



UNIVERSITY OF SOUTH FLORIDA

Disposal of Hazardous Waste Pharmaceuticals

Environmental Health & Safety

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1. Introduction

On February 22, 2019, The U.S. Environmental Protection Agency (EPA) published a final rule entitled “Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine” with an effective date of August 21, 2019. The final rule, codified at 40 CFR Part 266 Subpart P:

- 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 therapies¹ (i.e., nicotine patches, gums and lozenges) from regulation as hazardous wastes when discarded.

Previously, Florida regulated the disposal of hazardous pharmaceutical wastes as Universal Pharmaceutical Waste under 62-730.186 F.A.C. Since the EPA final rule for managing hazardous waste pharmaceuticals is more stringent than the State rule, Florida was required to adopt those portions of the final rule, which it did on June 26, 2019. Since removing nicotine from regulation as hazardous waste is less stringent than State hazardous waste rules, Florida was not required to adopt that part of the final rule, but it did. Florida repealed 62-730.186 F.A.C. on August 16, 2019.

Since the prohibition against discharging hazardous waste pharmaceuticals to sewers is promulgated under the authority of the Federal Hazardous and Solid Waste Amendments, the prohibition became effective in all states on August 21, 2019.

One of the more important aspects of the final rule is its incentive to over-manage “non-hazardous” pharmaceuticals as “hazardous.” This relieves healthcare facilities from having to determine whether each individual waste pharmaceutical is a “hazardous waste” or not. EPA feels managing all waste pharmaceuticals as hazardous waste pharmaceuticals will be of even more benefit to the environment.

This document outlines responsibilities and procedures designed to assist USF healthcare facilities in compliance with the management of hazardous waste pharmaceuticals (HWP) other than DEA Controlled Substances, which also must not be discharged to the sewer and must be managed and disposed in compliance with DEA regulations.

2. Roles & Responsibilities

To ensure compliance with the regulatory requirements, various responsibilities are assigned to the following entities:

Environmental Health and Safety (EH&S)

- Serve as the administrator of the University’s contract with the HWP disposal vendor.

¹ Note: This does not include “vaping” products like e-liquids/e-juices in e-cigarettes, cartridges, or vials.

- Act as the contact between the university and the vendor for program-related issues including site setup, container delivery, and pickup scheduling.
- Monitor vendor for satisfactory service.
- Receive and file copies of all shipping manifests and invoices from the vendor and make them available for audit by regulatory agencies.
- Charge-back Colleges/Departments/Units for actual costs incurred.
- Maintain current [HWP program information on the USF EH&S website](#).
- Assist Colleges/Departments/Units in maintaining compliance with HWP regulations.
- Assist with cleanup of pharmaceutical spills/releases that are beyond the response capabilities of Colleges/Departments/Units.
- Ensure all spill cleanup waste resulting from the release of HWP is properly disposed.

Colleges/Departments/Units

- Implement and comply with the requirements listed in this document and ensure all personnel managing waste pharmaceuticals receive initial and annual refresher training.
- Identify locations in which to accumulate HWP waste.
- Work with EH&S to determine appropriate waste pickup schedules. Notify EH&S if more/less frequent, or out-of-cycle, pickups are needed.
- Manage containers in accordance with regulatory requirements.
- Appoint a representative who will sign and receive the original copy of shipping papers (Uniform Hazardous Waste Manifests) from the HWP disposal vendor.
- Maintain original signed copies of Uniform Hazardous Waste Manifests for at least three (3) years, and send scanned copies to EH&S at ehs@usf.edu within 24 hours.
- Provide chartfield information to EH&S for charge-back payments for services.
- Clean up spills/releases of pharmaceuticals immediately. Contact EH&S at (813) 974-4036 for assistance if needed.
- Dispose of waste from the release of pharmaceuticals as Non-creditable HWP. Contact EH&S with any questions.

HWP Disposal Vendor

- Assist USF Colleges/Departments/Units with setup and implementation of HWP disposal programs including identification of storage locations for HWP containers.
- Provide collection, transportation, and disposal of HWP from designated areas in Colleges/Departments/Units at agreed-upon intervals, or on an as-needed basis as scheduled by EH&S.
- Complete and provides copies of uniform hazardous waste manifests to designated representative and/or EH&S at the completion of HWP pickups.
- Invoice EH&S for all services provided to USF Colleges/Departments/Units.

Any questions about this program should be directed to Environmental Health and Safety at (813) 974-4036 or ehs@usf.edu.

3. Key Definitions

Pharmaceutical means

- 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.

Hazardous waste pharmaceutical means

- 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.

Healthcare facility means

- 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.

