

Frequently Asked Questions Regarding Disposal of Hazardous Waste Pharmaceuticals

On February 22, 2019, The U.S. Environmental Protection Agency (EPA) published a final rule entitled “Management Standards for Hazardous Waste Pharmaceuticals (HWP) and Amendment to the P075 Listing for Nicotine” with an effective date of August 21, 2019.

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What does the new rule do?

- Establishes cost-saving, streamlined standards for handling hazardous waste pharmaceuticals at healthcare facilities,
- Prohibits regulated facilities from discharging hazardous waste pharmaceuticals to sewers, thereby making drinking and surface waters safer and healthier, and
- Removes FDA-approved, over-the-counter nicotine replacement therapies (i.e., nicotine patches, gums and lozenges) from regulation as hazardous wastes when discarded.
 - Note: This does not include “vaping” products like e-liquids/e-juices in e-cigarettes, cartridges, or vials.

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What about Florida’s Universal Pharmaceutical Waste Rule?

Florida repealed its Universal Pharmaceutical Waste Rule, 62-730.186 F.A.C., on August 15, 2019, so Pharmaceutical Waste is now regulated under the new Federal rule.

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What are “regulated facilities?”

This rule specifically regulates healthcare facilities and reverse distributors.

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What is considered a “healthcare facility?”

EPA defines a healthcare facility as:

- Any person that is 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.
- This definition includes, but is not limited to, wholesale distributors, third-party logistics providers 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, veterinary clinics, and veterinary hospitals.
- This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

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What is a “hazardous waste pharmaceutical?”

To understand what a hazardous waste pharmaceutical is one must first understand what a “pharmaceutical” is. EPA defines a pharmaceutical as:

- Any drug or dietary supplement for use by humans or other animals
- Any electronic nicotine delivery system (ENDS)
 - e.g., electronic cigarette or vaping pen
- Any liquid nicotine/e-liquid packages for retail sale for use in electronic nicotine delivery systems
 - e.g., pre-filled cartridges or vials

EPA further defines a hazardous waste pharmaceutical as:

- A pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D.
- A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed.
- An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

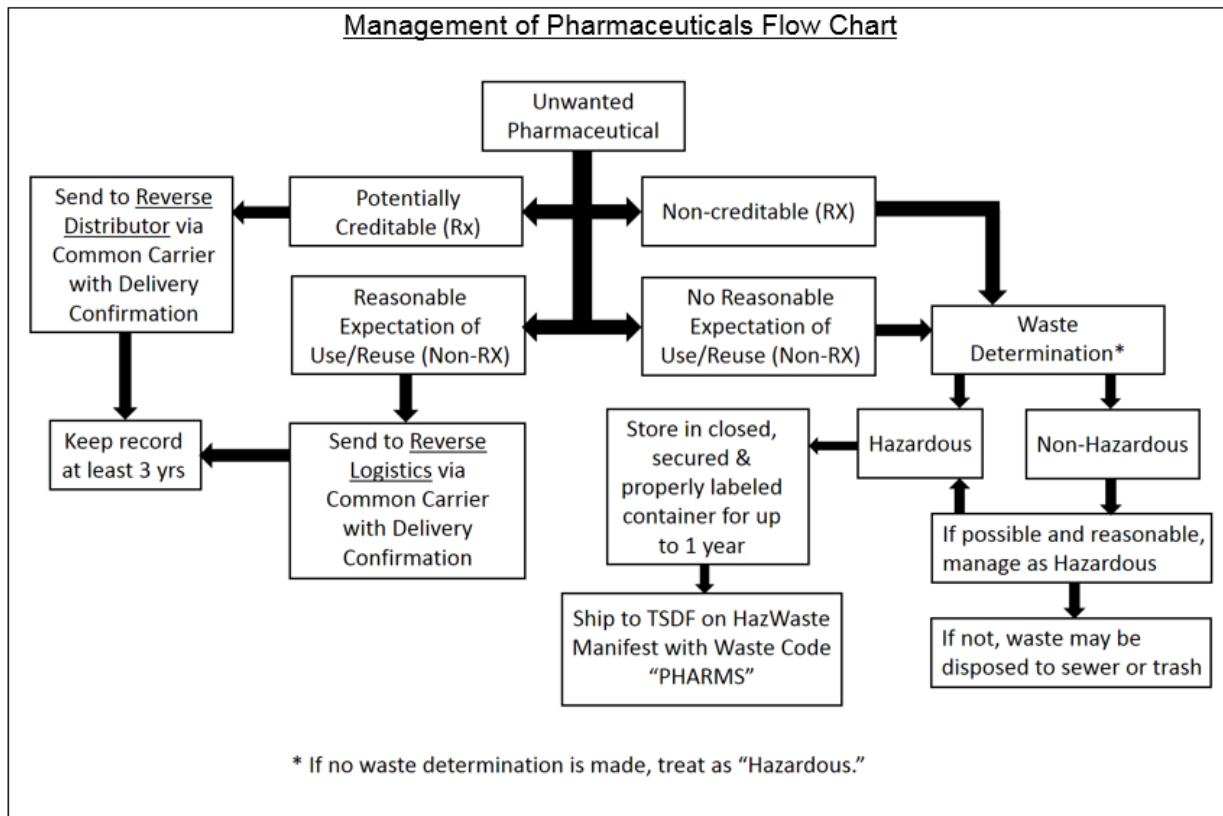
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What must I do with my waste pharmaceuticals?

