Division of Environmental Response and Revitalization
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Environmental Protection Agency

Management of Hazardous Waste Pharmaceuticals from Healthcare Facilities

THIS POLICY DOES NOT HAVE THE FORCE OF LAW

Hazardous Waste Program

The purpose of this document is to help healthcare facilities understand the requirements and management standards for hazardous waste pharmaceuticals that are outlined in **OAC rules 3745-266-500 through 3745-266-510***. The hazardous waste pharmaceutical rule, also known as Subpart P, was adopted by Ohio EPA on October 5, 2020.*

What's New in this Rule?

These new standards were developed to improve the overall management of hazardous waste pharmaceuticals for the healthcare sector by tailoring rules toward them and addressing some of the challenges posed by the existing hazardous waste regulations, such as the requirement for healthcare professionals to make hazardous waste determinations. The rule also prohibits the disposal of hazardous waste pharmaceuticals down the drain (Sewer Ban) by entities subject to this rule and amends the P075 acute hazardous waste listing for nicotine and salts to indicate that FDA-approved over-the-counter nicotine replacement therapies (patches, gums, and lozenges) are no longer included in the listing.

What is the Sewer Ban?

Per OAC rule ***3745-266-505***, all healthcare facilities and reverse distributors are prohibited from discharging (e.g., no disposal down the drain and no flushing) hazardous waste pharmaceuticals to a sewer system that passes through to a publicly owned treatment works. This includes hazardous waste pharmaceuticals that are also DEA controlled substances. The Ohio EPA strongly discourages the sewering of any pharmaceuticals.

What is the Nicotine Amendment?

OAC rule ***3745-51-33*** has been amended to specifically exclude patches, gums and lozenges that are "FDA-approved" over-the-counter nicotine replacement therapies. Generators of these wastes may discard them as non-hazardous waste. All other unused formulations of nicotine (e.g. e-liquids, prescription nicotine, nicotine used in research and manufacturing, and legacy pesticides containing nicotine) are still considered P075 listed hazardous waste when discarded.

Am I Subject to the Rules?

The hazardous waste pharmaceutical rules apply to healthcare facilities and reverse distributors. All healthcare facilities that generate above Very Small Quantity Generator (VSQG) amounts of hazardous waste are subject to the requirements of this rule. Healthcare facilities include, but are not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics (including those co-located within facilities that are not healthcare facilities), physicians' offices, optical and dental providers, chiropractors, long term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, and veterinary clinics and hospitals. This healthcare facility definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers (centers that receive and manage nonprescription pharmaceuticals that have a reasonable expectation of being legitimately used/reused or reclaimed).

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"Pharmaceutical" is defined in OAC rule ***3745-266-500*** as any drug or dietary supplement for use by humans or other animals, any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen), or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials). Pharmaceuticals include but are not limited to, dietary supplements, prescription drugs, over-the-counter drugs, homeopathic drugs, compounded drug, investigational new drugs, pharmaceuticals remaining in non-empty containers, personal protective equipment contaminated with pharmaceuticals, and cleanup-up material from spills of pharmaceuticals. The definition does not include dental amalgam or sharps. Additionally, medical devices such as diagnostic kits are not considered pharmaceuticals. However, some medical delivery devices (e.g. insulin injector pens or metered dose inhalers) may contain pharmaceuticals.

Do I Need to Notify Ohio EPA?

Possibly. Healthcare facilities are required to notify Ohio EPA that they are operating under OAC rules ***3745-266-500 through 3745-266-510*** by submitting the RCRA Subtitle C Site Identification Form electronically using myRCRAid or on paper using EPA Form 9029. The notification must be submitted within 60 days of becoming subject to the rules. If a healthcare facility still qualifies as a Large Quantity Generator (LQG) after becoming subject to rules 3745-266-500 to 3745-266-510, the healthcare facility's notification can be part of the next Biennial Report submission due 3/1/2022.

Information on how to notify can be found on the Notification of Regulated Waste Activity ***Webpage***.

A healthcare facility that is co-located within a larger facility that is not a healthcare facility does not need to notify if the entire site is a VSQG. Additionally, VSQGs who are not opting into the rule are not required to notify, but they must follow certain requirements that are outlined below.

