

HANDLING UNWANTED PHARMACEUTICALS AND PHARMACEUTICAL CONTAINERS IN HEALTHCARE

Guidance

INTRODUCTION

Discarded pharmaceuticals and their containers are waste streams subject to environmental or public health regulations, or both. They become subject to waste regulations once they have been administered or partially administered to a patient and can no longer be further administered to a patient. They also become subject to waste regulation when they are expired, contaminated, or damaged, to such an extent they can no longer be administered to a patient (human or animal). To understand how a waste must be managed to meet the *waste* regulations, you must first understand how the waste (pharmaceutical and pharmaceutical container) is classified. This can be difficult as the classification (typically called waste characterization) varies based on:

- The formulation in the container
- If the container is empty
- How much waste is generated at a site monthly
- How the waste is collected (mixed with other waste types)

Beyond the waste regulations, pharmaceutical use and handling in a healthcare setting is also subject to regulations intended to protect patient and worker safety (exposure concerns); protect drug integrity; prevent drug diversion; and to ensure safe transport of pharmaceuticals. This guidance focuses solely on the environmental and public health regulations related to *waste* pharmaceuticals and their containers. However, healthcare providers are encouraged to review all the regulations that apply to each healthcare site when establishing a pharmaceutical waste management program.

PHARMACEUTICAL WASTE CHARACTERIZATION

Under the environmental regulations, all non-households generating waste must characterize their waste following prescriptive steps codified in the regulations. Each drug at each dose must be characterized to determine how it must be handled. Once evaluated, a record of the waste determination must be created, maintained for at least three years, and made available to Department of Environment, Great Lakes, and Energy (EGLE) staff upon request. Anywhere between 5 percent and 15 percent of a hospital’s formulary may be classified as a hazardous waste pharmaceutical.

Some drugs are classified as **acutely toxic hazardous waste**. Drugs that are acutely toxic hazardous waste when discarded are specifically listed in the hazardous waste regulations. They carry a hazardous number that is used for tracking their cradle to grave disposal. All acutely toxic hazardous waste numbers begin with a “P.” Containers that contained a formulation that is identified as an acutely toxic hazardous waste are not *empty* unless they are triple rinsed to remove all residues, and then the rinsate remains subject to hazardous waste regulation. Even

Examples of Pharmaceutical Containers

Blister Packs	Carpules
Pill Bottles	Syringes
Auto Injectors	Vials
Inhalers	Ampules
Delivery Devices (e.g., nebulizers)	Tubes (e.g. ointment, gels, and creams)
Aerosol cans	IV Bags and Tubing
Closed System Drug Transfer Devices	Unit Dose Containers (e.g. packets, cups)

Examples of Listed Acutely Toxic Hazardous Waste Pharmaceuticals

Arsenic Trioxide (P012)	Physostigmine (P024)
Warafin/Coumadin >0.3% (P001)	Physostigmine Salicylate (P188)
Epinephrine (P042) ¹	Nicotine (P075)
Nitroglycerine (P081)	Sodium Azide (P105)
Phentermine (P046) ²	Strychnine (P108)

¹Excludes Epinephrine salts

²Excludes phentermine salts

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a paper cup used to administer a single dose of any of these formulations is classified as a hazardous waste unless the formulation was coated to prevent pharmaceutical residues from contaminating the paper cup/foil pack, etc. For purposes of limiting worker exposure and enhancing patient and environmental safety, the [National Institute for Occupational Safety and Health Hazardous Drugs](#) are recommended to be classified and managed as acutely toxic hazardous waste in light of their known human health hazards and the [U.S. Inspector General](#) finding that U.S. Environmental Protection Agency has not used its authority since 1980 to determine whether pharmaceuticals approved for use since 1980 qualify as a hazardous waste.

Some drugs are classified a **non-acute hazardous waste** under the environmental regulations because they use a sole active ingredient identified as a listed hazardous waste when unused and discarded. These drugs are also found in lists in the hazardous waste regulations. The non-acute hazardous waste numbers for chemicals with a sole active ingredient begin or end with a “U.” A formulation is also considered a non-acute hazardous waste if the drug exhibits a characteristic that makes it hazardous. It is a non-acute hazardous waste if it is ignitable, toxic, corrosive, and/or reactive.

