



Compliance Bulletin **Hazardous Waste Evaluating Wastes In the Health Care Setting Including Pharmaceutical Waste**

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This fact sheet is intended to help health care providers correctly identify waste pharmaceuticals that are RCRA hazardous wastes as well as give guidance on other wastes generated in the health care setting.

Background on the Rules and Regulations

In 1976, Congress passed the Resource Conservation and Recovery Act (RCRA), which directed the U.S. Environmental Protection Agency (EPA) to develop and implement a program to protect human health and the environment from improper hazardous waste management practices. The program is designed to control the management of hazardous waste from its generation to its ultimate disposal – from “cradle to grave.”

Colorado passed state laws governing hazardous waste in 1981 and has since adopted regulations that cover hazardous waste management in the state. Congress has also seen the need for states to be the primary enforcement agency for hazardous waste rules. Congress therefore set up a system for authorizing state agencies, using state rules, to implement the federal hazardous waste program in place of the EPA. The Colorado Department of Public Health and Environment (CDPHE) was authorized by the U.S. Environmental Protection Agency (EPA) to implement the federal hazardous waste program in 1984.

What is “Pharmaceutical Waste?”

Pharmaceutical waste may include, but is not limited to:

- Expired drugs;
- Patients’ personal medications;
- Waste materials containing excess drugs (IV bags, tubing, vials, etc.)
- Drugs that can no longer be used;
- Containers that held drugs;
- Drugs that are intended to be discarded; and
- Contaminated garments, absorbents and spill cleanup material.

Pharmaceutical waste does not include used discarded syringes with residual P and U listed drugs. Pharmaceutical waste also does not include epinephrine salts or most medicinal nitroglycerine.

How to Determine if a Pharmaceutical Waste is a Hazardous Waste

Health care providers must evaluate each pharmaceutical waste to determine whether it is hazardous, then dispose of it properly. A decision tree is attached at the end of this document that walks through how to make a hazardous waste determination. Hazardous waste has specific management requirements for labeling waste containers, time limits for storage of the containers, the type of transportation that can be used, disposal methods, disposal locations, manifesting, and record-keeping. For more information about these requirements, visit the Department’s web site at: <http://www.cdphe.state.co.us/hm/>

Reverse Distributors

Using a reverse distributor does not relieve health care organizations from making appropriate hazardous waste determinations, ensuring proper waste management and disposal, and/or documenting that pharmaceuticals will be reused or recycled rather than disposed. An entity claiming that a given recyclable material is not regulated as a solid waste or a hazardous waste bears the burden of proof demonstrating that such materials are actually recycled (6 CCR 1007-3, section 261.2(f)). It is not acceptable to merely assume that the pharmaceuticals will be recycled by the reverse distributor. The generator of any solid or hazardous waste maintains liability for its waste from the point of waste generation through final recycling or disposal.

Colorado considers pharmaceuticals returned to a reverse distributor to be a waste and not a commodity. Therefore, a hazardous waste determination must be made on all pharmaceuticals that have expired or that are being returned to the reverse distributor for credit. If such a pharmaceutical meets the definition of a hazardous waste, the health care facility or pharmacy becomes the generator of the waste and must ensure that this waste is managed as a hazardous waste and meets all the requirements of the Colorado Hazardous Waste Regulations

There is occasionally a conflict between RCRA and Drug Enforcement Agency (DEA) policy with regard to

disposal of medications. In cases where a waste medication meets the definition of hazardous waste and is also regulated by the DEA, the medication can be sent back through a reverse distributor.

Pharmaceutical Waste Regulation by Other Agencies

Pharmaceuticals can be regulated by both RCRA hazardous waste regulations and by other rules. For example:

- Pharmaceutical hazardous waste may also be regulated by the Occupational Safety and Health Administration (OSHA) as infectious waste, such as a wasted syringe containing a pharmaceutical with a mercury preservative;
- Pharmaceutical hazardous waste may also be regulated by the U.S. Drug Enforcement Agency (DEA) as a controlled substance, such as waste chloralhydrate (U034), Paral (U182), and Paraldehyde (U182).
- Pharmaceutical hazardous waste may also be regulated by the U.S. Nuclear Regulatory Commission (USNRC) as a radioactive waste, such as waste liquid scintillation cocktail.
- Pharmaceutical wastes may also be regulated by CDPHE as a solid waste that is a medical or infectious waste. These requirements can be found at 6 CCR 1007-2.

When evaluating a waste, be sure to consider all regulations, not just hazardous waste, that affect how you must manage and dispose of the waste. Remember, the guidance offered in this fact sheet only considers hazardous waste regulations.

Other Hazardous Wastes

In addition to the pharmacy, hazardous wastes may be generated in many areas of your facility including the laboratory, radiology, housekeeping, and maintenance. In the laboratory, you may generate hazardous waste reagents, including analyzer reagent cuvettes that are not RCRA empty. In housekeeping you may generate expired autoclave tape that may be TCLP for lead. All areas of the health care facility must be evaluated for hazardous wastes.

Evaluation Tool

The attached flow chart can help determine whether pharmaceuticals or other health care wastes are RCRA hazardous wastes. You will need to also determine

whether the wastes are regulated under other rules as discussed above.

Before you begin, **make an inventory** of all pharmaceuticals and chemicals used in your health care facility. Follow the flowchart for each pharmaceutical or chemical. Note that a waste may fit more than one hazardous waste type. **You must evaluate all wastes in your facility.**

For more information:

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This Compliance Bulletin is intended to provide guidance on the appropriate management of wastes based on Colorado solid and hazardous waste statutes and regulations only. The wastes described in this guidance may also be regulated under other statutes and regulations.

Evaluation Tool

Is your health care waste a RCRA hazardous waste?

**Begin
Here**

