

Title 21 Code of Federal Regulations

PART 1317 — DISPOSAL

Subpart B — Disposal of Controlled Substances Collected From Ultimate Users and Other Non-Registrants

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§1317.30 Authorization to collect from non-registrants.

(a) The following persons are authorized to collect controlled substances from ultimate users and other non-registrants for destruction in compliance with this chapter:

(1) Any registrant authorized by the Administration to be a collector pursuant to §1317.40; and

(2) Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to §1317.35.

(b) The following non-registrant persons in lawful possession of a controlled substance in Schedules II, III, IV, or V may transfer that substance to the authorized persons listed in paragraph (a) of this section, and in a manner authorized by this part, for the purpose of disposal:

(1) An ultimate user in lawful possession of a controlled substance;

(2) Any person lawfully entitled to dispose of a decedent's property if that decedent was an ultimate user who died while in lawful possession of a controlled substance; and

(3) A long-term care facility on behalf of an ultimate user who resides or resided at such long-term care facility and is/was in lawful possession of a controlled substance, in accordance with §1317.80 only.

§1317.35 Collection by law enforcement.

(a) Federal, State, tribal, or local law enforcement may collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property using the following collection methods:

(1) Take-back events in accordance with §1317.65;

(2) Mail-back programs in accordance with §1317.70; or

(3) Collection receptacles located inside law enforcement's physical address.

(b) Law enforcement that conducts a take-back event or a mail-back program or maintains a collection receptacle should maintain any records of removal, storage, or destruction of the controlled substances collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

(c) Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

(d) Any controlled substances collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for transferring illicit controlled substances.

(e) Law enforcement that transfers controlled substances collected from ultimate users pursuant to this part to a reverse distributor for destruction should maintain a record that contains the following information: If a sealed inner liner as described in §1317.60 is used, the unique identification number of the sealed inner liner transferred, and the size of the sealed inner liner transferred (e.g., 5-gallon, 10-gallon, etc.); if a mail-back package as described in §1317.70 is used, the unique identification number of each package; the date of the transfer; and the name, address, and registration number of the reverse distributor to whom the controlled substances were transferred.

§1317.40 Registrants authorized to collect and authorized collection activities.

(a) Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors shall modify their registration to obtain authorization to be a collector in accordance with §1301.51 of this chapter. Authorization to be a collector is subject to renewal. If a registrant that is authorized to collect ceases activities as a collector, such registrant shall notify the Administration in accordance with §1301.52(f) of this chapter.

(b) Collection by registrants shall occur only at the following locations:

(1) Those registered locations of manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that are authorized for collection; and

(2) Long-term care facilities at which registered hospitals/clinics or retail pharmacies are authorized to maintain collection receptacles.

(c) Collectors may conduct the following activities:

(1) Receive and destroy mail-back packages pursuant to §1317.70 at an authorized registered location that has an on-site method of destruction;

(2) Install, manage, and maintain collection receptacles located at their authorized collection location(s) pursuant to §§1317.75 and 1317.80; and

(3) Promptly dispose of sealed inner liners and their contents as provided for in §1317.05(c)(2).

§1317.55 Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement.

(a) A reverse distributor is authorized to acquire controlled substances from law enforcement that collected the substances from ultimate users. A reverse distributor is authorized to acquire controlled substances collected through a collection receptacle in accordance with §§1317.75 and 1317.80.

(b) A distributor is authorized to acquire controlled substances collected through a collection receptacle in accordance with §§1317.75 and 1317.80.

(c) A reverse distributor or a distributor that acquires controlled substances in accordance with paragraph (a) or (b) of this section shall:

(1) Acquire the controlled substances in the manner authorized for reverse distributors in §1317.15(b)(1) and (2);

(2) Dispose of the controlled substances in the manner authorized for reverse distributors §1317.15(c) and (d); and

(3) Securely store the controlled substances in a manner consistent with the security requirements for Schedule II controlled substances until timely destruction can occur.

§1317.60 Inner liner requirements.

(a) An inner liner shall meet the following requirements:

(1) The inner liner shall be waterproof, tamper-evident, and tear-resistant;

(2) The inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents;

- (3) The contents of the inner liner shall not be viewable from the outside when sealed;
 - (4) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.); and
 - (5) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.
- (b) Access to the inner liner shall be restricted to employees of the collector.
- (c) The inner liner shall be sealed by two employees immediately upon removal from the permanent outer container and the sealed inner liner shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§1317.65 Take-back events.

