

COVER SHEET FOR FINAL PROPOSAL

Notice Number **2022-41**

Rule Number **Env-Hw 1300**

1. Agency Name & Address:

Department of Environmental Services
29 Hazen Drive
P.O. Box 95
Concord, NH 03302-0095

2. RSA Authority:

RSA 147-A:3;

RSA 147-B:7

3. Federal Authority:

42 U.S.C. §§6921 - 6939e;

40 CFR Parts 260 - 279

4. Type of Action:

☒ Adoption

☐ Repeal

☐ Readoption

☐ Readoption w/amendment

5. Short Title: Hazardous Waste Pharmaceuticals

6. Contact person for copies and questions:

Name: Wendy Bonner

Title: Regulatory Manager

Address: Department of Environmental Services
29 Hazen Drive
P.O. Box 95
Concord, NH 03302-0095

Phone #: (603) 271-2937

7. Yes ☐ No ☒ Agency requests review by Committee legal staff in the Office of Legislative Services and delayed Committee review pursuant to RSA 541-A:12, I-a

8. The rulemaking notice appeared in the Rulemaking Register on **March 17, 2022**.

SEE THE INSTRUCTIONS--PLEASE SUBMIT 2 COPIES OF THIS COVER SHEET

AND 2 COPIES OF THE FOLLOWING:

(and numbered correspondingly)

9. The "Final Proposal-Fixed Text", including the cross-reference table required by RSA 541-A:3-a, II as an appendix.

10. Yes ☐ N/A ☒ Incorporation by Reference Statement(s) because this rule incorporates a document or Internet content by reference for which an Incorporation by Reference Statement is required pursuant to RSA 541-A:12, III.

11. Yes ☒ N/A ☐ The "Final Proposal-Annotated Text" indicating how the proposed rule was changed because the text of the rule changed from the Initial Proposal pursuant to RSA 541-A:12, II(e).

12. Yes ☐ N/A ☒ The amended fiscal impact statement because the change to the text of the Initial Proposal affects the original fiscal impact statement (FIS) pursuant to RSA 541-A:5, VI.

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2. RSA Authority:

**RSA 147-A:3, I-VI;
RSA 147-B:7, I**

3. Federal Authority:

**42 U.S.C. §§6921 - 6939e;
40 CFR Parts 260 - 279**

4. Type of Action:

Adoption	<u> X </u>
Repeal	<u> </u>
Readoption	<u> </u>
Readoption w/amendment	<u> </u>

5. Short Title: **Hazardous Waste Pharmaceuticals**

6. (a) Summary of what the rule says and of any proposed amendments:

The Resource Conservation and Recovery Act (RCRA), Subtitle C, establishes federal requirements for the management of hazardous waste (HW) and provides for federal authorization of state programs that are at least as stringent as the federal program. Once authorized, the state program is enforceable in lieu of the federal program. Federal requirements for the management of HW pharmaceuticals have been adopted as 40 CFR 266 Subpart P and are considered more stringent than current federal standards that apply to this type of HW. Therefore, authorized states are required to adopt rules to implement 40 CFR 266 Subpart P.

The proposed rules, Env-Hw 1300, incorporate by reference the federal requirements for the management of HW pharmaceuticals. The Department proposes to incorporate most of 40 CFR 266 Subpart P requirements with some modifications to conform with state-specific terminology, cross-references, and existing requirements in subtitle Env-Hw.

The proposed rules, once adopted, require healthcare facilities to determine the applicability of Env-Hw 1300 to their facilities by counting all the HW (pharmaceuticals and other HW) they generate per month. Healthcare facilities that, when counting all their HW, are federal small quantity generators or large quantity generators (collectively called full quantity generators in New Hampshire), as well as reverse distributors, shall manage their HW pharmaceuticals under these new sector-specific rules in lieu of the existing HW generator rules. The sector-specific rules incorporate cost-saving, streamlined standards for handling HW pharmaceuticals to better fit the operations of the healthcare sector while maintaining protection of human health and the environment. Federal very small quantity generators (known in New Hampshire as small quantity generators) when counting all their HW will have the option to manage their HW pharmaceuticals under Env-Hw 1300 or under the existing HW generator rules in subtitle Env-Hw.

In addition, the proposed rules incorporate the federal prohibition on disposal of HW pharmaceuticals to a sewer system that connects to a publicly owned treatment works (POTW) and eliminate the dual regulation of HW pharmaceuticals that are also Drug Enforcement Administration (DEA) controlled substances.

6. (b) Brief description of the groups affected:

The rules affect any healthcare facility or reverse distributors that generate or manage hazardous waste pharmaceuticals.

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6. (c) Specific section or sections of state statute or federal statute or regulation which the rule is intended to implement:

Rule Section(s)	State Statute Implemented	Federal Statute/Regulation Implemented
Env-Hw 1300	RSA 147-A:3, I-VI; RSA 147-B:7; RSA 147-B:8; RSA 147-B:9; RSA 147-B:11	40 CFR 266 Subpart P

7. Contact person for copies and questions including requests to accommodate persons with disabilities:

Name:	Wendy Bonner	Title:	Regulatory Manager
Address:	Department of Environmental Services 29 Hazen Drive P.O. Box 95 Concord, NH 03302-0095	Phone #:	(603) 271-2937
		Fax#:	(603) 271-2456
		E-mail:	Wendy.S.Bonner@des.nh.gov

The rules also can be viewed in PDF in the Public Comment Opportunities section of the NHDES website at <https://www.des.nh.gov/public-comment-opportunities> and selecting "Rulemaking"

TTY/TDD Access: Relay NH 1-800-735-2964 or dial 711 (in NH)

8. Deadline for submission of materials in writing or, if practicable for the agency, in the electronic format specified: **4:00 p.m. on Friday, April 15, 2022**

☒ Fax

☒ E-mail

☐ Other format (specify):

9. Public hearing scheduled for:

Date and Time: **Friday, April 8, 2022 at 11:00 a.m.**

Place: **Room 208C, DES Offices, 29 Hazen Drive, Concord NH**

NOTE: NHDES security procedures require all visitors to sign in and present photo identification (such as a driver's license). If you plan to attend the public hearing in person, please bring photo identification with you.

You also may attend the hearing via GoToWebinar, which can be accessed through the following link:

<https://attendee.gotowebinar.com/register/8580869539956104462>

After registering using this link, interested participants will be provided a confirmation email with information about joining the hearing remotely.

You also may join the meeting by phone:

Call in Number: 1 (562) 247-8422

Access Code: 872-463-431

Webinar ID: 853-426-339

If you have any questions or technical issues connecting to the hearing, contact Tara Albert at Tara.M.Albert@des.nh.gov or (603) 271-3713.

10. Fiscal Impact Statement (Prepared by Legislative Budget Assistant):

FIS #22:032 dated: 03/07/22 :

1. Comparison of the costs of the proposed rule(s) to the existing rule(s):

Not applicable these are new rules.

