



Summary of DEA Final Rule Disposal of Controlled Substances

On September 8, 2014, the Drug Enforcement Administration published the final rule on the disposal of controlled substances. The rule becomes effective on October 9, 2014.

OVERVIEW

The final rule sets requirements for DEA registrants (including pharmacies) that voluntarily decide to establish disposal programs to collect unwanted controlled substances from ultimate users. The final rule expressly states that disposal programs are voluntary and no person is required to establish or operate a disposal program. The rule allows numerous DEA registrants to become authorized to establish disposal programs including manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies. These persons may become authorized to have disposal programs by modifying their DEA registrations.

The final rule allows a number of disposal program options including mail-back programs, collection receptacles, and collection events. In addition, federal, state, tribal and local law enforcement may maintain collection receptacles at the law enforcement's physical location, voluntarily hold take back events, and administer mail back programs. Authorized hospitals/clinics and retail pharmacies may maintain collection receptacles at long-term care facilities. In addition, long-term care facilities may dispose of controlled substances on behalf of an ultimate user residing or previously residing at the facility in the collection receptacle maintained by the hospital/clinic or retail pharmacy.

The rule requires destruction of collected controlled substances. It does not require a specific method but does require that the destroyed substances be rendered non-retrievable i.e. unavailable, unusable, and not capable of being transformed into a controlled substance. It also sets specific requirements for process and records for the destruction of collected controlled substances. Once a controlled substance is considered "*non-retrievable*," it is no longer subject to DEA regulations. Non-retrievable means, for the purposes of destruction, a process that permanently alters a controlled substance e.g. making it unavailable, unusable, cannot be transformed to a controlled substance.

The final rule makes a number of definitional changes including adding definitions for "*collection*" and "*collector*." It also adds a definition for "*reverse distribute*" meaning to acquire controlled substances from another registrant or law enforcement for the purpose of: (1) return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf; or (2) destruction. A

definition of “*reverse distributor*” is added to mean a person registered with the DEA as a reverse distributor.

The final rule adds a new section on Disposal of Controlled Substances and also makes changes to other CFR sections. The new 21 CFR Part 1317 is discussed below. The changes to the other code of federal regulations follow.

NEW PART 21 CFR 1317 DISPOSAL OF CONTROLLED SUBSTANCES

The final rule includes 3 subparts: (1) Disposal of controlled substances by registrants, (2) disposal of controlled substances collected from ultimate users and other non-registrants, and (3) destruction of controlled substances.

1. Subpart A: Disposal of controlled substances by registrants.

Subpart A of the rule sets requirements for registrant practitioners and non-practitioners disposal, return or recall, and reverse distributor registration and authorized activities. Practitioners include pharmacies.

Requirements include destruction in accord with subpart C of Part 1317 using on-site destruction, delivery to a reverse distributor’s registered location or pick-up by the reverse distributor. Returns and recalls are handled through delivery to or pickup by the person from whom it was obtained, registered manufacturer or its authorized registrant, or requesting DEA assistance by submitting DEA Form 41.

For controlled substances collected from an ultimate user or other authorized non-registrant, collectors may collect and dispose of the substances by (1) mail-back packages through on-site destruction or securely store the package at the collector’s registered location until prompt on-site destruction can occur; or (2) by removing, sealing and destroying the inner liner from a collection receptacle or by securely storing the inner liner until it can be destroyed, or (3) by securely storing the sealed inner liner at a long-term care facility until it can be destroyed.

- Disposal of sealed inner liners

Practitioners that collect controlled substances (retail pharmacies and hospitals/clinics) are required to dispose of sealed inner liners by onsite destruction, delivery to a reverse

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distributor, DEA Form 41 submission, or delivery to a distributor's registered location or distributor pick-up. There are very detailed recordkeeping requirements with respect to inner liners. More detail on the recordkeeping requirements is provided later in this summary.

- Records of returns and recalls

Registrants must keep records of each return and recall and use the required form for returns and recalls of a Schedule I or II substance. A freight forwarding facility may be used.

- Reverse distributor registration and authorized activities

Any person that reverse distributes a controlled substance must be registered as a reverse distributor unless exempted. The rule sets requirements for the reverse distributor's pick-up, receipt and secure storage of controlled substances and handling of returned and recalled controlled substances. Reverse distributors must destroy or cause the destruction of controlled substances within 30 days of receipt.

2. Subpart B: Disposal of controlled substances collected from ultimate users and other non-registrants

This subpart establishes requirements for collecting controlled substances from ultimate user and non-registrants for destruction.

Certain persons are allowed to collect controlled substances from ultimate users and other non-registrants for destruction including:

- Authorized collectors, e.g. registrant manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and **retail pharmacies**. These entities are required to modify their DEA registration to obtain authorization to be a collector and notify DEA if they cease collector activities. Collection may only occur at the registrants registered location and LTCF where hospitals/clinics or retail pharmacies are authorized to maintain collection receptacles. Collectors may (1) receive and destroy mail-back packages at an authorized registered location that has an on-site method of destruction, (2) install, manage, and maintain collection receptacles at their

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authorized locations, and dispose of sealed inner liners as required under the rule i.e. on-site destruction or store securely until on-site destruction can occur.

- Law enforcement: Federal, state, tribal, and local law enforcement may collect controlled substances through take-back events, mail-back programs, and collection receptacles inside the law enforcement's physical address.
- Non-registrants allowed to transfer controlled substances to collectors (including pharmacies) are (1) ultimate users (who must lawfully possess the controlled substances), (2) any person lawfully allowed to dispose of a decedent ultimate user's property, and (3) a long-term care facility (LTCF) on behalf of an ultimate user who resides or resided at the LTCF.
- Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement: Reverse distributors may acquire controlled substances collected by (1) law enforcement from ultimate users and (2) through a collection receptacle. The reverse distributor must acquire, securely store and dispose of the controlled substances as required by the rule.
- Take-back events: Federal, state and local law enforcement may conduct take back events to collect controlled substances from ultimate users and persons lawfully entitled to dispose of ultimate user's controlled substances. Any person may partner with law enforcement to hold a collection take back event. Each event must have at least collection receptacle. Controlled and non-controlled substances may be comingled, but it is not required.
- Mail-back programs: These may be conducted by any collector and law enforcement. Only controlled substances from ultimate users and persons lawfully entitled to dispose of ultimate user's controlled substances may be collected. Controlled and non-controlled substances may be comingled, but it is not required. Any person may partner with a collector or law enforcement to provide the mail-back packages. A collector must:
 - Have a method of destruction at their registered location.
 - Provide the mail-back packages either for free or at a fee.

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- The mail-back packages must:
 - Have a unique identification number
 - Be non-descript, not have any markings to indicate they contain controlled substances, be water and spill proof, tamper evident, tear resistant and sealable, and pre-addressed with the collector's registered address or the participating law enforcement's address and have prepaid postage.
 - Include instructions for the user on mailing only in the U.S., substances that may be included, and that only packages provided by the collector will be accepted.

The ultimate user and other persons entitled to dispose of their controlled substances may not be required to personally identifiable information.

Collectors that receive packages that the collector did not agree to receive must notify the local DEA field office within 3 days of receipt.

Collectors that stop mail-back programs must make a reasonable effort to notify the public and obtain written agreement from another collector to receive the remaining disseminated, but unreturned, mail-back packages.

Only law enforcement and employees of the collector are permitted to handle the mail-back packages. The packages may not be opened, x-rayed, analyzed or penetrated.

- Collection receptacles: Only controlled substances from ultimate users and persons lawfully entitled to dispose of ultimate user's controlled substances may be collected. The controlled substances may, but are not required, to be comingled with non-controlled substances. Collectors may only allow ultimate users or other authorized non-registrant persons to deposit the controlled substances in the receptacle at the registered location. The deposited substances may not be counted, sorted, inventoried or individually handled.
 - Location: Collection receptacles must be:
 - Inside the collector's registered location, inside law enforcement's physical location, or inside the authorized LTCF.

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- In immediate proximity of a designated area where controlled substances are stored and an employee is present (e.g. can be seen from the pharmacy counter) with exceptions for LTCF, hospital/clinic, narcotic treatment program.
- Inner liner requirements: The inner liner must be water-proof, tamper-evident and tear-resistant, removable, sealed immediately on removal with no emptying or touching the contents or ability to view the contents, have the size clearly marked, and have a permanent unique identification number that allows tracking. Access to the inner liner is restricted to the collector's employees and must be sealed immediately on removal and may not be opened, x-rayed, analyzed or penetrated.
- Receptacles must be securely fastened to a permanent structure, locked, securely constructed with permanent outer container and removable inner, have a small opening to allow adding contents but not allow removal of the inner liner, have a prominent display sign indicating only controlled substances (and non-controlled substances if the collector chooses to comingle) may be accepted, and the small opening must be locked if an employee is not present.
- Receptacles at LTCF: A LTCF may dispose of controlled substances from the ultimate user who resides or resided at the facility by transferring those substances to an authorized receptacle at the LTCF. The transfer must occur immediately or not later than 3 business days after the ultimate user discontinues use (prescriber stops use, or resident is transferred or dies.)

Only authorized retail pharmacies or hospitals/clinics with an on-site pharmacy may install, manage, maintain the collection receptacles at the LTCF and remove, seal, transfer, store the inner liners. These responsibilities must be performed by or under the supervision of one employee of the authorized collector and one supervisor-level employee of the LTCF designated by the authorized collector or under supervision

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of two employees of the collector. Sealed inner liners may only be stored at the LTCF for 3 days.

3. Subpart C: Destruction of controlled substances

All controlled substances destroyed or caused to be destroyed must be made non-retrievable. Once a controlled substance is “non-retrievable” it is no longer subject to DEA regulations.

- Transfer to person registered or authorized to accept controlled substances for destruction: Two employees of the transferring registrant must load and unload or observe loading and unloading until the transfer is complete.
- Transport by a registrant to a registered location for destruction: Transport must:
 - Be direct to the registered location with no unnecessary or unrelated stops and extended stops.
 - Have two employees of the transporting registrant accompany the controlled substances to the registered location and load/unload or observe loading/unloading.
- Transport to a nonregistered location: This requires specific procedures including direct transportation, two employees accompanying the transport and loading/unloading or observing the loading/unloading, two employees handling or observing the handling and witnessing the controlled substances being made non-retrievable.
- On-site destruction: For on-site destruction at a registrant’s registered location, two employees must handle or observe the handling and personally witness the substances being rendered non-retrievable.

OTHER AND MORE DETAILED CHANGES IN THE FINAL RULE

1. Amends Part 1301 Registration of manufacturers, distributors and dispensers of controlled substances

21 CFR 1301.13 is amended to allow a registrant to acquire Schedules II-V controlled substances from collectors for purposes of destruction.

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2. Amends 21 CFR 1301.51 Modification in Registration

Among other changes, it allows any manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy registered pursuant to this part, to apply to modify its registration to become authorized as a collector by submitting a written request or online. The rule specifies the information that must be in the request e.g. intended methods of collection (collection receptacle and/or mail-back) and other specifics. No fee is required to modify the registration. If the modification is approved, a new DEA Form 223 certificate of registration is issued.

3. Amends 21 CFR 1301.52 Termination of registration; transfer of registration, distribution on discontinuance of business

Collectors of controlled substances that want to stop collection of controlled substances from ultimate users must notify the DEA in writing or online and must give DEA the name, registered address, and registration number of the collector that will receive the remaining mail-back packages.

4. Adds 21 CFR 1301.71 Security requirements generally

Prohibits collectors from employing as an agent or employee any person who has been convicted of any felonies relating to controlled substances, had DEA registration denied, revoked, suspended for cause.

