

Fact Sheet

Simplifying Compliance

Health care facilities can generate hazardous waste from many sources, including disposal of pharmaceuticals. Hazardous waste, if managed improperly, may harm human health and the environment. This fact sheet offers general guidance to help health care providers evaluate pharmaceutical wastes and determine whether they meet the definition of hazardous waste.

What is a “pharmaceutical waste”?

Pharmaceutical waste may include, but is not limited to

- Unused or expired drugs,
- Unusable drugs or drugs intended to be discarded,
- Waste materials containing excess drugs (syringes, IV bags, tubing, vials, etc.),
- Containers that held certain drugs, or
- Contaminated garments or absorbents.



Must all discarded pharmaceutical wastes be evaluated?

All discarded pharmaceutical materials that have been determined to be waste must be evaluated except:

- Pharmaceuticals that can be reused or returned to the manufacturer or reverse distributor are not considered waste; thus, are not subject to evaluation. These pharmaceuticals must not be mixed together, leaking, partially used liquids or pastes, inherently waste-like or display any other characteristics that would reasonably preclude their beneficial reuse as products.
- Medical supplies and containers that are considered empty under the Resource Conservation and Recovery Act, or “RCRA empty,” are not subject to evaluation.

“RCRA empty” means that **all** of the following **criteria are met**:

- a. All material that can be removed by normal means has been removed.
- b. Less than 3 percent by weight of the total container capacity remains.
- c. Supplies and containers do not contain residue from a P-listed hazardous waste. P-listed waste is defined in 401 KAR 31:040.
 - If a container that held P-listed pharmaceutical is not triple rinsed or cleaned by another method that has been demonstrated to achieve equivalent removal or had the inner liner removed, the container is not considered “RCRA empty,” even though the pharmaceutical may be fully dispensed.



*Waste that meets the definition of “RCRA empty” should be disposed of as infectious or solid waste – whichever is appropriate.

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Hazardous Waste Generator Registration

As a generator of hazardous waste, a facility is not only responsible for correctly identifying and categorizing waste materials, it must register with the Division of Waste Management (DWM) and provide annual reports. Annual reports detail the type and amount of hazardous waste, name of the transporter and the treatment, storage and disposal facility used. There are different regulatory requirements depending on the quantity and type of hazardous waste generated within a calendar month. To help your facility identify its generator status and the steps necessary for meeting regulatory requirements, please see the [Hazardous Waste Generators Handbook](#) and the Environmental Protection Agency's guide to [Managing Hazardous Waste for Small Businesses](#). These and other resources may be accessed at <http://dca.ky.gov/Pages/ResourceDocuments.aspx>.

**Pharmaceutical Hazardous Wastes Regulated by Other Rules**

In addition to hazardous waste regulations as enforced through RCRA and DWM, there may be other regulations that apply to hazardous pharmaceutical waste. For example, a syringe containing a pharmaceutical with a mercury preservative may also be regulated by the Occupational Safety and Health Administration (OSHA). Another example would be a controlled substance regulated by the U.S. Drug Enforcement Agency (DEA) or a radioactive waste regulated by the U.S. Nuclear Regulatory Commission (NRC).

Develop a Waste Management Program

A program that combines regulatory requirements and best management practices will help minimize the harmful effects to human health and the environment. In accordance with RCRA and DWM regulations, hazardous pharmaceutical waste is subject to certain requirements involving management, storage, packaging, labeling, transportation, treatment and disposal. Be aware of other types of waste produced by your facility. Pharmaceutical wastes are not the only hazardous wastes that may be generated at your business. Other examples of hazardous wastes can include florescent bulbs, solvents and caustic cleaners. Also, provide client education about how to properly dispose of pharmaceuticals at residential households (solidify, seal and dispose of the waste with regular municipal waste).

Common Best Management Practices for Pharmaceutical Waste:

- Follow all applicable federal and state regulations.
- Return pharmaceuticals to the manufacturer or a reverse distributor when possible.
- Maintain inventory records and properly label and store containers.
- Segregate required materials and maintain transportation, treatment and disposal records.
- Never pour or flush pharmaceuticals down a drain unless permitted by authorities and be sure to follow both state wastewater regulations and local sewer use ordinances.
- Train employees on proper identification and disposal of pharmaceutical waste.

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Waste Determination Flowchart

When deciding how to discard pharmaceuticals, evaluate each drug to determine whether it is considered a solid waste or a hazardous waste. Some pharmaceutical waste is considered nonhazardous and regulated as a municipal solid waste; however, many pharmaceuticals are considered hazardous and regulated as such. Before beginning, make a list of all pharmaceuticals used in the health care facility. **All pharmaceutical wastes in the facility must be evaluated.** This flowchart only helps determine whether a waste pharmaceutical is a hazardous waste. It is necessary to determine whether the waste is regulated under other rules in addition to the hazardous waste rules.

Reminder: Any rinseate or residual from containers that contained a hazardous waste must be collected and evaluated to see if it meets the criteria of hazardous waste.

Step 1. Does the pharmaceutical have more than one active ingredient? The active ingredient is the component that performs the function of the product. Fillers, solvents, carriers, propellants, preservatives, etc., are not active ingredients.

