

Subchapter 10: HAZARDOUS WASTE PHARMACEUTICALS**§ 7-1001 DEFINITIONS**

The following definitions apply to this subchapter:

“Evaluated hazardous waste pharmaceutical” means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with **40 CFR § 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 waste, as defined in **§ 7-103**, and exhibits one or more characteristics identified in **§§ 7-205 through 7-208** or is listed in **§§ 7-210 through 7-215**. A pharmaceutical is not a waste, as defined in **§ 7-103**, 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 waste, as defined in **§ 7-103**, 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:

- (a) 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
- (b) 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 waste, as defined in **§ 7-103**, but is excluded from being a hazardous waste under **§ 7-203(a)**.

“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 waste, as defined in § 7-103, and is not listed in §§ 7-210 through 7-215, and does not exhibit a characteristic identified in §§ 7-205 through 7-208.

“Non-pharmaceutical hazardous waste” means a waste, as defined in § 7-103, that is listed in §§ 7-210 through 7-215, or exhibits one or more characteristics identified in §§ 7-205 through 7-208, but is not a pharmaceutical, as defined in this section.

“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:

- (a) In original manufacturer packaging (except pharmaceuticals that were subject to a recall);
- (b) Undispensed; and
- (c) 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.

§ 7-1002 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 **§ 7-306** and is not subject to this subchapter, except for **§§ 7-1006 and 7-1008** and the optional provisions of **§ 7-1005**.
- (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 **§ 7-1002(d)** for the management of its hazardous waste pharmaceuticals as an alternative to complying with **§ 7-306** and the optional provisions of **§ 7-1005**.
- (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 **subsection (a) of this section**, a healthcare facility is subject to the following in lieu of **subchapters 3 through 5**:
 - (1) **Sections 7-1003 and 7-1006 through 7-1009 of this subchapter** with respect to the management of:
 - (A) Non-creditable hazardous waste pharmaceuticals, and
 - (B) Potentially creditable hazardous waste pharmaceuticals if they are not destined for a reverse distributor.
 - (2) **Sections 7-1003(a), 7-1004, 7-1006 through 7-1008, and 7-1010 of this subchapter** 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 **§§ 7-1006 through 7-1011 of this subchapter** in lieu of **subchapters 3 through 5** 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 subchapter. Other generators are subject to **Subchapter 3** for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.
- (g) The following are not subject to **Subchapters 1 through 9**, except as specified:
 - (1) Pharmaceuticals that are not waste, as defined in **§ 7-103**, 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 wastes, as defined in § 7-103, 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 subchapter 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 subchapter 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 subchapter 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.
 - (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 §§ **7-1007(a)(2) and 7-1007(b)**.

§ 7-1003 STANDARDS FOR HEALTHCARE FACILITIES MANAGING NON-CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS

- (a) Notification and withdrawal from this subchapter for healthcare facilities managing hazardous waste pharmaceuticals:
 - (1) Notification. A healthcare facility must notify the Secretary, using the **Hazardous Waste Handler Site Identification Form** (EPA Form 8700-12), that it is a healthcare facility operating under this subchapter. 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.

- (A) A healthcare facility that already has an EPA identification number must notify the Secretary, using the **Hazardous Waste Handler 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 subchapter, or within 60 days of becoming subject to this subchapter.
 - (B) A healthcare facility that does not have an EPA identification number must obtain one by notifying the Secretary, using the **Hazardous Waste Handler 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 subchapter, or within 60 days of becoming subject to this subchapter.
 - (C) A healthcare facility must keep a copy of its notification on file for as long as the healthcare facility is subject to this subchapter.
- (2) Withdrawal. A healthcare facility that operated under this subchapter but is no longer subject to this subchapter, because it is a very small quantity generator under § 7-306, and elects to withdraw from this subchapter, must notify the Secretary using the **Hazardous Waste Handler Site Identification Form** (EPA Form 8700-12) that it is no longer operating under this subchapter. 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.
- (A) A healthcare facility must submit the **Hazardous Waste Handler Site Identification Form** (EPA Form 8700-12) notifying that it is withdrawing from this subchapter before it begins operating under § 7-306.
 - (B) 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.
- (b) 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) A healthcare facility that generates a 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 §§ 7-205 through 7-208 or is listed in §§ 7-210 through 7-215) in order to determine whether the waste is subject to this subchapter. A healthcare facility may choose to manage its non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under this subchapter.

