than current regulations and therefore is only effective in other states if adopted.**

- Subpart P changes to pharmaceutical waste generator categories and requirements.
    - Hazardous pharmaceutical waste is currently regulated under 40 CFR part 262
    - When adopted, healthcare facilities will manage hazardous pharmaceutical waste under 40 CFR part 266 subpart P
        - Creation of two categories for healthcare facility hazardous pharmaceutical waste: potentially creditable waste non-creditable waste pharmaceuticals. Each category has different requirements for accumulation, handling, and disposal.
            - Potentially creditable: unused or un-administered and unexpired less than one year past expiration date.

        - Non-creditable: hazardous waste pharmaceutical that is not expected to be eligible for manufacturer credit (e.g. removed from original container, refused by patient after attempt to administer, returned dispense after pharmacy has received payment, more than one year past expiration).
    - Containers that previously contained hazardous waste pharmaceuticals no longer need to be triple rinsed to be considered RCRA empty.
    - Conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances.
- **This change is effective as of August 21st for EPA non-authorized states and territories: Iowa, Alaska, Native American Country, and U.S. Territories.**
- **Other states *must* adopt this change; however, they have until July 1, 2021 to do so.**

In general, the changes in the EPA final rule are less restrictive and burdensome than current EPA regulations. Health systems should check with their state EPA to determine the adoption status of the nicotine and Subpart P provisions.

Key Abbreviations

- BR: Biennial Report
- CFR: Code of Federal Regulations
- CPSC: Consumer Product Safety Commission
- DOT: Department of Transportation
- LDR: Land Disposal Restrictions
- LQG: Large Quantity Generator
- NRT: Nicotine Replacement Therapy
- RCRA: Resource Conservation and Recovery Act
- SQG: Small Quantity Generator
- TSDF: Treatment, Storage and Disposal Facility
- VSQG: Very Small Quantity Generator

Key Definitions

- **Healthcare Facility:** Lawfully authorized to (1) provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care and counseling, service, assessment or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or (2) distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals.

    - Does **not** include: pharmaceutical manufacturers, reverse distributors, or reverse logistics centers
- **Reverse Distributor:** 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.

Who does this rule apply to?

This final rule applies to healthcare facilities that generate, accumulate, or otherwise handle hazardous waste pharmaceuticals and reverse distributors engaged in the management of prescription hazardous waste pharmaceuticals.

The list includes: Pharmacies and drug stores, outpatient care centers, other ambulatory health care services, hospitals, nursing care facilities (e.g., assisted living facilities, nursing homes), and continuing care retirement communities (e.g., assisted living facilities with on-site nursing facilities).

Healthcare facilities and reverse distributors are still subject to:

- Part 262 (Standards Applicable to Generators of Hazardous Waste) for the management of non-pharmaceutical hazardous wastes
- Part 273 (Standards for Universal Waste Management) for the management of universal wastes

When does the new rule go into effect?

- Non-Authorized States and Territories: Iowa, Alaska, Native American Country, U.S. Territories
    - All sections of new EPA rules effective August 21, 2019.
- Authorized States and Territories: All remaining states
    - Sewer ban effective August 21, 2019.
    - Authorized states are not required to adopt nicotine changes – check with state EPA regulations and requirements.
    - Required to adopt Subpart P by July 1, 2021 – check with state EPA for specific adoption date.

Rationale and Goals for New Regulations Differentiating Healthcare Facilities and Reverse Distributors from Other Entities

- In general, healthcare personnel are not prepared to assume hazardous waste management responsibilities, nor is it EPA's expectation that they assume primary hazardous waste management responsibilities. EPA's goal was to create regulations that are a better fit for the healthcare sector.
- In the healthcare setting, a wide variety of hazardous waste pharmaceuticals are generated in relatively small quantities by a number of different employees across the facility, differing from a typical manufacturing facility.
- Pharmaceutical wastes come in many different forms, such as tablets, transdermal patches, lozenges, gums, creams, and liquids, and are delivered by a variety of devices, such as nebulizers, intravenous (IV) tubing, syringes, etc. The combination of having thousands of different

pharmaceutical products and little expertise in hazardous waste regulations makes it difficult for healthcare personnel to make appropriate hazardous waste determinations when pharmaceuticals are disposed.

- Eliminate the intentional sewering of hazardous waste pharmaceuticals
- Several of the hazardous waste pharmaceuticals generated by healthcare facilities are P-listed acute hazardous wastes, which are regulated with more stringent requirements at much smaller amounts.
- Reduce overlapping regulations between EPA's RCRA hazardous waste regulations and the DEA regulations for controlled substances.
- Clarify the regulatory status of a major practice used by healthcare facilities, including retailers in particular, for the management of unused and/or expired pharmaceuticals, known as reverse distribution.

High Level Summary of the Proposal

- Healthcare facilities that are SQGs or LQGs and all reverse distributors, regardless of their RCRA generator category, will be required to manage their hazardous waste pharmaceuticals under 40 CFR part 266 subpart P, instead of the generator regulations in 40 CFR part 262.
    - Healthcare facilities that are VSQGs can opt into 266 subpart P in lieu of operating under §262.14
- Healthcare facilities must determine whether a waste pharmaceutical is a hazardous waste pharmaceutical for both potentially creditable and non-creditable waste pharmaceuticals. However, if a healthcare facility manages all of its waste pharmaceuticals as hazardous, individual hazardous waste determinations are not necessary.
- Non-creditable hazardous waste pharmaceuticals (i.e., not expected to be eligible for manufacturer credit) are managed on site
- When shipped off site, the non-creditable hazardous waste pharmaceuticals must be transported as hazardous wastes, including the use of the hazardous waste manifest, and sent to a RCRA-designated facility, such as an interim status or permitted TSDF.
- Reverse distributors will no longer be regulated under 40 CFR part 262 as hazardous waste generators, nor will they be regulated under 40 CFR parts 264, 265, and 270 as TSDFs. Rather, the proposal establishes a new category of hazardous waste entity, called pharmaceutical reverse distributors.
- Several additional standards that apply to both healthcare facilities and reverse distributors include
    - EPA prohibits healthcare facilities and reverse distributors from disposing of hazardous waste pharmaceuticals down a toilet or drain
    - Hazardous waste pharmaceuticals managed under subpart P are not counted toward calculating the site's generator category
    - Conditional exemption for hazardous waste pharmaceuticals that are also DEA controlled substances
    - New management standards for determining when a container with hazardous waste pharmaceutical residues is considered RCRA empty

