

3745-266-510

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 an Ohio hazardous waste permit or without having permit by rule, provided that the reverse distributor complies with the following conditions:

(A) Standards for reverse distributors that manage potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals.

(1) Notification. A reverse distributor shall notify Ohio EPA, using Ohio EPA form EPA 9029, that the reverse distributor is a reverse distributor operating in accordance with rules 3745-266-500 to 3745-266-510 of the Administrative Code.

(a) A reverse distributor that already has an EPA identification number shall notify Ohio EPA, using Ohio EPA form EPA 9029, that the reverse distributor is a "reverse distributor," as defined in rule 3745-266-500 of the Administrative Code, within sixty days after the first effective date of rules 3745-266-500 to 3745-266-510 of the Administrative Code, or within sixty days after becoming subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code.

(b) A reverse distributor that does not have an EPA identification number shall obtain one by notifying Ohio EPA, using Ohio EPA form EPA 9029, that the reverse distributor is a "reverse distributor," as defined in rule 3745-266-500 of the Administrative Code, within sixty days after the first effective date of rules 3745-266-500 to 3745-266-510 of the Administrative Code, or within sixty days after becoming subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code.

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

(a) A reverse distributor shall inventory each potentially creditable hazardous waste pharmaceutical within thirty calendar days of each waste arriving at the reverse distributor.

- (b) The inventory shall include the identity (e.g., name or national drug code) and quantity of each potentially creditable hazardous waste pharmaceutical and evaluated hazardous waste pharmaceutical.
 - (c) 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 reverse distributor is not required to provide a separate inventory pursuant to this rule.
- (3) Evaluation by a reverse distributor that is not a manufacturer. A reverse distributor that is not a pharmaceutical manufacturer shall evaluate a potentially creditable hazardous waste pharmaceutical within thirty calendar days after the waste's arrival at the reverse distributor to establish whether the waste is destined for another reverse distributor for further evaluation or verification of manufacturer credit or for a permitted or interim standards treatment, storage, or disposal facility.
- (a) A potentially creditable hazardous waste pharmaceutical that is destined for another reverse distributor is still considered a "potentially creditable hazardous waste pharmaceutical" and shall be managed in accordance with paragraph (B) of this rule.
 - (b) A potentially creditable hazardous waste pharmaceutical that is destined for a permitted or interim standards treatment, storage, or disposal facility is considered an "evaluated hazardous waste pharmaceutical" and shall be managed in accordance with paragraph (C) of this rule.
- (4) Evaluation by a reverse distributor that is a manufacturer. A reverse distributor that is a pharmaceutical manufacturer shall evaluate a potentially creditable hazardous waste pharmaceutical to verify manufacturer credit within thirty calendar days after the waste's arrival at the facility and following the evaluation shall manage the evaluated hazardous waste pharmaceuticals in accordance with paragraph (C) of this rule.
- (5) Maximum accumulation time for hazardous waste pharmaceuticals at a reverse distributor.
- (a) A reverse distributor may accumulate potentially creditable hazardous waste pharmaceuticals and evaluated hazardous waste pharmaceuticals on-site for one hundred eighty calendar days or less. The one hundred eighty 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 the

hazardous waste pharmaceuticals are destined for another reverse distributor (i.e., potentially creditable hazardous waste pharmaceuticals) or a permitted or interim standards treatment, storage, or disposal facility (i.e., evaluated hazardous waste pharmaceuticals).

(b) Aging pharmaceuticals. Unexpired pharmaceuticals that are otherwise creditable but are awaiting the expiration date (i.e., aging in a holding morgue) can be accumulated for up to one hundred eighty days after the expiration date, provided that the unexpired pharmaceuticals are managed in accordance with paragraph (A) of this rule and the container labeling and management standards in paragraph (C)(4) of this rule.

(6) Security at the reverse distributor facility. A reverse distributor shall 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.

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

(i) A twenty-four-hour continuous monitoring surveillance system.

(ii) An artificial barrier such as a fence.

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

(b) 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 reverse distributor is not required to provide separate security measures pursuant to this rule.

(7) Contingency plan and emergency procedures at a reverse distributor. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site shall prepare a contingency plan and comply with rules 3745-52-250 to 3745-52-265 of the Administrative Code.

(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 shall comply with paragraphs (A)(8)(b) and (A)(8)(c) of rule 3745-52-17 of the Administrative Code.

(9) Reporting by a reverse distributor.

