

AUTHENTICATED, OHIO LEGISLATIVE SERVICE COMMISSION DOCUMENT #331795

Ohio Administrative Code

Rule 3745-266-503 Standards for healthcare facilities that manage potentially creditable hazardous waste pharmaceuticals.

Effective: March 7, 2025

(A) Hazardous waste determination for potentially creditable pharmaceuticals. A healthcare facility that generates a waste that is a potentially creditable pharmaceutical shall determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (i.e., listed in rules 3745-51-30 to 3745-51-35 of the Administrative Code or exhibits a characteristic identified in rules 3745-51-20 to 3745-51-24 of the Administrative Code). A healthcare facility may choose to manage the healthcare facility's potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals in accordance with rules 3745-266-500 to 3745-266-510 of the Administrative Code.

(B) Accepting potentially creditable hazardous waste pharmaceuticals from an off-site healthcare facility that is a very small quantity generator. A healthcare facility may accept potentially 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 a permit or without having a permit by rule, provided the receiving healthcare facility:

(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 potentially creditable hazardous waste pharmaceuticals off-site ("control," for the purpose of this rule, means the power to direct the policies of the healthcare facility, whether by ownership of stock, voting rights, or otherwise, except that contractors who operate healthcare facilities on behalf of a different person 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 in accordance with rules 3745-266-500 to 3745-266-510 of the Administrative Code for the management of the healthcare facility's potentially creditable hazardous waste pharmaceuticals;



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(3) Manages the potentially 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; and

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

(C) Prohibition. Healthcare facilities are prohibited from sending hazardous wastes other than potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(D) 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 potentially creditable hazardous waste pharmaceuticals managed in accordance with rules 3745-266-500 to 3745-266-510 of the Administrative Code.

(E) Recordkeeping by healthcare facilities.

(1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor shall keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years after 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 rule are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the director.

(3) All records shall be readily available upon request by an inspector.

(F) Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities. A healthcare facility shall immediately contain all spills of potentially creditable



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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.

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