TCEQ REGULATORY GUIDANCE
Program Support and Environmental Assistance Division
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Pharmaceutical Waste Management for Very Small Quantity Generators

If you are a very small quantity generator (VSQG) in the health care sector, this guide will help you understand how to manage pharmaceutical hazardous wastes.

Pharmaceuticals are considered a waste when they cannot legitimately and lawfully be used, reused, or reclaimed. If they are also hazardous, we call them hazardous waste pharmaceuticals. You can find rules on managing these wastes in Title 30 Texas Administrative Code (30 TAC) Chapter 335 Subchapter W[1].

These rules better fit the operations of the health care sector. They also offer regulatory options to choose from so that VSQGs can efficiently manage their hazardous waste pharmaceuticals.

Health care facilities offer at least one of the following services:

- Preventative, diagnostic, therapeutic, rehabilitative, maintenance, or palliative care or counseling of a human or animal.
- Distributes, sells, or dispenses pharmaceuticals.

Examples include physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, pharmaceutical retailers, veterinary clinics, and hospitals.

Determining if a Waste is Hazardous

A waste is any product that is no longer needed or that can no longer be used for its intended purpose. Facilities need to classify each waste as hazardous or nonhazardous. If it is hazardous, you will also need to determine if it is classified as acute hazardous waste.

Types of Hazardous Waste

Hazardous waste has properties that make it dangerous or capable of having a harmful effect on human health or the environment. There are two types or categories of hazardous waste: listed and characteristic. A waste can be hazardous for multiple reasons, so it can be included in both categories.

1. www.tceq.texas.gov/goto/hazwastepharmaceuticals

Listed Hazardous Waste

The EPA has listed over 400 chemicals that are hazardous wastes if they are disposed of without being used. They use four-character codes — a letter followed by three numbers — to indicate the hazards of a waste. EPA hazardous waste codes beginning with "P" and "U" identify products that have become a waste because they have exceeded their shelf life and cannot be used for their intended purpose.

Discarding a P- or U-listed chemical (or a product whose sole active ingredient is one) without using it generates the same type of waste. Chemicals used for their intended purpose are not considered P- or U-listed hazardous wastes. Find a complete list of P- and U-listed wastes in Title 40, Code of Federal Regulations (40 CFR), Section 261.33[2].

P-listed waste, like warfarin (P001) or epinephrine (P042), is considered **acute hazardous waste**. These wastes can be especially harmful, even in small quantities. Generating more than 1 kilogram of them makes a facility a large quantity generator (LQG).

The U-list contains nonacute hazardous wastes such as acetone (U002) or melphalan (U150).

Characteristic Hazardous Waste

EPA classifies many wastes as hazardous because they demonstrate one or more hazardous characteristics — ignitability, corrosivity, reactivity, and toxicity. See Table 1 below for some properties that define these characteristics and some examples of each.

Table 1. Hazardous Characteristics

Hazardous Characteristic	Properties	Examples
Ignitability	Flash point of less than 140 degrees Fahrenheit (easily combustible or flammable)	Gasoline, some degreasers and solvents
Corrosivity	pH of **less than or equal to 2** (very acidic) or **greater than or equal to 12.5** (very strong base)	Acids used in lab processing or alkaline cleaning fluid
Reactivity	Unstable or undergoes a rapid, violent chemical reaction with water or other materials	Certain bleaches and oxidizers
Toxicity	Leach certain contaminants at high levels*	Mercury, arsenic, and chloroform

2. www.ecfr.gov/current/title-40/chapter-I/subchapter-I/part-261/subpart-D/section-261.33

*You can find a full list of contaminants and the levels that make them hazardous in 40 CFR 261.24[3].

Determining the Rules That Apply

Health care facilities generate two types of hazardous waste:

- **Pharmaceutical waste**, such as prescription pills or IV bags.
- **Nonpharmaceutical waste**, such as waste reagents from lab processing or waste paint from a remodel.

You must include both types when calculating your total amount of waste generated, though only nonpharmaceutical waste will be counted toward your generator status. **Your facility's requirements depend on the amount of both nonpharmaceutical and pharmaceutical waste you generate** (site-wide) during a calendar month.

Generators That Must Follow these Rules

Facilities that generate ***either*** of the following combined monthly quantities of pharmaceutical and nonpharmaceutical waste, ***must*** manage their **hazardous waste pharmaceuticals** under 30 TAC Chapter 335, Subchapter W:

- More than 100 kilograms of nonacute hazardous waste.
- More than 1 kilogram of acute hazardous waste.

