

3745-266-501**Applicability - hazardous waste pharmaceuticals.**

- (A) A healthcare facility that is a very small quantity generator when counting all of the generator's hazardous waste, including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste, remains subject to rule 3745-52-14 of the Administrative Code and is not subject to rules 3745-266-500 to 3745-266-510 of the Administrative Code, except for rules 3745-266-505 and 3745-266-507 of the Administrative Code and the optional provisions of rule 3745-266-504 of the Administrative Code.
- (B) A healthcare facility that is a very small quantity generator when counting all of the generator's hazardous waste, including both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste, has the option of complying with paragraph (D) of this rule for the management of the hazardous waste pharmaceuticals as an alternative to complying with rule 3745-52-14 of the Administrative Code and the optional provisions of rule 3745-266-504 of the Administrative Code.
- (C) A healthcare facility or reverse distributor remains subject to all applicable hazardous waste regulations with respect to the management of non-pharmaceutical hazardous waste.
- (D) With the exception of healthcare facilities identified in paragraph (A) of this rule, a healthcare facility is subject to the following in lieu of Chapters 3745-52, 3745-53, 3745-54 to 3745-57, 3745-65 to 3745-69, 3745-205, and 3745-256 of the Administrative Code:
- (1) Rules 3745-266-502 and 3745-266-505 to 3745-266-508 of the Administrative Code with respect to the management of both of the following:
    - (a) Non-creditable hazardous waste pharmaceuticals.
    - (b) Potentially creditable hazardous waste pharmaceuticals if the potentially creditable pharmaceuticals are not destined for a reverse distributor.
  - (2) Paragraph (A) of rule 3745-266-502 and rules 3745-266-503, 3745-266-505 to 3745-266-507, and 3745-266-509 of the Administrative Code 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 rules 3745-266-505 to 3745-266-510 of the Administrative Code in lieu of Chapters 3745-52, 3745-53, 3745-54 to 3745-57, 3745-65 to 3745-69, 3745-205, and 3745-256 of the Administrative Code 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 rules 3745-266-500 to 3745-266-510 of the Administrative Code. Other generators are subject to Chapter 3745-52 of the Administrative Code for the generation and accumulation of hazardous wastes, including hazardous waste pharmaceuticals.
- (G) The following are not subject to Chapters 3745-50, 3745-51, 3745-52, 3745-53, 3745-54 to 3745-57, 3745-65 to 3745-69, 3745-205, 3745-256, 3745-266, and 3745-273 of the Administrative Code, except as specified:
- (1) Pharmaceuticals that are not "waste," as defined in rule 3745-51-02 of the Administrative Code, because the pharmaceuticals are legitimately used or reused (e.g., lawfully donated for the pharmaceuticals' intended purpose) or reclaimed.
  - (2) Over-the-counter pharmaceuticals, dietary supplements, or homeopathic drugs that are not "wastes," as defined in rule 3745-51-02 of the Administrative Code, because the items have a reasonable expectation of being legitimately used or reused (e.g., lawfully redistributed for the items' intended purpose) or reclaimed.
  - (3) Pharmaceuticals being managed in accordance with a recall strategy that has been approved by the food and drug administration (FDA) in accordance with 21 C.F.R. Part 7 subpart C. Rules 3745-266-500 to 3745-266-510 of the Administrative Code do apply to the management of the recalled hazardous waste pharmaceuticals after the FDA approves the destruction of the recalled items.
  - (4) Pharmaceuticals being managed in accordance with a recall corrective action plan that has been accepted by the consumer product safety commission in accordance with 16 C.F.R. Part 1115. Rules 3745-266-500 to 3745-266-510 of the Administrative Code apply to the management of the recalled hazardous waste pharmaceuticals after the consumer product safety commission approves the destruction of the recalled items.
  - (5) Pharmaceuticals stored according to a preservation order or during an investigation or judicial proceeding until after the preservation order, investigation, or judicial proceeding has concluded or a decision is made to discard the pharmaceuticals.
  - (6) Investigational new drugs for which an investigational new drug application is in effect in accordance with the FDA's regulations in 21 C.F.R. Part 312.

Rules 3745-2636-500 to 3745-266-510 of the Administrative Code apply to the management of the investigational new drug after the decision is made to discard the investigational new drug or the FDA approves the destruction of the investigational new drug, if the investigational new drug is a hazardous waste.

(7) Household waste pharmaceuticals, including those that have been collected by an "authorized collector," as defined by the drug enforcement administration, provided the authorized collector complies with the conditional exemption in paragraphs (A)(2) and (B) of rule 3745-266-506 of the Administrative Code.

[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

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Certification

09/21/2020

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Date

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