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GUIDEBOOK TO NEW HAMPSHIRE ADMINISTRATIVE RULES

CHAPTER Env-Hw 1300 – HAZARDOUS WASTE PHARMACEUTICALS

Effective July 23, 2022

This guidebook is provided to assist regulated entities and the public in understanding New Hampshire Administrative Rules Chapter Env-Hw 1300, which incorporates by reference portions of the Code of Federal Regulations (CFR). **This guidebook is intended to be used as a convenient aid to understanding the New Hampshire Administrative Rules pertaining to hazardous waste pharmaceuticals. The guidebook should not be considered a substitute for the actual text of the rules.** In the unlikely event of a conflict between this guidebook and Env-Hw 1300, the language and the application of the rule shall apply.

40 CFR Part 266, Subpart P (July 1, 2020, edition) is incorporated by reference in Env-Hw 1302.01 with amendments made in Env-Hw 1302.02; select amendments reference other sections of the New Hampshire Hazardous Waste Rules (subtitle Env-Hw). In addition, certain federal terms are substituted with New Hampshire terms as specified in Env-Hw 102.02. This document provides the text of 40 CFR Part 266, Subpart P (July 1, 2020, edition) with the amendments of Env-Hw 1302.02 and the substitutions of Env-Hw 102.02 shown using "track changes." Federal text that was changed is shown ~~struck through~~, and New Hampshire's revisions are shown underlined. Editorial changes or issues are noted in [brackets]. Footnotes provide additional information.

Please note that New Hampshire's "small quantity generator" category aligns with the federal "very small quantity generator" category, and revisions have been made throughout the rule text. See New Hampshire's definition of "small quantity generator" at Env-Hw 104.50 and further information on generator categories at Env-Hw 503.

All chapters of the New Hampshire Hazardous Waste Rules (Env-Hw 100-1300) are available at the Administrative Rules webpage. Questions and requests for accommodations with this file should be directed to the NHDES Hazardous Waste Management Bureau at (603) 271-2942, toll-free within New Hampshire at 866-HAZWAST (M-F 8 a.m.-4 p.m.), or via email at hwcomp@des.nh.gov.

PART 266 - STANDARDS FOR THE MANAGEMENT OF SPECIFIC HAZARDOUS WASTES AND SPECIFIC TYPES OF HAZARDOUS WASTE MANAGEMENT FACILITIES.

Subpart P—Hazardous Waste Pharmaceuticals

§ 266.500 Definitions for this subpart.

The following definitions apply to this subpart:

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.

~~*Household waste pharmaceutical* means a pharmaceutical that is a solid waste, as defined in § 261.2, but is excluded from being a hazardous waste under § 261.4(b)(1).~~

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).

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

Non-hazardous waste pharmaceutical means a pharmaceutical that is a solid waste, as defined in § 261.2, and is not listed in 40 CFR part 261 subpart D, and does not exhibit a characteristic identified in 40 CFR part 261 subpart C.

~~*Non-pharmaceutical hazardous waste* means a solid waste, as defined in § 261.2, that is listed in 40 CFR part 261 subpart D, or exhibits one or more characteristics identified in 40 CFR part 261 subpart C, but is not a pharmaceutical, as defined in this section.~~

Non-pharmaceutical hazardous waste means a hazardous waste that is not a pharmaceutical.

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.

§ 266.501 Applicability.

~~(a) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, including both its hazardous waste pharmaceuticals and its non-pharmaceutical hazardous waste, remains subject to § 262.14 and is *not* subject to this subpart, except for §§ 266.505 and 266.507 and the optional provisions of § 266.504.~~

~~(b) A healthcare facility that is a very small quantity generator when counting all of its hazardous waste, 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 § 262.14 and the optional provisions of § 266.504.~~

(a) A healthcare facility that is a small quantity generator[1] 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.

(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.

[1] Env-Hw 1300 amended all instances of "very small quantity generator" in 40 CFR 266 Subpart P to read "small quantity generator," which is the name of New Hampshire's equivalent generator category. See New Hampshire's definition of "small quantity generator" at Env-Hw 104.50 and further information on generator categories at Env-Hw 503.

(c) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of its non-pharmaceutical hazardous waste.

(d) With the exception of healthcare facilities identified in paragraph (a) of this section, a healthcare facility is subject to the following in lieu of ~~parts 262 through 265~~ Env-Hw 500 through Env-Hw 700:

(1) Sections 266.502 and 266.505 through 266.508 of this subpart with respect to the management of:

(i) Non-creditable hazardous waste pharmaceuticals, and

(ii) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.

(2) Sections 262.502(a), 266.503, 266.505 through 266.507, and 266.509 of this subpart with respect to the management of potentially creditable hazardous waste pharmaceuticals that are prescription pharmaceuticals and are destined for a reverse distributor.