Examples of Listed Non-Acute Hazardous Waste Pharmaceuticals

Antimycin A (O14U)	Niridazole (O97U)
Chlorambucil (U035)	Nithiazide (O98U)
Chloroform (U044)	Nitrogen Mustard (104U)
Clonitralid (O40U)	Phenazapyridine Hydrochloride (113U)
Cycloheximide (O46U)	Phenobarbitol (115U)
Cyclophosphamide (U058)	Phenytoin (116U)
Daunomycin (U059)	Phenytoin Sodium (117U)
Dichlorodifluoromethane (U075)	Phosmet (119U)
Diethylstilbestrol (U089)	Propiolactone (124U)
Formaldehyde (U122)	Propylthiouracil (127U)
Hexachlorophene (U132)	Rotenone (128U)
Isonicotinic Acid Hydrazine (O73U)	Tributyltin (and other sales and esters) (171U)
Melphalan (U150)	Warfarin < 0.3% (U248)
Mercury (U151)	
Naled (O94U)	

Containers that contained non-acute hazardous waste are **empty** if they have been emptied using common practices used by industry to empty that container type. If there are residuals still in the container after removing all the contents using common practices and it is 3 percent of the volume of the container or more, then it must be managed as a hazardous waste unless the site meets an alternate exemption from the hazardous waste regulations.

Examples of Characteristic Non-Acute Hazardous Waste Pharmaceuticals

Ignitable (D001)	Corrosive (D002)	Reactive (D003)	Toxic
Hand sanitizers	Wart removers	Picric acid	Barium hydroxide (D005)
Usiorioyl alcohol	Eye medications	Clinatest	Thimerosal (D009)
Ammonia inhalants	Glycopyrrolate		Silver nitrate cream (D011)
Paregoric	Sodium hydroxide		Preparation H (D009)
Faslodex	Glacial Acetic Acid		
Paclitaxel			
Rubbing alcohol			
Nyquil			

Some drugs are a **liquid industrial by-product** under the environmental regulations. If a pharmaceutical is not a hazardous waste and is liquid, it is generally subject to Michigan’s regulations that apply to liquid industrial by-products. If the pharmaceutical meets the definition of a hazardous waste but is managed to meet an exclusion from hazardous waste regulation and is liquid, it must also be managed to meet the liquid industrial by-product regulations. Containers of liquid industrial by-product have the same empty standard as non-acute hazardous waste. However, they have no waste codes. They are **empty** if they have been emptied using common practices used across the industry to empty that container type. If there are residuals still in the container after removing all the contents using common practices and it is 3 percent of the volume of the container or more, then it must be managed as a liquid industrial by-product.

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Some drugs are a [solid waste](#) under the environmental regulations. Unwanted drugs are subject to solid waste regulations if they are not a hazardous waste and do not contain free liquids at standard atmospheric pressure and temperatures. Drugs that meet the definition of hazardous waste, are solid, and meet an exemption from the hazardous waste regulations may also be managed as a solid waste if a special waste approval is granted by the receiving disposal facility. There are no codes for non-hazardous solid waste pharmaceuticals. There are no *empty* provisions for materials that are a non-hazardous solid waste either as they are authorized to be landfilled and disposed with other municipal solid waste which have no special accumulation requirements at the present time under the environmental regulations.

Examples of Solid Waste Pharmaceuticals

Solid forms (pill or capsules) of:

Benadryl	Zocor
Augmentin	Avandia
Amoxicillin	Acetaminophen

Examples of Liquid Industrial By-product Pharmaceuticals

Liquid forms of:

Potassium Chloride	Sodium Phosphate
Calcium	Sodium Bicarbonate
Dextrose	Saline
Augmentin	Benadryl
Amoxicillin	Acetaminophen

Some drugs contain a live or attenuate virus and are considered a [medical waste](#) subject to the medical waste regulations and a waste subject to the additional environmental waste regulations discussed above. Drugs that contain a live or attenuated virus cannot be disposed in a medical waste autoclave. The autoclave is not equipped to treat and properly dispose of the chemicals in pharmaceuticals, nor do they possess air permits authorizing the treatment of pharmaceuticals. Non-hazardous drugs that are also a medical waste may be incinerated at a permitted medical waste incinerator authorized to accept pharmaceuticals or they may be managed as a [mixed medical waste](#) or **dual waste** and sent for hazardous waste incineration. Mixed medical waste or dual waste is a medical, infectious waste due to the presence of the virus and contains a pharmaceutical that must be characterized to determine the management standards that apply.

Examples of Mixed Medical or Dual Waste Pharmaceuticals

Vaccinations preserved with thimerosal (D009)
Pharmaceutical waste mixed with medical waste*
Carpules containing blood or body fluids from humans or animals*

**All unused pharmaceutical waste numbers that apply*

All drugs may be managed as a [universal waste pharmaceutical](#) under Michigan specific waste management regulations established to simplify the management standards that apply to healthcare waste. EGLE encourages healthcare to simplify the management standards that apply to managing pharmaceuticals by presuming they are all a hazardous waste and managing pharmaceuticals as a universal waste, sending them for hazardous waste incineration. This method destroys the chemical formulations and helps protect our water resources that we use for drinking water, while simplifying the collection and management in the healthcare setting.

