

3745-266-500**Definitions - hazardous waste pharmaceuticals.**

The following definitions apply to rules 3745-266-500 to 3745-266-510 of the Administrative Code.

(A) "Evaluated hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has been evaluated by a reverse distributor in accordance with paragraph (A)(3) of rule 3745-266-510 of the Administrative Code and will not be sent to another reverse distributor for further evaluation or verification of manufacture credit.

(B) "Hazardous waste pharmaceutical" means a pharmaceutical that is a waste, as defined in rule 3745-51-02 of the Administrative Code, and exhibits one or more characteristics identified in rules 3745-51-20 to 3745-51-24 of the Administrative Code or is listed in rules 3745-51-30 to 3745-51-35 of the Administrative Code. A pharmaceutical is not a waste, as defined in rule 3745-51-02 of the Administrative Code, and therefore not a hazardous waste pharmaceutical, if the pharmaceutical is legitimately used or reused (e.g., lawfully donated for the waste's intended purpose) or reclaimed. An over-the-counter pharmaceutical, dietary supplement, or homeopathic drug is not a waste, as defined in rule 3745-51-02 of the Administrative Code, and therefore not a hazardous waste pharmaceutical, if such item has a reasonable expectation of being legitimately used or reused (e.g., lawfully redistributed for the item's intended purpose) or reclaimed.

(C) "Healthcare facility" means any person that is lawfully authorized to do either of the following:

- (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.
- (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.

- (D) "Household waste pharmaceutical" means a pharmaceutical that is a waste, as defined in rule 3745-51-02 of the Administrative Code, but is excluded from being a hazardous waste under paragraph (B)(1) of rule 3745-51-04 of the Administrative Code.
- (E) "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.
- (F) "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 or 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.
- (G) "Non-hazardous waste pharmaceutical" means a pharmaceutical that is a "waste," as defined in rule 3745-51-02 of the Administrative Code, and is not listed in rules 3745-51-30 to 3745-51-35 of the Administrative Code, and does not exhibit a characteristic identified in rules 3745-51-20 to 3745-51-24 of the Administrative Code.
- (H) "Non-pharmaceutical hazardous waste" means a waste, as defined in rule 3745-51-02 of the Administrative Code, that is listed in rules 3745-51-30 to 3745-51-35 of the Administrative Code, or exhibits one or more characteristics identified in rules 3745-51-20 to 3745-51-24 of the Administrative Code, but is not a pharmaceutical, as defined in this rule.
- (I) "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 in 21 C.F.R. 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.

(J) "Potentially creditable hazardous waste pharmaceutical" means a prescription hazardous waste pharmaceutical that has a reasonable expectation to receive manufacturer credit and is all of the following:

(1) In original manufacturer packaging (except pharmaceuticals that were subject to a recall).

(2) Undispensed.

(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.

(K) "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.

[Comment: For dates of non-regulatory government publications, publications of recognized organizations and associations, federal rules, and federal statutory provisions referenced in this rule, see rule 3745-50-11 of the Administrative Code titled "Incorporated by reference."]

Effective: 10/5/2020

Five Year Review (FYR) Dates: Exempt

CERTIFIED ELECTRONICALLY

Certification

09/21/2020

Date

Promulgated Under: 119.03
Statutory Authority: 3734.12
Rule Amplifies: 3734.12