Amendment to the Acute Hazardous Waste Listing for Nicotine and Salts (Hazardous Waste No. P075)	
Summary: EPA has amending the acute hazardous waste listing for hazardous waste number P075 (commonly called "hazardous waste code") in § 261.33(e) to exempt FDA-approved over-the-counter (OTC) nicotine replacement therapies (NRTs). Specifically, the P075 listing for nicotine is amended with a parenthetical phrase stating that the listing does **not** include patches, gums, and lozenges that are FDA-approved OTC NRTs. Therefore, patches, gums, and lozenges are considered non-hazardous wastes (rather than acute hazardous wastes) and can be discarded as non-hazardous waste. The Agency recommends that healthcare facilities, including retailers, take the necessary security measures to discard unused, unwanted, or expired OTC NRTs where they are not freely accessible to the public. The Agency is not exempting e-cigarettes, e-liquids, cartridges, nicotine used in research and manufacturing or prescription NRTs from the P075 hazardous waste listing. These products are still to be managed as hazardous waste pharmaceuticals under 266 subpart P when they are discarded. The amendment to the nicotine listing applies to any generator of OTC NRT waste. It is not limited to healthcare facilities.	
Standards for Healthcare Facilities that Manage <u>Non-creditable</u> Hazardous Waste Pharmaceuticals (§ 266.502)	
Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals (§ 266.502(a))	• A healthcare facility (all healthcare facilities that generate above the VSQG thresholds and healthcare facilities that are VSQGs choosing to operate under subpart P) must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility operating under this subpart. ○ If the facility is not a VSQG, then it is required to operate under subpart P. • If a VSQG does not want to track how much hazardous pharmaceutical waste it generates, then it should choose to operate under subpart P and therefore submit notification as above. • Notification is required within 60 days of this new subpart becoming effective, or within 60 days of becoming subject to this new subpart. Healthcare facilities can also submit their notification as part of the Biennial Report, if the facility is required to do so due to its non-pharmaceutical hazardous waste (i.e. LQGs for their non-pharmaceutical hazardous wastes).
Training of personnel managing non-creditable hazardous	• A healthcare facility must train employees to the extent that they are thoroughly familiar with the proper handling and emergency procedures relevant to their responsibilities during normal operations and emergencies. The information can be disseminated verbally, via printed materials, or other means.

waste pharmaceuticals at healthcare facilities (§ 266.502(b))	
Hazardous waste determination for non-creditable pharmaceuticals. (§ 266.502(c))	• When a healthcare facility generates a solid waste pharmaceutical, the healthcare facility must determine if the discarded pharmaceutical is listed in 40 CFR part 261 subpart D (Lists of Hazardous Wastes)and/or if it exhibits one or more of the four characteristics of hazardous waste identified in 40 CFR part 261 subpart C (ignitability, corrosivity, reactivity, and toxicity). ○ If it **is** a non-creditable hazardous waste pharmaceutical then it must be managed under part 266 subpart P instead of 40 CFR part 262 • A healthcare facility that generates solid waste that is a non-creditable pharmaceutical has two options for hazardous waste determination; (1) determine if each non-creditable pharmaceutical is a listed or characteristic hazardous waste to determine whether it is subject to the subpart P requirements, or (2) manage **all** of its non-creditable waste pharmaceuticals under the subpart P requirements as non-creditable hazardous waste pharmaceuticals.
Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. (§ 266.502(d))	• (1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions. • (2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals, must manage the container so that it does not have the potential to: (i) Generate extreme heat or pressure, fire or explosion, or violent reaction; (ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health; (iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions; (iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or, (v) Through other like means threaten human health or the environment. • (3) Containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents. • (4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non- creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste numbers (i.e., hazardous waste codes)

Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. (§ 266.502(e))	• Accumulation containers for non-creditable hazardous waste pharmaceuticals must be labeled with the phrase "Hazardous Waste Pharmaceuticals." • Hazardous waste numbers (codes) are NOT required to be listed on the label.
Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities. (§ 266.502(f))	• A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status. • A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. This can be done by any of the following methods: ○ Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste; ○ Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste; ○ Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste. • Accumulation time limits only apply to a healthcare facility's non-creditable hazardous waste pharmaceuticals and does not apply to any other types of non-pharmaceutical hazardous waste generated on-site nor to potentially creditable hazardous waste pharmaceuticals.
Land disposal restrictions (LDR) for non-creditable hazardous waste pharmaceuticals. (§ 266.502(g)	• Healthcare facilities are **not** subject to the requirements for the management of hazardous waste pharmaceuticals based on CFR 40 subpart 262. • Labeling can be limited to "hazardous waste pharmaceuticals". Hazardous waste codes in labeling are no longer required when transporting waste offsite nor for LDR notification. **However,** • Healthcare facilities must comply with the LDR requirements prior to disposal of the hazardous waste pharmaceuticals they generate (40 CFR part 268). • Healthcare facilities may accumulate non-creditable hazardous and non-hazardous waste in the same container, except from non-creditable hazardous waste that cannot be combusted, which need to be stored in separate containers (268.3(c)).

Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals. (§ 266.502(h))	• Healthcare facilities have up to 90 days to ship a rejected shipment of non-creditable hazardous waste to a new designated facility, provided that: o They sign either item 18c of the original manifest or item 20 on new manifest for returned shipment o Provide the transporter a copy of the manifest o Send a copy of the manifest to the facility that returned the shipment within 30 days of receipt of the rejected shipment o Transport the rejected shipment to the new facility within 90 days of receipt of the rejected shipment
Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals. (§ 266.502(i))	• Healthcare facilities that are required to submit a Biennial Report are no longer required to include their non-creditable hazardous waste pharmaceuticals in the report. • Healthcare facilities managing non-creditable hazardous waste pharmaceuticals have reporting requirements similar to generators (40 CFR 262.44(b,c)) o 60 day requirement for reporting to the EPA Regional Administrator if shipment of non-creditable pharmaceutical is rejected, or if hazardous waste manifest not received. o 60 day requirement for reporting to alternative facilities when shipment is rejected by designated facility chosen by the healthcare facility. o Administrator may require additional reports concerning the quantities and disposition of hazardous waste pharmaceuticals.
Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals. (§ 266.502(j))	• Healthcare facilities managing non-creditable hazardous waste pharmaceuticals must maintain records similar to the records that must be kept by generators regulated (40 CFR part 262.40) o Excluding hazardous waste determinations. • These new provisions only apply if the healthcare facility chooses to manage all of its non-creditable waste pharmaceuticals as hazardous waste under subpart P. **Specifically,** • Healthcare facilities must keep a signed copy of each hazardous waste manifest as a record for three years from the date that the non-creditable hazardous waste pharmaceutical was accepted by the initial hazardous waste transporter. • Exception reports must be filed within 60 days of the date the hazardous waste pharmaceutical was accepted by the initial transporter, and kept for period of three years. • The retention periods would be automatically extended during the course of ongoing enforcement actions against any activity associated with hazardous waste pharmaceutical management or as requested by the Regional Administrator.

	• All records must be kept on site of the healthcare facility and readily available upon request by inspector.
Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities. (§ 266.502(k))	• Basic spill response requirements for non-creditable hazardous waste pharmaceuticals generated and managed by healthcare facilities include: ○ Healthcare facilities must immediately contain all spills of, and other residues from, hazardous waste pharmaceuticals. ○ Healthcare facilities determine whether any material (e.g., residue, contaminated clean-up materials, or debris resulting from the spill) is or contains a hazardous waste pharmaceutical and, if so, the healthcare facility must manage it under the management standards for non-creditable hazardous waste pharmaceuticals.
Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator (§ 266.502(l))	• A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG without contract provided that the receiving facility: ○ First, is under control of the same person as the VSQG or has contractual or other documented business relationship for receiving healthcare facility supplies pharmaceuticals; ○ Second, is operating under subpart P for the management of its non-creditable hazardous waste pharmaceuticals; ○ Third, manages all hazardous waste pharmaceuticals in accordance with subpart P once it arrives at the receiving healthcare facility. ○ Fourth, keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received. • Of note under the new regulations, VSQGs have the option to send potentially creditable hazardous waste pharmaceuticals directly to a reverse distributor or a healthcare facility operating under part 266 subpart P and above provisions.
§ 266.503 Standards for Healthcare Facilities Managing Potentially <u>Creditable</u> Hazardous Waste Pharmaceuticals	
Hazardous waste determination for potentially creditable pharmaceuticals. (§ 266.503(a))	• Healthcare facilities have two choices in regard to making a hazardous waste determination for potentially creditable pharmaceuticals: ○ (1) make a hazardous waste determination in accordance with § 266.503(a) on each potentially creditable waste pharmaceutical and determine individually which are hazardous waste and thus subject to regulation under this subpart and which are non-hazardous waste or, ○ (2) commingle all potentially creditable pharmaceutical waste whether it is hazardous waste or non-hazardous waste and manage all of the commingled pharmaceuticals under this subpart (therefore they would not have to make any individual waste determinations). • If potentially creditable non-hazardous and hazardous waste pharmaceuticals are commingled, then all will be subject to subpart

	P management standards while they remain commingled. These pharmaceuticals would also all be subject to shipping standards of 266.509. ○ When the reverse distributor receives the commingled potentially creditable non-hazardous and hazardous waste pharmaceuticals, the reverse distributor has the option to segregate the non-hazardous waste pharmaceuticals from the hazardous waste pharmaceuticals.
Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. (§ 266.503(b))	• Healthcare facilities operating under subpart P can accept potentially creditable and non-creditable hazardous waste pharmaceuticals (including commingled) from an off-site VSQG healthcare facility without a hazardous waste manifest, provided four conditions are met. These are the same four conditions required for both non-creditable and potentially creditable hazardous waste pharmaceuticals. • Under § 266.503(b) a healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG under § 262.14, provided the receiving healthcare facility: ○ Is under control of the same person as the VSQG or has contractual or other documented business relationship for receiving healthcare facility supplies pharmaceuticals; ○ Is operating under subpart P for the management of its non-creditable hazardous waste pharmaceuticals; ○ Manages all hazardous waste pharmaceuticals in accordance with subpart P once it arrives at the receiving healthcare facility. ○ Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received. • Previously, part 262 VSQG regulations did not allow a healthcare facility to send its hazardous waste off-site to another healthcare facility, unless the receiving healthcare facility is one of the eight types of facilities listed in § 262.14(a)(5)(i–viii).
Accumulation Time, Container Management and Labeling for Healthcare Facilities Managing Potentially Creditable Hazardous Waste Pharmaceuticals	• EPA did not propose a limit on how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals or specific standards for how the containers must be managed during accumulation. EPA does recommend that liquids and aerosols be put in sealed plastic bags, containers, or other management practices during accumulation to reduce the risk of spills and releases. EPA does not have specific requirements for labeling of accumulation areas for potentially creditable hazardous waste pharmaceuticals in healthcare facilities.

