
ENVIRONMENTAL Fact Sheet



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HW-38

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Hazardous Waste Pharmaceuticals Rule: Applicability and Resulting Generator Category

Effective July 23, 2022, the New Hampshire Department of Environmental Services (NHDES) adopted Env-Hw 1300, the Hazardous Waste Pharmaceuticals Rule, which incorporates by reference regulations promulgated by the US Environmental Protection Agency (EPA) at 40 CFR 266 Subpart P. This rule regulates the management of hazardous waste pharmaceuticals by health care facilities and reverse distributors. NHDES is not aware of any reverse distributors operating in New Hampshire at the time the rules were promulgated, so this guidance focuses on health care facilities only. Below is a four-step evaluation to help determine whether your site is subject to the requirements of Env-Hw 1300, and if so, how your site's resulting generator category might change.

Question 1: Is your site (or part of your site) a "health care facility"?

Health care facility means any entity that is lawfully authorized to:

- 1) Provide preventative, diagnostic, therapeutic, rehabilitative, maintenance or palliative care, and counseling, service, assessment, or procedure with respect to the physical or mental condition, or functional status, of a human or animal or that affects the structure or function of the human or animal body; or
- 2) Distribute, sell, or dispense pharmaceuticals, including over-the-counter pharmaceuticals, dietary supplements, homeopathic drugs, or prescription pharmaceuticals. (See Step 2 for a definition of "pharmaceutical.")

The definition of health care facility includes, but is not limited to:

- Wholesale distributors.
- Third-party logistics providers that serve as forward distributors.
- Long-term care facilities.
- Military medical logistics facilities.
- Hospitals.
- Psychiatric hospitals.
- Ambulatory surgical centers.
- Health clinics.
- Chiropractors.
- Ambulance services.
- Pharmacies.
- Long-term care pharmacies.
- Mail-order pharmacies.
- Retailers of pharmaceuticals.
- Veterinary clinics.
- Veterinary hospitals.

The definition of health care facility does not include pharmaceutical manufacturers, reverse distributors or reverse logistics centers.

A health care facility may be part of a site (in other words, “co-located” at a site), so Env-Hw 1300 provisions could apply to a portion of a site like a university, military base or manufacturing facility that has a health care component (e.g., nurse’s office, clinic, area where employee blood monitoring is performed or vaccines are administered, etc.).

If you answered **YES** to Question 1, continue to Question 2. If **NO**, Env-Hw 1300 does not apply to your site.

Question 2: Does your site generate hazardous waste pharmaceuticals?

Env-Hw 1300 applies to “hazardous waste pharmaceuticals” generated at health care facilities and handled at reverse distributors. Definitions for “pharmaceuticals” and “hazardous waste pharmaceuticals” are as follows.

Pharmaceutical means any drug or dietary supplement for use by humans or other animals; any electronic nicotine delivery system (e.g., electronic cigarette or vaping pen); or any liquid nicotine (e-liquid) packaged for retail sale for use in electronic nicotine delivery systems (e.g., pre-filled cartridges or vials).

The definition of pharmaceutical includes, but is not limited to:

- Dietary supplements, as defined by the Federal Food, Drug and Cosmetic Act.
- Prescription drugs, as defined by 21 CFR 203.3(y).
- Over-the-counter drugs.
- Homeopathic drugs.
- Compounded drugs.
- from spills of pharmaceuticals.
- Pharmaceuticals remaining in non-empty containers.
- Personal protective equipment contaminated with pharmaceuticals.
- Investigational new drugs.
- Clean-up material.

The definition of pharmaceutical does not include dental amalgam or sharps.

If a product is required by the US Food and Drug Administration (FDA) to include “Drug Facts” on the label, it would be considered a pharmaceutical for the purposes of this rule. If an item meets the criteria to be considered a pharmaceutical under Env-Hw 1300 but is not labeled with Drug Facts, it should still be managed as a pharmaceutical.

Hazardous waste pharmaceutical means a pharmaceutical (as defined above) that is a waste and is either listed in Env-Hw 402 or exhibits one or more characteristics in Env-Hw 403. Note, however, that Env-Hw 1300 does not apply to New Hampshire-only wastes (e.g., NH02 – corrosive solids).

