

## Outline of DEA Rules for Controlled Substance Disposal Programs

Published December 21, 2012, 77 Fed. Reg. 75784

Comments Due: February 19, 2013

1. What methods of disposing medications, including Schedule II-V medications, does DEA propose?

The rule proposes three methods of disposal for ultimate users or individuals lawfully authorized to dispose of an ultimate user decedent's property:

- Take-back events
- Mail-back programs
- Collection receptacle programs

Any entity offering to dispose of medications is acting on a voluntary basis and must be registered with the DEA as a collector (with the exception of law enforcement agencies).

2. How does a DEA registrant become a registered "collector" of controlled substances for disposal?

A registrant must submit a letter of request for modification of their registration to the Registration Unit, Drug Enforcement Administration that includes: the registrant's name, address, and registration number as printed on the registration certificate; as well as the type(s) of collection (mail-back program and/or collection receptacle) the registrant intends to conduct. Only registered manufacturers, distributors, reverse distributors, or retail pharmacies can become authorized "collectors". Registered hospitals themselves cannot themselves be authorized as collectors; however, retail pharmacies co-located with hospitals can be authorized collectors.

3. Take-Back Events

- a. Who can return controlled substances for disposal during a take-back event?

Ultimate users and individuals lawfully authorized to dispose of an ultimate user decedent's property.

- b. Who can conduct a take-back event?

Law enforcement agencies only.

- c. What procedures are required to conduct a law enforcement take-back event?

A law enforcement officer who is employed full time by the agency must be appointed to oversee the collection.

Law enforcement officers employed and authorized by the law enforcement agency must maintain control and custody of the controlled substances from the time of collection until a secure transfer or destruction takes place. No other person may handle or touch the collected controlled substances at any time.

- d. What recordkeeping is required for a law enforcement take-back event?

DEA recommends law enforcement agencies maintain records of receipt, collection, or destruction of controlled substances in a manner that is consistent with the agency's recordkeeping requirements for illicit controlled substance evidence. DEA also recommends law enforcement agencies keep a record of any transfers of controlled substances to reverse distributors for destruction.

4. Mail-back Programs

- a. Who can return controlled substances for disposal through a mail-back program?

Ultimate users and individuals lawfully authorized to dispose of an ultimate user decedent's property

- b. Who can conduct a mail-back program?

Law enforcement agencies and registered manufacturers, distributors, reverse distributors, or retail pharmacies.

- c. What procedures are required to conduct a mail-back program?

The registered manufacturer, distributor, reverse distributor, or retail pharmacy must be authorized as a collector (see question #2 above).

The registered manufacturer, distributor, reverse distributor, or retail pharmacy must have and utilize an on-site method of destruction at its registered location.

The authorized collector or law enforcement agency conducting the mail-back program must produce and provide specified packages to ultimate users.

- d. What requirements attach to packages used in a mail-back program?

The packages must:

Be postage paid, pre-addressed to the authorized collector's registered location (or the law enforcement agency's physical address).

Be nondescript, tamper-evident, and tear-resistant.

Contain a unique identification number so the package can be tracked.

Instruct the user on the process for mailing back the package and permitted substances that can be sent.

Contain a notice that only packages provided by the authorized collector will be accepted for destruction.

- e. What should the authorized collector do upon receipt of a package in the mail-back program?

The authorized collector shall not open, x-ray, analyze, or otherwise penetrate the package. The collector must promptly destroy the package on-site or securely store the package under the same security requirements of Schedule II controlled substances until prompt on-site destruction can occur. The date of receipt and the unique identification number of the package is to be recorded. If the authorized collector is a reverse distributor, destruction must occur as soon as practicable, but no later than fourteen calendar days of receipt.

- f. What if an authorized collector inadvertently and unknowingly accepts controlled substances from an ultimate user in a package that was not the specified package provided?

The authorized collector must notify the DEA office in their area within three business days of receipt of the package. The collector must store the package in a manner consistent with the routine mail-back package requirements until the collector receives further instructions from DEA.

- g. Can a mail-back program accept packages from ultimate users, or individuals lawfully authorized to dispose of an ultimate user decedent's property, residing in other states?

Yes, an authorized mail-back program is able to receive specified packages from any location within the U.S.

- h. What recordkeeping is required for mail-back programs?

The date of inventory, number of mail-back packages, and unique identification number of each package on hand (whether unused or awaiting destruction) must be recorded.

For packages the collector provides to a third party to distribute to ultimate users (ex. grocery store, etc.), the name and physical address of the third party, date and number of unused packages supplied to third party, and the unique identification number associated with the unused packages supplied to third party must be recorded.

For packages the collector provides to ultimate users at the collector's registered address, the date unused package was provided, the number of unused packages provided, and the unique identification number associated with the package(s) provided must be recorded.