No. (Red arrow pointing down)

Yes. The pharmaceutical is not subject to evaluation by the P or U lists. Proceed to Step 3. (Green arrow pointing right)

Step 2. Is the active ingredient a P-listed or U-Listed waste? P-listed and U-listed drugs are defined in 401 KAR 31:040.

No. Proceed to Step 3. (Red arrow pointing down)

Yes. Per Kentucky State Regulation 401 KAR 31:010, Section 3, pharmaceuticals placed on the P and U Lists solely for the characteristic of ignitability, corrosivity or reactivity that do not exhibit that characteristic at the point they become waste are not considered P- or U-Listed hazardous wastes. However, they must still be evaluated for all other hazardous waste criteria. Characteristic hazardous waste is defined in 401 KAR 31:030. Dispose of an unused or unusable pharmaceutical (e.g. open medication, residual IV solution) P- and U-Listed wastes as hazardous wastes. Manage contaminated equipment, garments, absorbents and spill clean-up materials as hazardous wastes. Used pharmaceuticals (e.g. removed nicotine patches) are not considered P or U-Listed wastes; however, they must be evaluated for all other hazardous waste criteria. Waste residue remaining in a used syringe is considered a used pharmaceutical. The EPA has clarified that epinephrine salts are not included in the P042 listing. Proceed to Step 3. (Green arrow pointing right)



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Waste Determination Flowchart, cont.



Step 3. Is the waste ignitable? Ignitable wastes have a flash point of less than 140°F or meet one of the other criteria for ignitability given at 401 KAR 31:030.

No.   **Yes.** Manage a waste pharmaceutical that is ignitable as a hazardous waste. Also, manage moist, contaminated materials as a hazardous waste that exhibit this characteristic. Do not air dry absorbents as this is considered treatment on-site requiring permitting by DWM.


Step 4. Is the waste corrosive? A waste exhibits corrosivity (401 KAR 31:030) if it has either of the following properties: 1) It is aqueous and has a pH of less than 2 or greater than or equal to 12.5. or 2) It is a liquid and corrodes steel at a rate greater than 6.35 mm per year.

No.   **Yes.** Manage pharmaceuticals meeting the definition of corrosives as hazardous waste. Also, manage overtly contaminated absorbents and materials and spill material as hazardous waste that exhibit the characteristic.

Step 5. Does the waste exhibit the characteristic of reactivity? Reactivity is a characteristic regulated in Kentucky. Reactivity is defined in 401 KAR 31:030.

No.   **Yes.** Determine the reactivity threshold concentration of the pharmaceutical as a waste. When the concentration of the waste pharmaceutical is at or greater than the reactivity threshold concentration, manage the waste as a hazardous waste. Also manage contaminated materials that exhibit reactivity as hazardous waste.

Step 6. Does the waste exhibit the characteristic of toxicity? A toxic waste contains one or more contaminants (such as mercury) at or above maximum allowable concentrations. For a complete list of toxic contaminants, see <http://www.lrc.ky.gov/kar/401/031/030.htm>.

No. The pharmaceutical is not a hazardous waste. Determine appropriate management as an infectious, solid, radioactive waste or controlled substance. 

Yes. Manage waste pharmaceuticals that exhibit the toxicity characteristic as a hazardous waste. Also manage contaminated materials that exhibit the toxic characteristic as hazardous waste. Be sure any in-house testing is done in accordance with proper methodology, and equipment is capable of meeting regulatory detection limits.

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For household pharmaceutical waste, the recommended practice is to solidify, seal and dispose of the waste with regular municipal waste. If households return unused or expired medications to your business, the waste must then be managed according to the appropriate waste management regulations. For more information about household pharmaceuticals, view the Household Pharmaceuticals Waste Booklet at DCA.ky.gov.

For additional information

Kentucky Department for Environmental Protection; Division of Waste Management (DWM) and Division of Compliance Assistance (DCA)

Contact DCA or the DWM (Frankfort location or nearest regional office) for more information about and assistance with managing hazardous waste. The fact sheets that provide detailed information about Kentucky's hazardous waste requirements are available at <http://waste.ky.gov/factsheets/>. For guidance on regulatory issues and interpretations on a variety of health care topics, please see the fact sheets located at DWM and DCA websites.

Kentucky Division of Waste Management

Frankfort : 502-564-6716

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Kentucky Division of Compliance Assistance

Phone: 502-782-6189

Website: <http://dca.ky.gov>

Field Operations Hazardous Waste Offices

Website: <http://waste.ky.gov/FOB/>

For direct links to the **Code of Federal Regulations (CFR)** regarding hazardous waste definitions, please see <http://waste.ky.gov/branches/hw/Hazardous+Waste+Regulations+with+links.htm>.

Kentucky Pollution Prevention Center (KPPC)

KPPC is a technical assistance resource center. As part of the J.B. Speed School of Engineering at the University of Louisville, KPPC has the resources, expertise and experienced staff to help Kentucky's businesses, industries and other organizations stay environmentally sustainable and competitive. They may be contacted toll-free at 800-334-8635 or by visiting <http://www.kppc.org>.



Practice Greenhealth

Practice Greenhealth, a nonprofit membership organization, is a source for environmental solutions for the healthcare sector and lends support to create better, safer, greener workplaces and communities. Please visit <https://practicegreenhealth.org/>.

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