- (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:
 - (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 non-creditable hazardous waste pharmaceuticals; or
 - (E) 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 **40 CFR § 268.3(c)** must be accumulated in separate containers and labeled with all applicable hazardous waste codes.
- (e) 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:
 - (A) Marking or labeling the container of non-creditable hazardous waste pharmaceuticals with the date that the non-creditable hazardous waste pharmaceuticals became a waste;
 - (B) Maintaining an inventory system that identifies the date the non-creditable hazardous waste pharmaceuticals being accumulated first became a waste;
 - (C) 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) The non-creditable hazardous waste pharmaceuticals generated by a healthcare facility are subject to the land disposal restrictions of **40 CFR Part 268**. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals must comply with the land disposal restrictions in accordance with **40 CFR § 268.7(a)** requirements, except that it is not required to identify the hazardous waste codes on the land disposal restrictions notification.
- (h) 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 **40 CFR § 264.72 or 40 CFR § 265.72** 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 **subsections (d) and (e) of this section**. Upon receipt of the returned shipment, the healthcare facility must:
 - (1) 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;
 - (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 § 7-1009(a).
- (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 § 7-708(a), with respect to non-creditable hazardous waste pharmaceuticals managed under this subchapter.
 - (2) Exception reporting by healthcare facilities for a missing copy of the manifest:
 - (A) For shipments from a healthcare facility to a designated facility.

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:

- (i) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Secretary; and
- (ii) 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) For shipments rejected by the designated facility and shipped to an alternate facility.

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:

- (i) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the Secretary; and
- (ii) 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.

- (3) Additional reports. The Secretary may require healthcare facilities to furnish additional reports concerning the quantities and disposition of 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 §§ **7-702(b)(2) through (5)** for three years or until it receives a signed copy from the designated facility which received the non-creditable 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.
 - (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 § **7-202(b)(6)**, 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 Secretary.
 - (5) All records must be readily available upon request by an inspector.
- (k) 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 subchapter.
- (l) A healthcare facility may accept non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § **7-306**, 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 § **7-103**) as the very 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 § 7-103 of this chapter 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 healthcare facility;
- (2) Is operating under this subchapter 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 subchapter; 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.

§ 7-1004 STANDARDS FOR HEALTHCARE FACILITIES MANAGING POTENTIALLY CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS

- (a) A healthcare facility that generates a 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 §§ 7-210 through 7-215 or exhibits a characteristic identified in §§ 7-205 through 7-208). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subchapter.
- (b) A healthcare facility may accept potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator under § 7-306, 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 § 7-103, as the very 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 healthcare facility;
 - (2) Is operating under this subchapter 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 subchapter; 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) Healthcare facilities are prohibited from sending hazardous wastes other than potentially

creditable hazardous waste pharmaceuticals to a reverse distributor.

- (d) Healthcare facilities are not subject to biennial reporting requirements under **§ 7-708(a)** with respect to potentially creditable hazardous waste pharmaceuticals managed under this subchapter.
- (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:
 - (A) The confirmation of delivery; and
 - (B) 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 Secretary.
 - (3) All records must be readily available upon request by an inspector.
- (f) 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 subchapter.

§ 7-1005 HEALTHCARE FACILITIES THAT ARE VERY SMALL QUANTITY GENERATORS FOR BOTH HAZARDOUS WASTE PHARMACEUTICALS AND NON-PHARMACEUTICAL HAZARDOUS WASTE

- (a) A healthcare facility that is a very 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) A healthcare facility that is a very 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 **§ 7-1003(1)** and **§ 7-1004(b)**, as applicable; or
 - (2) The very small quantity generator healthcare facility meets the conditions in **§ 7-306(c)(2)(d)** and the receiving large quantity generator meets the conditions in **§ 7-308(d)**.

