

DEA Short Rules for Drop Boxes in Pharmacy Locations

DEA is permitting certain registered hospitals/clinics to become authorized collectors. [21 CFR 1317.40](#). In order to counterbalance the diversion risks of allowing collection receptacles to be located inside hospitals/clinics, the DEA is only allowing those hospitals/clinics with on-site pharmacies to become collectors. The DEA is requiring these collectors to place collection receptacles in locations that are regularly monitored by employees, and is prohibiting these collectors from placing collection receptacles in the proximity of any area where emergency or urgent care is provided. [21 CFR 1317.75](#).

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).**

****YOU must modify your DEA Registration Number to house a drop box collection site prior to beginning collections. ** You can do this by going to the DEA Diversion website.**

The rule requires that a registrant must apply to modify their DEA registration prior to initiating any collection activities. [21 CFR part 1301](#). Authorization as a collector is subject to renewal in the same manner as registration. The DEA will consider an authorized collector to be conducting collection activities until the registration is modified, revoked, surrendered, suspended, or otherwise terminated. If an authorized collector stops collection activities, he/she must modify his/her registration to indicate such. The requirement to modify a registration requires a simple written notification to the DEA. This written notification can be easily and quickly conducted online in a few minutes. [21 CFR part 1301](#). The registrant may go online and select the option to indicate that the registrant has ceased collecting. Registrants without ready access to the online notification method can easily and quickly communicate such information to the DEA in writing via the mail, which the DEA will process promptly upon receipt.

§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. (Sealed box)

(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.

The Meds do not have to be sorted for take back events. You can either count the dosage units or you can do a total weight to report to Safe Kids the amounts collected.

If an authorized collector or other entity wishes to conduct a take-back event, the event must be held in partnership with law enforcement, as provided in the rule. [21 CFR 1317.65](#). Take-back events are intended to be limited-duration events that may take place at an unregistered location that is easily accessible to the public, such as a community center or town center. Given the likelihood of publicity and low physical security at such locations, the DEA believes that it is imperative to ensure active law enforcement participation for the safety of the event participants and the community, as well as to help deter theft and diversion of pharmaceutical controlled substances.

These take-back events may be held at public locations such as, supermarkets, pharmacies, etc. with whom you have partnered and Law Enforcement is present on site to co-sponsor the event and secure and collect the collected items for disposal. This would include Safe Kids Events.

§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. I interpret this to mean there does not have to be a camera on the

container, but it cannot be accessed during non-business hours due to the monitoring requirement by an employee.

- (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.

Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled.

So, what I can discern from this is that they do not want you handle it in order to count or inventory it. See the DEA Form 41 on how to report disposal/destruction of collected items from a drop box.

http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf#search=DEA form 41

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

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 observe 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.

Hospital/clinic staff **must also** not dispose of any controlled substances **in inventory or stock** in a collection receptacle.” 79 Fed. Reg. 53,523 (emphasis added). I take this to mean you cannot commingle outdated pharmacy medications with collection box items for disposal. It must be reported separately on the DEA Form 41.

Helpful websites:

<https://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances#h-26>

http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_public.pdf

<http://www.awarerx.org/get-informed/find-disposal-information#InfoOnCS>

<http://www.deadiversion.usdoj.gov/>

http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_registrant.pdf

http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_ltcf.pdf