2. Cite the Federal mandate. Identify the impact on state funds:

Resource Conservation and Recovery Act (RCRA), Subtitle C, establishes federal requirements for the management of hazardous waste and provides for federal authorization of state programs that are at least as stringent as the federal program. Regulation 40 CFR 271 specifies the requirements that must be met by a state's hazardous waste program (including adoption of requirements promulgated by Environmental Protection Agency (EPA) under the authority of RCRA, the Hazardous and Solid Waste Amendments of 1984, or the Hazardous Waste Electronic Manifest Establishment Act) to receive and maintain final authorization from EPA. Once authorized, the state program is enforceable in lieu of the federal program. The Department has been authorized by EPA to implement the RCRA Subtitle C program in New Hampshire and currently receives approximately \$522,000 annually to implement the program. The Department states if rules are not updated and if issues identified during New Hampshire's RCRA authorization application process are not addressed, EPA may initiate proceedings to revoke the authorization, and the Department will lose the federal funds and the ability to enforce the state program.

3. Cost and benefits of the proposed rule(s):

The proposed rules, Env-Hw 1300, incorporate by reference the federal requirements for the management of hazardous waste pharmaceuticals. Once a healthcare facility has determined the applicability of Env-Hw 1300 and manages hazardous waste pharmaceuticals under those provisions, those HW pharmaceuticals will no longer be counted toward the healthcare facility's hazardous waste generator classification, thereby potentially lowering the classification and, as a result, their operating costs. These potential savings are attributable to federal requirements and not to the rules.

The proposed rule includes two modifications to 40 CFR 266 Subpart P that are not existing requirements in the HW rules as described above and are more stringent than the federal requirements. The costs of these provisions are attributable to the state rules. First, at Env-Hw 1302.02(c)(1), the Department is proposing to require all healthcare facilities to notify the Department of pharmaceutical activities within 60 days, instead of allowing those healthcare facilities subject to federal biennial reporting to notify the Department as part of their biennial report, which could be up to two years in the future. Second, at Env-Hw 1302.02(e)(2), the Department is proposing to require long-term care facilities (LTCFs) with 20 beds or fewer to determine the applicability of Env-Hw 1300, instead of presuming that such LTCFs are federal very small quantity generators (i.e., New Hampshire small quantity generators) and therefore not subject to most provisions of Env-Hw 1300. These changes may increase costs to healthcare facilities and LTCFs with 20 or fewer beds by an indeterminable, but likely small, amount.

A. To State general or State special funds:

The proposed incorporation by reference of 40 CFR 266 Subpart P will likely reduce revenues to the Hazardous Waste Cleanup Fund by an indeterminate amount. Once a healthcare facility has determined the applicability of Env-Hw 1300 and manages hazardous waste pharmaceuticals under those provisions, those hazardous waste pharmaceuticals will no longer be counted toward the healthcare facility's generator classification, thereby potentially lowering the classification. As a result, the Certified Hazardous Waste Coordinator Program and the Small Quantity Hazardous Waste Generator Self-Certification Program are expected to see a decrease in participation, and therefore revenue. Due to the number and variability of factors involved, an estimate of the costs cannot be made.

No impact on state general fund.

B. To State citizens and political subdivisions:

There may be an impact to costs to a political subdivision, to the extent it operates a health care facility (see 3 above). No impact on state citizens.

C. To independently owned businesses:

There may be an impact to costs to a privately owned business, to the extent it operates a health care facility (see 3 above).

11. Statement Relative to Part I, Article 28-a of the N.H. Constitution:

The proposed rules incorporate federal requirements that are required to be adopted in accordance with the State's federal RCRA authorization. In the absence of a State authorized program, the federal rules would apply to regulated entities. The proposed rules do include two modifications to the federal rules that are not existing requirements in the State's rules. The costs of these modifications are attributable to the rules. There are no healthcare facilities currently operated by political subdivisions that are subject to the proposed modifications. Accordingly, the proposed rules do not violate Part I, Article 28-a of the New Hampshire Constitution, because the rules do not assign any new, modified, or expanded programs or responsibilities to any political subdivision of the state in such a way as to increase local expenditures.



The State of New Hampshire
DEPARTMENT OF ENVIRONMENTAL SERVICES

Robert R. Scott, Commissioner



FP 2022-41, Env-Hw 1300 – Hazardous Waste Pharmaceuticals
Summary of Comments on Initial Proposal with DES Responses
June 23, 2022

Introduction

The existing rules in subtitle Env-Hw implement RSA 147-A by establishing requirements governing the generation, storage, treatment, transportation, and disposal of hazardous waste (HW). The New Hampshire Department of Environmental Services (NHDES) is required to adopt or incorporate federal HW regulations on an ongoing basis to maintain authorization to administer the federal Resource Conservation and Recovery Act (RCRA) in New Hampshire. NHDES proposed revisions to adopt federal HW regulations for management of HW pharmaceuticals. More detail was provided in the Rulemaking Notice published in the March 17, 2022, Rulemaking Register.

At the public hearing held on April 8, 2022, NHDES received no comments on the Initial Proposal (IP). Written comments were received from stakeholders, including CVS Health, PharmEcology Services, and the New Hampshire Hospital Association. Listed below, in numerical order, are the comments and NHDES' responses for the changes that NHDES is making in the Final Proposal. Editorial comments were received from the Office of Legislative Services, Administrative Rules (OLS); NHDES made edits as noted on page 2. Section numbers refer to numbers in the Initial Proposal unless otherwise noted.

Env-Hw 1300 generally re: calculating applicability of Env-Hw 1300

Comment: New Hampshire's existing rules require a generator to determine their generator category by considering both the quantity of HW they generate in a month and the quantity of HW accumulated at the site at any time. EPA only considers generation rates and not accumulation amounts when determining federal generator categories and when determining the applicability of 40 CFR 266, Subpart P. Please clarify whether these proposed rules require the applicability of Env-Hw 1300 to be determined by considering accumulation amounts in addition to generation rates.

Response: NHDES has revised Env-Hw 1302.02(b)(1) to clarify that both generation and on-site accumulation be included when determining the applicability of Env-Hw 1300. (Clarifying revisions are also proposed in a companion rulemaking for rules in Env-Hw 500 and 600.) This requirement provides internal consistency with New Hampshire's existing generator category classifications and avoids confusion. Based on 2021 manifest data for healthcare facilities, it appears that factoring in onsite accumulation will not result in any additional facilities being subject to the requirements of Env-Hw 1300. In other words, the proposed change will not cause New Hampshire's existing universe of healthcare facilities to be more stringently regulated.

Env-Hw 1302 generally re: generator category nomenclature

Comment: New Hampshire's generator categories do not align with EPA's categories. The federal pharmaceuticals rule mentions very small quantity generators in several places. The Initial Proposal changes some of them to match New Hampshire's terminology but leaves others unchanged. DES should make them consistent.

Response: The NHDES agrees and proposed revisions in Env-Hw 1302.02(c)(7)-(9), (d)(1)-(3), (e)(1)-(5), and (f) to change all remaining instances of "very small quantity generator" to "small quantity generator."

