Pharmaceutical Waste: Empty Containers

Guidance on Hazardous Waste Requirements



Introduction

Wisconsin has adopted the federal Environmental Protection Agency's Resource Conservation and Recovery Act (RCRA) Hazardous Waste Pharmaceuticals regulations, which in many cases allow for alternative and streamlined management options. For example, the regulations identify when a hazardous waste pharmaceutical container is considered empty under RCRA's definition of that term, and therefore no longer subject to RCRA requirements. [Subchapter P of ch. NR 666, Wis. Adm. Code]

Hazardous waste regulations are found in chapters NR 600-679 of the Wisconsin Administrative Code.

This document provides information on how to determine if a hazardous waste pharmaceutical container meets the new RCRA-empty requirements under s. NR 666.507, Wis. Adm. Code.

- While the regulations apply only to hazardous waste pharmaceutical containers, they can be used as a best management practice for all waste pharmaceutical containers.
- If the hazardous waste pharmaceutical container is not RCRA empty, the container and its contents must be managed as a hazardous waste pharmaceutical following the requirements in s. NR 666.502, Wis. Adm. Code.

This document does not apply to household hazardous waste pharmaceuticals unless these pharmaceuticals are separated for management at a collection facility regulated under subch. HH of NR 666 or s. 666.506, Wis. Adm. Code.

Definitions

Acute hazardous wastes are hazardous wastes that present specific health or safety risks that subject them to more stringent management requirements. These are hazardous wastes that meet the listing criteria specified in s. NR 661.0011(1)(b), Wis. Adm. Code. [s. NR 660.10(3m), Wis. Adm. Code]

Container means any portable device in which a material is stored, transported, treated, disposed of or otherwise handled. [s. NR 660.10(14), Wis. Adm. Code]

Non-acute hazardous waste is all hazardous wastes that are not acute hazardous waste.

Non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical for which there is not a reasonable expectation that it will be eligible for manufacturer credit, or a nonprescription hazardous waste pharmaceutical for which there is not a reasonable expectation that it will be legitimately used, reused, or reclaimed. This includes investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals. [s. NR 666.500(6), Wis. Adm. Code]

Potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical:

- 1. for which there is a reasonable expectation that it will receive manufacturer credit.
- 2. that is in original manufacturer packaging, except pharmaceuticals that were subject to a recall.
- 3. that is un-dispensed.
- 4. that is unexpired or less than one-year past expiration date.

The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including over-the-counter drugs, homeopathic drugs, or dietary supplements.

This definition distinguishes these pharmaceuticals from 'Non-creditable hazardous waste pharmaceutical.' [s. NR 666.500(10), Wis. Adm. Code]

Evaluating Pharmaceutical Containers

There are many types of containers used in the healthcare industry. This section outlines when containers and common medical delivery devices are considered RCRA empty. Unless otherwise noted, these are found in s. NR 666.507, Wis. Adm. Code.

- 1. Stock, dispensing, and unit-dose containers. A stock bottle, dispensing bottle, vial or ampule that does not exceed 1 liter or 10,000 pills, or a unit-dose container (e.g., a unit-dose packet, cup, wrapper, blister pack, or delivery device), is considered empty and the residues remaining in these containers are not regulated as hazardous waste when the pharmaceuticals have been removed from these containers using the practices commonly employed to remove those materials from that type of container.
 - a. Stock bottles are used to fill the dispensing bottles provided to the patients and customers.
 - b. Dispensing bottles are those that are provided to patients when they get a prescription filled.
 - c. Ampules are containers with a sealed neck and typically contain a small single dosage.
 - d. Vials are containers with a screw on cap or plug and typically consist of multi-doses.
 - e. Unit-dose containers consist of packets, cups, wrappers, blister packs, and delivery devices. A delivery device's primary purpose is to deliver or dispense the pharmaceutical. Examples of delivery devices include medicinal dermal patches, inhalers, aerosols, nebulizers, and intravenous (IV) tubing.