Note: Healthcare facilities who didn't notify within 60 days of the rule effective date are encouraged to notify even though that timeframe has passed.

How do these rules this affect my Generator Category?

Once a healthcare facility is either subject to the rule or opts into the rule, there are no generator categories for hazardous waste pharmaceuticals. There is no need to count monthly generation amounts of hazardous waste pharmaceuticals. The generator would still have a category associated with any non-pharmaceutical hazardous waste generated at the facility. These hazardous wastes must be managed in accordance with OAC Chapter ***3745-52***.

Note: A VSQG that chooses not to opt into the rules must still count both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste towards their generator category and if they generate over the VSQG quantity limit (>220 pounds of hazardous waste or 2.2 pounds of acute hazardous waste) they will become subject to the hazardous waste pharmaceutical rules and are required to notify as a healthcare facility.

What are Non-Creditable Hazardous Waste Pharmaceuticals and How Do I Manage Them?

Non-creditable hazardous waste pharmaceuticals are prescription hazardous waste pharmaceuticals that do not have a reasonable expectation to be eligible for manufacturer credit or nonprescription hazardous waste pharmaceuticals that do not have a reasonable expectation to be legitimately used/reused or reclaimed. Examples of non-creditable hazardous waste pharmaceuticals include but are not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and cleanup material from the spills of pharmaceuticals. Management standards can be found in OAC rule ***3745-266-502*** and shipping requirements can be found in OAC rule ***3745-266-508***. Requirements include, but are not limited to, the following:

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Determination: Determine if a non-creditable pharmaceutical is a hazardous waste pharmaceutical in order to determine if it is subject to the new rules. A healthcare facility may choose to manage all waste pharmaceuticals as hazardous waste pharmaceuticals.

Container Standards: Containers must be structurally sound, compatible with the contents, and lack evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions. Containers must be kept closed and secured to prevent unauthorized access. Hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition in OAC rule ***3745-270-03***(C) must be accumulated in separate containers.

Labeling Requirements: Mark containers with the phrase "Hazardous Waste Pharmaceuticals." Containers of hazardous waste pharmaceuticals that are prohibited from being combusted must be labeled with applicable waste codes. Hazardous waste pharmaceuticals prohibited from being combusted include characteristic metal wastes (*i.e.,* D004-D011) prohibited from being combusted because of the dilution prohibition of OAC rule ***3745-270-03***(C), as well as the listed wastes U151 (mercury), U205 (selenium sulfide), and P012 (arsenic trioxide), unless they contain greater than 1% total organic carbon.

Accumulation Time: One year. The length of time can be demonstrated by marking the date on a container, maintaining and inventory system, or placing the non-creditable hazardous waste pharmaceuticals in a designated area and identifying a date for the whole area.

Spill Response: Immediately contain and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals.

Shipping/Manifesting: Comply with all Department of Transportation Requirements. A manifest is required, but hazardous waste numbers are not. Instead, healthcare facilities must write "PHARMS" or "PHRM" in item 13 of a manifest.

Land Disposal Restrictions: Healthcare facilities need to comply with the land disposal restrictions in accordance with OAC rule ***3745-270-07***(A), except hazardous waste numbers are not required to be listed on the notification form.

Exception Report: Submit report to Ohio EPA if a copy of the signed manifest is not received within 60 days the hazardous waste was accepted by the initial transporter.

Recordkeeping: Maintain signed manifests, exception reports, test results, waste analysis, or other determinations made to support waste determinations for 3 years.

What are Potentially Creditable Hazardous Waste Pharmaceuticals and How Do I Manage Them?

Potentially creditable hazardous waste pharmaceuticals are prescription hazardous waste pharmaceuticals that have a reasonable expectation to receive manufacturer credit. They need to be in original manufacturing packing (unless subject to a recall), undispensed, and unexpired or less than one year past the expiration date. Management standards can be found in OAC rule ***3745-266-503*** and shipping requirements can be found in OAC rule ***3745-266-509***. Management requirements include, but are not limited to, the following:

Determination: Determine if a potentially creditable pharmaceutical is a hazardous waste pharmaceutical. A healthcare facility may choose to manage all waste pharmaceuticals as hazardous waste pharmaceuticals.

Spill Response: Immediately contain and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals.