Env-Hw 1302.02(c)(1) re: information required on notification form

Comment: *The proposed amendment to 40 CFR 266.502(a)(1) includes the statement, “A healthcare facility is not required to provide EPA hazardous waste numbers for its hazardous waste pharmaceuticals in item 10 of the notification form.” Federally, a healthcare facility is also not required to provide a description of the waste nor an estimated quantity generated per month. Does NHDES intend to require that additional information?*

Response: NHDES has revised the rule to clarify that a healthcare facility is required to enter the word “pharmaceuticals” in item 10 and is not required to provide a narrative description of each pharmaceutical, EPA or state hazardous waste numbers, nor the estimated quantity generated per month.

Edits made to: 1302.02(c)(1) and (j)(8); Appendix D (new entry for 40 CFR 273.13(e)(4)(i) to address comment on companion rulemaking)

Explanatory comments in *{bracketed blue italics}*

Adopt Env-Hw 1300 to read as follows:

CHAPTER Env-Hw 1300 HAZARDOUS WASTE PHARMACEUTICALS

Statutory Authority: RSA 147-A:3

PART Env-Hw 1301 PURPOSE AND APPLICABILITY

Env-Hw 1301.01 Purpose. The purpose of this chapter is to establish requirements for management of hazardous waste pharmaceuticals.

Env-Hw 1301.02 Applicability. This chapter shall apply to healthcare facilities and reverse distributors, except as provided in 40 CFR 266 Subpart P as incorporated by reference in Env-Hw 1302.01.

Env-Hw 1301.03 Exemptions. This chapter shall not apply to NH-only wastes.

PART Env-Hw 1302 HAZARDOUS WASTE PHARMACEUTICALS

Env-Hw 1302.01 Federal Requirements Incorporated. Subject to the amendments specified in Env-Hw 1302.02, the provisions for management of hazardous waste pharmaceuticals in 40 CFR 266 Subpart P shall apply in New Hampshire.

Env-Hw 1302.02 Amendments to Incorporated Federal Requirements. The following amendments shall apply to the incorporated requirements:

(a) Amend 40 CFR 266.500 by:

- (1) Deleting the definition of “household waste pharmaceutical” and replacing it with “Household waste pharmaceutical means a pharmaceutical that is a household waste and is excluded from regulation as a hazardous waste pursuant to RSA 147-A:2, VII(b).”; and
- (2) Deleting the definition of “non-pharmaceutical hazardous waste” and replacing it with “Non-pharmaceutical hazardous waste means a hazardous waste that is not a pharmaceutical.”;

(b) Amend 40 CFR 266.501 as follows:

(1) Amend 40 CFR 266.501(a) and (b) to read as follows:

Edit. "shall not be"

“(a) A healthcare facility that is a small quantity generator when counting all of the hazardous waste it generates and accumulates in a calendar month, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to Env-Hw 500 and **is not** subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.

Edit. "shall have"

(b) A healthcare facility that is a small quantity generator when counting all of the hazardous waste it generates and accumulates in a calendar month, including both **its** hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, **has** the option of complying with § 266.501(d) for the management of its hazardous waste pharmaceuticals as an alternative to complying with Env-Hw 500 and the optional provisions of § 266.504.”;

(2) Amend 40 CFR 266.501(d) introductory language and (e) by replacing “parts 262 through 265” and with “Env-Hw 500 through Env-Hw 700”;

(3) Amend 40 CFR 266.501(f) by replacing “40 CFR part 262” with “Env-Hw 500”; and

(4) Amend 40 CFR 266.501(g) introductory language by replacing “40 CFR parts 260 through 273” and with “the hazardous waste rules”;

Explanatory comments in *{bracketed blue italics}*

(c) Amend 40 CFR 266.502 as follows:

(1) Amend 40 CFR 266.502(a) to read as follows:

“(a) Notification and withdrawal from this subpart for healthcare facilities managing hazardous waste pharmaceuticals—

(1) Notification. A healthcare facility shall notify the department that it is a healthcare facility operating under this subpart, by completing and submitting to the department a notification form obtained from the department that includes the information specified in Env-Hw 504.02(a), as applicable. When completing item 10 of the notification form, in lieu of providing a narrative description, EPA and state hazardous waste numbers, and estimated quantity generated per month for its hazardous waste pharmaceuticals, a healthcare facility shall enter the word “pharmaceuticals”. A healthcare facility shall submit a separate notification form for each site or EPA identification number.

(i) A healthcare facility that already has an EPA identification number shall notify the department, using the notification form, that it is a healthcare facility within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(ii) A healthcare facility that does not have an EPA identification number shall obtain one by notifying the department, using the notification form, that it is a healthcare facility within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.

(iii) A healthcare facility shall keep a copy of its notification on file for as long as the healthcare facility is subject to this subpart.

(2) Withdrawal. A healthcare facility that operated under this subpart but is no longer subject to this subpart, because it is a small quantity generator under Env-Hw 500 when counting all its hazardous waste, and elects to withdraw from this subpart, shall notify the department using the notification form identified in Env-Hw 504.02(a), that it is no longer operating under this subpart. A healthcare facility that is withdrawing from this subpart shall provide all applicable EPA and state hazardous waste numbers for its hazardous waste pharmaceuticals in item 10 of the notification form. A healthcare facility shall submit a separate notification form for each EPA identification number.

(i) A healthcare facility shall submit the notification form notifying that it is withdrawing from this subpart before it begins operating under Env-Hw 500.

(ii) A healthcare facility shall keep a copy of its withdrawal on file for three years from the date of signature on the notification of its withdrawal.”;

(2) Amend 40 CFR 266.502(g) by adding after “40 CFR part 268” the following: “, incorporated by reference in Env-Hw 1202”;

(3) Amend 40 CFR 266.502(h) by adding the following:

“(5) If a returned shipment is accompanied by a paper manifest or an electronic manifest that was printed for the healthcare facility’s signature, submit a copy of the signed manifest to the department within 5 days of receipt of the returned shipment.”;

(4) Amend 40 CFR 266.502(i) by adding the following:

“(4) A healthcare facility shall be subject to the quarterly reporting requirements of Env-Hw 512.02 with respect to non-creditable hazardous waste pharmaceuticals.”;

(5) Amend 40 CFR 266.502(j)(1) to read as follows:

Explanatory comments in *{bracketed blue italics}*

“(1) A healthcare facility shall keep a copy of each manifest signed in accordance with Env-Hw 510.02 and each signed copy from the designated facility that received the non-creditable hazardous waste pharmaceuticals for three years from the date of signature by the healthcare facility. A healthcare facility may rely on the electronic manifest system to satisfy manifest recordkeeping requirements only if the healthcare facility has registered in the electronic manifest system and has established access to manifest records stored therein, except as follows:

(i) For shipments using an electronic manifest that was printed for the healthcare facility’s signature, the healthcare facility shall retain the paper copy of the electronic manifest with the healthcare facility’s signature for three years from the date of signature by the healthcare facility.

