

3745-266-502**Standards for healthcare facilities that manage non-creditable hazardous waste pharmaceuticals.**

(A) Notification and withdrawal from rules 3745-266-500 to 3745-266-510 of the Administrative Code for healthcare facilities managing hazardous waste pharmaceuticals.

(1) Notification. A healthcare facility shall notify Ohio EPA, using Ohio EPA form EPA 9029, that the facility is a healthcare facility operating in accordance with rules 3745-266-500 to 3745-266-510 of the Administrative Code. A healthcare facility is not required to fill out waste codes for federally regulated hazardous waste on the form with respect to the healthcare facility's hazardous waste pharmaceuticals. A healthcare facility shall submit a separate notification for each site or EPA identification number.

(a) A healthcare facility that already has an EPA identification number shall notify Ohio EPA, using Ohio EPA form EPA 9029, that the facility is a healthcare facility as part of the healthcare facility's next biennial report, if the healthcare facility is required to submit a biennial report; or if not required to submit a biennial report, 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 healthcare facility that does not have an EPA identification number shall obtain one by notifying Ohio EPA, using Ohio EPA form EPA 9029, that the facility is a healthcare facility as part of the healthcare facility's next biennial report, if the healthcare facility is required to submit a biennial report; or if not required to submit a biennial report, 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.

(c) A healthcare facility shall keep a copy of the healthcare facility's notification on file for as long as the healthcare facility is subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code.

(2) Withdrawal. A healthcare facility that operated under rules 3745-266-500 to 3745-266-510 of the Administrative Code but is no longer subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code, because the healthcare facility is a very small quantity generator under rule 3745-52-14 of the Administrative Code, and elects to withdraw from rules 3745-266-500 to 3745-266-510 of the Administrative Code, shall notify Ohio EPA, using Ohio EPA form EPA 9029, that the healthcare facility is no longer operating

under rules 3745-266-500 to 3745-266-510 of the Administrative Code. A healthcare facility is not required to fill out the waste codes for federally regulated hazardous waste portion of Ohio EPA form EPA 9029 with respect to the healthcare facility's hazardous waste pharmaceuticals. A healthcare facility shall submit a separate Ohio EPA form EPA 9029 for each EPA identification number.

(a) A healthcare facility shall submit Ohio EPA form EPA 9029 notifying that the healthcare facility is withdrawing from rules 3745-266-500 to 3745-266-510 of the Administrative Code before the healthcare facility begins operating under the conditional exemption of rule 3745-52-14 of the Administrative Code.

(b) A healthcare facility shall keep a copy of the healthcare facility's withdrawal on file for three years after the date of signature on the notification of the healthcare facility's withdrawal.

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

(C) Hazardous waste determination for non-creditable pharmaceuticals. A healthcare facility that generates a waste that is a non-creditable pharmaceutical shall determine whether that pharmaceutical is a hazardous waste pharmaceutical (i.e., the waste exhibits a characteristic 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) in order to determine whether the waste is subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code. A healthcare facility may choose to manage non-hazardous waste pharmaceuticals as non-creditable hazardous waste pharmaceuticals under rules 3745-266-500 to 3745-266-510 of the Administrative Code.

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

(1) A healthcare facility shall place non-creditable hazardous waste pharmaceuticals in a container that is structurally sound, compatible with the 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 shall manage the container so that the container does not have the potential to do any of the following:
- (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.
 - (e) Through other like means threaten human health or the environment.
- (3) A healthcare facility shall keep containers of non-creditable hazardous waste pharmaceuticals closed and secured in a manner that prevents unauthorized access to the 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 paragraph (C) of rule 3745-270-03 of the Administrative Code shall be accumulated in separate containers and labeled with all applicable hazardous waste numbers.
- (E) Labeling containers used to accumulate non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility shall 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 an Ohio hazardous waste permit or a permit by rule.
 - (2) A healthcare facility that accumulates non-creditable hazardous waste pharmaceuticals on-site shall demonstrate the length of time that the non-

creditable hazardous waste pharmaceuticals have been accumulating, starting from the date the non-creditable hazardous waste pharmaceutical 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) 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 Chapter 3745-270 of the Administrative Code. A healthcare facility that generates non-creditable hazardous waste pharmaceuticals shall comply with the land disposal restrictions in accordance with paragraph (A) of rule 3745-270-07 of the Administrative Code, except that the healthcare facility is not required to identify the hazardous waste numbers 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 rule 3745-54-72 or 3745-65-72 of the Administrative Code, may accumulate the returned non-creditable hazardous waste pharmaceuticals on-site for up to an additional ninety days, provided the rejected or returned shipment is managed in accordance with paragraphs (D) and (E) of this rule. Upon receipt of the returned shipment, the healthcare facility shall do all of the following:

(1) Sign either of the following:

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

(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 thirty days after receipt of the rejected shipment, send a copy of the manifest to the designated facility that returned the shipment to the healthcare facility.

(4) Within ninety days after receipt of the rejected shipment, transport or offer for transport the returned shipment in accordance with the shipping standards of paragraph (A) of rule 3745-266-508 of the Administrative Code.

(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 in accordance with rule 3745-52-41 of the Administrative Code, with respect to non-creditable hazardous waste pharmaceuticals managed in accordance with rules 3745-266-500 to 3745-266-510 of the Administrative Code.

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

(a) For shipments from a healthcare facility to a designated facility:

(i) 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 sixty days after the date the non-creditable hazardous waste pharmaceuticals were accepted by the initial transporter, the healthcare facility shall submit all of the following:

(a) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the director.

(b) A handwritten or typed note on the manifest 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.

(ii) [Reserved.]

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

(i) 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 sixty days after 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 shall submit all of the following:

(a) A legible copy of the original manifest, indicating that the healthcare facility has not received confirmation of delivery, to the director.

(b) A handwritten or typed note on the manifest 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.

(ii) [Reserved.]

(3) Additional reports. The director 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 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 healthcare facility receives a signed copy from the designated facility which received the non-creditable hazardous waste pharmaceuticals. This signed copy shall be retained as a record for at least three years after the date the waste was accepted by the initial transporter.

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

- (3) A healthcare facility shall keep records of any test results, waste analyses, or other determinations made to support the healthcare facility's hazardous waste determinations consistent with paragraph (F) of rule 3745-52-11 of the Administrative Code, for at least three years after the date the waste was last sent to on-site or off-site treatment, storage or disposal. A healthcare facility that manages all of the 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 rule are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the director.
- (5) All records shall be readily available upon request by an inspector.
- (K) Response to spills of non-creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility shall 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 rules 3745-266-500 to 3745-266-510 of the Administrative Code.
- (L) Accepting non-creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very 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 in accordance with rule 3745-52-14 of the Administrative Code, without an Ohio hazardous waste permit or without having a permit by rule, provided the receiving healthcare facility meets all of the following:
- (1) Is under the control of the same "person," as defined in rule 3745-50-10 of the Administrative Code, as the very small quantity generator healthcare facility that is sending the non-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. ("Control," for the purposes of this rule, 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 rule 3745-50-10 of the Administrative Code, shall not be deemed to "control" such healthcare facilities.)
- (2) Is operating under rules 3745-266-500 to 3745-266-510 of the Administrative Code for the management of the healthcare facility's non-creditable hazardous waste pharmaceuticals.

(3) Manages the non-creditable hazardous waste pharmaceuticals that the healthcare facility receives from off-site in compliance with rules 3745-266-500 to 3745-266-510 of the Administrative Code.

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

[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."]

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Certification

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