MEDICAL WASTE

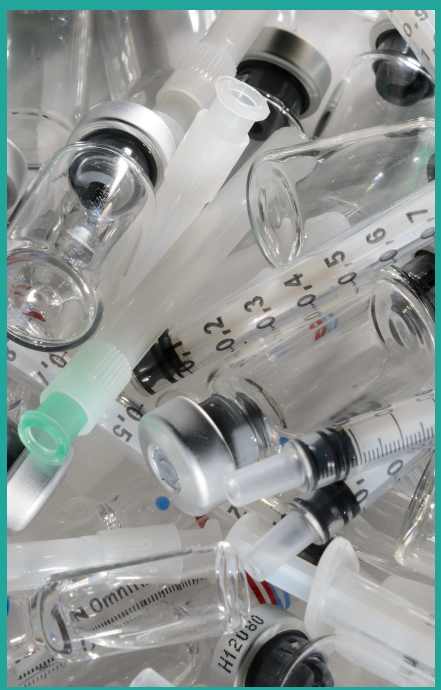
HAZARDOUS WASTE EXPERTS

Pharmaceutical Waste Management

Issues & Regulations Regarding Pharmaceutical Waste Management

Content by Jessica Hope & Jordan Rodewald

(888) 681-8923



PHARMACEUTICAL WASTE MANAGEMENT

CONTENTS

Pharmaceutical Waste: Things to Know

Pharmaceuticals save lives, and improve the quality of life for millions of people throughout the United States each year - but it doesn't come without a cost. Learn more about the top issues associated with pharmaceutical waste.

1 BIGGEST OFFENDERS

The "problem" categories of pharmaceuticals include those produced and consumed in high quantities, those highly potent at low concentrations, and those considered "particularly consistent."

2 PRIORITY SUBSTANCES

Antimicrobials are thought to play a role in the development of antibiotic resistance in bacteria. Hormones and endocrine disrupting drugs can interfere with proper growth of brain during fetal growth, infancy, and childhood.

3 INDUSTRY CONCERNS

The pharmaceutical industry is one of the most profitable - and fasting growing - industries in the United States. Many big pharmaceutical companies also produce pharmaceutical products for animals.

4 HAZARDOUS COMPONENT

Approximately 5% to 10% of pharmaceutical products can be classified as hazardous. Disposal of hazardous pharmaceuticals is regulated and governed by the Environmental Protection Agency.

5 PRESCRIPTIONS ISSUED

A 2015 Statista study estimated that 4.33 billion prescriptions were dispensed in the year 2014, a remarkable uptick from the estimated 3.95 billion prescriptions estimated in 2009.

6 ANTIBIOTICS SOLD

A 2009 NRDC study estimated that roughly 27.8 million pounds of antibiotics were sold in the United States in 2007. Without good disposal practices, these contaminants will surely make their way into the global aquatic environment.

7 REGULATORY BODIES

Manufacture, collection, discharge and disposal is regulated by a myriad of federal laws, and three federal agencies: the Environmental Protection Agency, the Food and Drug Administration, and the Drug Enforcement Agency.

8 IN THE NEWS

As of this writing, the Obama Administration has a proposal available for public comment, aiming to dramatically limit the flushing of pharmaceutical waste at hospitals and other healthcare facilities.

OVERVIEW

PHARMACEUTICAL WASTE MANAGEMENT

Pharmaceutical waste is a concern for all types of healthcare facilities, including pharmacies, hospitals, and clinics. It isn't limited to expired pharmaceuticals, either; vials and bags containing trace quantities of a toxic substance, protective gear, spilled liquids and pills, and even packaging can be classified as pharmaceutical waste.

Of course, different types of pharmaceutical wastes carry different types of risks, and are governed by different sets of regulations. **This whitepaper serves to primarily address challenges associated with hazardous pharmaceutical waste**, but pharmaceutical waste can also be classified as infectious waste, a controlled substance (meaning it is governed by the DEA), or otherwise a dangerous waste that is not specifically listed as RCRA hazardous (but still something that should be handled diligently).

