Division of Environmental Response and Revitalization
March 2021

The Disposal of Hazardous Waste Pharmaceuticals FAQs

THIS POLICY DOES NOT HAVE THE FORCE OF LAW **Hazardous Waste Program**

This guidance document supersedes all previous guidance on pharmaceutical waste disposal, because Ohio has adopted the Federal Regulations, Management Standards for Hazardous Waste Pharmaceuticals and Amendment to the P075 Listing for Nicotine (Subpart P). Healthcare facilities who are operating under the hazardous waste pharmaceutical rules, OAC rules 3745-266-500 through 510, can choose to manage all pharmaceutical wastes as hazardous waste pharmaceuticals instead of making individual waste determinations. Very Small Quantity Generators (VSQGs) who do not opt into the hazardous waste pharmaceutical rules will need to evaluate all waste to determine if it is hazardous waste.

Frequently Asked Questions

1. **If we are not doing anything to address the proper disposal of pharmaceutical wastes, are we out of compliance?**

   If a person generates pharmaceutical wastes is not evaluating their wastes, they could be out of compliance and in violation of the hazardous waste rules for improperly managing and disposing of hazardous waste. This could be a violation of Ohio Administrative Code (OAC) rules 3745-52-11 and 3745-266-502(C) and Ohio Revised Code 3734.02. Such a violation could result in the facility receiving a penalty of up $10,000 dollars a day per violation for illegal disposal of hazardous waste. Keep in mind, for healthcare facilities operating under the hazardous waste pharmaceutical rules, individual determinations are not required if managing all waste pharmaceuticals as hazardous waste pharmaceuticals, per OAC rule 3745-266-502(C),

   The hazardous waste pharmaceutical rules categorize hazardous waste pharmaceuticals as either non-creditable or potentially creditable. The management rules for non-creditable hazardous waste pharmaceuticals and potentially creditable hazardous waste pharmaceuticals are outlined in OAC rules ***3745-266-502*** and ***3745-266-503*** respectively.

2. **Medication remaining in an IV bag, is it used or unused for the purposes of making a hazardous waste determination?**

   For VSQG healthcare facilities who have not opted into the hazardous waste pharmaceutical rules, medication remaining in an IV bag (or other container) is unused for the purposes of making a hazardous waste determination. This is true even if a portion of the medication was administered (i.e., used) and the remaining medication is prohibited from being administered to another patient. This is an important concept because the P and U hazardous waste listings only apply to unused commercial chemical products. So, if medication remaining in a container is discarded, that portion is unused and must be evaluated to determine if it is a listed or characteristic hazardous waste.

   For healthcare facilities operating under the hazardous waste pharmaceutical rules, if an IV bag is not empty, the IV bag shall be placed with the remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical in accordance with OAC rules 3745-266-500 to 3745-266-510.

3. **How should hazardous pharmaceutical wastes be destroyed or otherwise properly removed from the facility for destruction?**

   There are several options available to generators with regard to managing hazardous waste pharmaceuticals, which are dependent on whether the healthcare facility is operating under the hazardous waste pharmaceutical rules. The options are:

A. Segregate the non-creditable hazardous waste pharmaceuticals from the potentially creditable hazardous waste pharmaceuticals (if operating under the hazardous waste pharmaceutical rules). Wastes do not need to be segregated by waste code, but they are still subject to the Land Disposal Restrictions (LDR), which means they need to be treated in accordance with the specified treatment standard provided in the Land Disposal Restrictions (LDR) rules for that waste code. The LDR rules, ***OAC chapter 3745-270***, dictate to what level a hazardous waste must be treated. The treatment of the wastes may be done on-site by the generator or be sent off-site to a permitted hazardous waste treatment facility for appropriate treatment; or Potentially creditable hazardous waste pharmaceuticals may be sent to a reverse distributor using a common carrier. A manifest is not required; however, shipping papers must be maintained if the potentially creditable hazardous waste pharmaceutical meets the definition of "hazardous material" in 49 C.F.R. 171.8.