Shipping/Manifesting: Potentially creditable hazardous waste pharmaceuticals must be shipped to a reverse distributor and healthcare facilities are prohibited from sending anything other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor. Shipments must comply with all Department of Transportation Requirements. A common carrier can be used, but confirmation of delivery must be provided. If confirmation of delivery is not received within 35 days after the shipment date, the healthcare facility must contact the carrier and reverse distributor to determine the status of the waste. A manifest is not required.

Recordkeeping: Maintain confirmation of delivery and shipping papers (if applicable) for 3 years after the date of shipment.

When are Containers that Held Hazardous Waste Pharmaceuticals Considered Empty?

For containers that held either acute or non-acute hazardous waste, the following needs to occur for the containers to be considered RCRA empty:

	"RCRA Empty"	
	Non-Acute Hazardous Waste Pharmaceuticals	**Acute Hazardous Waste Pharmaceuticals**
Stock/Dispending Bottles (1 liter or 10,000 pills) & Unit-dose Containers (*e.g.,* packets, cups, wrappers, blister packs, and delivery devices)	Remove contents	Remove contents
Syringes	Fully depress plunger	Fully depress plunger
IV Bags	Fully administer contents or OAC 3745-51-07(B)(1)	Fully administer contents
Other Containers	OAC 3745-51-07(B)(1) or (B)(2)	Cannot be RCRA empty

Containers such as inhalers, nebulizers, tubes of ointments gels or creams will be regulated under OAC rule ***3745-51-07*** and containers that held acute hazardous waste pharmaceuticals cannot be considered RCRA empty. Additionally, ***triple rinsing of containers of acute hazardous waste is not allowed.***

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Can I Accept Hazardous Waste Pharmaceuticals from Off-Site?

Healthcare facilities may accept both non-creditable and potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a VSQG, provided the receiving healthcare facility meets all of the following:

- The VSQG is under the control of the same "person" as defined in OAC rule ***3745-50-10*** or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the VSQG.
- Is operating in accordance with OAC rules ***3745-266-500 through 510***.
- Manages the hazardous waste pharmaceuticals received from off-site in accordance with OAC rules ***3745-266-500 through 510***.
- Keeps records of the shipments received from off-site for 3 years after the date the shipment is received.

What are My Training Responsibilities?

Healthcare facilities need to ensure facility personnel who handle non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal operations and emergencies. The training requirement is performance based and the information can be disseminated verbally, via printed materials, or other means.

Do I Need to File a Biennial Report?

No. Healthcare facilities are not required to file a biennial report for hazardous waste pharmaceuticals. If the healthcare facility is a LQG for non-pharmaceutical hazardous waste, it will file a biennial report for those hazardous wastes, per OAC rule ***3745-52-41***. The report will exclude non-creditable and potentially creditable hazardous waste pharmaceuticals.

If I'm VSQG do I Need to Follow These Rules?

VSQG healthcare facilities are subject to OAC rule ***3745-52-14*** and the following sections of the hazardous waste pharmaceutical rule:

- Prohibition of sewering (Sewer Ban) hazardous waste pharmaceuticals in OAC rule ***3745-266-505***
- Empty container standards in OAC rule ***3745-266-507***
- Optional provisions for VSQGs in OAC rule ***3745-266-504***

VSQGs are also able to opt into the hazardous waste pharmaceutical rule at which point they would be subject to ***OAC rules 3745-266-500 through 3745-266-510*** including obtaining an ID number, manifesting, land disposal restrictions (LDRs), training requirements, and container management standards that are not included under ***OAC rule 3745-52-14.***

Is There a Benefit for VSQGs to Opt into the Rules?

VSQGs who opt into the rules are not required to make individual hazardous waste determinations if all pharmaceutical waste is managed as hazardous. This could greatly reduce regulatory burden as healthcare facilities often generate hundreds of different types of wastes. There is also no requirement to track generation amounts because there are no generator categories.

Contact

If you have questions that aren't answered in this guidance, please contact the Hazardous Waste Compliance Assurance Section of the ***Division of Environmental Response and Revitalization*** at 614-644-2924.

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Additional Resources

Flushing of Hazardous Waste Pharmaceuticals is Prohibited

U.S. EPA FAQs

Federal Register: Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine