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findings of fact and conclusions of law has expired, the presiding officer shall prepare a report containing the following:

(1) His recommended rulings on the proposed findings of fact and conclusions of law;

(2) His recommended findings of fact and conclusions of law, with the reasons therefore; and

(3) His recommended decision.

(b) The presiding officer shall serve a copy of his report upon each party in the hearing. The report shall be considered to have been served when it is mailed to such party or its attorney of record.

(c) Not less than twenty-five days after the date on which he caused copies of his report to be served upon the parties, the presiding officer shall certify to the Administrator the record, which shall contain the transcript of testimony, exhibits, the findings of fact and conclusions of law proposed by the parties, the presiding officer's report, and any exceptions thereto which may have been filed by the parties.

[36 FR 7778, Apr. 24, 1971. Redesignated at 38 FR 26609, Sept. 24, 1973 and amended at 44 FR 55332, Sept. 26, 1979]

§ 1316.66 Exceptions.

(a) Within twenty days after the date upon which a party is served a copy of the report of the presiding officer, such party may file with the Hearing Clerk, Office of the Administrative Law Judge, exceptions to the recommended decision, findings of fact and conclusions of law contained in the report. The party shall include a statement of supporting reasons for such exceptions, together with evidence of record (including specific and complete citations of the pages of the transcript and exhibits) and citations of the authorities relied upon.

(b) The Hearing Clerk shall cause such filings to become part of the record of the proceeding.

(c) The Administrative Law Judge may, upon the request of any party to a proceeding, grant time beyond the twenty days provided in paragraph (a) of this section for the filing of a response to the exceptions filed by another party if he determines that no party in the hearing will be unduly

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prejudiced and that the ends of justice will be served thereby. Provided however, that each party shall be entitled to only one filing under this section; that is, either a set of exceptions or a response thereto.

[44 FR 55332, Sept. 26, 1979]

§ 1316.67 Final order.

As soon as practicable after the presiding officer has certified the record to the Administrator, the Administrator shall cause to be published in the FEDERAL REGISTER his final order in the proceeding, which shall set forth the final rule and the findings of fact and conclusions of law upon which the rule is based. This order shall specify the date on which it shall take effect, which date shall not be less than 30 days from the date of publication in the FEDERAL REGISTER unless the Administrator finds that the public interest in the matter necessitates an earlier effective date, in which event the Administrator shall specify in the order his findings as to the conditions which led him to conclude that an earlier effective date was required.

[44 FR 42179, July 19, 1979, as amended at 44 FR 55332, Sept. 26, 1979]

§ 1316.68 Copies of petitions for judicial review.

Copies of petitions for judicial review, filed pursuant to section 507 of the Act (21 U.S.C. 877) shall be delivered to and served upon the Administrator in quintuplicate. The Administrator shall certify the record of the hearing and shall file the certified record in the appropriate U.S. Court of Appeals.

[36 FR 7820, Apr. 24, 1971. Redesignated at 44 FR 42179, July 19, 1979]

PART 1317—DISPOSAL

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AUTHORITY: 21 U.S.C. 821, 822, 823, 827, 828, 871(b), and 958.

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§ 1317.01 Scope.

This part sets forth the rules for the delivery, collection, and destruction of damaged, expired, returned, recalled, unused, or otherwise unwanted controlled substances that are lawfully possessed by registrants (subpart A) and non-registrants (subpart B). The purpose of such rules is to provide prompt, safe, and effective disposal methods while providing effective controls against the diversion of controlled substances.

Subpart A—Disposal of Controlled Substances by Registrants

§ 1317.05 Registrant disposal.

(a) *Practitioner inventory.* Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C

of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other registrants at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.

(i) The request shall be made by submitting one copy of the DEA Form 41 to the Special Agent in Charge in the practitioner's area. The DEA Form 41 shall list the controlled substance or substances which the registrant desires to dispose.

(ii) The Special Agent in Charge shall instruct the registrant to dispose of the controlled substance in one of the following manners:

(A) By transfer to a registrant authorized to transport or destroy the substance;

(B) By delivery to an agent of the Administration or to the nearest office of the Administration; or

(C) By destruction in the presence of an agent of the Administration or other authorized person.

(5) In the event that a practitioner is required regularly to dispose of controlled substances, the Special Agent in Charge may authorize the practitioner to dispose of such substances, in accordance with subparagraph (a)(4) of this section, without prior application in each instance, on the condition that the practitioner keep records of such disposals and file periodic reports with the Special Agent in Charge summarizing the disposals. The Special Agent in Charge may place such conditions as he/she deems proper on practitioner procedures regarding the disposal of controlled substances.

