

§ 266.503

40 CFR Ch. I (7-1-21 Edition)

of a different person as defined in § 260.10 of this chapter 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 under this subpart for the management of its non-creditable hazardous waste pharmaceuticals;

(3) Manages the non-creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

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

**§ 266.503 Standards for healthcare facilities managing potentially creditable hazardous waste pharmaceuticals.**

(a) *Hazardous waste determination for potentially creditable pharmaceuticals.* A healthcare facility that generates a solid waste that is a potentially creditable pharmaceutical must determine whether the potentially creditable pharmaceutical is a potentially creditable hazardous waste pharmaceutical (*i.e.*, it is listed in 40 CFR part 261 subpart D or exhibits a characteristic identified in 40 CFR part 261 subpart C). A healthcare facility may choose to manage its potentially creditable non-hazardous waste pharmaceuticals as potentially creditable hazardous waste pharmaceuticals under this subpart.

(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 under § 262.14, without a permit or without having interim status, provided the receiving healthcare facility:

(1) Is under the control of the same person, as defined in § 260.10, as the very small quantity generator healthcare facility that is sending the potentially 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;

(2) Is operating under this subpart for the management of its potentially creditable hazardous waste pharmaceuticals;

(3) Manages the potentially creditable hazardous waste pharmaceuticals that it receives from off site in compliance with this subpart; and

(4) Keeps records of the potentially creditable hazardous waste pharmaceuticals shipments it receives from off site for three years from 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 under § 262.41 with respect to potentially creditable hazardous waste pharmaceuticals managed under this subpart.

(e) *Recordkeeping by healthcare facilities.* (1) A healthcare facility that initiates a shipment of potentially creditable hazardous waste pharmaceuticals to a reverse distributor must keep the following records (paper or electronic) for each shipment of potentially creditable hazardous waste pharmaceuticals for three years from the date of shipment:

(i) The confirmation of delivery; and  
(ii) The shipping papers prepared in accordance with 49 CFR part 172 subpart C, if applicable.

(2) The periods of retention referred to in this section are extended automatically during the course of any unresolved enforcement action regarding the regulated activity, or as requested by the EPA Regional Administrator.

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

(f) *Response to spills of potentially creditable hazardous waste pharmaceuticals at healthcare facilities.* A healthcare facility must immediately contain all spills of potentially creditable hazardous waste pharmaceuticals and

## Environmental Protection Agency

## § 266.506

manage the spill clean-up materials as non-creditable hazardous waste pharmaceuticals in accordance with this subpart.

### **§ 266.504 Healthcare facilities that are very small quantity generators for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste.**

(a) *Potentially creditable hazardous waste pharmaceuticals.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its potentially creditable hazardous waste pharmaceuticals to a reverse distributor.

(b) *Off-site collection of hazardous waste pharmaceuticals generated by a healthcare facility that is a very small quantity generator.* A healthcare facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may send its hazardous waste pharmaceuticals off-site to another healthcare facility, provided:

(1) The receiving healthcare facility meets the conditions in §266.502(1) of this subpart and §266.503(b), as applicable; or

(2) The very small quantity generator healthcare facility meets the conditions in §262.14(a)(5)(viii) and the receiving large quantity generator meets the conditions in §262.17(f).

(c) *Long-term care facilities that are very small quantity generators.* A long-term care facility that is a very small quantity generator for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste may dispose of its hazardous waste pharmaceuticals (excluding contaminated personal protective equipment or clean-up materials) in an on-site collection receptacle of an authorized collector (as defined by the Drug Enforcement Administration) that is registered with the Drug Enforcement Administration provided the contents are collected, stored, transported, destroyed and disposed of in compliance with all applicable Drug Enforcement Administration regulations for controlled substances.

(d) *Long-term care facilities with 20 beds or fewer.* A long-term care facility with 20 beds or fewer is presumed to be

a very small quantity generator subject to §262.14 for both hazardous waste pharmaceuticals and non-pharmaceutical hazardous waste and *not* subject to this subpart, except for §§266.505 and 266.507 and the other optional provisions of this section. The EPA Regional Administrator has the responsibility to demonstrate that a long-term care facility with 20 beds or fewer generates quantities of hazardous waste that are in excess of the very small quantity generator limits as defined in §260.10. A long-term care facility with more than 20 beds that operates as a very small quantity generator under §262.14 must demonstrate that it generates quantities of hazardous waste that are within the very small quantity generator limits as defined by §260.10.

### **§ 266.505 Prohibition of sewerage hazardous waste pharmaceuticals.**

All healthcare facilities—including very small quantity generators operating under §262.14 in lieu of this subpart—and reverse distributors are prohibited from discharging hazardous waste pharmaceuticals to a sewer system that passes through to a publicly-owned treatment works. Healthcare facilities and reverse distributors remain subject to the prohibitions in 40 CFR 403.5(b)(1).

### **§ 266.506 Conditional exemptions for hazardous waste pharmaceuticals that are also controlled substances and household waste pharmaceuticals collected in a take-back event or program.**

(a) *Conditional exemptions.* Provided the conditions of paragraph (b) of this section are met, the following are exempt from 40 CFR parts 262 through 273:

(1) Hazardous waste pharmaceuticals that are also listed on a schedule of controlled substances by the Drug Enforcement Administration in 21 CFR part 1308, and

(2) Household waste pharmaceuticals that are collected in a take-back event or program, including those that are collected by an authorized collector (as defined by the Drug Enforcement Administration) registered with the Drug