



METRA

Metropolitan Environmental
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Management Standards for Hazardous Waste Pharmaceuticals

October 2019

Management Standards for Hazardous Waste Pharmaceuticals

- Prohibits HW pharmaceuticals from discharge to sewer
- Conditional exemption for DEA controlled substances
- Redefines when containers are RCRA Empty
- Amends P075 Acute HW listing for nicotine & salts
- Establishes EPA policy on status of unsold retail items managed at reverse logistics centers



84 FR 5816 February 22, 2019

- **Effective date August 21, 2019**
- **Non-authorized states: Iowa, Alaska**
- **Indian Country**
- **US Territories (except Guam)**



84 FR 5816 February 22, 2019

- **Adopted in Florida on August 21, 2019**
- **The amendment to the nicotine listing is effective in Florida with the adoption**
- **62-730.186 – Universal Pharmaceutical Waste rule was vacated on August 16, 2019**



84 FR 5816 February 22, 2019

- **Sewer Prohibition**
- **Effective date is August 21, 2019 in ALL states regardless of whether or not Subpart P is adopted**
- **Applies to all generators, including VSQG's**



Amendment of the Nicotine Listing

- EPA is amending the P075 listing for nicotine to exempt FDA approved over-the-counter nicotine replacement therapies
- EPA has concluded that nicotine patches, gums, and lozenges do not meet the regulatory criteria for acute HW
- Nicotine patches, gums, and lozenges can be discarded as Non-HW



Nicotine is Still Listed as P075



- Other unused formulations of Nicotine will still be considered P075 when discarded, including
- E-Liquid / E-Juice in E-Cigarettes, Cartridges, or Vials
- Prescription Nicotine (e.g., nasal spray, inhaler)
- Pesticides containing Nicotine
- Nicotine used in research and manufacturing



84 FR 5816 February 22, 2019

- What is also covered in the February 2019 FR
- Reverse Distribution of Prescription (RX) Pharmaceuticals
- Reverse Logistics for Unsold Retail Items



New Definitions

- **Pharmaceutical**
- **Hazardous Waste
Pharmaceutical**
- **Non-Creditable HW
Pharmaceutical**
- **Potentially Creditable HW
Pharmaceutical**
- **Evaluated HW
Pharmaceutical**
- **Healthcare Facility**
- **Long-Term Care Facility**
- **Reverse Distributor**



Pharmaceutical

Definition applies to finished product electronic nicotine delivery systems, including components and parts, sealed in final packaging intended for consumer use (e.g., electronic cigarettes and vaping pens) and e-liquid that is packaged for retail for use in the electronic nicotine delivery systems (e.g., pre-filled cartridges and vials that are sold separately to consumers or as part of kits)



Definition of Pharmaceutical (Continued)

Pharmaceuticals Includes, but is not limited to:

- Dietary Supplements
- Prescription Drugs
- Over-the-Counter Drugs
- Homeopathic Drugs
- Compounded Drugs
- Investigational New Drugs
- Pharmaceuticals Remaining in Non-Empty Containers
- PPE Contaminated with Pharmaceuticals
- Clean-Up Material from Spills of Pharmaceuticals

Pharmaceuticals does NOT include:

- Dental Amalgam
- Sharps
- Medical Waste



Pharmaceutical

- E-liquid used by manufacturers of tobacco products (as defined by the FD&C Act) is not included in the final definition of “pharmaceutical”
- That means e-liquid that is sold or distributed for further manufacturing, mixing, or packaging into a finished electronic nicotine delivery system is not included



Healthcare Facility

Healthcare Facility includes, but is not limited to:

- Retailers of pharmaceuticals
- Wholesale distributors
- Hospitals
- Psychiatric hospitals
- Ambulatory surgical centers
- Health clinics
- Physician's offices
- Optical & Dental providers
- Chiropractors
- Long-Term care facilities
- Pharmacies
- Veterinary clinics & hospitals

Healthcare Facility does NOT include:

- Pharmaceutical manufacturers
- Reverse distributors
- Reverse logistics centers



Long-Term Care Facility

Long-Term Care Facility includes, but is not limited to:

- Hospice facilities
- Nursing facilities
- Skilled nursing facilities
- Nursing and skilled nursing care portions of continuing care retirement communities

Long-Term Care Facility does NOT include:

- Group homes
- Independent living communities
- Independent and assisted living portions of continuing care retirement communities



Prohibition on Sewering of HW Pharmaceuticals

- All healthcare facilities—including VSQGs operating under § 262.14 in lieu of this subpart— and reverse distributors are prohibited from discharging HW pharmaceuticals to a sewer system that passes through to a POTW
- Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1)



Empty Containers

- Residues of HW in empty containers
- Containers of HW pharmaceuticals are subject to § 266.507 for determining when they are considered empty, in lieu of this section, except as provided by § 266.507(c) and (d)



VSQG Healthcare Facilities

A healthcare facility that is a VSQG when counting all of its HW, including both its HW pharmaceuticals and its non-pharmaceutical HW, has the option of complying with § 266.501(d) (opting into ALL Subpart P) for the management of HW pharmaceuticals as an alternative to complying with § 262.14 (VSQG Requirements) and the optional provisions of § 266.504



DEA Controlled Substances

- Only a small number of HW that are also DEA controlled substances
- Two new conditional exemptions for healthcare facilities and reverse distributors for:
 - RCRA HW that are also DEA controlled substances
 - Household waste pharmaceuticals collected in DEA authorized collection receptacles (kiosks)



DEA Controlled Substances & RCRA HW

Name of Drug	Other Name(s)	Medical Uses	RCRA HW Code	DEA CS Schedule	Comment
Chloral; chloral hydrate	Acetaldehyde, trichloro-; Aquachloral, Notec, Somnote, Suppettes	Sedative	D034 Toxic	IV	Used in hospital pediatric units; common ingredient in vet anesthetics
Fentanyl sublingual spray	Subsys	Analgesic	D001 Ignitable	II	Ignitable due to alcohol content
Phenobarbital	Bellergal-S, Donnatal, Luminal	Anticonvulsant	D001 Ignitable	IV	Ignitable due to alcohol content
Testosterone gels / solutions	Androgel, Axiron, Fortesta, Testim	Hormone	D001 Ignitable	III	Ignitable due to alcohol content
Valium injectable gel	Diazepam, Diastat	Anti-anxiety	D001 Ignitable	IV	Ignitable due to alcohol content

Healthcare Facility Standards

**Standards for Non-Creditable Hazardous Waste
Pharmaceuticals – found at 40 CFR 266.502**



Healthcare Facility Standards

- **Notification: All Healthcare facilities must notify DEP using the Florida Notification of Regulated Waste Activity form, 8700-12FL, that they are operating under 40 CFR Part 266 Subpart P**
- **Facilities that already have an EPA ID that not required to submit a biennial report in 2020 for their non-pharmaceutical HW must notify within 60 days of the rule going into effect, October 20, 2019**
- **Facilities that are required to submit a biennial report may notify on their normal biennial reporting cycle, by March 1, 2020**
- **A copy of the notification must be kept on file for as long as the healthcare facility is subject to this Subpart**





Questions



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