B. Create a lab pack. A lab pack is a collection of different types of hazardous wastes (in small volume containers) that are placed in one large container for storage, transportation, and treatment. Please be aware that incompatible wastes cannot be placed in the same lab pack, see OAC rule ***3745-68-16***. Per the LDR rules, lab packs must be treated by incineration unless the lab pack is disassembled by the hazardous waste transporter or permitted facility into the individual waste groups and sent on for further treatment. Lab packs that will be incinerated in compliance with paragraph OAC rule ***3745-270-42***(C) of the Administrative Code are not required to be marked with EPA hazardous waste numbers, except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA hazardous waste numbers.

C. Healthcare facilities who are VSQGs who have not opted in to the hazardous waste pharmaceutical rules must manage their hazardous wastes onsite in accordance with the applicable generator management standards found in the ***Hazardous Waste Generator Handbook***. This handbook will answer 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. VSQGs 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.

4. Do generators need to be concerned with how much P-listed and U-listed waste is generated per month?

If a person is operating under the hazardous waste pharmaceutical rules there is no need to track the generation amount of P-listed or U-listed waste. Healthcare facilities that generate above VSQG limits and all reverse distributors are subject to the pharmaceutical rules instead of the hazardous waste rules in OAC Chapter 3745-52. If a healthcare facility is a VSQG when counting both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste, and chooses not to opt into the pharmaceutical rules, the healthcare facility would need to demonstrate it generates below VSQG levels and therefore would need to track the amount of P-listed and U-listed waste that is generated per month.

5. Does a healthcare facility or reverse distributor need to determine the total weight of hazardous wastes it generates per month?

There are no generator categories for healthcare facilities or reverse distributors operating under the hazardous waste pharmaceutical rules. However, VSQGs who have not opted into the rules still need to demonstrate their monthly generation rates are below the VSQG limit. A healthcare facility or reverse distributor does need to count non-pharmaceutical hazardous wastes and manage them in accordance with the appropriate hazardous waste generator standards.

6. **Virtually all insulin vials contain a concentration of M-Cresol (D024) greater than the regulatory level of 200mg/L. But this is clearly not the sole active ingredient in the insulin vial. In a hospital, do empty or partially used vials of insulin need to be managed as hazardous waste?**

   In short, yes, unless the container meets the criteria for being classified as empty according to Ohio Administrative Code (OAC) rule ***3745-266-507(A)***.

   M-cresol is a chemical that appears on the list of hazardous constituents that can cause a waste to be classified as a toxic characteristic hazardous waste (i.e., characteristic hazardous waste), OAC rule ***3745-51-24***. Based on the information provided - that insulin contains greater than 200 mg/L of m-cresol - the insulin would be classified as a toxic characteristic hazardous waste when disposed. Therefore, partially used vials or vials which contain residual insulin that does not meet the definition of empty in OAC rule ***3745-266-507(A)*** would contain a hazardous waste and be required to be managed and disposed of according to the non-creditable hazardous waste pharmaceutical rules (if operating under the hazardous waste pharmaceutical rules) or according to the hazardous waste rules (for VSQGs who have not opted into the hazardous waste pharmaceutical rules).

   Insulin vials which meet the criteria for being defined as empty are not classified as hazardous waste and may be disposed of into the regular trash.

   In addition, as was stated, m-cresol is not an active ingredient in insulin in this case. It is used as a preservative and is not a chemically active component for the function of insulin. Therefore, residual insulin in a vial would not be defined as a listed hazardous waste when disposed. Whether a chemical is the sole active ingredient is only important when determining if a discarded unused commercial chemical product is classified as a P or U listed hazardous waste, see OAC rule ***3745-51-33***.

7. **In the hospital we use a "Trace Elements" single dose vial that is 1 ml in size and contains chromium 10mg/1ml (D007). This exceeds the regulatory concentration. Once the vial has been used and is effectively empty, must it still be handled and disposed of as hazardous waste?**

   "Trace Elements" is a nutrient additive that can contain chromium, selenium and other micronutrients.