(e) A reverse distributor is subject to §§ 266.505 through 266.510 of this subpart in lieu of ~~parts 262 through 265~~ Env-Hw 500 through Env-Hw 700 with respect to the management of hazardous waste pharmaceuticals.

(f) Hazardous waste pharmaceuticals generated or managed by entities other than healthcare facilities and reverse distributors (*e.g.,* pharmaceutical manufacturers and reverse logistics centers) are not subject to this subpart. Other generators are subject to ~~40 CFR part 262~~ Env-Hw 500 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.

(g) The following are not subject to ~~40 CFR parts 260 through 273~~ the hazardous waste rules[2], except as specified:

(1) Pharmaceuticals that are not solid waste, as defined by § 261.2, because they are legitimately used/reused (*e.g.,* lawfully donated for their intended purpose) or reclaimed.

(2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not solid wastes, as defined by § 261.2, because they have a reasonable expectation of being legitimately used/reused (*e.g.,* lawfully redistributed for their intended purpose) or reclaimed.

(3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the Food and Drug Administration in accordance with 21 CFR part 7 subpart C. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Food and Drug Administration approves the destruction of the recalled items.

(4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the Consumer Product Safety Commission in accordance with 16 CFR part 1115. This subpart does apply to the management of the recalled hazardous waste pharmaceuticals after the Consumer Product Safety Commission approves the destruction of the recalled items.

(5) Pharmaceuticals stored according to a preservation order, or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded and/or a decision is made to discard the pharmaceuticals.

(6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the Food and Drug Administration's regulations in 21 CFR part 312. This subpart does apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the Food and Drug Administration approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

[2] "Hazardous waste rules" are defined in Env-Hw 103.68 to mean "the rules in subtitle Env-Hw."

(7) Household waste pharmaceuticals, including those that have been collected by an authorized collector (as defined by the Drug Enforcement Administration), provided the authorized collector complies with the conditional exemption in §§ 266.506(a)(2) and 266.506(b).

§ 266.502 Standards for healthcare facilities managing non-creditable hazardous waste pharmaceuticals.

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

~~(1) *Notification.* A healthcare facility must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each site or EPA identification number.~~

~~(i) A healthcare facility that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, 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 must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a healthcare facility as part of its next Biennial Report, if it is required to submit one; or if not required to submit a Biennial Report, within 60 days of the effective date of this subpart, or within 60 days of becoming subject to this subpart.~~

~~(iii) A healthcare facility must 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 very small quantity generator under § 262.14, and elects to withdraw from this subpart, must notify the appropriate EPA Regional Administrator using the Site Identification Form (EPA Form 8700-12) that it is no longer operating under this subpart. A healthcare facility is not required to fill out Box 10.B. (Waste Codes for Federally Regulated Hazardous Waste) of the Site Identification Form with respect to its hazardous waste pharmaceuticals. A healthcare facility must submit a separate notification (Site Identification Form) for each EPA identification number.~~

~~(i) A healthcare facility must submit the Site Identification Form notifying that it is withdrawing from this subpart before it begins operating under the conditional exemption of § 262.14.~~

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

(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.

(b) *Training of personnel managing non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must ensure that all personnel that manage non-creditable hazardous waste pharmaceuticals are thoroughly familiar with proper waste handling and emergency procedures relevant to their responsibilities during normal facility operations and emergencies.

(c) *Hazardous waste determination for non-creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a non-creditable pharmaceutical must determine whether that pharmaceutical is a hazardous waste pharmaceutical (*i.e.,* it exhibits a characteristic identified in 40 CFR part 261 subpart C or is listed in 40 CFR part 261 subpart D) in order to determine whether the waste is subject to this subpart. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subpart.

(d) *Standards for containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.*

(1) A healthcare facility must place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with its contents, and that lacks evidence of leakage, spillage, or damage that could cause leakage under reasonably foreseeable conditions.

(2) A healthcare facility that manages ignitable or reactive non-creditable hazardous waste pharmaceuticals, or that mixes or commingles incompatible non-creditable hazardous waste pharmaceuticals must manage the container so that it does not have the potential to:

(i) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(ii) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(iii) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(iv) Damage the structural integrity of the container of non-creditable hazardous waste pharmaceuticals; or

(v) Through other like means threaten human health or the environment.

(3) A healthcare facility must keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to its contents.

(4) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals and non-hazardous non-creditable waste pharmaceuticals in the same container, except that non-creditable hazardous waste pharmaceuticals prohibited from being combusted because of the dilution prohibition of § 268.3(c) must be accumulated in separate containers and labeled with all applicable hazardous waste numbers (*i.e.,* hazardous waste codes).

(e) *Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must label or clearly mark each container of non-creditable hazardous waste pharmaceuticals with the phrase "Hazardous Waste Pharmaceuticals."

(f) *Maximum accumulation time for non-creditable hazardous waste pharmaceuticals at healthcare facilities.*

(1) A healthcare facility may accumulate non-creditable hazardous waste pharmaceuticals on site for one year or less without a permit or having interim status.