(a) Unauthorized waste report. A reverse distributor shall submit an unauthorized waste report if the reverse distributor receives waste from off-site that the reverse distributor is not authorized to receive (e.g., non-pharmaceutical hazardous waste, regulated medical waste). The reverse distributor shall prepare and submit an unauthorized waste report to the director within forty-five calendar days after the unauthorized waste arrives at the reverse distributor, and shall send a copy of the unauthorized waste report to the healthcare facility (or other entity) that sent the unauthorized waste. The reverse distributor shall manage the unauthorized waste in accordance with all applicable rules. The unauthorized waste report shall be signed by the owner or operator of the reverse distributor, or an authorized representative, and contain all of the following information:

(i) The U.S. EPA identification number, name, and address of the reverse distributor.

(ii) The date the reverse distributor received the unauthorized waste.

(iii) The U.S. EPA identification number, name, and address of the healthcare facility that shipped the unauthorized waste, if available.

(iv) A description and the quantity of each unauthorized waste the reverse distributor received.

(v) The method of treatment, storage, or disposal for each unauthorized waste.

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

(b) Additional reports. The director may require reverse distributors to submit 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 shall keep all of the following records (paper or electronic) readily available upon request by an inspector. The periods of retention referred to in this rule are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the director.

- (a) A copy of the reverse distributor's notification on file for as long as the facility is subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code.
 - (b) A copy of the delivery confirmation and the shipping papers for each shipment of potentially creditable hazardous waste pharmaceuticals that the reverse distributor receives, and a copy of each unauthorized waste report, for at least three years after the date the shipment arrives at the reverse distributor.
 - (c) A copy of the reverse distributor's current inventory for as long as the facility is subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code.
- (B) Additional standards for reverse distributors that manage potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor. A reverse distributor that does not have an Ohio hazardous waste permit or permit by rule shall comply with the following conditions, in addition to paragraph (A) of this rule, 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 shall send those potentially creditable hazardous waste pharmaceuticals to another reverse distributor within one hundred eighty days after the potentially creditable hazardous waste pharmaceuticals have been evaluated, or follow paragraph (C) of this rule for evaluated hazardous waste pharmaceuticals.
 - (2) A reverse distributor that receives potentially creditable hazardous waste pharmaceuticals from another reverse distributor shall send those potentially creditable hazardous waste pharmaceuticals to a reverse distributor that is a pharmaceutical manufacturer within one hundred eighty days after the potentially creditable hazardous waste pharmaceuticals have been evaluated, or follow paragraph (C) of this rule for evaluated hazardous waste pharmaceuticals.
 - (3) A reverse distributor shall ship potentially creditable hazardous waste pharmaceuticals destined for another reverse distributor in accordance with rule 3745-266-509 of the Administrative Code.
 - (4) Recordkeeping by reverse distributors. A reverse distributor shall keep all of the following records (paper or electronic) readily available upon request

by an inspector for each shipment of potentially creditable hazardous waste pharmaceuticals that the reverse distributor initiates to another reverse distributor, for at least three years after the date of shipment. The periods of retention referred to in this rule are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the director.

(a) The confirmation of delivery.

(b) The department of transportation (DOT) shipping papers prepared in accordance with 49 C.F.R. Part 172 subpart C, if applicable.

(C) Additional standards for reverse distributors that manage evaluated hazardous waste pharmaceuticals. A reverse distributor that does not have an Ohio hazardous waste permit or permit by rule shall comply with the following conditions, in addition to paragraph (A) of this rule, for the management of evaluated hazardous waste pharmaceuticals:

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

(2) Inspections of on-site accumulation area. A reverse distributor shall inspect the reverse distributor's 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 who handle evaluated hazardous waste pharmaceuticals are subject to the training requirements of paragraph (A)(7) of rule 3745-52-17 of the Administrative Code.

(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 shall do all of the following:

(a) Label the containers with the words, "Hazardous Waste Pharmaceuticals."

(b) Ensure the containers are in good condition and managed to prevent leaks.

(c) Use containers that are made of or lined with materials which shall 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.

