



## TITLE:

**GUIDELINES FOR MANAGING HAZARDOUS WASTE PHARMACEUTICALS AT TEC/ESA SITES**

## 1.0 Introduction

### 1.1 Purpose

The purpose of this document is to provide The Emory Clinic and Emory Specialty Associates (TEC/ESA) staff guidance on ensuring compliance to the EPA's regulation regarding the management of hazardous waste pharmaceuticals.

### 1.2 Scope

This guideline only applies to Very Small Quantity Generators (VSQG) that have not opted into Subpart P of 40 CFR 266 adopted in 2019. Most ESA/TEC sites will not opt into the new rules and remain under the existing rules due to being classified as VSQG.

### 1.3 Definitions

**Hazardous Waste Pharmaceuticals.** Pharmaceutical wastes that are RCRA hazardous wastes in Healthcare Facilities.

### 1.4 Responsibilities

***Environmental Health and Safety Office (EHSO)***

- Responsible for maintaining these Guidelines in accordance with current regulations and internal practices.

***Directors, Supervisors, Managers, and Employees of TEC/ESA Sites***

- Responsible for adhering to these Guidelines.

### 1.5 Training Requirements

- All staff handling hazardous waste pharmaceuticals must take the **HLC Module Regulated Waste Management (Course Code 6505)** annually.
- All staff that prepare a package or sign shipping papers (manifest) must take the **HLC Module Shipping and Transportation of Hazardous Materials (KnowledgeQ)** every 3 years.

### 1.6 Recordkeeping Requirements

Training records, manifests and associated waste documentation must be maintained for 3 years.

## 2.0 Procedures

### 2.1 Sewer Prohibition

Hazardous waste pharmaceuticals are prohibited from being dumped down the sewer effective August 22, 2019.



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## 2.2 Hazardous Waste Determination

- All non-scheduled Hazardous and non-hazardous waste pharmaceuticals can be collected into the same container, except for the following:
  - Silver nitrate sticks.
  - Inhalers/Aerosols.
- FDA-Approved over-the-counter nicotine replacement therapies, patches, gums, and lozenges will no longer be considered hazardous waste and can be discarded as non-hazardous waste.
- EPA has eliminated the dual regulation of RCRA hazardous waste pharmaceuticals that are also DEA controlled substances and now allows for a conditional exemption. These drugs must be managed in compliance with DEA regulations and destroyed by a method that the DEA has publicly deemed in writing to meet their non-retrievable standard, or they must be combusted at a specified permitted site to be exempt from RCRA. They cannot be disposed via the sewer and need to be placed in the RxDestroyers which will ultimately be sent for incineration. See Table 2.0 below for the list of dual regulated pharmaceuticals.
- Scheduled pharmaceuticals must be returned to an authorized Reverse Distributor or placed in the RxDestroyer.

**Table 2.0 – Dual Regulated Pharmaceuticals**

Pharmaceutical	Other Names
Chloral; chloral hydrate	Acetaldehyde, trichloro-; Aquachloroal, Noctec, Somnote, Suppettes
Fentanyl sublingual spray	Subsys
Phenobarbital	Bellergal-S, Donnatal, Luminal
Testosterone gels	Androgel, Fortesta, Testim
Valium injectable	Diazepam

## 2.3 Waste Generation

Remove packaging before placing pharmaceuticals into waste container.

- Samples should not be accepted from pharmaceutical vendors. If they are, the vendor must also take back any unwanted pharmaceuticals before they expire.
- Eliminate aerosols where possible, including hand sanitizing stations.

## 2.4 Labeling

- All containers that will collect non-creditable pharmaceutical waste must be marked with the yellow “**Hazardous Waste**” label and hazard warning labels.
- If you are collecting one of the five DEA & RCRA Regulated pharmaceuticals in a RxDestroyer, labeling is **not** required on the RxDestroyer container or the container holding receptacle.