   A nutrient additive solution containing 10mg/ml of chromium would fail the toxicity characteristic due to its chromium content and be classified as a hazardous waste when disposed. Under the pharmaceutical rules in OAC rule ***3745-266-507*** if the vial has been emptied using practices commonly employed to empty this type of container, then it would be considered empty. If the generator is operating under the generator rules in OAC Chapter 3745-52, then the vial has to be emptied by common means to the extent possible and not contain more than 3% by weight of the waste or no more than 1 inch of material can remain in the container.

8. **Am I correct in assuming that the empty or partially used vials of lidocaine + epinephrine, or bupivacaine + epinephrine that we use in the hospital would NOT be considered hazardous pharmaceutical waste because the epinephrine (P042) is not the sole active ingredient?**

   Any residue in vials that meet the definition of empty under ***3745-266-507*** or ***3745-51-07*** would not be regulated as a hazardous waste. The residues in partially used vials would not be listed hazardous waste, P042, because the solutions contain two active ingredients. However, you do need to determine if the residues in non-empty vials meet the definition of a characteristic hazardous waste, or they could be managed as non-creditable hazardous waste pharmaceuticals. Please note: Epinephrine salts do not meet the listing description for the P042 waste listing description and therefore, would not be a listed hazardous waste. Common forms of epinephrine are hydrochloride, bitartrate or borate salts. Please see, US EPA's ***memo 14778***.

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9. **Do empty dose wrappers or soufflé cups (that once contained individual warfarin tablets, a P001 substance) need to be handled as hazardous waste?**

   If the warfarin tablets have been removed from the dose wrappers or soufflé cups using the practices commonly employed to remove materials from those type of containers, the containers are considered empty and the residues are not regulated as hazardous waste. Such containers may be disposed of into the regular trash. Please see OAC Rule ***3745-266-507***, Residues of hazardous waste pharmaceuticals in empty containers.

10. **Are expired epinephrine pens and tablets listed hazardous waste P042?**

    If the epinephrine used in the pharmaceutical is a salt then the pharmaceutical does not meet the listing description for epinephrine and is not listed hazardous waste P042. The P042 listing only applies to epinephrine CAS # 51-43-4 which does not include epinephrine salts. So, if the epinephrine in the pharmaceutical waste is not a salt then the waste is listed hazardous waste, P042.

11. How do I dispose of nicotine containing over the counter products?

    FDA-approved, over-the-counter nicotine replacement therapies (i.e., nicotine patches, gums and lozenges) are not considered hazardous waste when discarded. All other nicotine products (e.g., e-cigarette juices) are acutely listed hazardous wastes (P075) when discarded.

12. **Are discarded nitroglycerin tablets, capsules and sprays listed hazardous waste P081?**

    Nitroglycerin was listed as a hazardous waste solely due to its reactivity (i.e., ability to explode). However, medicinal nitroglycerin does not exhibit the characteristic of reactivity and therefore, is not classified as listed hazardous waste P081 but it may exhibit another hazardous waste characteristic.

13. **What is meant by "sole active ingredient?"**

    Sole active ingredient means the ingredient (that potentially may be a P or U listed hazardous waste) is the only chemically active component in the pharmaceutical that performs the function of the pharmaceutical.

14. **Are non-empty vials of vaccines containing the preservative thimerosal classified as a characteristic hazardous waste when disposed?**

    It is likely that discarded vaccines containing thimerosal will be classified as a toxic characteristic hazardous waste due to the presence of mercury. They can be disposed of as non-creditable hazardous waste pharmaceuticals under the hazardous waste pharmaceutical rules.

