ENVIRONMENTAL
Fact Sheet

NEW HAMPSHIRE DEPARTMENT OF Environmental Services

29 Hazen Drive, Concord, New Hampshire 03301 • (603) 271-3503 • www.des.nh.gov

HW-39 2022

Hazardous Waste Pharmaceuticals Rule: Guidance for Health Care Facilities

Effective July 23, 2022, the New Hampshire Department of Environmental Services (NHDES) has adopted Env-Hw 1300, the Hazardous Waste Pharmaceuticals Rule, which incorporates by reference the US Environmental Protection Agency (EPA) regulations at 40 CFR 266 Subpart P. This rule regulates the management of hazardous waste (HW) pharmaceuticals by healthcare facilities and reverse distributors. For help determining whether Env-Hw 1300 is required or optional for your site, please see fact sheet HW-38 "Hazardous Waste Pharmaceuticals Rule: Applicability and Resulting Generator Category."

This fact sheet describes the differences between New Hampshire's requirements and federal requirements, summarizes New Hampshire's requirements, and provides example scenarios for healthcare facilities of various sizes. Generators must review the New Hampshire Hazardous Waste Rules in their entirety to ensure compliance.

Differences Between New Hampshire and Federal Requirements

Below are some of the key differences between New Hampshire's and EPA's requirements for HW pharmaceuticals. Refer to the New Hampshire Hazardous Waste Rules (Env-Hw 100-1300) for full details.

- Notification: New Hampshire requires all sites subject to Env-Hw 1300 to notify within 60 days.
- Long-Term Care Facilities (LTCFs): New Hampshire requires LTCFs with 20 beds or fewer to determine the applicability of Env-Hw 1300, instead of presuming that such LTCFs are New Hampshire Small Quantity Generators (NHSQGs), known federally as Very Small Quantity Generators (VSQGs).
- Existing New Hampshire requirements apply, including:
  - All generators, including NHSQGs (i.e., VSQGs), must notify of HW activities (Env-Hw 504).
  - Generators must submit copies of paper manifests to NHDES within 5 days of shipment (Env-Hw 510.02).
  - Shipments of HW, including non-creditable HW, are subject to quarterly reporting and quarterly fees (Env-Hw 512.02).
  - Generators must keep copies of manifests (Env-Hw 512.01).

Summary of Env-Hw 1300 Requirements

Sewer prohibition – HW pharmaceuticals shall not be disposed of down the drain or by flushing. This includes DEA controlled substances that are HW.

DEA controlled substances – Some HW pharmaceuticals are also DEA controlled substances (e.g., chloral/chloral hydrate [U034]; phenobarbital [D001]). Such wastes are exempt from HW regulation provided they are:

- Not sewered.
- Managed in compliance with DEA regulations.
- Either destroyed by a method DEA has publicly deemed in writing to meet their non-retrievable standard or combusted at an approved facility.

Empty containers – Containers that meet the new "RCRA empty" standards, as well as the residues remaining in "RCRA empty" containers, are not regulated as HW and can be disposed of as solid waste. Triple rinsing of containers of acute HW pharmaceuticals is no longer allowed.

Container Type	"RCRA Empty" Standard	
	HW Pharmaceuticals	Acute HW Pharmaceuticals*
Stock/dispensing bottles (up to 1 liter or 10,000 pills) and unit-dose containers	Remove contents through normal practices	Remove contents through normal practices
Syringes	Fully depress plunger	Fully depress plunger
IV bags	Fully administer contents or meet Env-Hw 401.03(d)(1)	Fully administer contents
Other containers	Meet Env-Hw 401.03(d)(1) or (d)(2)	Cannot be RCRA empty. Manage as acute HW.

*Triple rinsing of containers of acute HW pharmaceuticals is NOT allowed.