Biennial Reporting by healthcare facilities. (§ 266.503(d))	• Healthcare facilities are <u>not</u> subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart. Potentially creditable hazardous waste pharmaceutical quantities will be captured by the reverse distributors' required biennial reports, therefore, a requirement for healthcare facilities to report quantities of potentially creditable hazardous waste pharmaceuticals generated would be duplicative.
Recordkeeping by healthcare facilities. (§ 266.503(e))	• Previously, healthcare facilities had to provide advanced notification of shipments of potentially creditable hazardous waste pharmaceuticals to reverse distributors. Under subpart P, healthcare facilities initiating shipments of potentially creditable hazardous waste pharmaceuticals must keep, (1) delivery confirmation for each shipment and (2) shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable. • These records must be retained for 3 years and all records must be readily available upon request by an inspector.
Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities (§ 266.503(f))	• A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with subpart P. The healthcare facility must determine whether the pharmaceuticals that remain in the containers are potentially creditable and manage them according to subpart P.
§ 266.504 Healthcare Facilities That Are Very Small Quantity Generators For Both Hazardous Waste Pharmaceuticals And Non-Pharmaceutical Hazardous Waste.	
Potentially creditable hazardous waste pharmaceuticals (§ 266.504(a))	● A healthcare facility that is a VSQG for both their hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste is given a choice. The healthcare facility may (1) operate as a standard VSQG under part 262 rules, and can use the optional provisions in Part 266 Subpart P (§ 266.504), or (2) choose to opt into operating under Part 266 Subpart P. ● VSQGs are subject to three provisions of part 266 subpart P: the sewer ban in § 266.505, the empty container standards in § 266.507, and the optional provisions in § 266.504 ○ The optional provisions of Subpart P include: 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 healthcare facility (see below) ● § 266.504 does not apply to healthcare facilities that become VSQGs under this rule as a result of not having to count their hazardous waste pharmaceuticals. Such healthcare facilities are VSQGs with respect to their non-pharmaceutical hazardous

	waste only and must operate under Subpart P for their hazardous waste pharmaceuticals. • A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may choose to send potentially creditable hazardous waste pharmaceuticals to a reverse distributor.
Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator (§ 266.504(b))	• A healthcare facility that is a VSQG for both their hazardous waste pharmaceuticals and their non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals to another healthcare facility provided the receiving healthcare facility is operating under part 266 subpart P and meets certain conditions, or is a LQG operating under part 262 and meets the conditions for off-site consolidation.
Long-term care facilities that are very small quantity generators (§ 266.504(c))	• A long-term care facility that is a VSQG for both hazardous waste pharmaceuticals and non- pharmaceutical hazardous waste has the option to dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector that is registered with the DEA provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable DEA regulations for controlled substances. o DEA collection receptacles can only be used for controlled substances that are from the ultimate user.
Long-term care facilities with 20 beds or fewer (§ 266.504(d))	Subpart P presumes that a long-term care facility with 20 beds or fewer is a VSQG subject to § 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste. o Therefore, these facilities are not subject to Subpart P, and are not required to keep track of the amount of hazardous waste generated each month. • The only sections of Subpart P that long-term care facilities with 20 beds or less are subject to is the sewer prohibition (§ 266.505), the empty container standards (§266.507), and the optional provisions of § 266.504. • Long-term care facilities with > 20 beds that operate as a VSQG under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the VSQG limits.
§ 266.505 Prohibition of Sewering Hazardous Waste Pharmaceuticals	
Summary of Proposal, Rules, and Comments	All healthcare facilities – including VSQG and reverse distributors operating under § 262.14 in lieu of this subpart are prohibited from disposing of pharmaceuticals that are listed hazardous waste and/or exhibit one or more of the four hazardous waste characteristics (i.e., ignitability, corrosivity, reactivity, or toxicity) by putting them down a drain (e.g., sink, toilet, or floor drain).

	o The sewer prohibition includes hazardous wastes that are DEA controlled substances o The sewer prohibition is effective in all states 6 months following publication in the Federal Register
§ 266.506 Conditional Exemptions for Hazardous Waste Pharmaceuticals That are Also Controlled Substances and Household Waste Pharmaceuticals Collected in A Take-Back Event or Program	
Summary of Proposal, Rules, and Comments	• Prior to this final rulemaking, the management and disposal of a pharmaceutical that was both a RCRA hazardous waste and a DEA controlled substance was regulated under both the RCRA Subtitle C hazardous waste regulations and the DEA. • Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the DEA in are now exempt from all RCRA Subtitle C requirements, provided they are: o Not sewered, and o Managed in compliance with all DEA regulations, and o Destroyed by a method that the DEA has publicly deemed in writing to meet their non-retrievable standard, or o Combusted at a permitted large or small municipal waste combustor, hospital medical and infectious waste incinerator, commercial and industrial waste incinerator, or hazardous waste combustor • The only dually regulated RCRA hazardous waste and DEA controlled substance that is currently listed as a hazardous waste pharmaceutical is chloral hydrate (paraldehyde, paregoric, and opium tincture are also dually regulated but it is EPA's understanding that these drugs are no longer in common use). Four other dually regulated hazardous wastes/controlled substances in common use that are considered hazardous due to ignitability include fentanyl sublingual spray, phenobarbital, testosterone gels, and valium injection. • Household waste pharmaceuticals collected during a take-back event or program should now be managed as a hazardous waste rather than a municipal solid waste and must be destroyed by combustion or other DEA-approved method, whether or not the household waste pharmaceuticals are commingled with DEA controlled substances. • So pharmaceuticals that are household hazardous waste (i.e., "household waste pharmaceuticals") and are collected in DEA authorized collection receptacles where they may be commingled with controlled substances will continue to be excluded from RCRA regulation, provided they are (1) combusted at a municipal solid waste or hazardous waste combustor, and (2) managed in accordance with all applicable DEA regulations.
§ 266.507 Residues of Hazardous Waste Pharmaceuticals in Empty Containers	
§ 266.507 Residues of	• 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

