



Secure and Responsible Drug Disposal Act of 2010

California State Board of Pharmacy Board Meeting

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The United States Department of Justice
Drug Enforcement Administration

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The Problem: Easy Access





National Take Back Initiative

Got Drugs?

Turn in your
unused or expired
medication for safe disposal
Saturday, Sept. 25th

Click here
for a collection
site near you.





National Take Back Initiative

- First Eight DEA Take Back Days (Combined)
 - Collection of 2,100+ tons
- September 27, 2014
 - Ninth (Final) DEA Take Back Day,
approximately 309 tons



Ultimate User Methods of Disposal Prior to Disposal Final Rule

Disposal in Trash (ONDCP method); or

Flushing (FDA opioids and select CSs)

National Take-back Event

Transfer to Law Enforcement (Police Station
Receptacles or local Take-back events)

DEA



Secure and Responsible Drug Disposal Act of 2010

- CSA amended to provide ultimate users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner
- Amendment authorizes DEA to inspect all collection facilities

21 USC §§ 822(f) and (g)



Secure and Responsible Drug Disposal Act of 2010

- Authorized DEA to promulgate regulations (Disposal Rule) that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal
- Created an exception for long-term care facilities (LTCF) to transfer pharmaceutical controlled substances for disposal on behalf of patients who reside or have resided at that facility.

21 USC §§ 822(f) and (g)



Secure and Responsible Drug Disposal Act of 2010

- Regulations did not limit the ways that ultimate users may dispose of pharmaceutical controlled substances—they expanded them.
- Any method of pharmaceutical disposal that was valid prior to these regulations continues to be valid.



Secure and Responsible Drug Disposal Act of 2010

- Participation is voluntary.
- DEA may not require any person to establish or operate a disposal program.

21 USC §§ 822(g)(2)



Secure and Responsible Drug Disposal Act of 2010

- Disposal rule eliminated existing 21 CFR §§ 1307.12 and 1307.21
- New part 1317 contains the requirements on:
 - disposal procedures;
 - collection of pharmaceutical controlled substances from ultimate users;
 - return and recall; and
 - destruction of controlled substances



Ultimate User

Ultimate user means as “a person who has lawfully obtained, and who possesses, a controlled substance for his own use or for the use of a member of his household or for an animal owned by him or a member of his household.”

21 USC § 802(27)



Disposal 21 CFR § 1317





Law Enforcement

- Law enforcement continues to have autonomy with respect to how they collect controlled substances from **ultimate users**, including:
 - maintaining collection receptacles
 - conducting mail-back programs
 - conducting take-back events

21 CFR § 1317.35



Law Enforcement

- Law Enforcement may continue to conduct take-back events.
- Any person may partner with Law Enforcement.
- Law Enforcement shall maintain control and custody of collected substances until secure transfer, storage, or destruction has occurred.
- Authorized collection receptacles and inner liners “should” be used.

21 CFR §§ 1317.35 and 1317.65





Collection

Collection means to receive a controlled substance for the purpose of destruction from an:

- Ultimate user,
- Person lawfully entitled to dispose of an ultimate user decedent's property, or
- and (54)
- LTCF on behalf of an ultimate user who resides or has resided at the facility.

21 USC § 822(g)(3) and (4)

21 CFR § 1300.01(b)



Authorized to Collection

Registrants authorized to collect:

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospitals/clinics with an on-site pharmacy
- Retail Pharmacies

21 CFR § 1317.40



Modification to Become Collector

- Must be registered to handle Schedule II - V
- Request modification in writing to the DEA or on-line at www.DEAdiversion.usdoj.gov
- No fee is required for this modification request

21 CFR §§ 1301.51(b) and (c)



Collection at LTCF

- A registered hospital/clinic with an on-site pharmacy or a registered retail pharmacy may request modification of their registration to become an authorized collector to maintain a collection receptacle at a LTCF (§ 1317.80).
- Request must include:
 - Name and physical location of each LTCF at which a collection receptacle will be operated
- No fee is required for this modification request.