(ii) For shipments using a paper manifest, a healthcare facility who has registered in the electronic manifest system shall retain the copy of the manifest signed in accordance with Env-Hw 510.02 until such time as the healthcare facility verifies, in the electronic manifest system, receipt of the shipment by the designated facility.”;

- (6) Amend 40 CFR 266.502(j)(3) by replacing “§ 262.11(f)” with “Env-Hw 502.01”;
- (7) Amend 40 CFR 266.502(l) paragraph heading by replacing “very small quantity generator” with “small quantity generator”;
- (8) Amend 40 CFR 266.502(l) introductory language by replacing “very small quantity generator under § 262.14” with “small quantity generator under Env-Hw 500”; and
- (9) Amend 40 CFR 266.502(l)(1) by:
- Replacing “(as defined in § 260.10)” with “(as defined in Env-Hw 104)”;
 - Replacing “very small quantity generator” with “small quantity generator”; and
 - Replacing “§ 260.10 of this chapter” with “Env-Hw 104”;
- (d) Amend 40 CFR 266.503 as follows:
- (1) Amend 40 CFR 266.503(b) paragraph heading by replacing “very small quantity generator” with “small quantity generator”;
 - (2) Amend 40 CFR 266.503(b) introductory language by replacing “very small quantity generator under § 262.14” with “small quantity generator under Env-Hw 500”; and
 - (3) Amend 40 CFR 266.503(b)(1) by:
 - Replacing “§ 260.10” with “Env-Hw 104”; and
 - Replacing “very small quantity generator” with “small quantity generator”;
- (e) Amend 40 CFR 266.504 as follows:
- (1) Amend 40 CFR 266.504 section heading by replacing “very small quantity generators” with “small quantity generators”;
 - (2) Amend 40 CFR 266.504(a), (b) paragraph heading, and (b) introductory language by replacing “very small quantity generator” with “small quantity generator”;
 - (3) Amend 40 CFR 266.504(b)(2) to read as follows:

“(2) The small quantity generator healthcare facility meets the conditions of Env-Hw 501.02(c)(1) and the receiving full quantity generator meets the conditions in Env-Hw 504.01(f), Env-Hw 504.02(a)(15), and Env-Hw 509.02(l)”;

Explanatory comments in *{bracketed blue italics}*

- (4) Amend 40 CFR 266.504(c) paragraph heading by replacing “very small quantity generators” with “small quantity generators”;
- (5) Amend 40 CFR 266.504(c) by replacing “very small quantity generator” with “small quantity generator”; and
- (6) Amend 40 CFR 266.504(d) to read as follows:
 - “(d) Long-term care facilities with 20 beds or fewer. A long-term care facility with 20 beds or fewer shall determine the applicability of 40 CFR 266 Subpart P in accordance with 40 CFR 266.501, as amended by Env-Hw 1302.02(b).”;
- (f) Amend 40 CFR 266.505 by replacing “very small quantity generators operating under § 262.14” with “small quantity generators operating under Env-Hw 500”;
- (g) Amend 40 CFR 266.506(a) introductory language by replacing “40 CFR parts 262 through 273” with “Env-Hw 300 and Env-Hw 500 through Env-Hw 1300”;
- (h) Amend 40 CFR 266.507 as follows:
 - (1) Amend 40 CFR 266.507(c) by replacing “defined in § 261.7(b)(1)” with “specified in Env-Hw 401.03(d)(1)”;
 - (2) Amend 40 CFR 266.507(d) by replacing “defined in § 261.7(b)(1) or (2)” with “specified in Env-Hw 401.03(d)(1) or (2), as applicable”;
- (i) Amend 40 CFR 266.508 as follows:
 - (1) Amend 40 CFR 266.508(a)(2) by replacing “40 CFR part 262 subpart B” with “Env-Hw 510, Env-Hw 511.02, and Env-Hw 512.01(a)(1) and (d) through (f)”;
 - (2) Amend 40 CFR 266.508(a)(2)(i) by replacing “EPA Form 8700–22” with “the manifest”;
 - (3) Amend 40 CFR 266.508(a)(2)(ii) by replacing “write the word “PHARMS” in Item 13 of EPA Form 8700–22” with “write the word “PHARMS” or “PHRM” in item 13 of the manifest”;
- (j) Amend 40 CFR 266.510 as follows:
 - (1) Amend 40 CFR 266.510(a)(1) to read as follows:
 - “(1) Notification. A reverse distributor shall notify the department that it is a reverse distributor operating under this subpart, by completing and submitting to the department a notification form obtained from the department that includes the information specified in Env-Hw 504.02(a), as applicable.
 - (i) A reverse distributor that already has an EPA identification number shall notify the department, using a notification form, that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.
 - (ii) A reverse distributor that does not have an EPA identification number shall obtain one by notifying the department, using a notification form, that it is a reverse distributor, as defined in § 266.500, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.”;

Explanatory comments in *{bracketed blue italics}*

- (2) Amend 40 CFR 266.510(a)(7) by replacing “40 CFR part 262 subpart M” with “Env-Hw 509.02(a)(4) and (a)(5)”;
- (3) Amend 40 CFR 266.510(a)(8) by replacing “§ 262.17(a)(8)(ii) and (iii)” with “Env-Hw 505.04 and Env-Hw 506”;
- (4) Amend 40 CFR 266.510(c)(3) by replacing “§ 262.17(a)(7)” with “Env-Hw 509.02(a)(2)”;
- (5) Amend 40 CFR 266.510(c)(7) by adding the following: “(v) If a returned shipment is accompanied by a paper manifest or an electronic manifest that was printed for the reverse distributor’s signature, submit a copy of the signed manifest to the department within 5 days of receipt of the returned shipment.”;
- (6) Amend 40 CFR 266.510(c)(8) by adding after “40 CFR part 268” the following words: “, incorporated by reference in Env-Hw 1202”;
- (7) Amend 40 CFR 266.510(c)(9) by adding the following: “(iii) A reverse distributor shall be subject to the quarterly reporting requirements of Env-Hw 512.02 with respect to evaluated hazardous waste pharmaceuticals.”;
- (8) Amend 40 CFR 266.510(c)(10)(ii) to read as follows:

“(ii) A reverse distributor shall keep a copy of each manifest signed in accordance with Env-Hw 510.02 and each signed copy from the designated facility that received the evaluated hazardous waste pharmaceuticals for 3 years from the date of signature by the reverse distributor. A reverse distributor may rely on the electronic manifest system to satisfy manifest recordkeeping requirements only if the reverse distributor has registered in the electronic manifest system and has established access to manifest records stored therein, except as follows:

(A) For shipments using an electronic manifest that was printed for the reverse distributor’s signature, the reverse distributor shall retain the paper copy of the electronic manifest with the reverse distributor’s signature for 3 years from the date of signature by the reverse distributor.