(2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site must demonstrate the length of time that the non-creditable hazardous waste pharmaceuticals have been accumulating, starting from the date it first becomes a waste. A healthcare facility may make this demonstration by any of the following methods:

(i) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;

(ii) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;

(iii) Placing the non-creditable hazardous waste pharmaceuticals in a specific area and identifying the earliest date that any of the non-creditable hazardous waste pharmaceuticals in the area became a waste.

(g) *Land disposal restrictions for non-creditable hazardous waste pharmaceuticals.* The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of 40 CFR part 268, incorporated by reference in Env-Hw 1202. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with § 268.7(a) requirements, except that it is not required to identify the hazardous waste numbers (*i.e.,* hazardous waste codes) on the land disposal restrictions notification.

(h) *Procedures for healthcare facilities for managing rejected shipments of non-creditable hazardous waste pharmaceuticals.* A healthcare facility that sends a shipment of non-creditable hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter may accumulate the returned non-creditable hazardous waste pharmaceuticals on site for up to an additional 90 days provided the rejected or returned shipment is managed in accordance with paragraphs (d) and (e) of this section. Upon receipt of the returned shipment, the healthcare facility must:

(1) Sign either:

(i) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(ii) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(2) Provide the transporter a copy of the manifest;

(3) Within 30 days of receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility; [~~and~~]

(4) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of § 266.508(a)[~~.~~; and]

(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.

(i) *Reporting by healthcare facilities for non-creditable hazardous waste pharmaceuticals —*

(1) *Biennial reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41, with respect to non-creditable hazardous waste pharmaceuticals managed under this subpart.

(2) *Exception reporting by healthcare facilities for a missing copy of the manifest —*

(i) *For shipments from a healthcare facility to a designated facility.*

(A) If a healthcare facility does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 60 days of the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the ~~EPA Regional Administrator~~ commissioner, or designee[~~,~~] [for the Region in which the healthcare facility is located][3]; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(ii) *For shipments rejected by the designated facility and shipped to an alternate facility.*

(A) If a healthcare facility does not receive a copy of the manifest for a rejected shipment of the non-creditable hazardous waste pharmaceuticals that is forwarded by the designated facility to an alternate facility (using appropriate manifest procedures), with the signature of the owner or operator of the alternate facility, within 60 days of the date the non-creditable hazardous waste was accepted by the initial transporter forwarding the shipment of non-creditable hazardous waste pharmaceuticals from the designated facility to the alternate facility, the healthcare facility must submit:

(*1*) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the ~~EPA Regional Administrator~~ commissioner, or designee[~~,~~] [for the Region in which the healthcare facility is located][4]; and

(*2*) A handwritten or typed note on the manifest itself, or on an attached sheet of paper, stating that the return copy was not received and explaining the efforts taken to locate the non-creditable hazardous waste pharmaceuticals and the results of those efforts.

(B) [Reserved]

(3) *Additional reports.* The ~~EPA Regional Administrator~~ commissioner, or designee, may require healthcare facilities to furnish additional reports concerning the quantities and disposition of non-creditable hazardous waste pharmaceuticals.

(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.

(j) *Recordkeeping by healthcare facilities for non-creditable hazardous waste pharmaceuticals.*

~~(1) A healthcare facility must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility which received the non-creditable~~

[3] Healthcare facilities in New Hampshire must submit documentation to NHDES instead of EPA Region 1.
[4] Healthcare facilities in New Hampshire must submit documentation to NHDES instead of EPA Region 1.

~~hazardous waste pharmaceuticals. This signed copy must be retained as a record for at least three years from the date the waste was accepted by the initial transporter.~~

(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- Adopted to be effective 07-23-22 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.

(2) A healthcare facility must keep a copy of each exception report for a period of at least three years from the date of the report.

(3) A healthcare facility must keep records of any test results, waste analyses, or other determinations made to support its hazardous waste determination(s) consistent with ~~§ 262.11(f)~~ Env-Hw 502.01, for at least three years from the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of its non-creditable non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals is not required to keep documentation of hazardous waste determinations.

(4) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the ~~EPA Regional Administrator~~ commissioner, or designee[~~,~~].

(5) All records must be readily available upon request by an inspector.

(k) *Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of non-creditable hazardous waste pharmaceuticals and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with the requirements of this subpart.

(l) *Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a ~~very small quantity generator~~ small quantity generator.* A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a ~~very small quantity generator under § 262.14~~ small quantity generator under Env-Hw 500, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person ~~(as defined in § 260.10)~~ (as defined in Env-Hw 104) as the ~~very small quantity generator~~ small quantity generator healthcare facility that is sending the non-creditable hazardous waste pharmaceuticals off-site ("control," for the purposes of this section, means the power to direct the policies of the healthcare facility, whether by the ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person as defined in ~~§ 260.10 of this chapter~~ Env-Hw 104 shall not be deemed to "control" such healthcare facilities) or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the ~~very small quantity generator~~ small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the non-creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.