hazardous waste pharmaceuticals in empty containers (§ 266.507(a))	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 from the container using the practices commonly employed to remove materials from that type of container o This provision applies to containers that held either non-acute or acute hazardous waste pharmaceuticals • For containers that once held non-acute waste pharmaceuticals to be considered empty, it will no longer be necessary to measure the remaining contents, and for containers that once held acute hazardous waste pharmaceuticals, it is no longer necessary to triple-rinse the containers or demonstrate an equivalent removal method.
C. Syringes (§ 266.507(b))	• If a syringe contains a pharmaceutical that is a hazardous waste and it is not empty because the plunger is not fully depressed, 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 as well as any applicable federal, state, and local requirements. o Thus the residue in the empty syringe (as well as the syringe) will not be regulated as hazardous waste • EPA notes that a syringe can become empty in three ways: (1) fully depressing the plunger of the syringe by administering the contents of the syringes to a patient, or (2) fully depressing the plunger by injecting the contents of the syringe into another delivery device such as an IV bag, or (3) fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container.
Intravenous (IV) bags and Other Containers, Including Delivery Devices (§ 266.507(c) & (d))	• Residues remaining in other types of unused or used containers, including, inhalers, aerosols, nebulizers, tubes of ointments, gels, or creams, will be regulated as hazardous waste if the residues are acute or non-acute hazardous waste • If such containers once held an acute hazardous waste pharmaceutical or if they held a non-acute hazardous waste pharmaceutical but cannot meet the RCRA empty container standard of § 261.7, then the residues of these hazardous waste pharmaceuticals (and their containers) must be managed as non-creditable hazardous waste pharmaceuticals under this Subpart • An intravenous (IV) bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the intravenous (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) (“RCRA Empty”).

§ 266.508 Shipping Non-Creditable Hazardous Waste Pharmaceuticals From A Healthcare Facility Or Evaluated Hazardous Waste Pharmaceuticals From A Reverse Distributor	
A. Shipping **Non-creditable** Hazardous Waste Pharmaceuticals from Healthcare Facilities to Treatment, Storage, and Disposal Facilities (§ 266.508(a))	• Non-creditable hazardous waste pharmaceuticals generated at healthcare facilities, when shipped off site, must be shipped to a designated facility and accompanied by a hazardous waste manifest. • Healthcare facilities must continue to comply with the existing DOT pre-transport requirements for packaging, labeling and marking. • Healthcare facilities are not required to list hazardous waste codes in Item 13 of the hazardous waste manifest for shipments of non-creditable hazardous waste pharmaceuticals. Instead, the facility must write only the word "PHARMS" on the manifest. • However, lab packs that contain D004 (arsenic), D005 (barium), D006 (cadmium), D007 (chromium), D008 (lead), D010 (selenium) or D011 (silver), must be marked or labeled with the EPA hazardous waste numbers (or electronic means may be used). • Reverse distributors sending evaluated hazardous waste pharmaceuticals to a TSDF for disposal are required to comply with all standards in § 266.508(a), which includes a requirement to list all applicable waste codes in Item 13 of the manifest, even though healthcare facilities do not. ○ They are not, however, required to write the word PHARMS in Item 13 or on the container label in addition to all other applicable waste codes. ○ Reverse distributors must keep copies of hazardous waste manifests for three years from the date evaluated hazardous waste pharmaceuticals are shipped.
Exporting non-**creditable** hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals. (§§ 266.508(b) Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous	• Healthcare facilities or reverse distributors exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals are subject to 40 CFR part 262 H. • Healthcare facilities and reverse distributors may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste form off site.

waste pharmaceuticals.266.508(c))	

§ 266.509 Shipping Potentially Creditable Hazardous Waste Pharmaceuticals From a Healthcare Facility or a Reverse Distributor to a Reverse Distributor

Summary:

- Potentially creditable hazardous waste pharmaceuticals can be shipped without a hazardous waste manifest and without the use of hazardous waste transporters when sending potentially creditable hazardous waste pharmaceuticals to a reverse distributor or when a reverse distributor is sending potentially creditable hazardous waste pharmaceuticals to another reverse distributor.
- If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days, the healthcare facility or reverse distributor that initiated the shipment must contact the shipper.
- Healthcare facilities and reverse distributors that initiate a shipment to a reverse distributor must keep (1) delivery confirmation for three years after the shipment was initiated, and (2) shipping papers or bills of lading.
- DOT requirements apply with the exception of manifest.

Amendments to the Part 268 Prohibitions on Storage

Summary of Amendments	• Existing storage prohibitions regarding hazardous waste apply to both healthcare facilities and reverse distributors. • Healthcare facilities and reverse distributors are prohibited from storing restricted wastes from land disposal. • Healthcare facilities must comply with the applicable requirements in §§ 266.502 and 266.503 and reverse distributors must comply with § 266.510 when accumulating hazardous waste pharmaceuticals on site.