(B) For shipments using a paper manifest, a reverse distributor who has registered in the electronic manifest system shall retain the copy of the manifest with the reverse distributor’s signature until such time as the reverse distributor verifies, in the electronic manifest system, receipt of the shipment by the designated facility.”;
- (9) Amend 40 CFR 266.510(c)(10)(v) by replacing “§ 262.17(a)(7)(iv)” with “Env-Hw 509.02(a)(2)”;
- (10) Amend 40 CFR 266.510(d) introductory language by replacing “40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270” with “Env-Hw 700 and the permit requirements of Env-Hw 300”.

Explanatory comments in *{bracketed blue italics}*

APPENDIX A: STATE STATUTES, FEDERAL STATUTES/REGULATIONS IMPLEMENTED

Rule Section(s)	State Statute Implemented	Federal Statute/Regulation Implemented
Env-Hw 1300	RSA 147-A:3, I-VI; RSA 147-B:7; RSA 147-B:8; RSA 147-B:9; RSA 147-B:11	40 CFR 266 Subpart P

APPENDIX B: INCORPORATION BY REFERENCE INFORMATION [NONE IN THIS CHAPTER]

APPENDIX C: STATE STATUTORY DEFINITIONS

RSA 147-A:2

III. “Disposal” means the discharge, deposit, incineration, injection, dumping, spilling, leaking or placing of any waste into or onto any land or water so that the waste or any constituent of the waste may enter the environment, be emitted into the air, or be discharged into any waters, including groundwaters.

IV. “Facility” means a location at which hazardous waste is subjected to treatment, storage or disposal and may include a facility where hazardous waste has been generated.

VI. “Generator” means any person who owns or operates a facility where hazardous waste is generated.

VII. “Hazardous waste” means a solid, semi-solid, liquid or contained gaseous waste, or any combination of these wastes:

(a) Which, because of either quantity, concentration, or physical, chemical, or infectious characteristics may:

(1) Cause or contribute to an increase in mortality or an increase in irreversible or incapacitating reversible illness; or

(2) Pose a present or potential threat to human health or the environment when improperly treated, stored, transported, disposed of or otherwise mismanaged.

(b) Or which has been identified as a hazardous waste by the department using the criteria established under RSA 147-A:3, I or as listed under RSA 147-A:3, II. Such wastes include, but are not limited to, those which are reactive, toxic, corrosive, ignitable, irritants, strong sensitizers or which generate pressure through decomposition, heat or other means. Such wastes do not include radioactive substances that are regulated by the Atomic Energy Act of 1954, as amended, or household pharmaceutical wastes collected pursuant to RSA 318-E.

VIII. “Hazardous waste management” means the systematic control of the generation, collection, sorting, storage, processing, treatment, recovery and disposal of hazardous waste.

X. “Manifest” means the form used for identifying the origin, quantity, composition, routing and destination of hazardous waste.

XI. “Operator” means any person who, either directly or indirectly, operates or otherwise controls or directs activities at a facility.

XI-a. “Owner” means any person who, either directly or indirectly owns a facility. The term “owner” does not include a person who, without participation in the management or actual operation of a facility, holds indicia of ownership primarily to protect a mortgage on real property on which a facility is located or a security interest in personal property located at the facility.

XII. “Person” means any individual, trust, firm, joint stock company, corporation (including a government corporation), partnership, association, state, municipality, commission, United States government or any agency thereof, political subdivision of the state, or any interstate body.

Explanatory comments in *{bracketed blue italics}*

XII-a. “Spent material” means any material that has been used and, as a result of contamination, can no longer serve the purpose for which it was produced without processing.

XIII. “Storage” means the containment of hazardous wastes, either on a temporary basis or for a period of years, in such a manner as not to constitute disposal of the hazardous wastes.

XIV. “Trade secret” means any confidential formula, pattern, device or compilation of information which is used in the employer's business and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. A trade secret is known to the employer and those employees to whom it is necessary to confide it.

XV. “Transport” means the movement of hazardous wastes from the point of generation to any intermediate points and, finally, to the point of ultimate storage or disposal.

XVI. “Transporter” means any person who transports hazardous waste.

XVII. “Treatment” means any process, including neutralization, designed to change the physical, chemical or biological character or composition of any hazardous waste so as to neutralize the waste or to render the waste not hazardous, safer for transport, amenable to recovery, amenable to storage or reduced in volume.

XVIII. “Waste” means any matter consisting of: garbage, refuse, sludge from a waste treatment plant, water supply treatment plant, or air pollution control facility and other spent, discarded or abandoned material including solid, liquid, semi-solid, or contained gaseous material resulting from industrial, commercial, mining, and agricultural operations, and from community activities, but does not include domestic sewage, irrigation return waters, wastewater discharges in compliance with applicable state or federal permits, or source, special nuclear, or by-product material as defined by the Atomic Energy Act of 1954, as amended.

RSA 147-B:2

III. “Facility” means any site, area or location where hazardous waste or hazardous materials are or have been treated, stored, generated, disposed of, or otherwise come to be located.

APPENDIX D: FEDERAL DEFINITIONS AND REGULATIONS

40 CFR 260.4

(a) In any case in which the state in which waste is generated, or the state in which waste will be transported to a designated facility, requires that the waste be regulated as a hazardous waste or otherwise be tracked through a hazardous waste manifest, the designated facility that receives the waste shall, regardless of the state in which the facility is located:

- (1) Complete the facility portion of the applicable manifest;
- (2) Sign and date the facility certification;
- (3) Submit to the e-Manifest system a final copy of the manifest for data processing purposes; and
- (4) Pay the appropriate per manifest fee to EPA for each manifest submitted to the e-Manifest system, subject to the fee determination methodology, payment methods, dispute procedures, sanctions, and other fee requirements specified in subpart FF of part 264 of this chapter.

40 CFR 260.5

(a) For purposes of this section, “state-only regulated waste” means:

- (1) A non-RCRA waste that a state regulates more broadly under its state regulatory program, or
- (2) A RCRA hazardous waste that is federally exempt from manifest requirements, but not exempt from manifest requirements under state law.

Explanatory comments in *{bracketed blue italics}*

(b) In any case in which a state requires a RCRA manifest to be used under state law to track the shipment and transportation of a state-only regulated waste to a receiving facility, the facility receiving such a waste shipment for management shall:

- (1) Comply with the provisions of §§ 264.71 (use of the manifest) and 264.72 (manifest discrepancies) of this chapter; and
- (2) Pay the appropriate per manifest fee to EPA for each manifest submitted to the e-Manifest system, subject to the fee determination methodology, payment methods, dispute procedures, sanctions, and other fee requirements specified in subpart FF of part 264 of this chapter.

40 CFR 260.10

Act or *RCRA* means the Solid Waste Disposal Act, as amended by the Resource Conservation and Recovery Act of 1976, as amended, 42 U.S.C. section 6901 *et seq.*

Administrator means the Administrator of the Environmental Protection Agency, or his designee.