(a) *Hazardous waste determination for potentially creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.*e.,* it is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(b) *Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a ~~very small quantity generator~~ small quantity generator.* A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a ~~very small quantity generator under § 262.14~~ small quantity generator under Env-Hw 500, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in ~~§ 260.10~~ Env-Hw 104, as the ~~very small quantity generator~~ small quantity generator healthcare facility that is sending the potentially creditable hazardous waste pharmaceuticals off site, or has a contractual or other documented business relationship whereby the receiving healthcare facility supplies pharmaceuticals to the ~~very small quantity generator~~ small quantity generator healthcare facility;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from the date that the shipment is received.

(c) *Prohibition.* Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(d) *Biennial Reporting by healthcare facilities.* Healthcare facilities are not subject to biennial reporting requirements under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) *Recordkeeping by healthcare facilities.*

(1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and

(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the ~~EPA Regional Administrator~~ commissioner, or designee[~~,~~].

(3) All records must be readily available upon request by an inspector.

(f) *Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals

and manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

§ 266.504 Healthcare facilities that are ~~very small quantity generators~~ small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a ~~very small quantity generator~~ small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a ~~very small quantity generator~~ small quantity generator.* A healthcare facility that is a ~~very small quantity generator~~ small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in § 266.502(l) of this subpart and § 266.503(b), as applicable; or

~~(2) The very small quantity generator healthcare facility meets the conditions in § 262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in § 262.17(f).~~

(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).

(c) *Long-term care facilities that are ~~very small quantity generators~~ small quantity generators.* A long-term care facility that is a ~~very small quantity generator~~ small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

~~(d) *Long-term care facilities with 20 beds or fewer.* A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to § 262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and *not* subject to this subpart, except for §§ 266.505 and 266.507 and the other optional provisions of this section. The EPA Regional Administrator has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in § 260.10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under § 262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by § 260.10.~~

(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).

§ 266.505 Prohibition of sewering hazardous waste pharmaceuticals.

All healthcare facilities—including ~~very small quantity generators operating under § 262.14~~ small quantity generators operating under Env-Hw 500 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

§ 266.506 Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.

(a) *Conditional exemptions.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from ~~40 CFR parts 262 through 273~~ Env-Hw 300 and Env-Hw 500 through Env-Hw 1300:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug Enforcement Administration that commingles the household waste pharmaceuticals with controlled substances from an ultimate user (as defined by the Drug Enforcement Administration).

(b) *Conditions for exemption.* The hazardous waste pharmaceuticals must be:

(1) Managed in compliance with the sewer prohibition of § 266.505; and

(2) Collected, stored, transported, and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances; and

(3) Destroyed by a method that Drug Enforcement Administration has publicly deemed in writing to meet their non-retrievable standard of destruction or combusted at one of the following:

(i) A permitted large municipal waste combustor, subject to 40 CFR part 62 subpart FFF or applicable state plan for existing large municipal waste combustors, or 40 CFR part 60 subparts Eb for new large municipal waste combustors; or

(ii) A permitted small municipal waste combustor, subject to 40 CFR part 62 subpart JJJ or applicable state plan for existing small municipal waste combustors, or 40 CFR part 60 subparts AAAA for new small municipal waste combustors; or

(iii) A permitted hospital, medical and infectious waste incinerator, subject to 40 CFR part 62 subpart HHH or applicable state plan for existing hospital, medical and infectious waste incinerators, or 40 CFR part 60 subpart Ec for new hospital, medical and infectious waste incinerators.

(iv) A permitted commercial and industrial solid waste incinerator, subject to 40 CFR part 62 subpart III or applicable state plan for existing commercial and industrial solid waste incinerators, or 40 CFR part 60 subpart CCCC for new commercial and industrial solid waste incinerators.

(v) A permitted hazardous waste combustor subject to 40 CFR part 63 subpart EEE.

§ 266.507 Residues of hazardous waste pharmaceuticals in empty containers.

(a) *Stock, dispensing and unit-dose containers.* A stock bottle, dispensing bottle, vial, or ampule (not to 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 are not regulated as hazardous waste provided the pharmaceuticals have been removed from the stock bottle, dispensing bottle, vial, ampule, or the unit-dose container using the practices commonly employed to remove materials from that type of container.

(b) *Syringes.* A syringe is considered empty and the residues are not regulated as hazardous waste under this subpart provided the contents have been removed by fully depressing the plunger of the syringe. If a syringe is not empty, the syringe must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart and any applicable federal, state, and local requirements for sharps containers and medical waste.

(c) *Intravenous (IV) bags.* An IV bag is considered empty and the residues are not regulated as hazardous waste provided the pharmaceuticals in the IV bag have been fully administered to a patient. If an IV bag is not empty, the IV bag must be placed with its remaining hazardous waste pharmaceuticals into a container that is managed and disposed of as a non-creditable hazardous waste pharmaceutical under this subpart, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as ~~defined in § 261.7(b)(1)~~ specified in Env-Hw 401.03(d)(1).

(d) *Other containers, including delivery devices.* Hazardous waste pharmaceuticals remaining in all other types of unused, partially administered, or fully administered containers must be managed as non-creditable hazardous waste pharmaceuticals under this subpart, unless the container held non-acute hazardous waste pharmaceuticals

and is empty as ~~defined in § 261.7(b)(1) or (2)~~ specified in Env-Hw 401.03(d)(1) or (2), as applicable. This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§ 266.508 Shipping non-creditable hazardous waste pharmaceuticals from a healthcare facility or evaluated hazardous waste pharmaceuticals from a reverse distributor.

(a) *Shipping non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility must ship non-creditable hazardous waste pharmaceuticals and a reverse distributor must ship evaluated hazardous waste pharmaceuticals off-site to a designated facility (such as a permitted or interim status treatment, storage, or disposal facility) in compliance with:

(1) The following pre-transport requirements, before transporting or offering for transport off-site:

(i) *Packaging.* Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR parts 173, 178, and 180.

(ii) *Labeling.* Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under 49 CFR part 172 subpart E.

(iii) *Marking.*

(A) Mark each package of hazardous waste pharmaceuticals in accordance with the applicable Department of Transportation (DOT) regulations on hazardous materials under 49 CFR part 172 subpart D;

(B) Mark each container of 119 gallons or less used in such transportation with the following words and information in accordance with the requirements of 49 CFR 172.304:

HAZARDOUS WASTE—Federal Law Prohibits Improper Disposal. If found, contact the nearest police or public safety authority or the U.S. Environmental Protection Agency.

Healthcare Facility's or Reverse Distributor's Name and Address _____

Healthcare Facility's or Reverse Distributor's EPA Identification Number _____

Manifest Tracking Number _____

(C) Lab packs that will be incinerated in compliance with § 268.42(c) are not required to be marked with EPA Hazardous Waste Number(s), except D004, D005, D006, D007, D008, D010, and D011, where applicable. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(iv) *Placarding.* Placard or offer the initial transporter the appropriate placards according to Department of Transportation regulations for hazardous materials under 49 CFR part 172 subpart F.

(2) The manifest requirements of ~~40 CFR part 262 subpart B~~ Env-Hw 510, Env-Hw 511.02, and Env-Hw 512.01(a)(1) and (d) through (f), except that:

(i) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste numbers (i.*e.,* hazardous waste codes) in Item 13 of ~~EPA Form 8700-22~~ the manifest.

(ii) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must ~~write the word "PHARMS" in Item 13 of EPA Form 8700-22~~ write the word "PHARMS" or "PHRM" in item 13 of the manifest.

(b) *Exporting non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that exports non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H.

(c) *Importing non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals.* Any person that imports non-creditable hazardous waste pharmaceuticals or evaluated

hazardous waste pharmaceuticals is subject to 40 CFR part 262 subpart H. A healthcare facility or reverse distributor may not accept imported non-creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals unless they have a permit or interim status that allows them to accept hazardous waste from off site.

§ 266.509 Shipping potentially creditable hazardous waste pharmaceuticals from a healthcare facility or a reverse distributor to a reverse distributor.

(a) *Shipping potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or a reverse distributor who transports or offers for transport potentially creditable hazardous waste pharmaceuticals off-site to a reverse distributor must comply with all applicable U.S. Department of Transportation regulations in 49 CFR part 171 through 180 for any potentially creditable hazardous waste pharmaceutical that meets the definition of hazardous material in 49 CFR 171.8. For purposes of the Department of Transportation regulations, a material is considered a hazardous waste if it is subject to the Hazardous Waste Manifest Requirements of the U.S. Environmental Protection Agency specified in 40 CFR part 262. Because a potentially creditable hazardous waste pharmaceutical does not require a manifest, it is not considered hazardous waste under the Department of Transportation regulations.

(b) *Delivery confirmation.* Upon receipt of each shipment of potentially creditable hazardous waste pharmaceuticals, the receiving reverse distributor must provide confirmation (paper or electronic) to the healthcare facility or reverse distributor that initiated the shipment that the shipment of potentially creditable hazardous waste pharmaceuticals has arrived at its destination and is under the custody and control of the reverse distributor.

(c) *Procedures for when delivery confirmation is not received within 35 calendar days.* If a healthcare facility or reverse distributor initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor and does not receive delivery confirmation within 35 calendar days from the date that the shipment of potentially creditable hazardous waste pharmaceuticals was sent, the healthcare facility or reverse distributor that initiated the shipment must contact the carrier and the intended recipient (i.*e.,* the reverse distributor) promptly to report that the delivery confirmation was not received and to determine the status of the potentially creditable hazardous waste pharmaceuticals.

