



The Disposal of Hazardous Pharmaceutical Waste from Businesses

THIS POLICY DOES NOT HAVE THE FORCE OF LAW

Hazardous Waste Program

The purpose of this document is to provide guidance to the medical community about the proper management and disposal of hazardous pharmaceutical wastes.

How can my pharmaceutical be a hazardous waste?

Hazardous pharmaceutical wastes are discarded pharmaceuticals that meet the regulatory definition of a listed or characteristic hazardous waste. Common generators of pharmaceutical wastes include pharmacies, hospitals, healthcare facilities, veterinary clinics, research facilities and other medical facilities.

Unused pharmaceutical wastes are simply any medications that have not passed through the body or been used for their intended purpose (e.g., applied to the skin) that are discarded.

In Ohio, a pharmaceutical waste is defined as either a hazardous, **solid** or **infectious waste**. Therefore, to determine how a pharmaceutical waste must be managed and disposed in Ohio, the person or company generating the pharmaceutical waste must determine its waste type. A pharmaceutical waste that meets both the definition of an infectious waste and a hazardous waste must be managed according to the hazardous waste rules, see Ohio Administrative Code (OAC) rule **3745-27-30(C)(7)**. Also, a mixture of infectious and hazardous wastes must be managed as a hazardous waste.

Lastly, a hazardous pharmaceutical waste that is also listed as a schedule II-V controlled substance must be managed according to both the hazardous waste rules and the rules of the U.S. **Drug Enforcement Administration (DEA)**. The DEA is the agency responsible for enforcing the controlled substances laws and regulations of the United States.

Hazardous pharmaceutical wastes generated in households are exempt from the hazardous waste rules. If you need information about the disposal of pharmaceutical wastes from households, please see DEFA **website** for household pharmaceuticals. Pharmaceuticals that have been distributed to resident of health care facilities may meet the definition of a hazardous waste but are classified as household hazardous wastes and are exempt from the hazardous waste rules when disposed. The household hazardous wastes exclusion does not apply to the pharmaceuticals generated by the health care facility operator for expired pharmaceuticals generated in an onsite pharmacy.

How do I determine if my pharmaceutical waste is a hazardous waste?

The generator of a pharmaceutical waste must evaluate the waste according to OAC rule **3745-52-11** to determine if it is a hazardous waste. Hazardous pharmaceutical wastes are subject to specific management, storage, packaging, labeling, transportation, treatment and disposal requirements; see the **Hazardous Waste Generator Handbook**. This handbook will answer you questions like; what requirements apply to hazardous waste that I accumulate on site, what are my container management standards, what am I required to do before I ship my hazardous waste off-site, and do I need to manifest my waste to an off-site disposal site. As a small and large quantity generator you must prepare a manifest before shipping hazardous waste off-site and the transporter must have a U. S. EPA hazardous waste identification number. CESQGs are not required to prepare a manifest. Manifests are multiple copied tracking documents that accompany hazardous waste shipments. The manifest acts as a chain of custody for the waste from the point it leaves your business until it reaches its final destination.

Unused pharmaceutical wastes are not the only hazardous wastes your facility may generate. Other hazardous wastes may include discarded or used items such as: fluorescent bulbs, solvents and caustic cleaners.

As required by Ohio law, a generator can only send hazardous waste to a facility which has a hazardous waste installation and operation permit. A list of Ohio's permitted hazardous waste facilities can be found on **DERR's Web Site**.

The Disposal of Hazardous Pharmaceutical Wastes from Businesses

OAC rule [3745-52-11](#) explains how to determine if a waste is a hazardous waste. In short, a waste can either be a *listed* waste or a *characteristic* waste.

Listed wastes are wastes from generic processes (F wastes), wastes from certain sectors of industry (K wastes), and unused pure or off-specification chemical products and formulations (P and U wastes). Formulations and mixtures can also be listed if they contain one of the chemicals on the list in OAC rule [3745-51-33](#) as the sole active ingredient. Possible examples of formulations and mixtures include: powders, tablets, creams, lotions, shampoos, gels, liquids, sprays, pastes and dermal patches.

If the discarded pharmaceutical contains only one active chemical ingredient and that chemical appears on the list in OAC rule [3745-51-33](#), then the waste is either a P or U listed hazardous waste. An active ingredient is the chemically active component for the function or purpose of the pharmaceutical. It does not include inert ingredients, preservatives or diluents.

- Examples of listed hazardous pharmaceutical wastes include substances such as discarded lindane, Coumadin, selenium dioxide, Mitomycin C, Nicotine, Warfarin and Phentermine.

If the discarded pharmaceutical contains two or more active chemical ingredients listed in OAC [3745-51-33](#), it does not meet the hazardous waste listing description and is not classified as a P or U listed hazardous waste.

After the generator determines if the discarded pharmaceutical is or is not a listed hazardous waste, the next step is to determine if it's a characteristic hazardous waste.

A discarded pharmaceutical is a characteristic hazardous waste if it exhibits one or more of the following characteristics: ***ignitability***, ***corrosivity***, ***reactivity***, and ***toxicity***. The generator must test the material and/or use knowledge of the ingredients in the discarded pharmaceutical to support the characteristic evaluation.