Implementation and Enforcement

Healthcare Facilities	• Healthcare facilities must determine if they are considered LQGs, SQGs or VSQGs based on the count of all hazardous waste (pharmaceutical and non-pharmaceutical) they produce within each calendar month. ○ Note that potentially creditable hazardous waste pharmaceuticals transported to a reverse distributor are considered solid and hazardous waste from the point of generation at the healthcare facility and therefore must now be counted towards their generator category. A healthcare facility previously considered a VSQG may no longer be a VSQG when it

	begins counting its potentially creditable hazardous waste pharmaceuticals. In that case, the facility is subject to 266 subpart P for its hazardous waste pharmaceuticals. • Healthcare facilities that are currently considered LQGs or SQGs for the management of hazardous waste pharmaceuticals are subject to the final 40 CFR part 266 subpart P. ○ That includes: A healthcare facility that generates more than 100 kg of hazardous waste per month, or more than 1 kg of acute hazardous waste per calendar month, or more than 100 kg 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 wastes listed in § 261.31, or 261.33(e). • VSQGs are subject to the prohibition on sewering hazardous waste pharmaceuticals in § 266.505, the empty container standards in § 266.507, and the optional standards of § 266.504 (unless choosing to operate under 266 subpart P – see below). • All healthcare facilities operating under 266 subpart P will be subject to the same regulations for managing hazardous waste pharmaceuticals, **regardless of the quantity of hazardous waste pharmaceuticals generated.** ○ A healthcare facility that generates both pharmaceutical and non-pharmaceutical hazardous waste must continue to manage the non-pharmaceutical hazardous waste pursuant to part 262, but need not count its hazardous waste pharmaceuticals toward determining the facility's monthly hazardous waste generator category for part 262. ■ This means that a facility may no longer be considered a LQG and therefore may not need to manage its non-pharmaceutical hazardous waste pursuant of the LQG regulations of 262 but rather operate under the reduced regulations of a SQG or VSQG. ○ **If a VSQG does not want to track the amount of hazardous waste pharmaceuticals it generates to ensure it does not exceed the VSQG quantity limits, it can choose to operate under 266 subpart P and must comply with all requirements for the management of its hazardous waste pharmaceuticals.**
Reverse Distributors and Reverse Logistics Centers	• Once the healthcare facility makes the decision to send a prescription pharmaceutical to a reverse distributor for credit, it is a solid waste at the healthcare facility. • A portion of the potentially creditable solid waste prescription pharmaceuticals at healthcare facilities that are destined for a reverse distributor will also meet the definition of hazardous waste (falling under 266 subpart P requirements). • Nonprescription pharmaceuticals are not solid wastes, and therefore not hazardous waste pharmaceuticals if they have a reasonable expectation of being legitimately used/reused or reclaimed. • All reverse distributors are subject to part 266 subpart P regardless of the amount of hazardous waste pharmaceuticals they manage.

Healthcare Facilities and Reverse Distributors Managing Non-pharmaceutical Hazardous Waste in Accordance with 40 CFR Part 262 or Part 273 (i.e., Complying with "More Than One RCRA")	• Non-pharmaceutical hazardous wastes will continue to be regulated under 40 CFR part 262 for both healthcare facilities and reverse distributors. • Retail stores, including pharmacies and grocery stores, may have non-pharmaceutical hazardous wastes on-site as well, which must be managed in accordance with the 40 CFR part 262 regulations and all other applicable RCRA Subtitle C regulations.
Intersection of Part 266 Subpart P with the Hazardous Waste Generator Improvements Rule	• EPA added regulatory flexibility allowing a hazardous waste generator to avoid increased burden of a higher generator category when generating episodic waste provided the episodic waste is properly managed in accordance with part 262 subpart L. • A healthcare facility that is a VSQG for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste can use the episodic generation provision of part 262 subpart L for all of its hazardous waste. • Under part 266 subpart P, EPA is not requiring re-notification by healthcare facilities and reverse distributors. • If a healthcare facility that is a VSQG accumulates more than 1 kg of acute hazardous waste, then it will remain subject to § 262.14(a)(3); the healthcare facility will not become subject to part 266 subpart P. The 2016 Hazardous Waste Generator Improvements final rule had (part 262): • Added a new requirement for periodic re-notification by SQGs. Under this new provision, SQGs must re-notify EPA starting in 2021 and every four years thereafter using EPA Form 8700-12. • Stated that if a VSQG accumulates at any time greater than 1 kg of acute hazardous waste, all quantities of that acute hazardous waste are subject to the additional conditions for exemption for LQGs • New provisions for episodic generation of hazardous waste outside normal activities allows more flexibility. ○ For example, if a VSQG healthcare facility is directed to dispose of recalled pharmaceuticals, it could use the episodic generator provisions of part 262 subpart L to avoid an increase in hazardous waste generator category, vs becoming subject to part 266 subpart P.

State Authorization	
Applicability of Rules in Authorized States	• EPA may authorize states to administer the RCRA Subtitle C hazardous waste program. • Authorized states are required to modify their programs only when EPA promulgates federal requirements that are more stringent or broader in scope than existing federal requirements. • Therefore, authorized states may, but are not required to, adopt federal regulations, both HSWA and non-HSWA, that are considered less stringent than previous federal regulations.
Effect on State Authorization	• Taken as a whole, the entire new subpart P under 40 CFR part 266 entitled "Standards for the Management of Specific Hazardous Wastes and Specific Types of Hazardous Waste Management Facilities" (sections VIII–XVII of this preamble) is considered more stringent than the current federal standards. Therefore, authorized states will be required to modify their programs to adopt these revisions. • The amendment to exempt from the P075 listing the nicotine patches, gums and lozenges that are FDA-approved OTC nicotine replacement therapies is less stringent that the current hazardous waste regulations (section V of this preamble). Thus, authorized states may, but are not required to, adopt the change to the P075 listing. • States may not add hazardous waste pharmaceuticals to their Universal Waste program.