The Environmental Protection Agency has taken a strong position on pharmaceutical waste in recent months, and at the time of this writing, a proposed rule (entitled "Management Standards for Hazardous Waste Pharmaceuticals" is available for public comment. It seeks to drastically reduce the amount of pharmaceutical waste flushed into waterways. In May of 2009, the Associated Press published a series that focused on pharmaceuticals in our drinking water, and the associated health risks. The EPA's position is one that aims to find a safe and sensible balance between providing life-saving or life-enhancing medications and protecting public health (and the environment) from unnecessary harm.

Regulation (under the Resource Conservation and Recovery Act of 1976, or RCRA) governing the disposal of pharmaceutical waste already exists, but the Environmental Protection Agency's recent focus signifies that existing legislation may become more stringent. **In this whitepaper, we will review current regulation as well as the proposed rule.**

"A proposed rule, 'Management Standards of Hazardous Pharmaceutical Waste,' is available for public comment. This rule seeks to drastically reduce the amount of pharmaceutical waste flushed into waterways."

HAZARDOUS PHARMACEUTICAL WASTE

Hazardous pharmaceutical waste, not surprisingly, is governed by the strictest set of regulations under RCRA. Currently, legislation states that healthcare facilities must manage these wastes in accordance with the same requirements as all other hazardous waste generators (though this is likely to change if a new rule is finalized and adopted).

Thankfully, most pharmaceutical waste is not classified as hazardous - it is estimated that only between 5% to 10% of pharmaceutical waste meets that criteria.

Substances such as physostigmine, warfarin, and chemotherapeutic agents are examples of fairly common pharmaceuticals that are regulated as hazardous waste.

Determining whether or not a pharmaceutical product is hazardous waste is accomplished by answering these four questions:

- **Is it a solid waste?**
- **Does it qualify for an exemption?**
- **Is it a characteristic waste?**
- **Is it a listed waste?**

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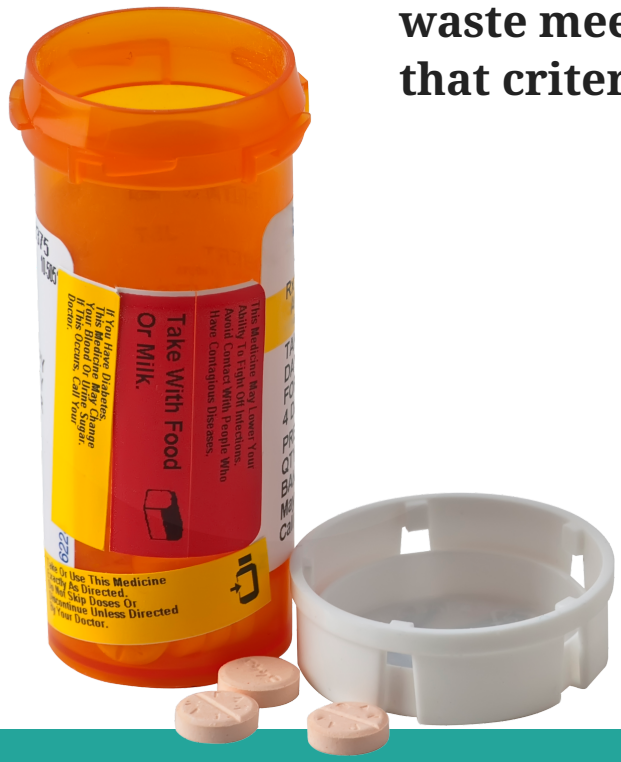

IS IT A SOLID WASTE?

The Environmental Protection Agency (EPA) provides an in-depth definition of solid waste, defining it as any “discarded material that is not excluded under § 261.4(a) or that is not excluded by a variance granted under §§ 260.30 and 260.31 or that is not excluded by a non-waste determination under §§ 260.30 and 260.34.” In other words, a solid waste is not necessarily "solid;" solid waste is just any discarded material that is abandoned, recycled, or waste-like.

Using the EPA’s definition, pharmaceutical waste is a solid waste and typically becomes so—because that is when most of it is discarded—on its expiration date. However, if it accumulates for disposal prior to its expiration date, it will obviously become a solid waste at that point.

All waste needs to go through an evaluation to determine whether or not it is a solid waste and, if it is, it must then be evaluated to determine whether or not it is hazardous waste. Of course, most solid waste types are not hazardous, but special care must be taken in that determination.

"Pharmaceutical waste is a solid waste, and typically becomes so - because that is when most of it is discarded - on its expiration date."