5. Amends or revises various provisions related to security controls for non-practitioners, narcotic treatment programs and compounders for treatment programs, storage areas including 21 CFR 1301.72, 1301.74

In particular, 21 CFR 1301.74 adds that a reverse distributor may not employ as an agent or employee any person who has been convicted of any felonies relating to controlled substances, or had a DEA registration denied, revoked, suspended for cause.

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6. Amends physical security controls for practitioners

Amends 21 CFR 1301.75. This change requires sealed mail-back packages and inner liners collected to be stored at a registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by 21 CFR 1317.80(d) which allows sealed inner liners from receptacles to be stored for up to 3 business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer occurs (per 1317.05(c)(2)(iv)).

Amends 21 CFR 1301.76 to require registrants who distribute controlled substances without being registered as a distributor to meet certain requirements.

7. Amends various parts of 21 CFR Part 1304 to require collectors to keep records

- Adds requirements for collectors to maintain records and inventories and file reports unless exempted, to keep records for a collection receptacle maintained at a long-term care facility,
- Adds collectors to requirements for keeping records, adds requirements for collectors to keep inventory information on each unused mail back package, and each returned mail back package on hand awaiting destruction including date of the inventory, number of mail back packages, and unique identification number of each package on hand whether used or unused.
- For collection receptacles, the inventory record must include the following for each unused inner liner on hand and each sealed inner liner on hand waiting destruction:
 - date of the inventory,
 - number and size of liners e.g. 5 gallon, and
 - unique identification number of each inner liner.
- In addition, the rule adds requirements for maintaining current records of each inner liner, sealed inner liner, and unused and returned mail-back packages except that there is no requirement for a perpetual inventory. Separate records must be kept for each independent activity and collection activity.

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- A registrant that destroys or causes the destruction of a controlled substance on-site (21 CFR 1317.95(d)) or if the controlled substances are transferred to a non-registered locations (21 CFR 1317.95(c)) must maintain a record of destruction on DEA Form 41.
- The rule adds requirements for collectors of controlled substances from ultimate users to maintain records for mail-back programs, and collection receptacle liners. For mail back programs records to be kept include:
 - date the unused mail-back packages were made available to ultimate users,
 - number of packages, and
 - unique identification number.
- For unused mail-back packages made available to third parties and other authorized non-registrants, records must be kept of
 - name of third party,
 - physical address of the locations receiving the unused packages,
 - date sent, and
 - number of unused packages and unique identification numbers.
- For sealed mail-back packages received by the collector, records must be kept of the date of receipt, and the unique identification number on each package.
- For sealed mail-back packages destroyed on-site by the collector, records must be kept of the number of sealed packages destroyed, date and method of destruction, unique identification number of each mail-back package destroyed and names and signatures of the two employees of the registrant who witnessed the destruction.
- For collection receptacles, records must be kept of
 - the date each unused inner liner was acquired,
 - unique identification number and size of each unused inner liner,
 - date each liner is installed,
 - address of location where each inner liner is installed,
 - unique identification number and size of each installed inner liner,
 - the registration number of the collector, and the names and signatures of the two employees that witnessed each installation,
 - the date each inner liner is removed and sealed,
 - the address of the location from which each inner liner is removed,

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- the unique identification number and size of each removed liner,
 - the registration number of the collector and names and signatures of the two employees that witnessed each removal,
 - date each sealed inner liner is transferred to storage,
 - the unique identification number and size of each sealed inner liner stored,
 - the names and signatures of the two employees that transferred each sealed inner liner to storage,
 - date each sealed inner liner is transferred for destruction,
 - the address and registration number of the reverse distributor or distributor to whom each sealed inner was transferred,
 - the unique identification number and size of each sealed inner liner transferred and the names and signatures of the two employees that transferred each sealer inner liner to the reverse distributor or distributor, and
 - for sealed inner liners destroyed on-site by the collector: the same information required of reverse distributors.
- Provision 21 CFR 1304.33 is amended to exempt collectors that acquire controlled substances from ultimate users from the ARCOS reporting requirements for controlled substances collected in mail-back programs and collection receptacles for purposes of disposal. Reverse distributors and distributors that acquire controlled substances collected through collection receptacles are exempt from ARCOS.

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