

Subpart P—Hazardous Waste Pharmaceuticals

SOURCE: 84 FR 5940, Feb. 22, 2019, unless otherwise noted.

§ 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, opti-

cal 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).

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

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part 261 subpart C, 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—

(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, in-

cluding 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.

(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:

(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 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 for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.