Pharmaceutical
Waste Solutions

Navigating the Complexities of Managing Pharmaceutical Waste

WHITE PAPER

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Pharmaceutical Waste Regulations

The management of pharmaceutical waste is a critical activity for health care facilities, yet it is often a challenge to determine how to meet regulatory, safety and environmental obligations. Many studies have found traces of pharmaceuticals in drinking water, which has prompted the Environmental Protection Agency (EPA) to develop programs that aim to reduce the introduction of pharmaceuticals into water supplies.

In response, regulators quickly expanded their inspections to capture all pharmaceutical waste beyond their initial focus on RCRA hazardous waste, such as chemotherapeutics. Under the Resource Conservation and Recovery Act (RCRA) of 1976, many pharmaceuticals have been classified as RCRA hazardous waste for more than 30 years.

This White Paper reviews the current pharmaceutical waste management requirements under EPA, RCRA, Drug Enforcement Administration (DEA) and Department of Transportation (DOT), and provides guidance for the classification, management and disposal of pharmaceuticals in accordance with their regulations. This paper does not address state regulatory requirements, nor requirements under other statutes that impact pharmaceuticals, such as the Clean Water Act, Food Drug and Cosmetic Act, etc.

Is it Waste?

Before you can establish what type of pharmaceutical waste you have, the first step is to determine if the item is considered waste (referred to as "solid waste" in the regulation). This is accomplished by conducting an assessment of how the material currently is—or ultimately will be—managed. For example, when a waste is first accumulated for its eventual disposal, such as when a pill is dropped into a waste container, it has been abandoned and is a solid waste.

A solid waste is defined as any discarded material that is either abandoned, recycled or is inherently waste-like.

How does this apply to shelf-life expired pharmaceuticals? In most cases, the expiration date is the date the product is abandoned; therefore making it the date the material becomes a solid waste. Of course, a pharmaceutical product could become a solid waste before its expiration date if it is accumulated for disposal.

What Are the Different Types of Pharmaceutical Waste?

Once the item is defined as a waste, there are five categories to consider when determining how to properly segregate and dispose of pharmaceutical waste. It is important to note that EPA state regulations for Michigan and Florida are different than what is listed below. Please refer to individual state regulations for more details.

Non-RCRA Waste

The first consideration is whether the waste is classified as RCRA hazardous or non-RCRA hazardous pharmaceutical waste. This will determine what the disposal method is. EPA regulations do not currently require that non-RCRA pharmaceuti¬cal wastes be captured as RCRA-hazardous waste. However, it is considered an environmental best practice to properly dispose of all pharmaceutical waste, whether RCRA or non-RCRA.

RCRA Waste

About 5% to 10% of typical pharmaceutical products can be classified as RCRA waste. To identify which of your pharmaceuticals are RCRA, it's important to understand how the EPA classifies hazardous waste. The hazardous waste classification process is no different for health care facilities than it is for a factory or chemical manufacturer. Surprising? But just as you would expect the service provider that changes your car oil or antifreeze to not toss it down the drain, the EPA does not condone disposing of RCRA pharmaceuticals via waste streams that could ultimately provide access to the water system.

Listed Waste

There are four lists of hazardous waste, known as the F-list, K-list, P-list and U-list. Only P- and U-listed wastes are relevant to pharmaceutical waste. These are summarized below along with common examples that can be found in health care settings.

P- and U-Lists

Both lists apply to unused chemicals such as those that are no longer needed, have exceeded their shelf life, spill residue or have residue remaining in the product container. What distinguishes the P-list from the U-list is their degree of danger. **Products on the P-list are acutely hazardous, while most of those on the U-list are toxic.**

The P- and U-lists apply to the specifically listed unused chemicals. For mixtures and formulations, the listings only apply when a single chemical on one of these lists is the only active ingredient. Examples of P- and U-list waste are shown in Tables 1 and 2. The complete lists are at 40 CFR 261.33.