Requirements for Health care Facilities Operating under Env-Hw 1300 – Health care facilities:

- Must notify NHDES that they are operating under Env-Hw 1300 within 60 days of being subject to the rules. Notification must be provided using the RCRA C Site Identification Form (i.e., notification form). See the form instructions for additional guidance on notifying.
- Must make HW determinations on all waste pharmaceuticals (potentially creditable and non-creditable). If a health care facility manages all waste pharmaceuticals as hazardous, individual HW determinations are not necessary.
- Can accumulate HW and non-HW pharmaceuticals in the same container:
  - Potentially creditable: hazardous and non-hazardous in same container.
  - Non-creditable: hazardous and non-hazardous in the same container.
- Do not need to include HW pharmaceuticals on its biennial report.
- Can receive both potentially creditable and non-creditable HW pharmaceuticals from an offsite healthcare facility that is a NHSQG, known federally as a Very Small Quantity Generator, when counting all of the HW it generates and accumulates in a calendar month, including both its HW pharmaceuticals and its non-pharmaceutical HW. To do so, the receiving facility must:
  - Be under the same control as the NHSQG.
  - Be operating under Env-Hw 1300.
  - Manage the received HW pharmaceuticals in compliance with Env-Hw 1300.
  - Keep records of shipments received for three years from the date of receipt.

Requirements for Management of Potentially Creditable HW Pharmaceuticals – To manage pharmaceuticals that will be sent to a reverse distributor for manufacturer credit, health care facilities:

- Are not subject to container labeling, container standards, or accumulation time limits.
- May use a common carrier, e.g., UPS, USPS. Only potentially creditable HW pharmaceuticals can be shipped to reverse distributors.
- Must follow U.S. Department of Transportation (USDOT) requirements if USDOT considers a shipment to be a hazardous material.
- Must receive delivery confirmation from the reverse distributor within 35 days of shipment date. Electronic delivery confirmation is sufficient.
- Must maintain records of shipments to a reverse distributer for three years.
- Must immediately contain spills. Cleanup materials must be managed as non-creditable HW pharmaceuticals.

Requirements for Management of Non-Creditable HW Pharmaceuticals – To manage HW pharmaceuticals that will be sent directly offsite for disposal, health care facilities:

- Must ensure personnel are thoroughly familiar with proper waste handling and emergency procedures.
- May accumulate HW pharmaceuticals for up to one year and must be able to demonstrate the length of time in storage (e.g., accumulation start date on container, inventory system, etc.).
- Must ensure containers are kept closed, structurally sound, compatible with the contents, not leaking, free from damage that could cause leakage, and secured to prevent unauthorized access.
- Must manage containers of ignitable or reactive wastes under additional requirements.
- Must label containers with the words "Hazardous Waste Pharmaceuticals."
- Must ensure shipments are delivered to a treatment, storage or disposal facility by a HW transporter.
- Must use a HW manifest with "PHARMS" or "PHRM" entered in Item 13. Other HW numbers (i.e., waste codes) are allowed but not required.
- Must meet land disposal restrictions, except that HW numbers are not required on land disposal restrictions notifications.
- Must file exception reports for missing manifests.
- Must keep generator and designated facility copies of manifests and exception reports for three years.
- Must keep HW determination records for three years from the date the waste was last shipped.
- Must immediately contain and cleanup spills.

Requirements for NHSQG Healthcare Facilities – A health care facility that is a NHSQG when counting all of the HW it generates and accumulates in a calendar month, including both its HW pharmaceuticals and its non-pharmaceutical HW, is subject to separate requirements. See Scenarios 4 and 5 below for additional guidance.

Example Scenarios for Sites that are Subject to Env-Hw 1300

If your site is required to comply with Env-Hw 1300 (see fact sheet HW-38 "Hazardous Waste Pharmaceuticals Rule: Applicability and Resulting Generator Category"), you do not have to count HW pharmaceuticals when subsequently determining the site's generator category. There are three different scenarios that could apply to your site based on how much non-pharmaceutical HW you generate.

Scenario 1: Full Quantity Generator (i.e., Federal Small Quantity Generator or Large Quantity Generator) of non-pharmaceutical HW – This site:

- Must manage all HW pharmaceuticals in accordance with Env-Hw 1300 and must manage all non-pharmaceutical HW in accordance with the rules for Full Quantity Generators (FQGs) in Env-Hw 500.
- Must notify NHDES it is operating under Env-Hw 1300 by completing the RCRA C Site Identification Form.
- Must participate in the HW Coordinator Certification Program.
- May receive and consolidate HW pharmaceuticals from NHSQG healthcare facilities under the same control (see summary of requirements, above).