(d) *Exporting potentially creditable hazardous waste pharmaceuticals.* A healthcare facility or reverse distributor that sends potentially creditable hazardous waste pharmaceuticals to a foreign destination must comply with the applicable sections of 40 CFR part 262 subpart H, except the manifesting requirement of § 262.83(c), in addition to paragraphs (a) through (c) of this section.

(e) *Importing potentially creditable hazardous waste pharmaceuticals.* Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to paragraphs (a) through (c) of this section in lieu of 40 CFR part 262 subpart H. Immediately after the potentially creditable hazardous waste pharmaceuticals enter the United States, they are subject to all applicable requirements of this subpart.

§ 266.510 Standards for the management of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals at reverse distributors.

A reverse distributor may accept potentially creditable hazardous waste pharmaceuticals from off site and accumulate potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals on site without a hazardous waste permit or without having interim status, provided that it complies with the following conditions:

(a) *Standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals —*

~~(1) *Notification.* A reverse distributor must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), that it is a reverse distributor operating under this subpart.~~

~~(i) A reverse distributor that already has an EPA identification number must notify the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), 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 must obtain one by notifying the EPA Regional Administrator, using the Site Identification Form (EPA Form 8700-12), 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.~~

(1) *Notification*. A reverse distributor shall notify the department that it is a reverse distributer 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.

(2) *Inventory by the reverse distributor.* A reverse distributor must maintain a current inventory of all the potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals that are accumulated on site.

(i) A reverse distributor must inventory each potentially creditable hazardous waste pharmaceutical within 30 calendar days of each waste arriving at the reverse distributor.

(ii) The inventory must include the identity (e.*g.,* name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.

(iii) If the reverse distributor already meets the inventory requirements of this paragraph because of other regulatory requirements, such as State Board of Pharmacy regulations, the facility is not required to provide a separate inventory pursuant to this section.

(3) *Evaluation by a reverse distributor that is not a manufacturer.* A reverse distributor that is not a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical within 30 calendar days of the waste arriving at the reverse distributor to establish whether it is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim status treatment, storage, or disposal facility.

(i) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and must be managed in accordance with paragraph (b) of this section.

(ii) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim status treatment, storage or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and must be managed in accordance with paragraph (c) of this section.

(4) *Evaluation by a reverse distributor that is a manufacturer.* A reverse distributor that is a pharmaceutical manufacturer must evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within 30 calendar days of the waste arriving at the facility and following the evaluation must manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (c) of this section.

(5) *Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.*

(i) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on site for 180 calendar days or less. The 180 days start after the potentially creditable hazardous waste pharmaceutical has been evaluated and applies to all hazardous waste pharmaceuticals accumulated on site, regardless of whether they are destined for another reverse

distributor (i.*e.,* potentially creditable hazardous waste pharmaceuticals) or a permitted or interim status treatment, storage, or disposal facility (i.*e.,* evaluated hazardous waste pharmaceuticals).

(ii) *Aging pharmaceuticals.* Unexpired pharmaceuticals that are otherwise creditable but are awaiting their expiration date (i.*e.,* aging in a holding morgue) can be accumulated for up to 180 days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (a) of this section and the container labeling and management standards in 266.510(c)(4)(i) through (vi).

(6) *Security at the reverse distributor facility.* A reverse distributor must prevent unknowing entry and minimize the possibility for the unauthorized entry into the portion of the facility where potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals are kept.

(i) Examples of methods that may be used to prevent unknowing entry and minimize the possibility for unauthorized entry include, but are not limited to:

(A) A 24-hour continuous monitoring surveillance system;

(B) An artificial barrier such as a fence; or

(C) A means to control entry, such as keycard access.

(ii) If the reverse distributor already meets the security requirements of this paragraph because of other regulatory requirements, such as Drug Enforcement Administration or State Board of Pharmacy regulations, the facility is not required to provide separate security measures pursuant to this section.

(7) *Contingency plan and emergency procedures at a reverse distributor.* A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must prepare a contingency plan and comply with the other requirements of ~~40 CFR part 262 subpart M~~ Env-Hw 509.02(a)(4) and (a)(5).

(8) *Closure of a reverse distributor.* When closing an area where a reverse distributor accumulates potentially creditable hazardous waste pharmaceuticals or evaluated hazardous waste pharmaceuticals, the reverse distributor must comply with ~~§ 262.17(a)(8)(ii) and (iii)~~ Env-Hw 505.04 and Env-Hw 506.

(9) *Reporting by a reverse distributor —*

(i) *Unauthorized waste report.* A reverse distributor must submit an unauthorized waste report if the reverse distributor receives waste from off site that it is not authorized to receive (e.*g.,* non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor must prepare and submit an unauthorized waste report to the ~~EPA Regional Administrator~~ commissioner, or designee, within 45 calendar days after the unauthorized waste arrives at the reverse distributor and must send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor must manage the unauthorized waste in accordance with all applicable regulations. The unauthorized waste report must be signed by the owner or operator of the reverse distributor, or its authorized representative, and contain the following information:

(A) The EPA identification number, name and address of the reverse distributor;

(B) The date the reverse distributor received the unauthorized waste;

(C) The EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available;

(D) A description and the quantity of each unauthorized waste the reverse distributor received;

(E) The method of treatment, storage, or disposal for each unauthorized waste; and

(F) A brief explanation of why the waste was unauthorized, if known.