When collecting unwanted pharmaceuticals and preparing them for shipment, be sure to review product compatibilities and whether they can be safely mixed. Some pharmaceuticals must be accumulated separately. For example, corrosive, oxidizers, like unused silver nitrate sticks and aerosols like inhalers or topical sprays must be accumulated separately to prevent release and ensure safe transport, even if they are managed as a universal waste and shipped to the same destination facility as the rest of the collected pharmaceuticals.

COMMONLY ASKED QUESTIONS

Can empty pharmaceutical containers go in the regular solid waste trash?

Yes, if a pharmaceutical container contained a pharmaceutical that was classified as a non-acute hazardous waste or a liquid industrial by-product and the container was emptied using common practices used by healthcare for emptying the container, it can be managed as a solid waste. However, if the container has 3 percent or more by volume of the pharmaceutical remaining in the container, it must be managed in accordance with the pharmaceutical waste classification.

Can empty pharmaceutical containers be placed in the sharps container?

No, empty pharmaceutical containers cannot be managed as a medical waste. When mixed with medical waste, the waste must be further evaluated to determine if it can legally be sent for medical waste incineration or must be managed as a mixed medical or dual waste and disposed at a licensed hazardous waste facility authorized to accept medical waste. Mixed medical waste is the costliest of all waste, so mixing waste should be avoided via proper segregation where possible to minimize cost and ensure compliance. Generally, only licensed hazardous waste disposal facilities also authorized to accept medical waste are authorized to accept and dispose of mixed medical waste. When mixed medical and pharmaceutical waste is managed as a medical waste, the practice results in improper disposal. Most medical waste from Michigan is sent to be treated in an autoclave under heat and pressure to kill the infectious agents in the blood, body fluids, organs, and sharps; and then landfilled in a licensed solid waste disposal facility. When vials, ampules, and carpules with residual chemicals are placed in a medical waste container and autoclaved, the pharmaceutical chemicals become vaporized and may impact the operator or they may be discharged in the wastewater from the autoclave. The autoclave is also not authorized to accept pharmaceutical waste for treatment. Ultimately, there is no benefit to this management method, only additional costs and liabilities associated with improper disposal.

How can non-empty containers of pharmaceutical waste be managed?

Non-empty containers of pharmaceutical waste must be managed to meet the management standards that apply based on how their contents are characterized. Any receiving facility must be permitted to accept the medical and/or pharmaceutical waste offered. As a best management practice to protect human health and preserve the quality of the water resources we use for drinking water, pharmaceuticals can be managed under Michigan's streamlined universal waste standards, separate from medical waste. When managing all drugs as a universal waste, the drugs are presumed to be a hazardous waste, managed at the highest level, and sent for hazardous waste incineration to prevent their discharge to the environment. Managing all pharmaceuticals under the universal waste standards serves to minimize the number of containers necessary for waste collection, extends the length of time the pharmaceuticals can be accumulated on-site, and simplifies staff training needs and costs. For a more detailed understanding of the various types of pharmaceutical and medical waste, how they are managed, and how their management impacts the environment, see the [Michigan Health and Hospital Association \(MHA\) Pharmaceutical Waste Management Guide Example Posting](#). For a summary of the requirements for managing non-empty universal waste pharmaceuticals, please see the [MHA Pharmaceutical Waste Management Guide](#), Guide Sheet for Universal Waste (page 17). For details on managing unused epinephrine auto injectors, please also see our [Epinephrine Auto Injector Guide](#).

How can carpules with pharmaceuticals and blood be managed?

Medications mixed with infectious medical waste like blood and body fluids, must be managed as a mixed medical or dual waste at a facility authorized to accept both medical waste and pharmaceutical waste. This is the most costly management alternative with the least disposal options. However, in some cases mixed medical waste cannot be avoided. An example of an unavoidable mixed medical waste is thimerosal preserved vaccinations that contain a live or attenuated virus. For a summary of the requirements for managing mixed medical or dual waste, please see the [MHA Pharmaceutical Waste Management Guide](#), Guide Sheet for Mixed Medical waste (page 23).

Where can I find more resources?

For more resources on pharmaceutical and medical waste, please see www.michigan.gov/egleDrugDisposal and/or Michigan.gov/EGLEMedWaste. For information on how pharmaceutical and healthcare are defined and/or the federal proposed rulemaking on hazardous pharmaceuticals, please see the [Recorded Webinar on Existing and Proposed Regulations and Strategies for Minimizing Pharm Waste in Healthcare](#) and/or the [September 25, 2015 Federal Register](#) announcing the proposed rules. For questions on pharmaceutical waste, please contact Christine Grossman at 517-284-6860 or GrossmanC@Michigan.gov. For questions on medical waste, please contact Andy Shannon at 517-230-9800 or MedicalWaste@Michigan.gov.

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