Questions and Clarifications:

- **What are the notification requirements for healthcare facilities regarding 266 Subpart P?**
  - All healthcare facilities must submit a one-time notification that they are operating under Subpart P using Site ID Form 8700-12 within 60 days of the rule going into effect. Facilities that are required to submit a biennial report may notify on their normal biennial reporting cycle.

- **What is proper disposal for a nicotine patches, gum, and lozenges?**
  - These items were previously treated as acute-hazardous waste, but with the new amendment, nicotine patches, gum, and lozenges are treated as non-hazardous waste.
  - Of note, e-cigarettes, e-liquids, cartridges, nicotine used in research and manufacturing or prescription NRTs must still be treated as a hazardous waste pharmaceutical.

- **How should an empty warfarin bottle be discarded?**
  - When present at concentrations greater than 0.3%, warfarin is a P-listed hazardous waste (acute-hazardous waste).

- Prior to subpart P, an empty warfarin bottle required triple rinsing with a solvent documented to remove the hazardous materials to be considered RCRA empty and disposed as non-hazardous waste.
- Under subpart P, residues remaining in empty containers are no longer regulated as hazardous waste and can be discarded in regular trash. If a warfarin tablet is discarded, it must still be treated as an acute hazardous waste pharmaceutical.

- **How are empty containers defined? How are they disposed of?**
  - Formerly, containers that held listed pharmaceutical waste required triple rinsing before being considered empty and suitable for disposal with regular waste. Under the new regulations, bottles, vials, or ampules that have held less than 1 liter or 10,000 pills are not regulated as hazardous waste provided the pharmaceutical has been removed from the container.
  - Syringes and IV bags that contained listed pharmaceutical waste but have been fully administered to a patient are now considered empty and are not regulated as hazardous waste.
  - Other types of containers (including inhalers, aerosols, nebulizers, and tubes of ointment, gels, or creams) that have held listed pharmaceutical waste must be managed as non-creditable hazardous waste pharmaceuticals.

- **Under subpart P, do hazardous waste pharmaceuticals count towards determining a generator category?**
  - Hazardous waste pharmaceuticals managed under subpart P will no longer count towards determining your generator category.
  - Hazardous waste pharmaceuticals that are also controlled substances are also not counted towards determining your generation category.

- **What are the three types of hazardous waste pharmaceuticals**
  - Non-creditable hazardous waste pharmaceutical: examples include broken, leaking, expired > 1 year, investigational new drug, contaminated personal protective equipment, and clean-up material. Partially administered containers of listed pharmaceuticals (i.e. syringes or IV bags still containing product) are also considered non-creditable hazardous waste.
  - Potentially creditable hazardous waste pharmaceutical: examples include pharmaceuticals in original manufacturer packaging, undispensed, and unexpired or expired < 1 year.
  - Evaluated hazardous waste pharmaceutical: Potentially creditable hazardous waste pharmaceuticals that have evaluated and determined to be non-creditable. No further evaluation or verification of manufacturer credit is necessary.

- **Are healthcare facilities required to accumulate their non-creditable hazardous waste pharmaceuticals in a central accumulation area (CAA) or satellite accumulation areas (SAA)?**
  - Under part 262, EPA outlined regulations on CAA and SAA, also known as the “less than 90 day (LQG) or 180 day (SQG) areas.” There are no longer volume accumulation limits and other requirements on central accumulation area and satellite accumulation areas for

healthcare facilities managing non-creditable hazardous waste pharmaceuticals. Healthcare facilities are no longer required to accumulate their non-creditable hazardous waste pharmaceuticals in a central accumulation area, but nothing prohibits them from doing so. Of particular concern regarding the SAA regulations for healthcare facilities was the one-quart accumulation limit for acute hazardous wastes (i.e., P-listed wastes) and the requirement that hazardous waste must be accumulated at or near the point of generation

- **How should healthcare facilities label hazardous waste containers?**
  - A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals"; hazardous waste codes are not required on the label.
  - Potentially creditable hazardous waste codes do not have any labeling requirements and do not require hazardous waste codes.

- **Is there a limit to how long healthcare facilities may accumulate containers of potentially creditable hazardous waste pharmaceuticals?**
  - No, EPA does not outline a specific time limit of accumulation. EPA also does not have specific requirements for labeling of accumulation areas in healthcare facilities. Of note, the accumulation limit for non-creditable hazardous waste is 1 year.

References

- Environmental Protection Agency (EPA). Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine. Washington, DC: EPA; 2018 Dec. EPA-HQ-RCRA-2007-0932.
- EPA. Introduction to Part 266 Subpart P. Presented at EPA Public Webinar. 2019 Feb and Mar.

Reverse Distribution and Reverse Logistics

Summary:

Previously, pharmaceuticals did not become wastes until the decision to discard was made by the manufacturer, wholesaler, or third-party service company that the pharmaceuticals were returned to. Now, the decision to discard is determinative of when an unsold product becomes a waste. Prescription pharmaceuticals moving through reverse distribution are solid wastes at the healthcare facility (e.g. retail store). In contrast, nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the healthcare or retail facility if they have a reasonable expectation of being legitimately used/reused (e.g. lawfully redistributed for their intended purpose) or reclaimed. Similarly, other retail items that are sent through reverse logistics are not wastes at the retail store if they have a reasonable expectation of being legitimately used/reused.