(ii) *Additional reports.* The ~~EPA Regional Administrator~~ commissioner, or designee, may require reverse distributors to furnish additional reports concerning the quantities and disposition of potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(10) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the ~~EPA Regional Administrator~~ commissioner, or designee[~~,~~].

(i) A copy of its notification on file for as long as the facility is subject to this subpart;

(ii) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that it receives, and a copy of each unauthorized waste report, for at least three years from the date the shipment arrives at the reverse distributor;

(iii) A copy of its current inventory for as long as the facility is subject to this subpart.

(b) *Additional standards for reverse distributors managing potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements in paragraph (a) of this section, for the management of potentially creditable hazardous waste pharmaceuticals that are destined for another reverse distributor for further evaluation or verification of manufacturer credit:

(1) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from a healthcare facility must send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor must send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within 180 days after the potentially creditable hazardous waste pharmaceuticals have been evaluated or follow paragraph (c) of this section for evaluated hazardous waste pharmaceuticals.

(3) A reverse distributor must ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with § 266.509.

(4) *Recordkeeping by reverse distributors.* A reverse distributor must keep the following records (paper or electronic) readily available upon request by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that it initiates to another reverse distributor, for at least three years from the date of shipment. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the ~~EPA Regional Administrator~~ commissioner, or designee[~~,~~].

(i) The confirmation of delivery; and

(ii) The DOT shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable

(c) *Additional standards for reverse distributors managing evaluated hazardous waste pharmaceuticals.* A reverse distributor that does not have a permit or interim status must comply with the following conditions, in addition to the requirements of paragraph (a) of this section, for the management of evaluated hazardous waste pharmaceuticals:

(1) *Accumulation area at the reverse distributor.* A reverse distributor must designate an on-site accumulation area where it will accumulate evaluated hazardous waste pharmaceuticals.

(2) *Inspections of on-site accumulation area.* A reverse distributor must inspect its on-site accumulation area at least once every seven days, looking at containers for leaks and for deterioration caused by corrosion or other factors, as well as for signs of diversion.

(3) *Personnel training at a reverse distributor.* Personnel at a reverse distributor that handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of ~~§ 262.17(a)(7)~~ Env-Hw 509.02(a)(2).

(4) *Labeling and management of containers at on-site accumulation areas.* A reverse distributor accumulating evaluated hazardous waste pharmaceuticals in containers in an on-site accumulation area must:

(i) Label the containers with the words, "hazardous waste pharmaceuticals";

(ii) Ensure the containers are in good condition and managed to prevent leaks;

(iii) Use containers that are made of or lined with materials which will not react with, and are otherwise compatible with, the evaluated hazardous waste pharmaceuticals, so that the ability of the container to contain the waste is not impaired;

(iv) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in their original, intact, sealed packaging; or repackaged, intact, sealed packaging, they are considered to meet the closed container standard;

(v) Manage any container of ignitable or reactive evaluated hazardous waste pharmaceuticals, or any container of commingled incompatible evaluated hazardous waste pharmaceuticals so that the container does not have the potential to:

(A) Generate extreme heat or pressure, fire or explosion, or violent reaction;

(B) Produce uncontrolled toxic mists, fumes, dusts, or gases in sufficient quantities to threaten human health;

(C) Produce uncontrolled flammable fumes or gases in sufficient quantities to pose a risk of fire or explosions;

(D) Damage the structural integrity of the container of hazardous waste pharmaceuticals; or

(E) Through other like means threaten human health or the environment; and

(vi) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of § 268.3(c) (e.*g.,* arsenic trioxide (P012)) in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.

(5) *Hazardous waste numbers.* Prior to shipping evaluated hazardous waste pharmaceuticals off site, all containers must be marked with the applicable hazardous waste numbers (i.*e.,* hazardous waste codes). A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA Hazardous Waste Number(s).

(6) *Shipments.* A reverse distributor must ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim status treatment, storage or disposal facility in accordance with the applicable shipping standards in § 266.508(a) or (b).