(b) *Non-practitioner inventory.* Any registrant that is a non-practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:

(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;

(2) Promptly deliver that controlled substance to a reverse distributor's registered location by common or contract carrier or by reverse distributor pick-up at the registrant's registered location;

(3) For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier or pick-up at the registrant's registered location to: The registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(4) Promptly transport that controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive that controlled substance for the purpose of return or recall as described in paragraph (b)(3) of this section.

(i) If a non-practitioner transports controlled substances by its own means to an unregistered location for destruction, the non-practitioner shall do so in accordance with the procedures set forth at § 1317.95(c).

(ii) If a non-practitioner transports controlled substances by its own means to a registered location for any authorized purpose, transportation shall be directly to the authorized registered location and two employees of the transporting non-practitioner shall accompany the controlled substances to the registered destination location. Directly transported means the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur.

(c) *Collected controlled substances.* Any collector in lawful possession of a controlled substance acquired by collec-

tion from an ultimate user or other authorized non-registrant person shall dispose of that substance in the following ways:

(1) *Mail-back program.* Upon receipt of a sealed mail-back package, the collector shall promptly:

(i) Destroy the package in accordance with subpart C of this part using an on-site method of destruction; or

(ii) Securely store the package and its contents at the collector's registered location in a manner consistent with § 1301.75(c) of this chapter (for practitioners), or in a manner consistent with the security requirements for Schedule II controlled substances (for non-practitioners) until prompt on-site destruction can occur.

(2) *Collection receptacles.* Upon removal from the permanent outer container, the collector shall seal it and promptly:

(i) Destroy the sealed inner liner and its contents;

(ii) Securely store the sealed inner liner and its contents at the collector's registered location in a manner consistent with § 1301.75(c) of this chapter (for practitioners), or in a manner consistent with § 1301.72(a) of this chapter (for non-practitioners) until prompt destruction can occur; or

(iii) Securely store the sealed inner liner and its contents at a long-term care facility in accordance with § 1317.80(d).

(iv) *Practitioner methods of destruction.* Collectors that are practitioners (*i.e.*, retail pharmacies and hospitals/clinics) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (a)(1), (a)(2), or (a)(4) of this section, or by delivering sealed inner liners and their contents to a distributor's registered location by common or contract carrier pick-up or by distributor pick-up at the collector's authorized collection location.

(v) *Non-practitioner methods of destruction.* Collectors that are non-practitioners (*i.e.*, manufacturers, distributors, narcotic treatment programs, and reverse distributors) shall dispose of sealed inner liners and their contents by utilizing any method in paragraph (b)(1), (b)(2), or (b)(4) of this section, or by delivering sealed inner liners and

their contents to a distributor's registered location by common or contract carrier or by distributor pick-up at the collector's authorized collection location for destruction. Freight forwarding facilities may not be utilized to transfer sealed inner liners and their contents.

§ 1317.10 Registrant return or recall.

(a) Each registrant shall maintain a record of each return or recall transaction in accordance with the information required of manufacturers in § 1304.22(a)(2)(iv) of this chapter.

(b) Each registrant that delivers a controlled substance in Schedule I or II for the purpose of return or recall shall use an order form in the manner described in part 1305 of this chapter.

(c) Deliveries for the purpose of return or recall may be made through a freight forwarding facility operated by the person to whom the controlled substance is being returned provided that advance notice of the return is provided and delivery is directly to an agent or employee of the person to whom the controlled substance is being returned.

§ 1317.15 Reverse distributor registration requirements and authorized activities.

(a) Any person that reverse distributes a controlled substance shall be registered with the Administration as a reverse distributor, unless exempted by law or otherwise authorized pursuant to this chapter.

(b) A reverse distributor shall acquire controlled substances from a registrant pursuant to §§ 1317.05 and 1317.55(a) and (c) in the following manner:

(1) Pick-up controlled substances from a registrant at the registrant's registered location or authorized collection site; or

(2) Receive controlled substances delivered by common or contract carrier or delivered directly by a non-practitioner registrant.

(i) Delivery to the reverse distributor by an authorized registrant directly or by common or contract carrier may only be made to the reverse distributor at the reverse distributor's registered location. Once en route, such deliveries may not be re-routed to any other loca-

tion or person, regardless of registration status.

(ii) All controlled substance deliveries to a reverse distributor shall be personally received by an employee of the reverse distributor at the registered location.

