



# DEP Frequently Asked Questions for Pharmaceutical Retailers: 40 CFR 266, Subpart P

The Florida Department of Environmental Protection (DEP) is the regulatory authority for hazardous waste management outlined in the Resource Conservation and Recovery Act (RCRA). Effective August 21, 2019, several changes to the management standards of hazardous waste pharmaceuticals have been made that will impact facilities currently operating under DEP's Universal Pharmaceutical Waste (UPW) Rules.

## Who is Affected by this Final Rule?

Healthcare facilities that generate and manage hazardous waste pharmaceuticals (HWPs), including facilities previously operating under the Department's UPW Rule, repealed August 16, 2019. (Rule 62-730.186, F.A.C.).

Subpart P is mandatory for all healthcare facilities that are: Small Quantity Generators (SQGs), Large Quantity Generators (LQGs), and reverse distributors (RDs).

## What is a Healthcare Facility?

A "healthcare facility" is any person that is lawfully authorized to either provide medical services to humans or animals or distribute, sell, or dispense pharmaceuticals, including over-the-counter (OTC) pharmaceuticals, dietary supplements, or homeopathic or prescription drugs.

EPA has identified that supermarkets and other grocery (not convenience) stores, pharmacies and drug stores, and warehouse clubs and supercenters meet the definition of a healthcare facility under Subpart P.

## Which Pharmaceuticals are Considered Hazardous Waste?

Pharmaceuticals that are listed in 40 CFR Part 261.33, or are characteristic for ignitability, corrosivity, toxicity, or reactivity, as defined in 40 CFR Part 261, Subpart C, are considered HWPs.

## Does the Sewer Prohibition Affect Me?

The Sewer Prohibition affects all healthcare facilities, regardless of generator status. A healthcare facility must ensure that HWPs are not discharged into sewer systems that pass through a publicly owned treatment works (POTW). Note that hazardous waste cannot be discharged into any septic system.

## Will Subpart P Affect My Generator Status?

Healthcare facilities will be required to manage HWPs under Subpart P. However, healthcare facilities must make a proper hazardous waste generator category determination for non-HWP waste streams.

## What if I Generate Nicotine Replacement Therapy Waste?

Certain nicotine replacement therapy wastes are no longer subject to the P075 listing with the adoption of Subpart P. If you generate wastes from e-cigarettes, e-liquids, or prescription NRTs, these are still subject to the P075 listing and must be managed in accordance with RCRA.

A nicotine exemption can be found in 40 CFR 261.33(e) that provides regulatory relief for FDA-approved OTC nicotine replacement therapies (NRTs). The exemption only applies to patches, gums, and lozenges. E-cigarettes, e-liquids, or prescription NRTs are still listed as P075.

## What is the Difference Between "Potentially Creditable and Non-Creditable?"

"Potentially Creditable" applies to a prescription HWP that has a reasonable expectation of credit and meets the following criteria: un-dispensed, in the manufacturer's original container, and is less than one year past the expiration date. Potentially creditable does not apply to OTC pharmaceuticals.

"Non-Creditable" is a prescription HWP that does not have a reasonable expectation of credit or a nonprescription HWP that does not have a reasonable expectation to be legitimately used/reused or reclaimed. Examples of non-creditable HWPs are damaged, leaking samples, repackaged drugs, floor sweepings, residues of pharmaceuticals in empty containers, contaminated PPE, cleanup material from pharmaceutical spills, expirations dating greater than one year, etc.

## I am a VSQG. Will Subpart P Affect Me?

VSQGs for the combined non-pharmaceutical hazardous waste and pharmaceutical hazardous waste are not required to follow Subpart P. However, they may elect to operate under Subpart P. If a VSQG elects to comply with Subpart P, the generator must submit the 8700-12 form and comply with all applicable standards in this subpart.

## How Long Can I Accumulate Non-Creditable Hazardous Waste Pharmaceuticals?

Non-creditable HWPs may be accumulated for up to one (1) year before shipment to a RCRA permitted Treatment, Storage or Disposal Facility (TSDF).

Non-creditable HWPs must be stored in a structurally sound container, labeled as "Hazardous Waste Pharmaceuticals" and with a start accumulation date. Containers must always be kept closed, except when adding or removing wastes.

## What Are the Requirements for Manifests and Disposal?

Non-creditable HWPs must be sent to a RCRA permitted TSDF. Healthcare facilities must use the Uniform Hazardous Waste Manifest (Form 8700-22; OMB #2050-0039) for off-site shipments. The manifests must contain the word "PHARMS" to identify the EPA waste code(s) and must be transported by a registered transporter.

Like RCRA, final signed copies of the manifest must be received for non-creditable HWPs. These records must be maintained for at least 3 years from the date of which the waste was accepted by the initial transporter.

## Am I Required to Submit a Notification?

Yes. Generators subject to Subpart P must notify the Department using the 8700-12 form. If the facility does not have an EPA Identification Number, one will be issued upon receipt of the form.

## Who Can I Contact for Information Regarding the Pharmaceutical Changes?

You may contact the Division of Waste Management at 850-245-8705 for additional information about Subpart P.