(7) *Procedures for a reverse distributor for managing rejected shipments.* A reverse distributor that sends a shipment of evaluated hazardous waste pharmaceuticals to a designated facility with the understanding that the designated facility can accept and manage the waste, and later receives that shipment back as a rejected load in accordance with the manifest discrepancy provisions of § 264.72 or § 265.72 of this chapter, may accumulate the returned evaluated hazardous waste pharmaceuticals on site for up to an additional 90 days in the on-site accumulation area provided the rejected or returned shipment is managed in accordance with § 266.510(a) and (c). Upon receipt of the returned shipment, the reverse distributor must:

(i) Sign either:

(A) Item 18c of the original manifest, if the original manifest was used for the returned shipment; or

(B) Item 20 of the new manifest, if a new manifest was used for the returned shipment;

(ii) Provide the transporter a copy of the manifest;

(iii) Within 30 days of receipt of the rejected shipment of the evaluated hazardous waste pharmaceuticals, send a copy of the manifest to the designated facility that returned the shipment to the reverse distributor; [~~and~~]

(iv) Within 90 days of receipt of the rejected shipment, transport or offer for transport the returned shipment of evaluated hazardous waste pharmaceuticals in accordance with the applicable shipping standards of § 266.508(a) or (b)[~~.~~; and]

(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.

(8) *Land disposal restrictions.* Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of 40 CFR part 268, incorporated by reference in Env-Hw 1202. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off site must comply with the land disposal restrictions in accordance with § 268.7(a) requirements.

(9) *Reporting by a reverse distributor for evaluated hazardous waste pharmaceuticals —*

(i) *Biennial reporting by a reverse distributor.* A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site must prepare and submit a single copy of a biennial report to the ~~EPA Regional Administrator~~ commissioner, or designee, by March 1 of each even numbered year in accordance with § 262.41.

(ii) *Exception reporting by a reverse distributor for a missing copy of the manifest.*

(A) *For shipments from a reverse distributor to a designated facility.*

(*1*) If a reverse distributor does not receive a copy of the manifest with the signature of the owner or operator of the designated facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor must contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(*2*) A reverse distributor must submit an exception report to the ~~EPA Regional Administrator~~ commissioner, or designee, [for the Region in which the reverse distributor is located][5] if it has not received a copy of the manifest with the signature of the owner or operator of the designated facility within 45 days of the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report must include:

(*i*) A legible copy of the manifest for which the reverse distributor does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(B) *For shipments rejected by the designated facility and shipped to an alternate facility.*

(*1*) A reverse distributor that does not receive a copy of the manifest with the signature of the owner or operator of the alternate facility within 35 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter must contact the transporter or the owner or operator of the alternate facility to determine the status of the hazardous waste. The 35-day time frame begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste shipment from the designated facility to the alternate facility.

[5] Reverse distributors in New Hampshire must submit documentation to NHDES instead of EPA Region 1.

(*2*) A reverse distributor must submit an Exception Report to the ~~EPA Regional Administrator~~ commissioner, or designee, [for the Region in which the reverse distributor is located][6] if it has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within 45 days of the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The 45-day timeframe begins the date the evaluated hazardous waste pharmaceuticals are accepted by the transporter forwarding the hazardous waste pharmaceutical shipment from the designated facility to the alternate facility. The Exception Report must include:

(*i*) A legible copy of the manifest for which the generator does not have confirmation of delivery; and

(*ii*) A cover letter signed by the reverse distributor, or its authorized representative, explaining the efforts taken to locate the evaluated hazardous waste pharmaceuticals and the results of those efforts.

(iii) A reverse distributor shall be subject to the quarterly reporting requirements of Env-Hw 512.02 with respect to evaluated hazardous waste pharmaceuticals.

(10) *Recordkeeping by a reverse distributor for evaluated hazardous waste pharmaceuticals.*

(i) A reverse distributor must keep a log (written or electronic) of the inspections of the on-site accumulation area, required by paragraph (c)(2) of this section. This log must be retained as a record for at least three years from the date of the inspection.

~~(ii) A reverse distributor must keep a copy of each manifest signed in accordance with § 262.23(a) for three years or until it receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy must be retained as a record for at least three years from the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.~~

(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.

(iii) A reverse distributor must keep a copy of each biennial report for at least three years from the due date of the report.

(iv) A reverse distributor must keep a copy of each exception report for at least three years from the submission of the report.

(v) A reverse distributor must keep records to document personnel training, in accordance with ~~§ 262.17(a)(7)(iv)~~ Env-Hw 509.02(a)(2).

(vi) All records must be readily available upon request by an inspector. The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action

[6] Reverse distributors in New Hampshire must submit documentation to NHDES instead of EPA Region 1.

regarding the regulated activity, or as requested by the ~~EPA Regional Administrator~~ commissioner, or designee[~~,~~].

(d) *When a reverse distributor must have a permit.* A reverse distributor is an operator of a hazardous waste treatment, storage, or disposal facility and is subject to the requirements of ~~40 CFR parts 264, 265, and 267 and the permit requirements of 40 CFR part 270~~ Env-Hw 700 and the permit requirements of Env-Hw 300, if the reverse distributor:

(1) Does not meet the conditions of this section;

(2) Accepts manifested hazardous waste from off site; or

(3) Treats or disposes of hazardous waste pharmaceuticals on site.