(c) Upon acquisition of a controlled substance by delivery or pick-up, a reverse distributor shall:

(1) Immediately store the controlled substance, in accordance with the security controls in parts 1301 and 1317 of this chapter, at the reverse distributor's registered location or immediately transfer the controlled substance to the reverse distributor's registered location for secure storage, in accordance with the security controls in parts 1301 and 1317 of this chapter, until timely destruction or prompt return of the controlled substance to the registered manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf;

(2) Promptly deliver the controlled substance to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(3) Timely destroy the controlled substance in a manner authorized in subpart C of this part.

(d) A reverse distributor shall destroy or cause the destruction of any controlled substance received for the purpose of destruction no later than 30 calendar days after receipt.

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

§ 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.

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(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

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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 comingle 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.

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§ 1317.80 Collection receptacles at long-term care facilities.

(a) A long-term care facility may dispose of controlled substances in Schedules II, III, IV, and V on behalf of an ultimate user who resides, or has resided, at such long-term care facility by transferring those controlled substances into an authorized collection receptacle located at that long-term care facility. When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, but no longer than three business days after the discontinuation of use by the ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the long-term care facility, or as a result of death.

(b) Only authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may install, manage, and maintain collection receptacles at long-term care facilities and remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at long-term care facilities. Collectors authorized to install, manage, and maintain collection receptacles at long-term care facilities shall comply with all requirements of this chapter, including §§ 1317.60, 1317.75, and 1317.80.

(c) The installation, removal, transfer, and storage of inner liners shall be performed either: By or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector; or, by or under the supervision of two employees of the authorized collector.

(d) Upon removal, sealed inner liners may only be stored at the long-term care facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer in accordance with § 1317.05(c)(2)(iv).

(e) Neither a hospital/clinic with an on-site pharmacy nor a retail pharmacy shall operate a collection receptacle at a long-term care facility until

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its registration has been modified in accordance with § 1301.51 of this chapter.

§ 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs.

(a) In the event of a product recall, an ultimate user in lawful possession of a controlled substance listed in Schedule II, III, IV, or V may deliver the recalled substance to the manufacturer of the substance or another registrant authorized by the manufacturer to accept recalled controlled substances on the manufacturer's behalf.

(b) An ultimate user who is participating in an investigational use of drugs pursuant to 21 U.S.C. 355(i) and 360b(j) and wishes to deliver any unused controlled substances received as part of that research to the registered dispenser from which the ultimate user obtained those substances may do so in accordance with regulations promulgated by the Secretary of Health and Human Services pursuant to 21 U.S.C. 355(i) and 360b(j).

Subpart C—Destruction of Controlled Substances

§ 1317.90 Methods of destruction.

(a) All controlled substances to be destroyed by a registrant, or caused to be destroyed by a registrant pursuant to § 1317.95(c), shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable.

(b) Where multiple controlled substances are comingled, the method of destruction shall be sufficient to render all such controlled substances non-retrievable. When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present.

(c) The method of destruction shall be consistent with the purpose of rendering all controlled substances to a non-retrievable state in order to prevent diversion of any such substance to illicit purposes and to protect the public health and safety.

§ 1317.95 Destruction procedures.

The destruction of any controlled substance shall be in accordance with the following requirements:

(a) *Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction.* If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

(b) *Transport to a registered location.* If the controlled substances are transported by a registrant to a registered location for subsequent destruction, the following procedures shall be followed:

(1) Transportation shall be directly to the registered location (the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the registered location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete;

(c) *Transport to a non-registered location.* If the controlled substances are transported by a registrant to a destruction location that is not a registered location, the following procedures shall be followed:

(1) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;

(4) Two employees of the transporting registrant shall handle or ob-

serve the handling of any controlled substance until the substance is rendered non-retrievable; and

(5) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

(d) *On-site destruction.* If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures shall be followed:

(1) Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(2) Two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

PART 1318—CONTROLS TO SATISFY THE REQUIREMENTS OF THE ACT APPLICABLE TO THE MANUFACTURING OF MARIHUANA

Sec.

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AUTHORITY: 21 U.S.C. 801(7), 821, 822(a)(1), (b), 823(a), 871(b), 886a.

SOURCE: 85 FR 82352, Dec. 18, 2020, unless otherwise noted.

§ 1318.01 Scope of this part.

Procedures governing the registration of manufacturers seeking to plant, grow, cultivate, or harvest marihuana are set forth by this part.

§ 1318.02 Definitions.

(a) Except as provided in paragraph (e) of this section, the term *cannabis* means any plant of the genus *Cannabis*.

(b) Except as provided in paragraph (e) of this section, the term *medicinal cannabis* means a drug product made