Pharmaceutical wastes must not be discharged to the sanitary sewer or disposed in the regular trash unless a waste determination has indicated they are non-hazardous.

If a hazardous waste determination has not been performed, pharmaceutical wastes must be managed and disposed as hazardous waste pharmaceuticals.

See the flow chart below.



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What about residues of HWP in empty containers?

The HWP rule establishes standards on what is considered an empty container with respect to residues of HWP. Empty containers are not regulated as hazardous waste and may be disposed as regular trash provided the following conditions are met:

Stock, Dispensing and 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 provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

Syringes

A syringe is considered provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is 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 and any applicable federal, state, and local requirements for sharps containers and medical waste.

Intravenous (IV) Bags*

An IV bag is considered empty provided 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 follows:

- All wastes have been removed that can be removed using the practices commonly employed to remove materials from the IV bag; and,
- No more than 2.5 centimeters (one inch) of residue remain on the bottom of the IV bag; or
- No more than 3 percent by weight of the total capacity of the IV bag remains in the IV bag.

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, unless the container held non-acute hazardous waste pharmaceuticals and is empty as follows:

- All wastes have been removed that can be removed using the practices commonly employed to remove materials from that type of container, e.g., pouring, pumping, and aspirating, and;

- No more than 2.5 centimeters (one inch) of residue remain on the bottom of the container or inner liner; or
- No more than 3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is less than or equal to 119 gallons in size; or
- No more than 0.3 percent by weight of the total capacity of the container remains in the container or inner liner if the container is greater than 119 gallons in size.
- A container that has held a hazardous waste that is a compressed gas is empty when the pressure in the container approaches atmospheric.
- This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

*** IV Bags and Other Containers, including Delivery Devices that contain acutely hazardous waste pharmaceuticals (i.e P-listed wastes) can never be considered empty and must be managed as non-creditable hazardous waste pharmaceuticals.**

Electronic Nicotine Delivery System (ENDS) or Liquid Nicotine/E-Liquid Packages

- Liquid nicotine or e-liquid packages must be separated from the rest of the electronic cigarette or vape pen and handled as non-creditable hazardous waste pharmaceuticals.
- The battery component of the ENDS must be separated from the rest of the electronic cigarette or vape pen, placed in an individual plastic bag or tape placed over the connectors, and stored in a closed box marked "Used Lithium Batteries." Contact your campus facilities management department for disposal of batteries.

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Is training available?

Yes, EH&S provides in-person and on-line Hazardous Waste Pharmaceuticals training, see the [EH&S training page](#).

Those who generate pharmaceutical wastes must complete initial training and annual refresher training.

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Where can I get more information?

- Contact EH&S (813) 974-4036 or ehs@usf.edu.
- [USF Disposal of Hazardous Waste Pharmaceuticals](#)
- [EPA Final Rule Site](#)
- [EPA Final Rule Webinar Slides](#)

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