

NOVA SOUTHEASTERN UNIVERSITY	ENVIRONMENTAL HEALTH AND SAFETY
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# HAZARDOUS WASTE PHARMACEUTICALS

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## **Section 1: Introduction**

Nova Southeastern University is committed to establishing and maintaining safe and healthy working conditions and promoting safe practices by all staff, faculty, and students. The University is also committed to working in ways that reflect its deep concern for its neighbors and the quality of the surrounding environment.

## **Section 2: Scope**

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.

## **Section 3: Purpose**

- 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.

## **Section 4: Definitions**

### **Pharmaceutical**

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

### **Hazardous Waste Pharmaceutical**

A pharmaceutical that is a solid waste, as defined in § 261.2, 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, 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, defined in § 261.2. 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**

Any person that is lawfully authorized to—

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- (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.

### **Potentially creditable hazardous waste pharmaceutical means**

A prescription hazardous waste pharmaceutical that has a reasonable expectation of receiving manufacturer credit and is:

1. In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
2. Undispensed; and
3. Unexpired or less than one-year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or 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 of being eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed.

### **Reverse distributor**

Any person who receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals to facilitate or verify manufacturer credit.

Any person, including forwarding distributors, third-party logistics providers, and pharmaceutical manufacturers, who processes prescription pharmaceuticals to facilitate or verify manufacturer credit is considered a reverse distributor.

### **Reverse Logistics**

Nonprescription pharmaceuticals and other retail items sent through reverse logistics are not solid wastes at the retail store if they reasonably expect to be legitimately used/reused (e.g., lawfully redistributed for their intended purpose) reclaimed.

## **Section 5: Roles and Responsibilities**

### **Environmental Health and Safety (EHS)**

- Serve as the administrator of the University's contract with the HWP disposal vendor.
- Act as the contact between the University and the vendor for program-related issues, including site setup, container delivery, and pickup schedule.
- Receive and file copies of all shipping manifests and invoices from the vendor and make them available for audit by regulatory agencies.
- Maintain current HWP program information on the NSU EHS website at: <http://www.nova.edu/ehs>
- Assist Colleges/Departments/Units in maintaining compliance with HWP regulations.
- Assist with cleanup of pharmaceutical spills/releases beyond the response capabilities of Colleges/Departments/Units.

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- Ensure all spill cleanup waste resulting from the release of HWP is correctly disposed of.

### **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 EHS to determine appropriate waste pickup schedules. Notify EHS if more/less frequent or out-of-cycle pickups are needed.
- Manage containers following regulatory requirements.
- Clean up spills/releases of pharmaceuticals immediately. Contact EHS for assistance if needed.
- Dispose of waste from the release of pharmaceuticals as non-creditable HWP. Contact EHS with any questions.

## **Section 6: Managing Hazardous Waste Pharmaceuticals**

When a pharmaceutical is no longer wanted or needed, a determination needs to be made as to whether the drug is potentially creditable (Rx), has a reasonable expectation of legitimate use/reuse or reclamation (Non-Rx), or the pharmaceutical is non-creditable (Rx or Non-Rx)

The only time non-hazardous waste pharmaceuticals are not required to be managed/disposed of as HWP is when a documented waste determination has been made confirming the waste pharmaceutical is not a hazardous waste pharmaceutical. To be considered potentially creditable (Rx) or to have a reasonable expectation of legitimate use/reuse or reclamation (Non-Rx), 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
- Investigational new drug
- Contaminated PPE
- Floor sweepings/clean-up material

### **Examples of Pharmaceutical**

- Partial vials (safety cap removed)
- Pre/Partial filled syringes
- Discontinued meds
- Un-administered meds
- Patient prescriptions

### **6.1 Non-pharmaceuticals waste**

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

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### 6.2 Sewer

Hazardous waste pharmaceuticals must not be sewerred (e.g., no disposal down the drain and no flushing)

### 6.3 Empty containers

If the pharmaceutical is removed from the container completely via the method normally used to remove it, the container is empty and therefore not regulated.

## **Section 7: Spills**

**Responsibility** of the end users to perform spill clean-up and maintain spill kits in their perspective location. End users include but not limited to:

- Dental assistants
- Medical assistants or
- Researcher/assistants

**Wear PPE**, use spill kit materials to contain and collect all materials

- Place in container or disposal bags with twist or tapes
- Label container or bags using hazardous waste label
- Place in accumulation area for disposal

**\*NOTE** If assistance is needed contact EHS office at [ehs@nova.edu](mailto:ehs@nova.edu)

## **Section 8: Storage and labeling**

**Storage:** Non-creditable HWPs must be stored in structurally sturdy containers that will not react with their 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.” The best practice is to label the container with the date waste was first added to the container to help ensure HWPs are not accumulated for more than one (1) year.

## **Section 9: Shipping/disposal**

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.

End users will ensure that potentially creditable pharmaceuticals are shipped via (e.g., UPS, USPS, FedEx) is acceptable to the distributors and receive confirmation of receipt 35 days from the date the shipment was sent. Electronic delivery confirmation that common carriers use will typically be sufficient. This is known as reverse distribution.

EHS will ensure that Non-credible pharmaceuticals are picked up by hazardous waste transporter. EHS will sign hazardous waste manifest and maintain records for three years.

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### **Section 10: Training**

A healthcare facility must ensure that all personnel that manages 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. To accomplish this, NSU Healthcare Facility personnel who dispose of HWP must complete Hazardous Waste Pharmaceutical Disposal Training annually.

Training may be completed online. Colleges/Departments/Units must retain training records for all personnel who dispose of HWP.