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## 2.5 Storage

- All waste containers must be closed except when adding pharmaceutical waste and stored in a way that prevents release into the environment.
- Aerosols (inhalers, cryofreeze, air freshener) and silver nitrate sticks must be separated from other waste.
- Standard container sizes are as follows (yours may vary if your operations require it):

Silver nitrate sticks: 2.5 gallon

Inhalers only: 2.5 gallon

Pharmaceuticals: 8 gallon

Inhalers and aerosol cans: 5  
gallon

## 2.6 Accumulation Time Limit

There is no time limit for storage. Waste containers should be disposed of when they are full.

## 2.7 Empty Container Requirements

Empty containers may be placed in general trash if they meet the following definitions:

- Stock, Dispensing, vials, unit-dose container, or ampule (< 1-liter or 10,000 pills), are considered empty when the pharmaceuticals have been removed from the container using the practices commonly employed to remove materials from that type of container.
- Syringes can become empty by fully depressing the plunger of the syringe by administering the contents to a patient; or
- By injecting the contents of the syringe into another delivery device such as an IV bag.

## 2.8 Disposal and Shipping

- Email Matt Paurowski at [MPaurowski@mcfsystems.com](mailto:MPaurowski@mcfsystems.com) and cc: [chemwaste@emory.edu](mailto:chemwaste@emory.edu) when your container needs to be picked up. Include the following information:
  - Type of waste in the container (silver nitrate, aerosols, or misc. pharmaceuticals)
  - Size of container (2.5, 5, 8 or 18 gallon).
  - Size and quantity of replacement containers needed.
- Vendor will schedule with site if they have a trained manifest signer onsite. If there is no onsite signer, vendor **must** schedule with EHSO to sign paperwork.
- Once signed, receipt paperwork will stay at site and should be filed with other compliance paperwork.
- Original will be mailed back to site after received at final disposal facility and filed with receipt received on day of pickup. Notify EHSO if not received within 30 days.



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- Invoices will be received and processed by EHSO.

## 2.9 References

- Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine, 40 C.F.R. § 266 Subpart P (2019).
- Conditions for Exemption for a Very Small Quantity Generator, 40 C.F.R. § 262.14

## 3.0 List of Associated Documents

- TEC\_ESA Pharmaceutical Waste Quick Facts
- Guidelines for Managing Hazardous Waste Pharmaceuticals at Emory Hospitals and Winship Cancer Institute
- Emory Hospitals and WCI Pharmaceutical Waste Quick Facts

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## Appendix A: Managing Hazardous Waste Pharmaceuticals (HWP) at ESA/TEC Sites

Topic	Rules
Sewering Regulations	Can no longer dispose of HWP via sewerage.
Accumulation Time Limit	No limit. Accumulate until full.
Quantity Limit	Can accumulate up to 100kg (220lbs) per month.
Shipping of HWP	Email Matt Paurowski at MPaurowski@mcfsystems.com and cc: chemwaste@emory.edu when your container needs to be picked up.
Nicotine Waste Determination	FDA-Approved over-the-counter nicotine replacement therapies, patches, gums, and lozenges will no longer be considered hazardous waste and can be discarded as non-hazardous waste.
Labeling for Containers	Must be labeled with the words "Hazardous Waste" and hazard warning labels.
Storage of Containers Collecting HWP	Containers must be closed except when adding HWP & stored in a way that prevents release into the environment.
Empty Containers	Containers are considered empty when the pharmaceuticals have been removed from the container using the practices commonly employed to remove materials from that type of container.
Training	Regulated Waste Management HLC Course Code 6505 Must be taken annually.  Shipping and Transportation of Hazardous Materials HLC KnowledgeQ Must be taken every 3 years.
DEA Scheduled Substances	All non-Scheduled pharmaceuticals may be placed in the pharmaceutical waste containers. Scheduled pharmaceuticals must be returned to an authorized Reverse Distributor. RxDestroyer is also an accepted method of disposal.