DOES IT QUALIFY FOR AN EXEMPTION?

No. Exemptions have a specific purpose: to promote recycling practices or to avoid stringent regulations when the waste type is very low-risk. These exemptions apply to very specific waste types. Pharmaceutical products are rarely recycled, so exemptions are not applicable.

IS IT A CHARACTERISTIC WASTE?

As we've discussed, hazardous waste is heavily regulated, and requires special disposal practices. As such, understanding the waste your organization generates is imperative. To know if you're handling hazardous waste, the first step is to assess its characteristics.

When categorizing hazardous waste, the EPA breaks it down by four characteristics:

- ignitability, or something flammable (D001)
- corrosivity, or something that can rust or decompose (D002)
- reactivity, or something explosive (D003)
- toxicity, or something poisonous (D004 - D043)

"Exemptions apply to very specific waste types. Pharmaceutical products are rarely recycled, so exemptions are not applicable."

IGNITABILITY

There are three types of ignitable forms: liquids with a flash point–the lowest temperature at which fumes above waste ignite–of 60 degrees Celsius or 140 degrees Fahrenheit, solids that spontaneously combust, and oxidizers and compressed gasses. Examples of ignitable wastes include methanol, bromine tablets, and alcohol-based cough syrups (among others).

CORROSIVITY & REACTIVITY

CORROSIVITY

Corrosive substances have the ability eat through containers, causing the leakage of harmful materials. A corrosive is anything liquid with a pH of less than or equal to 2 or greater than or equal to 12.5, or has the ability to corrode steel. Common examples of corrosive wastes include formic acid, glutaraldehyde, sodium hydroxide solution, and hydrochloric acid.

REACTIVITY

Given their instability, reactive wastes can be very dangerous. The EPA recognizes that there are too many conditions and situations to identify all types of reactive materials. However, they use the following as guidelines to assist generators:

- unstable, and routinely experiences violent change without detonating
- potential for explosive mixture or violent reaction when combined with water
- toxic gasses are released when mixed with water

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

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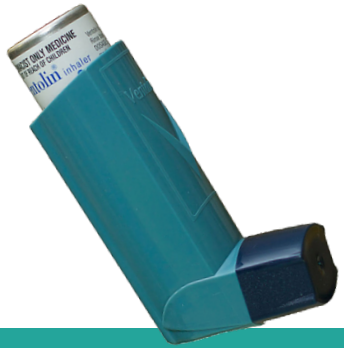

TOXICITY & LISTED WASTES

TOXICITY

Poisonous materials pose a threat to our groundwater, which can have long term effects to human health and the environment. This is different from the first three characteristic groups, which the EPA views as containing immediate and firsthand dangers. There are 60 contaminants on the toxicity characteristics list.

These contaminants are identified solely through a test method called Toxicity Characteristic Leaching Procedure or TCLP. Common chemicals to look for include chromium, mercury, selenium, silver, and cresol. Bear in mind that mercury and m-cresol are frequently used in vaccines as preservatives.

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IS IT A LISTED WASTE?

Listed wastes are those that are related to certain manufacturing processes, pharmaceutical wastes, and unused chemicals and are set apart from other hazardous wastes.

The four RCRA listed wastes are the F, K, P, U list wastes. Knowing which of your wastes fits under what list allows you to better manage each of your waste streams.

For example, each waste on the four lists is hazardous. Although some may also go beyond the hazardous label, like the entirety of those the P-list, which are acutely toxic wastes, and those wastes on the U-list, which are toxic.

The F-List and K-List pertain to wastes that are generated during manufacturing processes that are carried out at a facility. The P-List and U-List of wastes are usually related to unused, expired, or spilled commercial chemicals.

Knowing which kind of waste you're generating will allow you to better handle, dispose, and treat it, not to mention will help with understanding the Environmental Protection Agency's (EPA) more stringent rules on manifests and recordkeeping that go along with certain listed wastes.

F-LIST

The F-List of hazardous wastes are from nonspecific sources. This list covers processes from a wide range of sectors, including the manufacturing industry, government, and schools. These wastes can range from general solvent use to metal finishing industry wastes. Some might be found in hospital settings, but rarely in pharmacies.