Drug packages are considered hazardous waste if they formerly held any P-list chemicals and if they are not empty. Empty is defined differently for each of these lists. Packages that formerly held U-list commercial chemical products are empty after they have been emptied to the best of your ability, using your conventional methods, and they contain less than 1 inch of residue or less than 3 percent by weight.

P-List Pharmaceutical (Table 1)	
Waste Code	**Waste Stream**
P001	Warfarin > 0.3%
P012	Arsenic trioxide
P042	Epinephrine*
P046	Phentermine
P081	Nitroglycerin (R)**
P188	Physostigmine salicylate
P204	Physostigmine

* This listing refers to epinephrine, with the CAS number 51-43-4. The EPA issued an interpretation on salts in October 2007 indicating that the salts are not P042 waste. However, you should check with your state environmental agency to determine if it follows EPA's interpretation.

** When listed wastes are annotated with an I, C, or R in parentheses, this indicates that the waste is subject to the hazardous waste regulations when the waste displays the ignitability, corrosivity, or reactivity characteristics. Nitroglycerin patches, for example, typically do not display the characteristic of reactivity.

U-List Pharmaceutical (Table 2)	
Waste Code	**Waste Stream**
U010	Mytomycin C
U034	Chloral hydrate
U035	Chlorambucil
U058	Cyclophosphamide
U059	Daunomycin
U129	Lindane
U150	Melphalan
U202	Saccharin
P204	Physostigmine
U205	Selenium sulfide
U206	Streptozotocin
U237	Uracil mustard
U248	Warfarin & salts > 0.2%

Source: 40 CFR 261 .33

Characteristic Waste

If a solid waste displays any of the following properties or characteristics, the waste must be managed as a RCRA hazardous waste: ignitability, corrosivity, reactivity, toxicity. These characteristics have very precise definitions, which are briefly summarized below. This summary does not take into account every exception or exclusion; therefore, we encourage you to refer to the full text of the regulations at 40 CFR 261 for additional details.

Ignitability (D001)

If a solid waste displays any of the following properties, it is an ignitable hazardous waste and is assigned the waste code D001:

- It is a liquid with a flash point less than 140° F. However, if an alcohol is the only constituent of the product that contributes to its ignitability, and if it is an aqueous alcohol solution containing less than 24% alcohol by volume, it is not ignitable. Bear in mind that a waste with more than 24% alcohol cannot be diluted to a lower concentration to reclassify it as non-hazardous without a hazardous waste treatment permit or similar authorization. (40 CFR 261.21)
- It is a non-liquid that causes fire through friction, absorption of moisture or spontaneous chemical change.
- It is a flammable gas or an oxidizer. (40 CFR 261.21)

Examples of ignitable wastes include alcohol-based cough syrups, ethylene oxide, methanol, bromine tablets, zinc powder, xylene, aerosol cans with flammable propellants, and petroleum naphtha.

Corrosivity (D002)

Strong acids, bases and materials that are corrosive to steel are classified as corrosive, with the waste code D002. This definition includes aqueous wastes with a pH of < 2 or > 12.5 as well as liquids that can corrode steel at a rate greater than ¼ inch per year. Examples include glutaraldehyde, formic acid, hydrochloric acid and sodium hydroxide solution.

Reactivity (D003)

If the waste displays any of the following properties, it is classified as reactive hazardous waste. Unlike the other characteristics, there are no EPA-defined testing procedures. Therefore, you should refer to the product insert, the Safety Data Sheet or other available data to determine if the waste could display any of these properties:

- It is normally unstable and readily undergoes violent change without detonating.
- It reacts violently with water.
- It forms potentially explosive mixtures with water.
- When mixed with water, it generates toxic gases, vapors or fumes in a quantity sufficient to present a danger to health or the environment.
- It is a cyanide or sulfide-bearing waste which, when exposed to pH conditions between 2 and 12.5, can generate toxic gases, vapors or fumes that pose a danger to health or the environment.
- It is readily capable of detonation, explosive decomposition or reaction at standard temperature or pressure.
- It is an explosive that is classified by DOT as being forbidden in transportation or it is classified as DOT divisions 1.1 through 1.3.