21 CFR §§ 1301.51(b)(2) and (c)



Collection Receptacles



Collection Receptacles

Collection receptacle

- Any authorized collector may operate a collection receptacle at their registered location
- Retail pharmacies and hospitals/clinics with an on-site pharmacy may manage collection receptacles at LTCFs

21 CFR §§ 1317.75 and 1317.80



Collection Receptacles

- Ultimate users *shall* put the substances directly into the collection receptacle.
- Controlled and non-controlled substances may be comingled.
- Collected substances shall not be counted, sorted, inventoried, or otherwise individually handled.
- Registrants shall not dispose of stock/inventory in collection receptacles.

21 CFR § 1317.75(b) and (c)



Design of Collection Receptacles





Design of Collection Receptacles

- Securely fastened to a permanent structure.
- Securely locked, substantially constructed container with permanent outer container and removable inner liner.
- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.



21 CFR § 1317.75(e)



Design of Collection Receptacles

- Outer container must display a sign stating only Schedule II-V and non-controlled substances are acceptable substances.
- Substances **Not Permitted** to be collected:
 - **Schedule I** controlled substances,
 - Controlled substances that were **not lawfully possessed** by the ultimate user, and
 - All other illicit substances (including **marijuana in states like CO and WA**)

21 CFR § 1317.75(e)



Collection Receptacle Location

- Must be securely placed and maintained:
 - Inside collector's registered location
 - Inside law enforcement's physical location, or
 - Inside an authorized LTCF





Collection Receptacle Location

- **Registered location** – immediate proximity of designated area where controlled substances are stored and at which an employee is present.
- **LTCF** – located in secure area regularly monitored by LTCF employees.
- **Hospital/clinic** – located in an area regularly monitored by employees---**not** in proximity of where emergency or urgent care is provided.
- **NTP** – located in a room that does not contain any other controlled substances and is securely locked with controlled access.



Collection Receptacle Inner Liner

- Waterproof, tamper-evident, and tear-resistant.
- Removable and sealable upon removal without emptying or touching contents.
- Contents shall not be viewable from the outside when sealed (i.e., can't be transparent).
- Size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.).
- Outside of liner shall have permanent, unique ID number.

21 CFR § 1317.60(a)



Handling Inner Liners

- Only employees of the collector may access the inner liners.
- The inner liner shall be sealed by **two employees** immediately upon removal from the permanent outer container.
- Sealed inner liner ***shall not*** be opened, x-rayed, analyzed, or otherwise penetrated.
- Practitioners ***cannot*** transport collected controlled substances.

21 CFR §§ 1317.60(b) and (c), 1317.05(c)



Records for Collectors

Collection Receptacle Inner Liners Inventory

- For each unused inner liner on hand and sealed inner liner on hand:
 - Inventory date
 - Number and size of liners
 - Unique ID number for each liner

21 CFR § 1304.11(e)(7)



Records for Collectors

- Unused inner liners:
 - Date acquired, number acquired, unique ID number, and size
- Installed inner liners
 - Date, address where installed, unique ID number, size, DEA number of collector, and names and signatures of witnesses (2 employees)
- Inner liners removed and sealed
 - Date, address of removal location, unique ID number, size, DEA number of collector, names and signatures of witnesses (2 employees)



Records for Collectors

- Sealed inner liners transferred to storage
 - Date sealed and transferred to storage, unique ID number, size, names and signatures of witnesses (**2 employees**)
- Sealed inner liners transferred for destruction
 - Date transferred for destruction, address and DEA number of reverse distributor or distributor to whom transferred, unique ID number, size, names and signatures of witnesses (**2 employees**)
- Sealed inner liners destroyed on-site
 - The same information required of reverse distributors in § 1304.22(e)(4)(ii).

21 CFR § 1304.22(f)(2)



Mail-Back Programs



Mail-Back Program – Who is Authorized?

Any authorized collector that has and utilizes at its registered location (on-site) a method of destruction consistent with § 1317.90

21 CFR § 1317.70



Collection in LTCF



Collection at LTCF

- LTCF may dispose of a current or former resident's unwanted or unused controlled substances in a collection receptacle located at the LTCF.



- Transfer is to be immediate, but no longer than **3** business days after discontinuation of use.
- Discontinuation of use includes discontinuation directed by the prescriber, and as a result of patient transfer or death.