The F-List has seven distinct subgroups, including:

- Spent solvent wastes (F001 – F005)
- Wastes from electroplating and other metal finishing operations (F006 – F012, and F019)
- Dioxin bearing wastes (F020 – F023 and F026 – F028)
- Wastes from production of certain chlorinated aliphatic hydrocarbons (F024 and F025)
- Wastes from wood preserving (F032, F034, and F035)
- Petroleum refinery wastewater treatment sludges (F037 and F038)
- Multisource leachate (F039)

though this is considered the more general list, there can be many F-listed wastes that can be quite specific. Healthcare facilities most commonly deal with the following types of F-list wastes: acetone, methanol, toluene, xylene, and methylene chloride.

K-LIST

The K-List of wastes are those that are considered source-specific, such as petroleum refining or pesticide manufacturing wastes. Even certain wastewaters and sludges can be found on this list.

The K-List is divided into 13 different subgroups, including:

- Wood preservation (K001)
- Inorganic pigment manufacturing (K002 – K008)
- Organic chemicals manufacturing (K009 – K011, K013 – K030, K083, K085, K093 – K096, K103 – K105, K107 – K118, K136, K149 – K151, K156 – K159, K161, K174 – K175, and K181)
- Inorganic chemicals manufacturing (K071, K073, K106, and K176 – K178)
- Pesticides manufacturing (K031 – K043, K097 – K099, K123 – K126, and K131 – K132)
- Explosives manufacturing (K044 – K047)
- Petroleum refining (K048 – K052, and K169 – K172)
- Iron and steel production (K061 and K062)
- Primary aluminum production (K088)
- Secondary lead processing (K069 and K100)
- Veterinary pharmaceuticals manufacturing (K084 and K101 – K102)
- Ink formulation (K086)
- Coking (K060, K141 – K145, and K147 – K148)

P LIST & U LIST

THE P-LIST AND THE U-LIST

Both the P-and-U-Lists govern unused pharmaceuticals, chemicals, and pesticides.

The P-List contains about 239 acutely toxic substances, with 135 different waste codes. This is because some waste codes will span several substances.

A few examples of those wastes (including the substance, the waste code, and the substance's uses and applications) on the P-List are:

- Arsenic (P012 veterinary medicine, severe parasitic diseases)
- Arsenic Trioxide (P012 chemotherapy)
- Chloropropionitrile (P027 pharmaceutical synthesis)
- Cyanide Salts (P030 laboratory)
- Epinephrine P042 emergency allergy kits, eye surgery, cardiac arrest

U-List wastes are all toxic. Five examples of the wastes on this list include:

- Arsenic (P012 veterinary medicine, severe parasitic diseases)
- Arsenic Trioxide (P012 chemotherapy)
- Chloropropionitrile (P027 pharmaceutical synthesis)
- Cyanide Salts (P030 laboratory)
- Epinephrine P042 emergency allergy kits, eye surgery, cardiac arrest

Drug packages are considered hazardous if they held P- or U-list chemicals at any point, and/or if they are not empty. Bear in mind that "empty" is defined somewhat differently for each list.

GENERATOR STATUS: CESQG & SQG

The EPA has three distinct categories for generators of hazardous waste, each category being differentiated by the amount of waste that a generator produces or manages.

According to the EPA, the three categories of hazardous waste generators (and the regulations for these generator classifications) are as follows:

CONDITIONALLY EXEMPT SMALL QUANTITY GENERATORS (CESQG)

- CESQGs generate 100 kilograms or less of hazardous waste per month, or 1 kilogram or less per month of acutely hazardous (highly toxic) waste;
- They must not accumulate above 1,000 kilograms of waste at any period of time;
- CESQGs must identify all generated hazardous waste; and
- CESQGs must ensure, along with all other generators, that the hazardous waste they send off-premises is delivered to a company, landfill, or treatment, storage, and disposal facility (TSDF) that is expressly permitted to handle it.

SMALL QUANTITY GENERATORS

- SQGs generate in between 100 kilograms and 1,000 kilograms per month;
- A SQG's quantity of hazardous waste held on-site can never exceed 6,000 kilograms;
- They may accumulate waste, without a permit, on-site for up to 180 days (and up to 270 days if shipping the hazardous waste over a distance that exceeds 200 miles); and
- SQGS must always have at least one employee who acts in an emergency coordinator capacity, available at all times in case of an emergency.