5. Collection Receptacle Programs

- a. Who can return controlled substances for disposal through a collection receptacle program?

Ultimate users, individuals lawfully authorized to dispose of an ultimate user decedent's property, and long-term care facilities ("LTCF") on behalf of an ultimate user who resides or has resided at that LTCF (when a receptacle is located at that LTCF).

- b. Who can maintain a collection receptacle?

Law enforcement agencies and registered manufacturers, distributors, reverse distributors, or retail pharmacies that are authorized as collectors (see question #2 above).

- c. Where can a collection receptacle be located?

The collection receptacle must be at the physical address of the law enforcement agency or the DEA registered collector's location (which includes certain authorized LTCFs). The receptacle must be located within the immediate proximity of a designated area where controlled substances are stored and where an authorized employee is present. Collection receptacles cannot be placed at non-registered locations such as libraries or community centers.

- d. What are the physical requirements of the collection receptacle?

The receptacle must have a permanent outer container with a removable inner liner. The outer container must have an opening big enough to allow contents to be added to the inner liner, but small enough to prevent removal of the inner liner contents. The opening of the receptacle must be capable of being locked when an authorized employee is not present, unless the receptacle is located in a secured area of a LTCF which is regularly monitored by LTCF personnel. The outer container must be securely fastened to a permanent structure (ex. wall, floor) so it cannot be removed.

- e. What are the requirements for a collection receptacle inner liner?

The inner liner must:

Be waterproof, tamper-evident, tear-resistant;

Be removable and sealable immediately upon removal without emptying or touching the contents;

Be opaque from the outside once the liner is sealed, such that the contents are not visible;

Have the size clearly marked on the outside of the liner (ex. 5 gallon);

Contain a permanent, unique identification number on it that allows the liner to be tracked.

- f. Who can remove the inner liner?

At least two authorized employees of the authorized collector are required to remove or supervise the removal of the inner liner. An "authorized employee" is a person directly employed full time by the registrant and must not have been

convicted of any felony offense related to controlled substances and not have had at any time an application for registration with DEA denied, had a DEA registration revoked or suspended, or surrendered a DEA registration for cause.

- g. What must be done once the inner liner is removed?

The authorized collector must promptly either:

Destroy the inner liner and its contents; or

Store the inner liner and its contents at the collector's registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur.

- h. What recordkeeping requirements apply to a collection receptacle program?

Records must include the date of inventory, the number of inner liners, the unique identification number of each inner liner, and the size of the inner liner for all unused inner liners on hand and those on hand awaiting destruction.

Upon installation of each inner liner in a collection receptacle, the date of installation, the address and DEA registration number of the location of the collection receptacle where the inner liner is installed, the unique identification number of the inner liner, the size, and the name of two authorized employees who witnessed the installation must be recorded.

Upon removal of each inner liner, the date of removal, the address and DEA registration number of the location of the collection receptacle, the unique identification number of the inner liner, the size, and the name of two authorized employees who witnessed the removal must be recorded.

Upon transfer of a sealed inner liner to a reverse distributor or distributor, the date of transfer, the address and DEA registration number of the reverse distributor or distributor to whom the inner liner is being transferred to, the unique identification number of the inner liner, the size, and the name of the two authorized employees who transferred the inner liner to the reverse distributor or distributor must be recorded.

Upon acquisition of each inner liner, the date the inner liner is acquired, the unique identification number associated with the acquired inner liner, and the size of the inner liner must be recorded.

6. Disposal Logistics

- a. What form are registered collectors required to use when disposing of/destroying collected controlled substances?

DEA Form 41 is the record of destruction and must bear the signature of two authorized employees who witnessed the destruction.

- b. How long does the registered collector need to keep the DEA Form 41 in its records?

At least two years.

- c. How are registered manufacturers, distributors, and reverse distributors required to dispose of controlled substances?

On-site method of destruction; or

Delivery of the substance to a registered reverse distributor at its registered location (either by contract carrier or its own means), or by reverse distributor pick-up.

- d. How are registered retail pharmacies required to dispose of controlled substances?

Any of the following:

On-site method of destruction; or

Delivery of the substance to a registered reverse distributor at its registered location by contract carrier or reverse distributor pick-up (a retail pharmacy is not permitted to deliver the substances for disposal by its own means); or

Request assistance from the Special Agent in Charge (SAC) of the Administration in the area in which the pharmacy is located by submitting one copy of DEA Form 41.

- e. What method of destruction is required?

DEA does not require a particular method of destruction as long as the desired result is achieved. The standard for destruction is rendering the controlled

substance “non-retrievable”, meaning to make the physical and/or chemical state of the controlled substance permanently altered through irreversible means, resulting in that controlled substance being unavailable and unusable for all practical purposes. Destruction method must be in accordance with applicable federal, state, tribal, and local laws and regulations.