Aerosol can means a non-refillable receptacle containing a gas compressed, liquefied, or dissolved under pressure, the sole purpose of which is to expel a liquid, paste, or powder and fitted with a self-closing release device allowing the contents to be ejected by the gas.

Aquifer means a geologic formation, group of formations, or part of a formation capable of yielding a significant amount of ground water to wells or springs.

Authorized representative means the person responsible for the overall operation of a facility or an operational unit (i.e., part of a facility), e.g., the plant manager, superintendent or person of equivalent responsibility.

Battery means a device consisting of one or more electrically connected electrochemical cells which is designed to receive, store, and deliver electric energy. An electrochemical cell is a system consisting of an anode, cathode, and an electrolyte, plus such connections (electrical and mechanical) as may be needed to allow the cell to deliver or receive electrical energy. The term battery also includes an intact, unbroken battery from which the electrolyte has been removed.

Boiler means an enclosed device using controlled flame combustion and having the following characteristics:

(1)(i) The unit must have physical provisions for recovering and exporting thermal energy in the form of steam, heated fluids, or heated gases; and

(ii) The unit's combustion chamber and primary energy recovery sections(s) must be of integral design. To be of integral design, the combustion chamber and the primary energy recovery section(s) (such as waterwalls and superheaters) must be physically formed into one manufactured or assembled unit. A unit in which the combustion chamber and the primary energy recovery section(s) are joined only by ducts or connections carrying flue gas is not integrally designed; however, secondary energy recovery equipment (such as economizers or air preheaters) need not be physically formed into the same unit as the combustion chamber and the primary energy recovery section. The following units are not precluded from being boilers solely because they are not of integral design: process heaters (units that transfer energy directly to a process stream), and fluidized bed combustion units; and

(iii) While in operation, the unit must maintain a thermal energy recovery efficiency of at least 60 percent, calculated in terms of the recovered energy compared with the thermal value of the fuel; and

(iv) The unit must export and utilize at least 75 percent of the recovered energy, calculated on an annual basis. In this calculation, no credit shall be given for recovered heat used internally in the same unit. (Examples of internal use are the preheating of fuel or combustion air, and the driving of induced or forced draft fans or feedwater pumps); or

Explanatory comments in *{bracketed blue italics}*

(2) The unit is one which the Regional Administrator has determined, on a case-by-case basis, to be a boiler, after considering the standards in § 260.32.

Certification means a statement of professional opinion based upon knowledge and belief.

Confined aquifer means an aquifer bounded above and below by impermeable beds or by beds of distinctly lower permeability than that of the aquifer itself; an aquifer containing confined ground water.

Container means any portable device in which a material is stored, transported, treated, disposed of, or otherwise handled.

Containment building means a hazardous waste management unit that is used to store or treat hazardous waste under the provisions of subpart DD of parts 264 or 265 of this chapter.

Contingency plan means a document setting out an organized, planned, and coordinated course of action to be followed in case of a fire, explosion, or release of hazardous waste or hazardous waste constituents which could threaten human health or the environment.

Dike means an embankment or ridge of either natural or man-made materials used to prevent the movement of liquids, sludges, solids, or other materials.

Drip pad is an engineered structure consisting of a curbed, free-draining base, constructed of non-earthen materials and designed to convey preservative kick-back or drippage from treated wood, precipitation, and surface water run-on to an associated collection system at wood preserving plants.

Electronic manifest (or e-Manifest) means the electronic format of the hazardous waste manifest that is obtained from EPA's national e-Manifest system and transmitted electronically to the system, and that is the legal equivalent of EPA Forms 8700–22 (Manifest) and 8700–22A (Continuation Sheet).

Electronic Manifest System (or e-Manifest System) means EPA's national information technology system through which the electronic manifest may be obtained, completed, transmitted, and distributed to users of the electronic manifest and to regulatory agencies.

Explosives or munitions emergency means a situation involving the suspected or detected presence of unexploded ordnance (UXO), damaged or deteriorated explosives or munitions, an improvised explosive device (IED), other potentially explosive material or device, or other potentially harmful military chemical munitions or device, that creates an actual or potential imminent threat to human health, including safety, or the environment, including property, as determined by an explosives or munitions emergency response specialist. Such situations may require immediate and expeditious action by an explosives or munitions emergency response specialist to control, mitigate, or eliminate the threat.

Explosives or munitions emergency response means all immediate response activities by an explosives and munitions emergency response specialist to control, mitigate, or eliminate the actual or potential threat encountered during an explosives or munitions emergency. An explosives or munitions emergency response may include in place render-safe procedures, treatment or destruction of the explosives or munitions and/or transporting those items to another location to be rendered safe, treated, or destroyed. Any reasonable delay in the completion of an explosives or munitions emergency response caused by a necessary, unforeseen, or uncontrollable circumstance will not terminate the explosives or munitions emergency. Explosives and munitions emergency responses can occur on either public or private lands and are not limited to responses at RCRA facilities.

Explosives or munitions emergency response specialist means an individual trained in chemical or conventional munitions or explosives handling, transportation, render-safe procedures, or destruction techniques. Explosives or munitions emergency response specialists include Department of Defense (DOD) emergency explosive ordnance disposal (EOD), technical escort unit (TEU), and DOD-certified civilian or contractor personnel; and other Federal, State, or local government, or civilian personnel similarly trained in explosives or munitions emergency responses.

Free liquids means liquids which readily separate from the solid portion of a waste under ambient temperature and pressure.

Explanatory comments in *{bracketed blue italics}*

Ground water means water below the land surface in a zone of saturation.

Incompatible waste means a hazardous waste which is unsuitable for:

(1) Placement in a particular device or facility because it may cause corrosion or decay of containment materials (e.g., container inner liners or tank walls); or

(2) Commingling with another waste or material under uncontrolled conditions because the commingling might produce heat or pressure, fire or explosion, violent reaction, toxic dusts, mists, fumes, or gases, or flammable fumes or gases.

(See appendix V of parts 264 and 265 of this chapter for examples.)

Injection well means a well into which fluids are injected. (See also “underground injection”.)

Inner liner means a continuous layer of material placed inside a tank or container which protects the construction materials of the tank or container from the contained waste or reagents used to treat the waste.

International shipment means the transportation of hazardous waste into or out of the jurisdiction of the United States.

Lamp, also referred to as “universal waste lamp”, is defined as the bulb or tube portion of an electric lighting device. A lamp is specifically designed to produce radiant energy, most often in the ultraviolet, visible, and infra-red regions of the electromagnetic spectrum. Examples of common universal waste electric lamps include, but are not limited to, fluorescent, high intensity discharge, neon, mercury vapor, high pressure sodium, and metal halide lamps.

Land treatment facility means a facility or part of a facility at which hazardous waste is applied onto or incorporated into the soil surface; such facilities are disposal facilities if the waste will remain after closure.

Leachate means any liquid, including any suspended components in the liquid, that has percolated through or drained from hazardous waste.

Liner means a continuous layer of natural or man-made materials, beneath or on the sides of a surface impoundment, landfill, or landfill cell, which restricts the downward or lateral escape of hazardous waste, hazardous waste constituents, or leachate.