These facilities must do all the following:

- Notify TCEQ.
- Train staff on proper waste handling and emergency procedures.
- Properly label waste.
- Comply with accumulation time limits.
- Manage **nonpharmaceutical hazardous waste** as described in the general standards for hazardous waste generators[4].

Visit our webpage on Hazardous Waste Pharmaceutical Management[5] to learn more.

Determine Your Generator Status

Your generator status [LQG, Small Quantity Generator (SQG), or VSQG] is based on the quantities for **nonpharmaceutical hazardous wastes only**. See Table 2 below to determine your generator status.

3. www.ecfr.gov/current/title-40/chapter-I/subchapter-I/part-261#261.24
4. www.tceq.texas.gov/goto/hazwastestandards
5. www.tceq.texas.gov/permitting/registration/ihw/pharm

Table 2. Nonpharmaceutical Waste Generator Status

Nonacute Hazardous Waste (Per Month)	Acute Hazardous Waste (Per Month)	Nonpharmaceutical Waste Generator Status
Less than or equal to 220 pounds (lbs.) or 100 kilograms (kg)	Less than or equal to 2.2 lbs. (1 kg)	VSQG
More than 220 lbs. (100 kg) but less than 2,200 lbs. (1,000 kg)	Less than or equal to 2.2 lbs. (1 kg)	SQG
Greater than or equal to 2,200 lbs. (1,000 kg)	Any amount	LQG
Any amount	More than 1 kg	LQG

Long-Term Health Care Facilities

Long-term health care facilities with:

- **20 or fewer beds** are presumed to be VSQGs without calculating monthly hazardous waste generation.
- **More than 20 beds** must show they generate waste within the VSQG quantity limits.

Managing Your VSQG Hazardous Waste

You may choose one of three management options if your VSQG facility generates ***less than***:

- 100 kilograms of hazardous waste
- 1 kilogram of acute waste

This is based upon the **combined** monthly generated quantities of pharmaceutical and nonpharmaceutical hazardous waste.

Option 1: Managing All Hazardous Waste Under General Standards

VSQGs can choose to manage all hazardous wastes (both pharmaceutical **and** nonpharmaceutical) as described in the general standards for hazardous waste generators. Below is a summary of these requirements for VSQGs[6]:

- Classify your hazardous waste.
- Never store more than 2,200 pounds (1,000 kg, or approximately five 55-gallons drums) of hazardous waste on your property at any time.
- Maintain the following records: waste determinations, shipping records, and quantities of hazardous waste generated each month to prove you are a VSQG.

Read Industrial and Hazardous Waste: Rules and Regulations for Small Quantity Generators[7] (RG-234) to learn more about the requirements for VSQGs.

Choosing this option allows you to handle all your hazardous waste under the same rules. This helps minimize confusion over what regulations apply to a waste stream. You also would not need to notify TCEQ of your waste activities.

Under this option, you may dispose of waste at any of the following types of facilities:

- A permitted hazardous waste treatment, storage, or disposal facility.
- A permitted municipal or industrial solid waste management facility (such as a municipal solid waste landfill).
- An LQG under the control of the same person as the VSQG facility.
    - Only if you mark the shipping containers with the words “Hazardous Waste” and list the specific hazards.

Option 2: Sending Pharmaceutical Waste to a Reverse Distributor or Another Health Care Facility

In addition to managing hazardous waste under the general standards in 30 TAC Section 335.53, you can send wastes to a reverse distributor or consolidate at another health care facility controlled by the same person.

A VSQG can send potentially creditable hazardous waste pharmaceuticals[8] to a reverse distributor. You do not need to notify TCEQ of this activity and we do not consider you to be operating under 30 TAC Chapter 335 Subchapter W.

Under this option, you may dispose of waste at any of the following types of facilities:

- A permitted hazardous waste treatment, storage, or disposal facility.

6. See 30 TAC 335.53
7. www.tceq.texas.gov/goto/rg-234
8. A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit.

- A permitted municipal or industrial solid waste management facility, such as a city landfill.
- An LQG under the control of the same person as the VSQG facility.
    - Only if you mark the shipping containers with the words “Hazardous Waste” and list the specific hazards.
- A reverse distributor if the waste is a potentially creditable hazardous waste pharmaceutical.
- A health care facility operating under 30 TAC Chapter 335 Subchapter W under the control of the same person as the VSQG facility.
    - Only if you mark the shipping containers with the words “Hazardous Waste” and list the specific hazards.