Please see Ohio EPA's guidance documents on [waste determinations](#) and the use of [generator knowledge](#) in making waste determinations. Also, chapter one of the [Hazardous Waste Generator Handbook](#) explains how a generator should perform a hazardous waste determination. It also contains a flow diagram on how to evaluate your waste.

Characteristic hazardous pharmaceutical wastes are:

- *Ignitable*
- *Reactive*
- *Corrosive*
- *Toxic*

The US EPA is in the process of proposing new rules for the [management of hazardous waste pharmaceuticals](#).

Can hazardous pharmaceutical waste be sent back to the manufacturer; to a reverse distribution company or to a pharmaceutical waste return and disposal company?

Yes. Hazardous pharmaceutical waste may be returned to the manufacturer or another company if there is a reasonable likelihood that it will be recycled by being used, reused or reclaimed. In such situations the pharmaceutical is defined as a commercial chemical product and therefore not defined as a waste under the hazardous waste rules. Also, a generator may send hazardous waste pharmaceuticals to the manufacturer or third party if, the generator is certain that it will receive a monetary credit for the pharmaceutical.

When the generator does not have a reasonable expectation (which can be documented) that a pharmaceutical can be recycled or credited, the generator must consider the pharmaceutical to be a waste. The generator must evaluate the waste as required by OAC rule [3745-52-11](#) to determine if it is a hazardous waste and manage it accordingly. For more information about the use of reverse distribution operations please see the document, [Product Return Systems Under Ohio's Hazardous Waste Rules](#).

The Disposal of Hazardous Pharmaceutical Wastes from Businesses

Can a container having a trace amount of pharmaceutical residue be regulated as a hazardous waste?

Yes, in certain situations. The term “trace amount” has no regulatory meaning under the hazardous waste rules. The appropriate consideration is whether the container is “empty” as defined in OAC rule [3745-51-07](#).

Except for containers that held a P listed hazardous waste, a container is empty when:

- All waste was removed using commonly employed methods (for example, pouring, pumping, aspirating, etc.), **and**
- No more than one inch of material remains in the container, **or**
- No more than three percent by weight of the total capacity of the container remains in the container, if the container is less than or equal to 119 gallons in size, **or**
- No more than 0.3 percent by weight of the total capacity of the container remains in the container, if the container is greater than 119 gallons in size.

Medical-related containers can include:

IV bags	Vials
Ampoules	Syringes
Bottles	Aerosol cans
Dose wrappers	Soufflé cups

A container that held an acute hazardous waste (i.e., P listed substances listed in OAC rule 3745-51-33) is empty only if the container was triple rinsed using a solvent capable of removing the commercial chemical product. The rinsate from the container is defined as a listed hazardous waste but the residue that remains in the empty container is not subject to the hazardous waste rules.

Can hazardous pharmaceutical wastes be poured down the drain?

For a limited time, before you pour hazardous waste down a drain, you must receive prior permission, in writing, from the publically owned treatment works (POTW) that receives your sewage. You must specifically identify all hazardous wastes for which you are requesting permission, provide credible estimates of the quantity, and discuss the disposal procedure (e.g., flush with water for 10 minutes).

Certain wastes are prohibited from being discharged to the sewer system under the Clean Water Act rules. These prohibited discharges include wastes which pass through the treatment system without being treated; are corrosive to POTW facilities; ignitable; solid or viscous and will obstruct the flow of the system; or any pollutant that interferes with the POTW. See [OAC rule 3745-3-04](#) or contact Ohio EPA’s Division of Surface Water for more information.

However, on **August 21, 2019**, U. S. EPA’s Final rule for *Hazardous Pharmaceutical* take effect in non-authorized states. Ohio is an authorized state; therefore, the rule will not take effect until it is adopted in Ohio. The one exception to this is the rule concerning **the prohibition on the sewerage of pharmaceuticals**. The prohibition on sewerage of hazardous waste pharmaceuticals applies to the following facilities, which are defined in the link above, to all reverse distributors and all healthcare facilities, including healthcare facilities that are VSQGs nationwide on this day.

Will there be new rules for hazardous pharmaceuticals?

On February 22, 2019, U. S. EPA in a Federal Register proposed new “*Management Standards for Hazardous Waste Pharmaceuticals and Amendments to the P075 Listing for Nicotine*.” Once Ohio EPA adopts these rules this guidance document will be obsolete. To stay informed about the rule changes please sign up for Ohio EPA *Updates* at the link provided.



The Disposal of Hazardous Pharmaceutical Wastes from Businesses

Contact

For more information, contact the Hazardous Waste Compliance and Inspection Support Unit of the *Division of Environmental Response and Revitalization* at 614-644-2924, or the [District Office](#). For more information about pharmaceutical waste, please also review the DEFA web site regarding *Pharmaceutical waste*.

Resources

US EPA letter concerning "Containers used to hold listed chemotherapy drugs"
<https://rcrapublic.epa.gov/files/12946.pdf>

Chemo Waste Disposal flow chart
https://www.epa.ohio.gov/portals/34/document/guidance/gd_074.pdf

Florida Department of Environmental Protection
"List of pharmaceuticals that are potentially hazardous wastes when discarded"
https://floridadep.gov/sites/default/files/Waste_Pharm_Guidance_Feb_2017.pdf