- (d) Keep containers closed, if holding liquid or gel evaluated hazardous waste pharmaceuticals. If the liquid or gel evaluated hazardous waste pharmaceuticals are in the original, intact, sealed packaging; or repackaged, intact, sealed packaging, the evaluated hazardous waste pharmaceuticals are considered to meet the closed container standard.
 - (e) 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 do any of the following:
 - (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 hazardous waste pharmaceuticals.
 - (v) Through other like means threaten human health or the environment.
 - (f) Accumulate evaluated hazardous waste pharmaceuticals that are prohibited from being combusted because of the dilution prohibition of paragraph (C) of rule 3745-270-03 of the Administrative Code [e.g., arsenic trioxide (P012)] in separate containers from other evaluated hazardous waste pharmaceuticals at the reverse distributor.
- (5) EPA hazardous waste numbers. Prior to shipping evaluated hazardous waste pharmaceuticals off-site, all containers shall be marked with the applicable EPA hazardous waste numbers. A nationally recognized electronic system, such as bar coding or radio frequency identification, may be used to identify the EPA hazardous waste numbers.
- (6) Shipments. A reverse distributor shall ship evaluated hazardous waste pharmaceuticals that are destined for a permitted or interim standards treatment, storage, or disposal facility in accordance with the applicable shipping standards in paragraph (A) or (B) of rule 3745-266-508 of the Administrative Code.

(7) Procedures for a reverse distributor to manage 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 rule 3745-54-72 or 3745-65-72 of the Administrative Code, may accumulate the returned evaluated hazardous waste pharmaceuticals on-site for up to an additional ninety days in the on-site accumulation area, provided the rejected or returned shipment is managed in accordance with paragraphs (A) and (C) of rule 3745-266-510 of the Administrative Code. Upon receipt of the returned shipment, the reverse distributor shall do all of the following:

(a) Sign either of the following:

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

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

(b) Provide the transporter a copy of the manifest.

(c) Within thirty days after 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.

(d) Within ninety days after 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 paragraph (A) or (B) of rule 3745-266-508 of the Administrative Code.

(8) Land disposal restrictions. Evaluated hazardous waste pharmaceuticals are subject to the land disposal restrictions of Chapter 3745-270 of the Administrative Code. A reverse distributor that accepts potentially creditable hazardous waste pharmaceuticals from off-site shall comply with the land disposal restrictions in accordance with paragraph (A) of rule 3745-270-07 of the Administrative Code.

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

(a) Biennial reporting by a reverse distributor. A reverse distributor that ships evaluated hazardous waste pharmaceuticals off-site shall prepare and submit a single copy of a biennial report to the director by March first

of each even numbered year in accordance with rule 3745-52-41 of the Administrative Code.

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

(i) For shipments from a reverse distributor to a designated facility, the reverse distributor shall do the following:

(a) 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 thirty-five days after the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter, the reverse distributor shall contact the transporter or the owner or operator of the designated facility to determine the status of the evaluated hazardous waste pharmaceuticals.

(b) A reverse distributor shall submit an exception report to the director if the reverse distributor has not received a copy of the manifest with the signature of the owner or operator of the designated facility within forty-five days after the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter. The exception report shall include both of the following:

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

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

(ii) For shipments rejected by the designated facility and shipped to an alternate facility, the reverse distributor shall do the following:

(a) 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 thirty-five days after the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter shall contact the transporter or the owner or operator of the alternate facility to determine the status of

the hazardous waste. The thirty-five-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.

(b) A reverse distributor shall submit an exception report to the director if the reverse distributor has not received a copy of the manifest with the signature of the owner or operator of the alternate facility within forty-five days after the date the evaluated hazardous waste pharmaceuticals were accepted by the initial transporter. The forty-five-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 shall include both of the following:

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

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

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

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

(b) A reverse distributor shall keep a copy of each manifest signed in accordance with paragraph (A) of rule 3745-52-23 of the Administrative Code for three years or until the reverse distributor receives a signed copy from the designated facility that received the evaluated hazardous waste pharmaceutical. This signed copy shall be retained as a record for at least three years after the date the evaluated hazardous waste pharmaceutical was accepted by the initial transporter.

(c) A reverse distributor shall keep a copy of each biennial report for at least three years after the due date of the report.

(d) A reverse distributor shall keep a copy of each exception report for at least three years after the submittal of the report.

(e) A reverse distributor shall keep records to document personnel training, in accordance with paragraph (A)(7)(d) of rule 3745-52-17 of the Administrative Code.

(f) All records shall be readily available upon request by an inspector. The periods of retention referred to in this rule are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the director.

(D) When a reverse distributor shall 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 Chapters 3745-54 to 3745-57, 3745-65 to 3745-69, 3745-205, and 3745-256 and rules 3745-50-40 to 3745-50-235 of the Administrative Code, if the reverse distributor does any of the following:

(1) Does not meet the conditions of this rule.

(2) Accepts manifested hazardous waste from off-site.

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

[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: 10/05/2025

CERTIFIED ELECTRONICALLY

Certification

09/21/2020

Date

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