Scenario 2: New Hampshire Small Quantity Generator (i.e., Federal Very Small Quantity Generator) of non-pharmaceutical HW – This site:

- Must manage all HW pharmaceuticals in accordance with Env-Hw 1300 and must manage all non-pharmaceutical HW in accordance with the rules for NHSQGs in Env-Hw 500.
- Must notify NHDES it is operating under Env-Hw 1300 by completing the RCRA C Site Identification Form.
- Must participate in the NHSQG Self-Certification Program.
- May receive and consolidate HW pharmaceuticals from NHSQG health care facilities under the same control (see summary of requirements, above).

Scenario 3: Generates HW pharmaceuticals only and no other HW – This site:

- Must manage all HW pharmaceuticals in accordance with Env-Hw 1300.
- Must notify NHDES it is operating under Env-Hw 1300 by completing the RCRA C Site Identification Form.
- Is not required to participate in either of NHDES' certification programs.
- May receive and consolidate HW pharmaceuticals from NHSQG healthcare facilities under the same control (see summary of requirements, above).

Example Scenarios for Sites that are NOT Subject to Env-Hw 1300

A health care facility that is a New Hampshire Small Quantity Generator (NHSQG), known federally as a Very Small Quantity Generator, when counting all of the HW it generates and accumulates in a calendar month, including both its HW pharmaceuticals and its non-pharmaceutical HW, can choose to manage its HW pharmaceuticals under the provisions of Env-Hw 1300 but is not required to do so. The requirements for and options available to NHSQG healthcare facilities vary depending on whether the site generates only HW pharmaceuticals or generates both HW pharmaceuticals and non-pharmaceutical HW.

Scenario 4: New Hampshire Small Quantity Generator (i.e., Federal Very Small Quantity Generator) of HW pharmaceuticals only and no other HW – This site must manage its HW pharmaceuticals in one of two ways:

Option 4A: Opting into and managing under the requirements of Env-Hw 1300 – The site:

- Must notify NHDES it is opting into Env-Hw 1300 by completing the RCRA C Site Identification Form.
- May receive and consolidate HW pharmaceuticals from NHSQG health care facilities under the same control (see summary of requirements, above).

Option 4B: Managing under the requirements for NHSQGs in Env-Hw 500 – The site has the following options for its HW pharmaceuticals:

- Sending potentially creditable HW pharmaceuticals to a reverse distributor.
- Sending HW pharmaceuticals (potentially creditable or non-creditable) to either:
  - A healthcare facility operating under Env-Hw 1300, under the same control as the NHSQG.
  - A Full Quantity Generator health care facility that meets the conditions in Env-Hw 509.02(*l*) and has notified NHDES that it is consolidating NHSQG waste.

Sites operating under Option 4B are subject to the NHSQG Self-Certification Program, while those operating under Option 4A are not.

Scenario 5: New Hampshire Small Quantity Generator (i.e., Federal Very Small Quantity Generator) of both HW pharmaceuticals and non-pharmaceutical HW – This site must manage its non-pharmaceutical HW under the requirements for NHSQGs in Env-Hw 500, including the NHSQG Self-Certification Program. The site must also manage its HW pharmaceuticals in one of two ways:

Option 5A: Opting into and managing HW pharmaceuticals under the requirements of Env-Hw 1300 – The site:

- Must notify NHDES it is opting into Env-Hw 1300 by completing the RCRA C Site Identification Form.
- May receive and consolidate HW pharmaceuticals from NHSQG healthcare facilities under the same control (see summary of requirements, above).

Option 5B: Managing under the requirements for NHSQGs in Env-Hw 500 – The site has the following options for its HW pharmaceuticals:

- Sending potentially creditable HW pharmaceuticals to a reverse distributor.
- Sending HW pharmaceuticals (potentially creditable or non-creditable) to either:
  - A healthcare facility operating under Env-Hw 1300, under the same control as the NHSQG.
  - A Full Quantity Generator healthcare facility that meets the conditions in Env-Hw 509.02(*l*) and has notified NHDES that it is consolidating NHSQG waste.

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.