DEP Frequently Asked Questions for Reverse Distributors: 40 CFR 266, Subpart P

The Florida Department of Environmental Protection (DEP) is the regulatory authority for hazardous waste management outlined in the Resource Conversation 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hazardous waste pharmaceuticals (HWPs), including facilities previously operating under the Department's UPW Rule, repealed August 16, 2019 (Rule 62-730.186, F.A.C.).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 and a Reverse Distributor?

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.

A reverse distributor is anyone that receives prescription hazardous waste pharmaceuticals for the purposes of facilitating or verifying manufacturer credits. Depending on the functions performed, this could include forward distributors (drug wholesalers and distributors), manufacturers, and/or third-party logistics (3PLs).

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 are considered hazardous waste pharmaceuticals

Does the Sewer Prohibition Affect Me?

The Sewer Prohibition affects all healthcare facilities and RDs, 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.

Do I Need a Permit?

No, a storage permit is not required for a reverse distributor so long as the requirements in 40 CFR 266.510(d) are met.

Does Reverse Distribution Apply to Non-Prescription Hazardous Waste Pharmaceuticals?

No, reverse distribution is only allowed for prescriptions hazardous waste pharmaceuticals that are potentially creditable.

What Type of Hazardous Waste Pharmaceuticals Can I Accept?

An RD may only accept potentially creditable hazardous waste pharmaceuticals.

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

"Potentially Creditable" applies to a prescription hazardous waste pharmaceutical 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 hazardous waste pharmaceutical that does not have a reasonable expectation of credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. Examples of non-creditable hazardous waste pharmaceuticals 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, pharmaceuticals returned to the retail pharmacy by the consumer, etc.

How Long Can I Store Waste On-Site?

RDs may keep potentially creditable hazardous waste pharmaceuticals for a total of 210 Days. RDs have a 30-day evaluation period for potentially creditable hazardous waste pharmaceuticals. Once it has been evaluated and determined to be a hazardous waste, the RD is allowed to store the waste on-site for 180 days before shipment to a RCRA permitted treatment, storage, or disposal (TSDF).

What are the Standards for Potentially Creditable Hazardous Waste Pharmaceuticals?

Potentially creditable hazardous waste pharmaceuticals are only subject to the accumulation timeframes in Subpart P and must be evaluated within 30 days of receipt. The RD must evaluate if the waste is creditable and if it needs to be either 1.) sent to another RD for additional evaluation and is potentially creditable, or 2.) sent to a RCRA permitted TSDF and is considered "Evaluated Hazardous Waste Pharmaceuticals"

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 hazardous waste transporter.

What Should I Do Once the Evaluated Pharmaceuticals are Determined to be Hazardous?

RDs will be required to: 1.) designate an on-site accumulation area and conduct weekly container inspections; 2.) conduct training similar to Large Quantity Generator requirements for personnel handling evaluated hazardous waste pharmaceuticals; 3.) label each container with the words "hazardous waste pharmaceuticals" during accumulation; 4.) ensure containers are in good conditions and managed to prevent leaks; 5.) use hazardous waste codes prior to transport off-site; and, 6.) include wastes on the facility's Biennial Report.

The RD must keep an inventory of accepted hazardous waste pharmaceuticals and implement additional security measures. RDs must also ensure that a confirmation of delivery is received.

Am I Required to Submit a Notification?

Yes. RDs must notify the Department using the 8700-12FL 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.