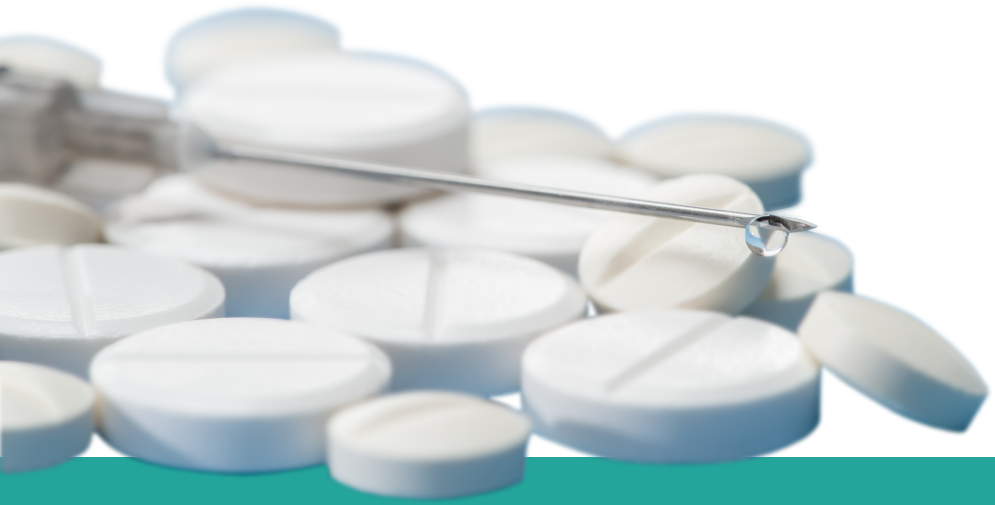
GENERATOR STATUS: LQG

LARGE QUANTITY GENERATORS (LQG)

- LQGs generate more than a 1,000 kilograms of hazardous waste per month, or more than 1 kilogram per month of highly-toxic or acutely toxic hazardous waste;
- LQGs have no limit on the amount of hazardous waste they may accumulate on site;
- LQGs may only store or accumulate waste on site for a period of 90 days, although some exceptions may apply;
- LQGs must submit a biennial hazardous waste report every two years; and
- LQGs must also always have at least one employee acting in an emergency coordinator capacity in case of an emergency.

Please also note that while these federal classifications hold true for most states, some have their own set limits on the amount of waste that a generator may produce or store that may differ from or conflict with EPA requirements and categories.

Some specific states may even have wholly discrete categories along with regulations which make up these definitions. For example, Massachusetts has what they refer to as a Very Small Quantity Generator (VSQG) classification, which can be thought of as fitting in between the federal definition of a Conditionally Exempt Small Quantity Generator (CESQG) and a Small Quantity Generator (SQG). Accordingly, each state may have their own stipulations on storage and transportation requirements as well.



ON-SITE STORAGE & CONTAINERIZATION

STORAGE

Generators commonly store hazardous waste on-site before transferring that waste to another facility. It's easier than shipping off the waste immediately and gives a newer company time to find the right facility for their waste. But knowing the EPA-recommended units of containerization is key for proper storage.

Common storage vessels that are sanctioned by the EPA include containers, tanks, containment buildings, waste piles, drip pads, and surface impoundments. Satellite accumulation points or central accumulation points are locations in which large and small quantity generators accumulate hazardous waste temporarily.

SAFETY STIPULATIONS

There are rules regarding safe storing. For example, containers must be properly marked with the amount and type of waste they hold, and ignitable or reactive waste types must be at least 50 feet from the perimeter of your facility and surface water.

How long hazardous waste may be held in containers on-site depends on the classification of generator and other factors.

Hazardous waste weighing less than 55 gallons may only be held at the site of actual waste generation, or the "satellite accumulation" zone, for 3 days before it must be moved into its proper container.

A large quantity generator (LQG) may store waste in a container for up to 90 days, whereas a small quantity generator (SQG) may store hazardous substances for up to 180 days.

TRANSPORTATION

Bear in mind that before hazardous waste can be shipped off-site, everything must be in proper order. That means the containers used must meet U.S. Department of Transportation requirements, a hazardous waste manifest has been prepared, and you have specified the appropriate placard for your waste transporter.