Long term health care facilities using this method can store their hazardous waste pharmaceuticals in an on-site collection receptacle. If they follow Drug Enforcement Agency rules, they may then dispose of it through an authorized collector.

Option 3: Managing All Pharmaceutical Waste Under These Rules

VSQGs may also manage all pharmaceutical hazardous wastes as described in 30 TAC Chapter 335 Subchapter W. If you choose this option, notify TCEQ of your activity using EPA form 8700-12[9].

If your hazardous waste generation varies and is sometimes more or less than 100 kg nonacute or 1 kg acute per month, this option streamlines your requirements throughout the year. These requirements include notifying TCEQ, training staff, labeling waste, and accumulation time limits.

You must manage your nonpharmaceutical hazardous waste (for example waste paint and waste reagents) under the general standards for hazardous waste generators.

Under this option, you may dispose of waste at any of the following types of facilities:

- A permitted hazardous waste treatment, storage, or disposal facility (TSDF).
- Reverse distributor if it is potentially creditable hazardous waste pharmaceuticals.

Additional Pharmaceutical Waste Provisions

Discharging to Sewer Systems (Sewering)

Health care facilities **cannot** discharge hazardous waste pharmaceuticals to a sewer system that passes through a publicly owned treatment works (referred to as

9. www.epa.gov/hwgenerators/instructions-and-form-hazardous-waste-generators-transporters-and-treatment-storage

"sewering"[10]). You cannot dispose of or dump hazardous waste pharmaceuticals down sink drains.

Empty Container Management

Empty containers have less management requirements. Make sure the containers are truly empty and document it with a waste determination. If they are not empty, you must continue to manage them as hazardous waste. For the complete rule, see 30 TAC 335.765[11].

Below is a list of different types of containers and when they are defined as empty.

- Stock, dispensing, and unit dose containers: If all pharmaceuticals have been removed from the container, they are empty and their residues are not considered hazardous waste.
- Syringes: If all contents have been removed by fully depressing the plunger of the syringe, it is empty.
- Intravenous (IV) bags: If all pharmaceuticals in the IV bag have been fully administered to a patient, it is empty.

Hazardous waste pharmaceuticals remaining in most other types of unused, partially administered, or fully administered containers are not considered empty[12].

Definitions

Acute hazardous waste: Hazardous waste that is toxic in small amounts. Acute hazardous wastes at a health care facility are discarded, unused commercial chemical products on the P list in 40 CFR 261.33[13].

Pharmaceutical: Any drug or dietary supplement for use by humans or other animals, including over-the-counter drugs, homeopathic drugs, and clean-up material from spills of pharmaceuticals.

Hazardous waste: Any solid waste that is defined as being hazardous in 40 CFR 261.3[14], unless it is excluded by 40 CFR 261.4[15]. There are two different ways that a waste can be designated "hazardous": it can be "listed" as hazardous (such as wastes from specific industries or can be generated from discarded commercial products) or exhibit a hazardous characteristic (such as toxicity or corrosivity).

Hazardous waste pharmaceutical: A pharmaceutical waste that is also hazardous. It is not a waste if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed.

Long term health care facility: A licensed entity that helps with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. Examples of long-term health care facilities include hospice

10. See 30 TAC 335.761.
11. www.tceq.texas.gov/goto/pharmemptycontainers
12. See exceptions in 30 TAC 335.765(d).
13. www.ecfr.gov/current/title-40/chapter-I/subchapter-I/part-261/subpart-D/section-261.33
14. www.ecfr.gov/current/title-40/chapter-I/subchapter-I/part-261#261.3
15. www.ecfr.gov/current/title-40/chapter-I/subchapter-I/part-261#261.4

facilities, nursing facilities, skilled nursing facilities, and the nursing and skilled nursing care portions of continuing care retirement communities. Not included within the scope of this definition are group homes, independent living communities, assisted living facilities, and the independent and assisted living portions of continuing care retirement communities.

Nonacute hazardous waste: Hazardous wastes that don't meet the definition of acute hazardous waste.

Nonpharmaceutical hazardous waste: A hazardous waste generated at a health care facility that is not a pharmaceutical. (For example, waste methanol solution from lab processing or spilled diesel fuel from an emergency generator.)

Potentially creditable hazardous waste: A prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit.

Reverse distributor: A facility that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of verifying manufacturer credit.