Military munitions means all ammunition products and components produced or used by or for the U.S. Department of Defense or the U.S. Armed Services for national defense and security, including military munitions under the control of the Department of Defense, the U.S. Coast Guard, the U.S. Department of Energy (DOE), and National Guard personnel. The term military munitions includes: confined gaseous, liquid, and solid propellants, explosives, pyrotechnics, chemical and riot control agents, smokes, and incendiaries used by DOD components, including bulk explosives and chemical warfare agents, chemical munitions, rockets, guided and ballistic missiles, bombs, warheads, mortar rounds, artillery ammunition, small arms ammunition, grenades, mines, torpedoes, depth charges, cluster munitions and dispensers, demolition charges, and devices and components thereof. Military munitions do not include wholly inert items, improvised explosive devices, and nuclear weapons, nuclear devices, and nuclear components thereof. However, the term does include non-nuclear components of nuclear devices, managed under DOE’s nuclear weapons program after all required sanitization operations under the Atomic Energy Act of 1954, as amended, have been completed.

Mining overburden returned to the mine site means any material overlying an economic mineral deposit which is removed to gain access to that deposit and is then used for reclamation of a surface mine.

On-site means the same or geographically contiguous property which may be divided by public or private right-of-way, provided the entrance and exit between the properties is at a cross-roads intersection, and access is by crossing as opposed to going along, the right-of-way. Non-contiguous properties owned by the same person but connected by a right-of-way which he controls and to which the public does not have access, is also considered on-site property.

Explanatory comments in *{bracketed blue italics}*

Pesticide means any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant, other than any article that:

- (1) Is a new animal drug under FFDCA section 201(w), or
- (2) Is an animal drug that has been determined by regulation of the Secretary of Health and Human Services not to be a new animal drug, or
- (3) Is an animal feed under FFDCA section 201(x) that bears or contains any substances described by paragraph (1) or (2) of this definition.

Pile means any non-containerized accumulation of solid, nonflowing hazardous waste that is used for treatment or storage and that is not a containment building.

Point source means any discernible, confined, and discrete conveyance, including, but not limited to any pipe, ditch, channel, tunnel, conduit, well, discrete fissure, container, rolling stock, concentrated animal feeding operation, or vessel or other floating craft, from which pollutants are or may be discharged. This term does not include return flows from irrigated agriculture.

Recognized trader means a person domiciled in the United States, by site of business, who acts to arrange and facilitate transboundary movements of wastes destined for recovery or disposal operations, either by purchasing from and subsequently selling to United States and foreign facilities, or by acting under arrangements with a United States waste facility to arrange for the export or import of the wastes.

Representative sample means a sample of a universe or whole (e.g., waste pile, lagoon, ground water) which can be expected to exhibit the average properties of the universe or whole.

Run-off means any rainwater, leachate, or other liquid that drains over land from any part of a facility.

Run-on means any rainwater, leachate, or other liquid that drains over land onto any part of a facility.

Sludge means any solid, semi-solid, or liquid waste generated from a municipal, commercial, or industrial wastewater treatment plant, water supply treatment plant, or air pollution control facility exclusive of the treated effluent from a wastewater treatment plant.

State means any of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Surface impoundment or *impoundment* means a facility or part of a facility which is a natural topographic depression, man-made excavation, or diked area formed primarily of earthen materials (although it may be lined with man-made materials), which is designed to hold an accumulation of liquid wastes or wastes containing free liquids, and which is not an injection well. Examples of surface impoundments are holding, storage, settling, and aeration pits, ponds, and lagoons.

Tank means a stationary device, designed to contain an accumulation of hazardous waste which is constructed primarily of non-earthen materials (e.g., wood, concrete, steel, plastic) which provide structural support.

Tank system means a hazardous waste storage or treatment tank and its associated ancillary equipment and containment system.

Totally enclosed treatment facility means a facility for the treatment of hazardous waste which is directly connected to an industrial production process and which is constructed and operated in a manner which prevents the release of any hazardous waste or any constituent thereof into the environment during treatment. An example is a pipe in which waste acid is neutralized.

Transport vehicle means a motor vehicle or rail car used for the transportation of cargo by any mode. Each cargo-carrying body (trailer, railroad freight car, etc.) is a separate transport vehicle.

Transportation means the movement of hazardous waste by air, rail, highway, or water.

Explanatory comments in *{bracketed blue italics}*

Treatability Study means a study in which a hazardous waste is subjected to a treatment process to determine: (1) Whether the waste is amenable to the treatment process, (2) what pretreatment (if any) is required, (3) the optimal process conditions needed to achieve the desired treatment, (4) the efficiency of a treatment process for a specific waste or wastes, or (5) the characteristics and volumes of residuals from a particular treatment process. Also included in this definition for the purpose of the § 261.4 (e) and (f) exemptions are liner compatibility, corrosion, and other material compatibility studies and toxicological and health effects studies. A “treatability study” is not a means to commercially treat or dispose of hazardous waste.

United States means the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Universal Waste Transporter means a person engaged in the off-site transportation of universal waste by air, rail, highway, or water.

Vessel includes every description of watercraft, used or capable of being used as a means of transportation on the water.

Wipe means a woven or non-woven shop towel, rag, pad, or swab made of wood pulp, fabric, cotton, polyester blends, or other material.

40 CFR 261.1(c)(3)

A “by-product” is a material that is not one of the primary products of a production process and is not solely or separately produced by the production process. Examples are process residues such as slags or distillation column bottoms. The term does not include a co-product that is produced for the general public’s use and is ordinarily used in the form it is produced by the process.

40 CFR 261.1(c)(6)

“Scrap metal” is bits and pieces of metal parts (e.g., bars, turnings, rods, sheets, wire) or metal pieces that may be combined together with bolts or soldering (e.g., radiators, scrap automobiles, railroad box cars), which when worn or superfluous can be recycled.

40 CFR 261.1(c)(9)

“Excluded scrap metal” is processed scrap metal, unprocessed home scrap metal, and unprocessed prompt scrap metal.

40 CFR 261.1(c)(10)

“Processed scrap metal” is scrap metal which has been manually or physically altered to either separate it into distinct materials to enhance economic value or to improve the handling of materials. Processed scrap metal includes, but is not limited to scrap metal which has been baled, shredded, sheared, chopped, crushed, flattened, cut, melted, or separated by metal type (i.e., sorted), and, fines, drosses and related materials which have been agglomerated. (Note: shredded circuit boards being sent for recycling are not considered processed scrap metal. They are covered under the exclusion from the definition of solid waste for shredded circuit boards being recycled (§ 261.4(a)(14)).

40 CFR 261.1(c)(11)

“Home scrap metal” is scrap metal as generated by steel mills, foundries, and refineries such as turnings, cuttings, punchings, and borings.

40 CFR 261.1(c)(12)

“Prompt scrap metal” is scrap metal as generated by the metal working/fabrication industries and includes such scrap metal as turnings, cuttings, punchings, and borings. Prompt scrap is also known as industrial or new scrap metal.