Potentially creditable hazardous waste pharmaceutical² means

- A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit or a nonprescription hazardous waste pharmaceutical that has a reasonable expectation to be legitimately used/reused or reclaimed, and is—
 - (1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);

² Note: This definition differs from the definition at 40 CFR 266.500, and is for USF use only.

- (2) Undispensed; and,
- (3) Unexpired or less than one year past expiration date. The term includes, nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Non-creditable hazardous waste pharmaceutical means

- A prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed.
- This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

Non-hazardous waste pharmaceutical means

- A pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in [40 CFR part 261](#) subpart D, and does not exhibit a characteristic identified in [40 CFR part 261](#) subpart C.

Non-pharmaceutical hazardous waste means

- A solid waste, as defined in § 261.2, that is listed in [40 CFR part 261](#) subpart D, or exhibits one or more characteristics identified in [40 CFR part 261](#) subpart C, but is not a pharmaceutical, as defined above.

Reverse distributor means

- Any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit.
- Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

Reverse logistics³ means

- A facility that receives nonprescription pharmaceuticals that have a reasonable expectation of being legitimately used/reused or reclaimed in order to capture some value or serve an intended purpose.
- Such products are not considered solid waste or hazardous waste.

Very Small Quantity Generator means

- A site that generates less than or equal to 1 kg (2.2 lbs.) of acutely hazardous waste, including acutely hazardous waste pharmaceuticals, in a calendar month.
- A site that generates less than or equal to 100 kg (220 lbs.) of hazardous waste, including hazardous waste pharmaceuticals, in a calendar month.

³ Note: EPA does not specifically define reverse logistics in 40 CFR Subpart P. This definition is USF's interpretation of the meaning of reverse logistics.

4. Procedures

Strictly speaking, the HWP rule only applies to hazardous waste pharmaceuticals; however, all USF generators of waste pharmaceuticals are strongly encouraged to manage both “hazardous waste pharmaceuticals” and “non-hazardous waste pharmaceuticals” as HWP. **The only time non-hazardous waste pharmaceuticals are not required to be managed/disposed as HWP is when a documented waste determination has been made confirming the waste pharmaceutical is not a hazardous waste pharmaceutical.** See the definition of a “Non-hazardous waste pharmaceutical” above and/or contact EH&S for assistance in making waste determinations.

Additionally, sites that are considered Very Small Quantity Generators (VSQGs) of hazardous waste/HWP are not regulated under the HWP rule, but are allowed to send potentially creditable HWP to reverse distributors, and must abide by the HWP sewer ban as well as the HWP rules for empty containers. VSQG sites are typically not located on the three (3) USF campuses, but not all off-campus sites are necessarily VSQGs. Contact EH&S if you have questions about your hazardous waste generator status.

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.

Pharmaceutical wastes that have a reasonable expectation of legitimate use/reuse (e.g., lawful donation or redistribution for their intended purposes) or reclamation are not hazardous waste pharmaceuticals. However, if these pharmaceuticals are not ultimately used, reused, or reclaimed, the pharmaceuticals shall be managed as Non-Creditable HWP unless a waste determination has indicated they are non-hazardous.

Summary of Requirements for Potentially Creditable HWP vs. Non-Creditable HWP

	Potentially Creditable HWP	Non-Creditable HWP
Container labeling & On-site Accumulation	<ul style="list-style-type: none"> No standards No time limit 	<ul style="list-style-type: none"> Container and labeling standards 1 year maximum
Off-site Shipping	<ul style="list-style-type: none"> Reverse Distributor (Rx) or Reverse Logistics (non-Rx) Common carrier Delivery confirmation required 	<ul style="list-style-type: none"> Haz Waste TSDF Haz Waste Manifest “PHARMS” waste code Haz Waste Transporter

Management of Waste Pharmaceuticals

A pharmaceutical is any drug (including over-the-counter or homeopathic drugs) or dietary supplement, any electronic nicotine delivery system, any liquid nicotine/e-liquid packages.

Pharmaceuticals also include, but are not limited to the following:

- Compounded drugs
- Investigational new drugs

- Pharmaceuticals remaining in non-empty containers (“empty” is defined below)
- PPE contaminated with pharmaceuticals
- Pharmaceutical spill clean-up materials

A pharmaceutical does not include dental amalgam, sharps, or medical waste.

When a pharmaceutical is no longer wanted or needed, a determination needs to be made as to whether the pharmaceutical is potentially creditable or the pharmaceutical is non-creditable.

Pharmaceuticals under preservation orders or during an investigation or judicial proceeding are not waste until a decision to discard them has been made.