    Thimerosal is a preservative that has been used in some vaccines since the 1930's. It is 49.6% mercury by weight and is metabolized or degraded into ethylmercury and thiosalicylate.[1]

    As a vaccine preservative, thimerosal is used in concentrations of 0.003% to 0.01%. A vaccine containing 0.01% thimerosal as a preservative contains 50 micrograms of thimerosal per 0.5 ml dose or approximately 25 micrograms of mercury per 0.5 ml dose.[1]

    Using the information above about the amount of thimerosal and mercury in some vaccines, a vaccine containing 0.01% of thimerosal contains 50 mg of mercury per liter of vaccine (50 mg/L). A vaccine containing 0.003% thimerosal

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[1] Federal Food and Drug Administration: Thimerosal in Vaccines http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/UCM096228

contains 15 mg of mercury/L. The regulatory level for classifying a waste as a hazardous waste due to the presence of mercury is 0.20 mg of mercury/L. Therefore, such vaccines would be classified as a characteristic hazardous waste due to the presence of mercury.

15. **Where can I find Ohio EPA's hazardous waste pharmaceutical rules?**

    You can find Ohio EPA's rules for hazardous waste pharmaceuticals on the Division of Response and Revitalization's Hazardous Waste Program's webpage.

16. **How do I classify a waste stream that has both a hazardous and an infectious waste component? For example, an IV bag containing 50 ml of mitomycin C chemotherapeutic agent, listed hazardous waste U010, that is contaminated with blood.**

    In Ohio, an infectious waste that is also a listed or characteristic hazardous waste must be managed, stored, transported, treated and disposed according to Ohio's hazardous waste rules.

    The infectious waste rule that states the requirement is OAC rule ***3745-27-30(C)(7***):

    "Any infectious waste or infectious waste mixture that meets the definition of hazardous waste as specified in rule 3745-51-03 of the Administrative Code shall be managed as a hazardous waste in accordance with Chapters 3745-50 to 3745-69 of the Administrative Code. No generator of infectious waste shall transport, or cause to be transported, wastes deemed hazardous in accordance with rule 3745-51-03 of the Administrative Code to an infectious waste treatment facility licensed in accordance with section 3734.05 of the Revised Code;"

17. **A medication I am administering by injection would be classified as a P-listed hazardous waste if disposed. Therefore, in order to dispose of the syringe as infectious waste, must the syringe be triple rinsed to render the syringe empty and no longer containing a P-listed hazardous waste?**

    If the medication has been fully dispensed from the syringe**,** the remaining residual medication in the needle and syringe is considered used for its intended purpose and no longer classified as a P-listed hazardous waste. Such a syringe should not be triple rinsed prior to disposing of it as infectious waste. This approach of not triple rinsing syringes was instituted due to needle stick risks incurred with additional handling. Additionally, the hazardous waste pharmaceutical rules do not allow triple rinsing of containers that once held acute hazardous waste. However, the syringe, itself, must be evaluated to determine if it is a characteristic hazardous waste.

18. **Can I Recycle Materials Instead of Managing Them as Waste?**
    Nonprescription pharmaceuticals that are sent through reverse logistics are not solid wastes at the retail store if they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed. When there is reasonable expectation on the part of the manufacturer, distributor or supplier that the material will be recycled, it may be shipped to a third-party contractor for handling as a product. For the purposes of this fact sheet, reasonable expectation means that unless an unexpected event occurs, it is believed that the materials will be reclaimed, reformulated or repackaged. When there is no reasonable expectation that the CCPs will be recycled (i.e., the products will be discarded), then the materials must be managed as wastes. They must be evaluated in accordance with OAC rule ***3745-52-11*** to determine if they are hazardous wastes. If the materials are hazardous wastes and will not be recycled, then they must be managed in accordance with the applicable hazardous waste regulations, including manifesting, storing and transporting. Be aware that the waste must be managed as hazardous from the point of generation if it will not be recycled. This means that if a particular product is consistently unusable and must be treated and disposed, it cannot be handled as a non-waste under a reverse distribution system. For more information on the requirements of managing a hazardous waste, please refer to ***the Hazardous Waste Generator Handbook***.

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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. For more information about pharmaceutical waste, please review the DMWM web site regarding Pharmaceutical waste or the DERR website regarding Hazardous Waste Pharmaceuticals