If the stock bottle, dispensing bottle, vial, ampule, or a unit-dose container does not meet the definition of RCRA empty, it must be managed and disposed of as a non-creditable hazardous waste pharmaceutical.

- **2. Syringes**. A syringe is considered empty and the residues remaining in the syringe are not regulated as hazardous waste when any of the following occur:
 - a. Fully depressing the plunger of the syringe by administering the contents of the syringes to a patient.
 - b. Fully depressing the plunger by injecting the contents of the syringe into another delivery device such as an IV bag.
 - c. Fully depressing the plunger of the syringe by emptying the remaining contents into a hazardous waste collection container.

If the syringe is not RCRA empty it must be managed and disposed of as a non-creditable hazardous waste pharmaceutical.

3. IV bags. An IV bag is considered empty and the residues remaining in the IV bag are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully

administered to a patient. An IV bag that contained a non-acute hazardous waste pharmaceutical is also considered empty when all waste that can be removed by normal means, such as by pumping, pouring or aspirating, has been removed; and one of the following two conditions has also been met:

- a. No more than 1 inch of residue remains on the bottom of the container or liner.
- b. No more than 3% of the material by weight remains inside a container or inner liner.

If the IV bag is not RCRA empty it must be managed and disposed of as a non-creditable hazardous waste pharmaceutical.

- 4. Other containers, including delivery devices. These would include containers exceeding 1 liter or 10,000 pills, containers and delivery devices for which it is difficult to determine how much residue is remaining in the container (e.g., inhalers, aerosol cans, tubes of ointments, gels, or creams), and all other types of unused, partially administrated, or fully administrated containers that are not listed in items 1 to 3 of this section.
 - a. Containers and delivery devices containing acute hazardous waste pharmaceuticals must be managed and disposed of as non-creditable hazardous waste pharmaceuticals under subchapter P.
 - b. Containers and delivery devices containing non-acute hazardous waste pharmaceuticals are RCRA empty when all waste that can be removed by normal means, such as by pumping, pouring or aspirating, has been removed; and conditions found in NR 661.0007(2)(a) or (b), Wis. Adm. Code, have also been met.
- 5. End user containers, such as the e-liquid vials used by electronic nicotine delivery systems (e.g., electronic cigarette or vaping pen) are hazardous waste pharmaceuticals and are subject to s. NR 666.507, Wis. Adm Code.
 - a. Clear unit dose containers (e.g., vials, cartridges) are RCRA empty when all of the nicotine liquid has been administered by the user in the manner in which it is intended to be used.
 - b. Opaque devices that cannot be verified to be RCRA empty must be managed and disposed of as non-creditable hazardous waste pharmaceuticals under Subchapter P.
- 6. Other hazards: Some pharmaceutical containers and delivery devices contain other hazards; for example, an injection pen may contain a lithium battery, a needle, and a small, compressed gas cylinder. These containers and delivery devices may be subject to additional regulatory requirements, such as the universal waste requirements for the battery and the infectious waste requirements in ch. NR 526, Wis. Adm. Code, for the needle.

Containers of e-liquid that are sold or distributed for further manufacturing, mixing, or packaging into a finished electronic nicotine delivery system (e.g., an e-liquid stock bottle used to fill the e-liquid vials) are <u>not</u> hazardous waste pharmaceuticals and instead remain subject to the RCRA empty container requirements under s. NR 661.0007(2)(c), Wis. Adm Code. [s. NR 666.500(9), Wis. Adm. Code] For more details on nicotine e-liquid regulations, see the <u>EPA FAQ</u>.

Resources and Contact Information

For more information including <u>publications</u>, <u>inspection forms</u>, <u>and administrative codes and statutes</u>, go to <u>dnr.wi.gov</u> and search "hazardous waste resources." Use the <u>Additional Resources</u> menu to navigate to specific topics. For staff contact information, go to the <u>staff directory</u>, and enter "hazardous waste requirements" in the subject field, and choose the appropriate county contact.

PUB-WA-1256 2022

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