In order to be considered potentially creditable, a pharmaceutical must be:

- In original manufacturer packaging (except recalled pharmaceuticals)
- Undispensed
- Unexpired or less than one year past expiration

A pharmaceutical is considered non-creditable if it is:

- Broken or leaking
- Repackaged
- Expired more than one year
- An investigational new drug
- Contaminated PPE
- Floor sweepings/clean-up material

Potentially Creditable Prescription (Rx) Pharmaceuticals

If a prescription (Rx) pharmaceutical meets the above conditions for potentially creditable, and it can be returned for potential manufacturer credit, then there are no labeling, containerization, or accumulation time limits. However, the usual storage, security, and handling requirements for prescription pharmaceuticals apply until they are sent to a **reverse distributor** for determination of potential credit. Shipping to a reverse distributor must be accomplished via common carrier with delivery confirmation. Delivery confirmation records must be kept for a minimum of three (3) years.

Potentially Creditable Non-Rx Pharmaceuticals

Similarly, non-prescription pharmaceuticals with a reasonable expectation of legitimate use/reuse or reclamation have no labeling, containerization, or accumulation time limits. However, the usual storage, security, and handling requirements for non-prescription pharmaceuticals apply until they are sent to **reverse logistics** for determination of legitimate use/reuse or reclamation. Shipping to a reverse logistics facility must be accomplished via common carrier with delivery confirmation. Delivery confirmation records must be kept for a minimum of three (3) years.

Non-creditable Hazardous Waste Pharmaceuticals

HWPs that are not potentially creditable, or do not have a reasonable expectation of legitimate use/reuse or reclamation, are considered non-creditable and must be properly stored, labeled, secured, and shipped to a hazardous waste disposal facility (TSDF) according to the following procedures:

- **Storage:** Non-creditable HWPs must be stored in a structurally sound container that will not react with its contents. The container must remain closed and secured in such a manner that prevents unauthorized access to its contents. Non-creditable HWPs may only be accumulated and stored for a maximum of one (1) year.
- **Labeling:** Storage containers must be labeled with the words “Hazardous Waste Pharmaceuticals” and the date waste was first added to the container to help ensure HWPs are not accumulated more than one (1) year.
- **Shipping:** Non-creditable HWPs must be shipped to a permitted Treatment, Storage and Disposal Facility (TSDF) for ultimate disposal. The shipment must be documented on a Uniform Hazardous Waste Manifest using the waste code, “PHARMS”, and transported by a licensed and permitted Hazardous Waste Transporter. Send a copy of the manifest to EH&S within 24 hours.

Hazardous Waste Determinations

If a waste determination has been performed and documented on a non-creditable waste pharmaceutical, and the waste pharmaceutical is non-hazardous, then it may be discarded as normal trash or flushed to the sanitary sewer. However, such wastes should still be managed as HWP, if possible and reasonable. There may be cases where it is overly burdensome, or costly, to manage non-hazardous waste pharmaceuticals as HWP. In those cases, as long as the waste has been subjected to a proper and documented waste determination, the non-hazardous waste may be discarded as normal trash or flushed to the sanitary sewer. Contact EH&S for assistance in making waste determinations.

A flow chart summarizing the procedures for management of waste pharmaceuticals at USF is provided in [Attachment A](#).

Pharmaceutical Spill Clean-up

Each healthcare facility must ensure there are adequate spill kit(s) available in order to respond to pharmaceutical spills immediately. All pharmaceutical spills will be managed and disposed as hazardous pharmaceutical waste unless a waste determination has been conducted and the spilled material has been deemed non-hazardous.

Recommended spill kit contents include:

- Personal Protective Equipment to be used “only” for spill cleanup
 - Disposable gloves, lab coat/apron, and shoe covers
 - Splash goggles

- Small plastic dustpan and brush
- Small plastic container for broken glass
- Vermiculite, clay, cellulose, or amorphous alumina silicate adsorbent(s)
- Adsorbent towels, pads, and/or mats
- Heavy duty (3 mil) polypropylene bags
- Pail or other container to hold kit contents

With the exception of placing the spill clean-up waste into a properly labeled Hazardous Waste Pharmaceutical container, use the [Small Chemical Spill Cleanup Procedure](#).

Residues of Hazardous Waste Pharmaceuticals in Empty Containers

The HWP rule establishes standards on what is considered an empty container with respect to residues of HWP.

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 and the residues are not regulated as hazardous waste 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 empty and the residues are not regulated as hazardous waste under this subpart 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 and the residues are not regulated as hazardous waste 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.

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.

5. Required Training

A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies. In order to accomplish this, USF Healthcare Facility personnel who dispose of HWP must complete Hazardous Waste Pharmaceutical Disposal Training annually. Training may be completed in-person or online. Colleges/Departments/Units must retain training records for all personnel who dispose of HWP.

Attachment A. Management of Waste Pharmaceuticals Flow Chart