- (c) A long-term care facility that is a very 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) A long-term care facility with 20 beds or fewer is presumed to be a very small quantity generator subject to § 7-306 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and not subject to this subchapter, except for §§ 7-1006 and 7-1008 and the other optional provisions of this section. The Secretary 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 § 7-103. A long-term care facility with more than 20 beds that operates as a very small quantity generator under § 7-306 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by § 7-103.

§ 7-1006 PROHIBITION OF SEWERING HAZARDOUS WASTE PHARMACEUTICALS

All healthcare facilities (including very small quantity generators operating under § 7-306 in lieu of this subchapter) 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)**.

§ 7-1007 CONDITIONAL EXEMPTIONS FOR HAZARDOUS WASTE PHARMACEUTICALS THAT ARE ALSO CONTROLLED SUBSTANCES AND HOUSEHOLD WASTE PHARMACEUTICALS COLLECTED IN A TAKE-BACK EVENT OR PROGRAM

- (a) Provided the conditions of **subsection (b) of this section** are met, the following are exempt from **40 CFR Parts 262 through 273**:
- (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 **§ 7-1006**; 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:
 - (A) 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
 - (B) 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
 - (C) 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.
 - (D) 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.
 - (E) A permitted hazardous waste combustor subject to **40 CFR Part 63 subpart EEE**.

§ 7-1008 RESIDUES OF HAZARDOUS WASTE PHARMACEUTICALS IN EMPTY CONTAINERS

- (a) 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) A syringe is considered empty and the residues are not regulated as hazardous waste under this subchapter 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 subchapter

and any applicable federal, state, and local requirements for sharps containers and medical waste.

- (c) 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 subchapter, unless the IV bag held non-acute hazardous waste pharmaceuticals and is empty as defined in § 7-203(j)(1).
- (d) 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 subchapter, unless the container held non-acute hazardous waste pharmaceuticals and is empty as defined in § 7-203(j)(1) or (2). This includes, but is not limited to, residues in inhalers, aerosol cans, nebulizers, tubes of ointments, gels, or creams.

§ 7-1009 SHIPPING NON-CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS FROM A HEALTHCARE FACILITY OR EVALUATED HAZARDOUS WASTE PHARMACEUTICALS FROM A REVERSE DISTRIBUTOR

- (a) 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:
 - (A) Packaging. Package the waste in accordance with the applicable Department of Transportation regulations on hazardous materials under **49 CFR Parts 173, 178, and 180.**
 - (B) Labeling. Label each package in accordance with the applicable Department of Transportation regulations on hazardous materials under **49 CFR Part 172 subpart E.**
 - (C) Marking
 - (i) 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;**
 - (ii) 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

- (iii) Lab packs that will be incinerated in compliance with **40 CFR § 268.42(c)** are not required to be marked with EPA Hazardous Waste Code(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 Code(s).
- (D) 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 § 7-702, except that:
 - (A) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals is not required to list all applicable hazardous waste codes in Item 13 of EPA Form 8700-22.
 - (B) A healthcare facility shipping non-creditable hazardous waste pharmaceuticals must write the word “PHRM” in Item 13 of EPA Form 8700-22.
 - (b) 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) 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.

§ 7-1010 SHIPPING POTENTIALLY CREDITABLE HAZARDOUS WASTE PHARMACEUTICALS FROM A HEALTHCARE FACILITY OR A REVERSE DISTRIBUTOR TO A REVERSE DISTRIBUTOR

- (a) 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) 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) 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) 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 **40 CFR § 262.83(c)**, in addition to **subsections (a) through (c) of this section**.
- (e) Any person that imports potentially creditable hazardous waste pharmaceuticals into the United States is subject to **subsections (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 subchapter.

§ 7-1011 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 requirements of **40 CFR § 266.510**.