40 CFR 261.4(a)(1)(ii)

“Domestic Sewage” means untreated sanitary wastes that pass through a sewer system.

Explanatory comments in *{bracketed blue italics}*

40 CFR 262.81

EPA Acknowledgment of Consent (AOC) means the letter EPA sends to the exporter documenting the specific terms of the country of import's consent and the country(ies) of transit's consent(s). The AOC meets the definition of an export license in U.S. Census Bureau regulations 15 CFR 30.1.

Exporter, also known as primary exporter on the RCRA hazardous waste manifest, means the person domiciled in the United States who is required to originate the movement document in accordance with § 262.83(d) or the manifest for a shipment of hazardous waste in accordance with subpart B of this part, or equivalent State provision, which specifies a foreign receiving facility as the facility to which the hazardous wastes will be sent, or any recognized trader who proposes export of the hazardous wastes for recovery or disposal operations in the country of import.

Importer means the person to whom possession or other form of legal control of the hazardous waste is assigned at the time the imported hazardous waste is received in the United States.

40 CFR 266.500

Evaluated hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with § 266.510(a)(3) and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

Hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and exhibits one or more characteristics identified in part 261 subpart C or is listed in part 261 subpart D. A pharmaceutical is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it is legitimately used/reused (e.g., lawfully donated for its intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a solid waste, as defined in § 261.2, and therefore not a hazardous waste pharmaceutical, if it has a reasonable expectation of being legitimately used/reused (e.g., lawfully redistributed for its intended purpose) or reclaimed.

Healthcare facility means any person 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. This definition includes, but is not limited to, wholesale distributors, third-party logistics providers that serve as forward distributors, military medical logistics facilities, hospitals, psychiatric hospitals, ambulatory surgical centers, health clinics, physicians' offices, optical and dental providers, chiropractors, long-term care facilities, ambulance services, pharmacies, long-term care pharmacies, mail-order pharmacies, retailers of pharmaceuticals, veterinary clinics, and veterinary hospitals. This definition does not include pharmaceutical manufacturers, reverse distributors, or reverse logistics centers.

Long-term care facility means a licensed entity that provides assistance with activities of daily living, including managing and administering pharmaceuticals to one or more individuals at the facility. This definition includes, but is not limited to, hospice 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.

Non-creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that does not have a reasonable expectation to be eligible for manufacturer credit or a nonprescription hazardous waste pharmaceutical that does not have a reasonable expectation to be legitimately used/reused or reclaimed. This includes but is not limited to, investigational drugs, free samples of pharmaceuticals received by healthcare facilities, residues of pharmaceuticals remaining in empty

Explanatory comments in *{bracketed blue italics}*

containers, contaminated personal protective equipment, floor sweepings, and clean-up material from the spills of pharmaceuticals.

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). This definition 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; investigational new drugs; pharmaceuticals remaining in non-empty containers; personal protective equipment contaminated with pharmaceuticals; and clean-up material from spills of pharmaceuticals. This definition does not include dental amalgam or sharps.

Potentially creditable hazardous waste pharmaceutical means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is—

- (1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
- (2) Undispensed; and
- (3) Unexpired or less than one year past expiration date. The term does not include evaluated hazardous waste pharmaceuticals or nonprescription pharmaceuticals including, but not limited to, over-the-counter drugs, homeopathic drugs, and dietary supplements.

Reverse distributor means any person that receives and accumulates prescription pharmaceuticals that are potentially creditable hazardous waste pharmaceuticals for the purpose of facilitating or verifying manufacturer credit. Any person, including forward distributors, third-party logistics providers, and pharmaceutical manufacturers, that processes prescription pharmaceuticals for the facilitation or verification of manufacturer credit is considered a reverse distributor.

40 CFR 268.2(c)

Land disposal means placement in or on the land, except in a corrective action management unit or staging pile, and includes, but is not limited to, placement in a landfill, surface impoundment, waste pile, injection well, land treatment facility, salt dome formation, salt bed formation, underground mine or cave, or placement in a concrete vault, or bunker intended for disposal purposes.

40 CFR 270.2

Site means the land or water area where any facility or activity is physically located or conducted, including adjacent land used in connection with the facility or activity.

40 CFR 273.2(c)(2)

An unused battery becomes a waste on the date the handler decides to discard it.

40 CFR 273.3(c)(1)

A recalled pesticide described in paragraph (a)(1) of this section becomes a waste on the first date on which both of the following conditions apply:

- (i) The generator of the recalled pesticide agrees to participate in the recall; and
- (ii) The person conducting the recall decides to discard (e.g., burn the pesticide for energy recovery).

40 CFR 273.3(c)(2)

An unused pesticide product described in paragraph (a)(2) of this section becomes a waste on the date the generator decides to discard it.

40 CFR 273.4(c)(2)

Unused mercury-containing equipment becomes a waste on the date the handler decides to discard it.

40 CFR 273.5(c)(2)

An unused lamp becomes a waste on the date the handler decides to discard it.

Explanatory comments in *{bracketed blue italics}*

40 CFR 273.6(c)(2)

An unused aerosol can becomes a waste on the date the handler decides to discard it.

40 CFR 273.13(e)(4)(i)

Conduct puncturing and draining activities using a device specifically designed to safely puncture aerosol cans and effectively contain the residual contents and any emissions thereof.

40 CFR 273.33(c)(2)

A large quantity handler of universal waste may remove mercury-containing ampules from universal waste mercury-containing equipment provided the handler:

- (i) Removes and manages the ampules in a manner designed to prevent breakage of the ampules;
- (ii) Removes the ampules only over or in a containment device (*e.g.*, tray or pan sufficient to collect and contain any mercury released from an ampule in case of breakage);
- (iii) Ensures that a mercury clean-up system is readily available to immediately transfer any mercury resulting from spills or leaks of broken ampules from that containment device to a container that is subject to all applicable requirements of 40 CFR parts 260 through 272;
- (iv) Immediately transfers any mercury resulting from spills or leaks from broken ampules from the containment device to a container is subject to all applicable requirements of 40 CFR parts 260 through 272;
- (v) Ensures that the area in which ampules are removed is well ventilated and monitored to ensure compliance with applicable OSHA exposure levels for mercury;
- (vi) Ensures that employees removing ampules are thoroughly familiar with proper waste mercury handling and emergency procedures, including transfer of mercury from containment devices to appropriate containers;
- (vii) Stores removed ampules in closed, non-leaking containers that are in good condition;
- (viii) Packs removed ampules in the container with packing materials adequate to prevent breakage during storage, handling, and transportation;

APPENDIX E: EMERGENCY TELEPHONE NUMBERS

Organization	Telephone Number	Days/Hours
DES Emergency Response Team	(603) 271-3899	Monday through Friday; 8 a.m. to 4 p.m.
N.H. State Police Headquarters Communications Unit	(603) 223-4381	Every day; 24 hours per day