Examples of reactive wastes include acetyl chloride, chromic acid, organic peroxides, hypochlorites, perchlorates, permanganates, sulfides and non-empty aerosol cans containing flammable gases.

Toxicity (D004 – D043)

Although there might be hundreds of thousands of products that could be toxic, the EPA only designates chemicals (see Table 3), which if present in a waste, render the waste toxic. To determine the concentration of these chemicals, a test known as the Toxicity Characteristic Leaching Procedure (TCLP) is used.

Some of the chemicals to look for include selenium, silver, chromium, mercury and cresol. Mercury and m-cresol are commonly used as vaccine preservatives.

Toxic Hazardous Waste and TCLP Thresholds (Table 3)					
EPA HW #	Contaminant	Regulatory Level (mg/l)	EPA HW #	Contaminant	Regulatory Level (mg/l)
D004	Arsenic	5.0	D032	Hexachlorobenzene	0.13
D005	Barium	100.0	D033	Hexachlorobutadiene	0.5
D018	Benzene	0.5	D034	Hexachloroethane	3.0
D006	Cadmium	1.0	D008	Lead	5.0
D019	Carbon Tetrachorlide	0.5	D013	Lindane	0.4
D020	Chlordane	0.03	D009	Mercury	0.2
D021	Chlorobenzene	100.0	D014	Methoxychlor	0.10
D022	Chloroform	6.0	D035	Methyl Ethyl Ketone	200.0
D007	Chromium	5.0	D036	Nitrobenzene	2.0
D023	o-Cresol	200.0	D037	Pentachlorophenol	100.0
D024	m-Cresol	200.0	D038	Pyridine	5.0
D025	n-Cresol	200.0	D010	Selenium	1.0
D026	Cresol	200.0	D011	Silver	5.0
D016	2,4-D	10.0	D039	Tetrachlorethylene	0.7
D027	1,4-Dichlorobenzene	7.5	D015	Toxaphene	0.5
D028	1,2-Dichloroethane	0.5	D040	Trichloroethylene	0.5
D029	1,1-Dichloroethylene	0.7	D041	2,4,5-Trichlorophenol	400.0
D030	2,4-Dinitrotolene	0.13	D042	2,4,6-Trichlorophenol	2.0
D012	Endrin	0.02	D017	2,4,5-TP (Silvex)	1.0
D013	Heptachlor (& its hydroxide)	0.008	D043	Vinyl Chloride	0.2

Source: 40 CFR 261 .24

Controlled Substance Waste

The diversion of controlled substances is an important topic receiving attention in the industry due to the concerns of drug security and patient safety. Medications are classified as controlled substances based on their likelihood to be abused or cause dependence, and are divided into five schedules.

After a controlled substance has been dispensed to a patient and administered, the DEA considers any remaining substance no longer in inventory and would classify it as waste. The DEA encourages practitioners to adhere to security controls to ensure that diversion of pharmaceutical wastage does not occur. The DEA also recommends that controlled substance waste is incinerated.

Generator Status, Storage and Transportation

The types and volume of pharmaceutical waste will impact your generator status, container types, how you store pharmaceutical waste and how it is transported for disposal.

Generator Status

Depending on the amount of hazardous waste generated at your facility, you could be a very small generator (VSQG)/small quantity generator (SQG) or a large quantity generator (LQG). The scope of the regulations increases along with the amount of hazardous waste you generate. Use Table 4 to determine your site's generator status.