21 CFR § 1317.80(a)



Collection at LTCF

Authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may:

- Install, manage, and maintain collection receptacles at LTCFs.
- Remove, seal, transfer, store, or supervise the removal, sealing, transferring, and storage of sealed inner liners.
- Upon removal, sealed inner liners may be transferred for destruction, or stored at the LTCF for up to **3** business days.

21 CFR §§ 1317.80(b) and (d); 1317.05(c)

Collection at LTCF – Handling Liners

- Persons who can handle sealed inner liners:
 - 2 employees of the authorized collector, or
 - 1 employee of the authorized collector and 1 supervisory-level employee of the LTCF (e.g., charge nurse)
 - Sealed inner liner **shall not** be opened, x-rayed, analyzed, or otherwise penetrated
- Inner liners may be stored at LTCF for up to **3 business days** in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, until transfer for destruction.

NOTE: Collectors shall NOT transport sealed liners from the LTCF for any purpose

21 CFR § 1317.80(c) and (d); 1317.05(c)

Collection at LTCF – Handling Mail-Back Package

- Any authorized collector may make mail-back packages available to ultimate users, and persons lawfully entitled to dispose of an ultimate user decedent's property
- LTCF personnel may dispose of a current resident's unwanted or unused controlled substances in a mail-back package based upon a request by the resident

21 CFR § 1317.70



Authorized Collector Physical Security

- Non-Practitioner

Collected substances must be stored as a C-II

21 CFR § 1317.05(c)(1)(ii) and (c)(2)(ii)

- **Practitioner**

Securely locked, substantially constructed cabinet, or a securely locked room with controlled access

21 CFR §§ 1317.05(c)(1)(ii) and (c)(2)(ii); 1317.80(d)

21 CFR § 1301.75(c)



Authorized Collector Personnel Security

- A Collector shall not employ, as an **agent or employee** who has access to or influence over controlled substances, any person who has:
 - A **felony offense conviction** related to controlled substances; or
 - Had a DEA application for **registration denied**, or had a DEA registration **revoked, suspended, or surrendered for cause**

21 CFR § 1301.71(f)



Termination of Authorization to Collect

Registrant shall notify the DEA in writing or online.

21 CFR §§ 1301.52(f) and 1317.70 (e)(3)





Registrant Disposal



Registrant Disposal

Destruction of Sealed Inner Liners

Practitioners & Non-Practitioners shall dispose of sealed inner liners by:

- Prompt on-site destruction
- Prompt delivery to reverse distributor by common or contract carrier or reverse distributor pick-up
- Deliver sealed inner liners to a **distributor's** registered location by common or contract carrier or distributor pick-up

Practitioner may **also** request assistance from the SAC -may not authorize destruction which is not in compliance with regulations

Non-Practitioner may **also** transport to reverse distributor
Freight forwarding facilities may NOT be used.

21 CFR § 1317.05(a) & (b) – Inventory; (c)(2)(iv) and (v) – Liners;



Pharmaceutical Wastage



Requirements for Destruction of Controlled Substances



Destruction of Controlled Substances

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

21 CFR § 1317.90



Destruction of Controlled Substances

Non-retrievable means the condition or state to which a controlled substance shall be rendered following a process that permanently alters the substance's physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes.

21 CFR § 1300.05



Destruction of Controlled Substances

- Destruction shall be in accordance with the following requirements:
 - Transfer to registrant or person authorized to accept for destruction
 - On-site destruction

21 CFR § 1317.95



Destruction Procedures

- 2 employees of the registrant shall handle or observe the handling of any controlled substance until it is rendered non-retrievable, and
- 2 employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

21 CFR § 1317.95(c) and (d)





DEA Form 41

- Form 41 shall be used to record the destruction of all controlled substances, including controlled substances acquired from collectors.
 - The Form 41 shall include the names and signatures of the two employees who witnessed the destruction.
 - Exceptions for DEA Form 41:
 - Destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (i.e. wastage) shall be properly recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41
 - Transfers by registrant to a reverse distributor must be recorded in accordance with § 1304.22(c), and such record **need not** be maintained on a Form 41



Thank You