In circumstances when prescription pharmaceuticals are lawfully donated for their intended purpose, they would not be considered a solid waste. Applicable Department of Transportation (DOT) regulations still apply for all pharmaceuticals.

EPA assumes that nonprescription pharmaceuticals and other unsold retail items that have expired are not wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed.

If a manufacturer has established business rules that prohibit unsold retail items from being legitimately used/reused because the items are subject to a "destroy disposition," and that prohibit the unsold retail items from being reclaimed, the items are considered solid waste at the retail store or healthcare facility.

EPA assumes that nonprescription pharmaceuticals and other unsold retail items that receive credit up-front through an adjustable rate policy are not wastes if they have a reasonable expectation of being legitimately used/reused or reclaimed.

EPA is choosing not to apply RCRA regulations to nonprescription pharmaceuticals and other unsold retail items while they are subject to a recall, provided the recall is regulated and overseen by FDA or CPSC. When FDA directs the destruction of some or all of the recalled retail items, or CPSC grants permission to dispose or destroy some or all of the recalled items the materials that are hazardous waste must be managed in accordance with RCRA, including the hazardous waste generator regulations standards in 40 CFR part 262.

If items are not in good condition, or are leaking or releasing to the environment, these items must be managed as wastes at the healthcare facility in accordance with the applicable hazardous waste regulations.

§ 266.510 Standards for the Management Of Potentially Creditable Hazardous Waste Pharmaceuticals and Evaluated Hazardous Waste Pharmaceuticals at Reverse Distributors	
EPA is finalizing a new category of hazardous waste management facilities under RCRA called a ‘‘reverse distributor,” which is defined as any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Reverse distributors will not be required to have a hazardous waste permit or interim status for on-site accumulation of creditable and evaluated hazardous waste pharmaceuticals provided it follows the final reverse distributor standards.	
Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals (§ 266.510(a))	• A reverse distributor must provide a one-time notification to EPA of its hazardous waste pharmaceutical activities using the Site ID Form (EPA Form 8700–12) within 60 days of the effective date of this subpart or within 60 days of becoming subject to this subpart. • Reverse distributors must keep an inventory of the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are on site. • Reverse distributors must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of arriving at the reverse distributor. • There is a 180-day accumulation limit for the hazardous waste pharmaceutical at each reverse distributor. EPA is not requiring a specific method to document the accumulation. • Reverse distributors must meet a performance-based security requirement which is based on the existing interim status TSDF security requirements found at § 265.14. • Reverse distributors must meet standards that are the same as those that appear in the federal LQG regulations for developing a contingency plan, emergency procedures, and closure. • If a shipment from a healthcare facility arrives at a reverse distributor that includes hazardous waste that it is not authorized to receive, the reverse distributor must submit an unauthorized waste report to the EPA Regional Administrator within 45 days • Reverse distributors must keep copies of notification forms to EPA indicating operations, records of shipments and inventory • Potentially creditable hazardous waste pharmaceuticals are not included on the BR.
Additional standards for reverse distributors managing potentially	• There is a limit of three transfers of potentially creditable hazardous waste pharmaceuticals before the hazardous waste pharmaceuticals are ultimately transported to a permitted or interim status TSDF. • Each reverse distributor must make an evaluation of them within 30 calendar days and may only accumulate the hazardous

creditable hazardous waste pharmaceuticals destined for another reverse distributor (§ 266.510(b))	waste pharmaceuticals on site for no more than 180 calendar days after the evaluation before it ships them off-site ○ Maximum accumulation time on-site at a reverse distributor is 210 days • Reverse distributors must keep records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor.
Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals (§ 266.510(c))	• A reverse distributor must establish an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals. • The accumulation area for evaluated hazardous waste pharmaceuticals must be inspected at least once every seven days to ensure containers are not leaking and that diversion of the hazardous waste pharmaceuticals is not occurring. • Reverse distributors must meet the same classroom or on-the-job personnel training requirements that LQGs must meet. Personnel that need to be trained are those persons who handle the evaluated hazardous waste pharmaceuticals • Containers of evaluated hazardous waste pharmaceuticals in the accumulation area must be marked with the words, ‘‘hazardous waste pharmaceuticals’’ ○ Liquids or gels must be kept closed during accumulation. Containers must be maintained in good condition to prevent leaks and the container material must be compatible with the hazardous waste pharmaceuticals placed in the container. • Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable RCRA hazardous waste numbers (codes). The vendor may label containers with applicable codes on behalf of the reverse distributor • Reverse distributors must meet the same procedures that LQGs must meet for rejected shipments in § 262.42(c). Reverse distributors are also subject to land disposal restrictions that apply to LQGs. • Reverse distributors submit a BR (requirements 262.41 similar to LQG) for the evaluated hazardous waste pharmaceuticals that are transported to a TSDF. The report should only include the evaluated hazardous waste pharmaceuticals and not potentially creditable ones. • Recordkeeping requirements for evaluated hazardous waste pharmaceuticals at reverse distributors include: ○ Log of inspections of the on-site accumulation area ○ Hazardous waste manifest records, records of biennial reports, exception reporting and training documentation

When a reverse distributor must have a permit (§ 266.510(d))	• EPA is not requiring that a reverse distributor have a RCRA permit or interim status for accumulating potentially creditable and evaluated hazardous waste pharmaceuticals, provided that the reverse distributor follows all the conditions of the permitting exemption in § 266.510 • A reverse distributor must have a RCRA permit (or interim status) if it treats or disposes of hazardous waste on site or if it accepts manifested hazardous waste from off site. • A reverse distributor is required to reject shipments of manifested hazardous waste that it may inadvertently receive from off site because a reverse distributor is not a designated facility and therefore is not eligible to receive hazardous waste shipped with a manifest.