- (a) Federal, State, tribal, or local law enforcement may conduct a take-back event and collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property in accordance with this section. Any person may partner with law enforcement to hold a collection take-back event in accordance with this section.
- (b) Law enforcement shall appoint a law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a Federal agency conducting a take-back event shall maintain control and custody of the collected substances from the time the substances are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer, storage, or destruction of the controlled substances has occurred.
- (c) Each take-back event should have at least one receptacle for the collection of controlled substances. The collection receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner as specified in §1317.60 of this chapter. The outer container should include a small opening that allows contents to be added to the inner liner, but that does not allow removal of the inner liner's contents.
- (d) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.
- (e) Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substance in Schedule II, III, IV, or V may transfer such substances to law enforcement during the take-back event. No other person may handle the controlled substances at any time.

§1317.70 Mail-back programs.

- (a) A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with §1317.90 of this chapter.
- (b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.
- (c) Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) as specified in this paragraph to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of controlled substances by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. The packages made available shall meet the following specifications:
- (1) The package shall be nondescript and shall not include any markings or other information that might indicate that the package contains controlled substances;
 - (2) The package shall be water- and spill-proof; tamper-evident; tear-resistant; and sealable;
 - (3) The package shall be preaddressed with and delivered to the collector's registered address or the participating law enforcement's physical address;
 - (4) The cost of shipping the package shall be postage paid;

- (5) The package shall have a unique identification number that enables the package to be tracked; and
- (6) The package shall include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.
- (d) Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property shall not be required to provide any personally identifiable information when mailing back controlled substances to a collector. The collector or law enforcement may implement a system that allows ultimate users or persons lawfully entitled to dispose of an ultimate user decedent's property to notify the collector or law enforcement that they are sending one of the designated packages by giving the unique identification number on the package.
- (e) A collector that conducts a mail-back program pursuant to paragraph (a) shall:
- (1) Accept only those controlled substances contained within packages that the collector made available for the collection of controlled substances by mail and packages that are lawfully forwarded to the collector pursuant to paragraph (e)(3) of this section.
 - (2) Within three business days of receipt, notify the Field Division Office of the Administration in their area of the receipt of a package that likely contains controlled substances that the collector did not make available or did not agree to receive pursuant to subparagraph (e)(3) of this section.
 - (3) When discontinuing activities as a collector or ceasing an authorized mail-back program:
 - (i) Make a reasonable effort to notify the public prior to discontinuing such activities or ceasing the authorized mail-back program; and
 - (ii) Obtain the written agreement of another collector that has and utilizes at its registered location a method of destruction consistent with §1317.90 of this chapter to receive all remaining mail-back packages that were disseminated but not returned and arrange for the forwarding of only such packages to that location.
 - (f) Only law enforcement officers employed by the law enforcement agency or law enforcement component of a Federal agency and employees of the collector shall handle packages received through an authorized mail-back program. Upon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened, x-rayed, analyzed, or otherwise penetrated.

§1317.75 Collection receptacles.

- (a) Collectors or Federal, State, tribal, or local law enforcement may manage and maintain collection receptacles for disposal.
- (b) Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or other authorized non-registrant person may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.
- (c) Collectors shall only allow ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in Schedule II, III, IV, or V to deposit such substances in a collection receptacle at a registered location. Collectors shall not permit an ultimate user to transfer such substance to any person for any reason. Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled.
- (d) Collection receptacles shall be securely placed and maintained:
- (1) Inside a collector's registered location, inside law enforcement's physical location, or at an authorized long-term care facility;
 - (2) At a registered location, be located in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter). Except as follows:
 - (i) At a hospital/clinic: A collection receptacle shall be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided;
 - (ii) At a narcotic treatment program: A collection receptacle shall be located in a room: That does not contain any other controlled substances and is securely locked with controlled access;

(iii) At a long-term care facility: A collection receptacle shall be located in a secured area regularly monitored by long-term care facility employees.

(e) A controlled substance collection receptacle shall meet the following design specifications:

(1) Be securely fastened to a permanent structure so that it cannot be removed;

(2) Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner as specified in §1317.60 of this chapter;

(3) The outer container shall include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;

(4) The outer container shall prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances, if a collector chooses to commingle substances, are acceptable substances (Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and

(f) Except at a narcotic treatment program, the small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees.

(g) The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least two employees of the authorized collector.