Generator Status (Table 4)		
Large Quantity Generator	> 1000 kg (2,205 lb) non-acute hazardous waste	> 1 kg acute hazardous waste
Small Quantity Generator	> 100 kg but < 1000 kg (220-2,205 lb)	< 1 kg acute hazardous waste
Conditionally Exempt Generator	< 100 kg (220 lb) hazardous waste	< 1 kg acute hazardous wste

Temporary Accumulation of Hazardous Waste

The locations in which large and small quantity generators accumulate hazardous waste are known as satellite accumulation points and central accumulation points. Although VSQG/SQG facilities need not establish these areas, these facilities find that it is an efficient way to accumulate their wastes.

Off-Site Transportation

Before hazardous waste can be shipped off-site, it must be placed in containers that meet U.S. Department of Transportation requirements, a hazardous waste manifest must be prepared, and you must specify the appropriate placard, if any is required, for the waste transporter.

Personnel who perform any of the following job functions must complete DOT hazardous materials training and be tested at least every three years so that they know how to: safely prepare hazardous waste (or other hazardous materials) for shipment, select containers, place hazardous waste into containers, mark or label containers, fill out or sign hazardous waste manifests, load hazardous waste onto vehicles, or specify the placard required on the transport vehicle.

Vehicle Loading

Generators must also ensure that hazardous waste is safely handled when it is shipped off-site. Critical questions to answer include:

- Are the waste containers sealed in accordance with the manufacturer's instructions?
- Are the waste containers secured on the transporter's vehicle?
- Confirmation that there are no incompatible materials loaded on the transporter's vehicle? (See the compatibility chart at 49 CFR 177.848)

Hazardous Waste Manifest

The hazardous waste manifest is a document that accompanies RCRA waste from your facility to the hazardous waste treatment, storage or disposal facility that you have selected for the waste. The manifest identifies your site as the waste generator, the transporter that carries the waste off-site, and the destination for the hazardous waste treatment, storage, disposal or recycling facility. The manifest is required for off-site shipments from facilities classified as large or small quantity generators.

As the generator of hazardous pharmaceutical waste, you are responsible for the completeness and accuracy of the information entered on the manifest. Some of the key information required includes:

- The DOT basic description of the waste, which includes the following information obtained from the hazardous material table at 49 CFR 172.101: proper shipping name, hazard class, identification number and packing group.
- The notation "RQ" added to each basic description for wastes shipped in an amount of at-least its reportable quantity. Reportable quantities are listed in 49 CFR 172.101 Appendix A.
- The total quantity of each waste type, together with the type of container, and the EPA hazardous waste code.
- A certification indicating that the waste is identified, packed, marked and labeled in accordance with applicable regulations.
- A certification indicating that your facility is implementing a waste minimization program.
- The signature of a designated person at your facility indicating that the above information is accurate. The person who signs the certification must have completed DOT hazardous materials training.

Consequences of Noncompliance

The primary objective of the hazardous waste regulations is to protect the environment and human health from the dangers of hazardous waste.

The primary consequence of non-compliance is environmental deterioration that ultimately impacts health and well-being.

Noncompliance can also result in monetary fines and imprisonment. The EPA has the authority to assess civil penalties of up to $27,500 per day per violation, or criminal penalties of $50,000 per day and up to 5 years in jail.1 Moreover, violators can face jail terms of 10 years or more, depending on the severity of the violation. Each state environmental agency has similar enforcement authority.

In Conclusion

While the management of RCRA pharmaceutical waste is required by the regulations, the appropriate disposal of all pharmaceutical waste is a best demonstrated practice to assure that pharmaceuticals do not inadvertently enter waterways. It's also important to keep in mind that the EPA will be issuing a final rule on new EPA regulations that can have an impact on the future of pharmaceutical waste management. Partner with an organization that has expertise and regulatory insight on how to properly manage pharmaceutical waste.

Reference

1. EPA, http://www.epa.gov/waste/inforesources/pubs/training/enforced.pdf, accessed 5/30/18.

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