The Hazardous Waste Pharmaceuticals Rule does not apply to reverse logistics, which is the reverse flow of non-prescription pharmaceuticals and other unsold retail items from a retail store to a reverse logistics center. Items sent through reverse logistics are not considered a waste at the retail store if they have a reasonable expectation of being legitimately used/reused (e.g., sold or lawfully donated for its intended purpose) or reclaimed.

If you answered **YES** to Question 2, continue 3. If **NO**, Env-Hw 1300 does not apply to your site.

Question 3: How much hazardous waste does your site generate and accumulate?

To answer the questions below, note that “RCRA empty” stock bottles, dispensing bottles, unit dose containers, syringes, or IV bags are not considered hazardous waste and may be disposed of as solid waste, even if they held acute hazardous waste. See fact sheet HW-39 “Hazardous Waste Pharmaceuticals Rule: Guidance for Health Care Facilities” for more information.

A) Calculate the total amount of hazardous waste generated at the entire site.

TOTAL Hazardous Waste = Hazardous Waste Pharmaceuticals + Non-Pharmaceutical Hazardous Waste

Is the TOTAL hazardous waste amount generated at the entire site in any calendar month GREATER THAN or equal to:

- 220 pounds (100 kg) of hazardous waste;
- 2.2 pounds (1 kg) of acute hazardous waste; or
- 220 pounds (100 kg) of residues from the cleanup of a spill of acute hazardous waste?

B) Calculate the total maximum amount of hazardous waste accumulated at the entire site at any time.

TOTAL Hazardous Waste = Hazardous Waste Pharmaceuticals + Non-Pharmaceutical Hazardous Waste

Is the TOTAL hazardous waste amount accumulated at the entire site at any time:

- Greater than 2,200 pounds (1,000 kg) of hazardous waste;
- Greater than or equal to 2.2 pounds (1 kg) of acute hazardous waste; or
- Greater than or equal to 220 pounds (100 kg) of residues from the cleanup of a spill of acute hazardous waste?

If you answered **YES** to either Question 3A or 3B, then your health care facility must comply with Env-Hw 1300 requirements, which include notifying NHDES as a health care facility. Continue to Question 4.

If you answered **NO** to both Questions 3A and 3B, then your health care facility is not required to comply with Env-Hw 1300 but has the option to do so. See fact sheet HW-39 "Hazardous Waste Pharmaceuticals Rule: Guidance for Health care Facilities" for more information.

Question 4: If your site is subject to Env-Hw 1300, what is your resulting generator category?

Health care facilities that exceed the generation or accumulation quantities when calculating the TOTAL hazardous waste for the entire site must comply with Env-Hw 1300 requirements. When operating under Env-Hw 1300, the site may then subtract the amount of hazardous waste pharmaceuticals generated and accumulated at the site from the total amount of hazardous waste to determine its hazardous waste generator category. The generator category will determine what rules apply to the site's non-pharmaceutical hazardous wastes.

This means that a health care facility that was a Full Quantity Generator (i.e., a federal Small Quantity Generator or Large Quantity Generator) before operating under Env-Hw 1300 may find its hazardous waste generator category is reduced to the less-stringent New Hampshire Small Quantity Generator (i.e., a federal Very Small Quantity Generator) category. Note that when a health care facility is able to lower its generator category because it does not have to count the hazardous waste pharmaceuticals managed under Env-Hw 1300 towards its generator category, the health care facility must still operate under and meet Env-Hw 1300 requirements for management of their pharmaceutical wastes. Only sites that are below the quantity limits provided in Question 3 when counting TOTAL hazardous waste (pharmaceuticals and non-pharmaceutical hazardous waste) have the option to manage hazardous waste pharmaceuticals either under the generator requirements in Env-Hw 500 or Env-Hw 1300.

When a health care facility notifies NHDES that it is operating under Env-Hw 1300, it must also update its hazardous waste generator category if the category has changed.

See fact sheet HW-39 "Hazardous Waste Pharmaceuticals Rule: Guidance for Health care Facilities" for more information.

For more information

Questions regarding this fact sheet should be directed to the NHDES Hazardous Waste Management Bureau at (603) 271-2942 or toll-free within New Hampshire at 866-HAZWAST (M-F 8 a.m.-4 p.m.) or email hwcomp@des.nh.gov. For a complete description of the requirements, refer to the New Hampshire Hazardous Waste Rules, Env-Hw 100-1300, available from NHDES' website at www.des.nh.gov.