LAND DISPOSAL

In 1984, the Resource Conservation and Recovery Act (RCRA) was updated to prevent the disposal of certain hazardous wastes on land. Out of this new rule came the Land Disposal Restrictions (LDR) program, which mandates that certain protective measures be taken before any hazardous waste is disposed of on land.

One major impetus for the program was the prevention of the pollution of groundwater, usually through leaching of hazardous contaminants into water supplies. LDR provisions focus on eliminating this possibility by proper treatment of hazardous or toxic constituents in waste before land disposal. **The processes of treatment may include:**

- Incineration (which destroys organic hazardous compounds)
- Stabilization or immobilization (which binds toxic metals to the mass of the waste itself, making them less likely to leach out)

There are three main sections to the LDR program:

- Disposal prohibition
- Dilution prohibition
- Storage prohibition

From the moment hazardous waste is generated onward, it is subject to land disposal restrictions. If a hazardous waste generator produces more than 220 pounds (or 2.2 pounds of acute hazardous waste) of hazardous materials in a calendar month, they must identify the type and nature of the waste, and also determine the course of applicable treatment of the before land disposal.

This means generators that produce less than these amounts of acute hazardous or hazardous waste are exempt from LDR requirements, as are waste pesticides and container residues which are disposed of by farmers on their own land, and newly-listed wastes which the EPA has yet to make a decision on regarding LDR treatment standards.

CONSEQUENCES OF NONCOMPLIANCE

Hazardous waste regulations were put into place for a reason; to protect the environment and the humans that inhabit it. Therefore, ignoring these regulations or not paying much attention to them has major consequences.

Failing to comply with these regulations not only can harm the environment and those around you, it can take a drastic toll on your business' bottom line and, potentially, could even land you in prison.

During the 2014 Fiscal Year, the EPA issued fines resulting in the following amounts:

- $163 million in combined federal administrative, civil judicial penalties, and criminal fines
- $16 million in court-ordered environmental projects resulting from criminal prosecutions
- $453.7 million in commitments from responsible parties to clean up Superfund sites
- 155 combined years of prison time for sentenced defendants

Given these staggering totals, it's important that you don't view these regulations as an annoyance. Taking the time to ensure you're in full compliance not only helps protect the environment and potentially public health, it prevents you from facing these stiff penalties.

With environmental issues receiving more attention all the time, it's possible the penalties could steepen in the future.

PROPOSED RULE

MANAGEMENT STANDARDS FOR HAZARDOUS WASTE PHARMACEUTICALS (2015)

At the time of this publication (December 2015), the EPA has proposed rule changes for managing the standards of hazardous pharmaceutical waste in an effort to find a middle ground when it comes to protecting public health—and the environment—from unnecessary harm and providing life-saving or life-enhancing medications.

The majority of the proposed rule focuses on healthcare environments.

Attempting to reduce the 6,400 tons that get flushed into waterways each year—and to create safer, healthier drinking water—the proposed rule would ban healthcare facilities from flushing hazardous waste pharmaceuticals down sinks or toilets. This should, theoretically, drastically reduce the amount of pharmaceutical waste that gets flushed down drains each year.

The proposal will also illustrate a specific set of regulations and standards aimed at hospitals, clinics, pharmacies, and other healthcare facilities. The intention of these measures is to ensure that the management of hazardous pharmaceutical waste in these facilities is done so as safely as possible.

"Attempting to reduce the 6,400 tons that get flushed into waterways each year—and to create safer, healthier drinking water—the proposed rule would ban healthcare facilities from flushing hazardous waste pharmaceuticals down sinks or toilets."

Conclusion

Benefits for All

Pharmaceutical products carry incredible benefits, and the people who need them should always have the opportunity to procure them. Thankfully, this availability does not have to come at the cost of environmental and public health. Ensuring that your facility disposes of its waste properly (and in accordance with the law) benefits everyone. It protects protects our waterways, and your business from consequences of noncompliance.

If you need further assistance with managing your pharmaceutical waste, call Hazardous Waste Experts at (888) 681-8923.

HAZARDOUS WASTE EXPERTS

Hazardous Waste Experts can assist you with all aspects of pharmaceutical waste management.

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