Disposal of Controlled Substances: DEA Final Rule
PSW Analysis – 10/13/14

Note: This analysis of the DEA Final Rule regarding the Disposal of Controlled Substances was completed as a member service by PSW staff and should not be considered a legal analysis of the Final Rule. Pharmacists should review the Final Rule in its entirety prior to planning for a disposal program.

On September 9, 2014, the DEA posted a Final Rule in the Federal Register related to the disposal of controlled substances. This rule governs the secure disposal of controlled substances by both DEA registrants, ultimate users (patients), and long term care facilities. These regulations implement the Secure and Responsible Drug Disposal Act of 2010 by expanding options available to collect controlled substances from ultimate users for purposes of disposal to include: take-back events, mail-back programs, and collection receptacle locations. These regulations contain specific language allowing law enforcement to voluntarily continue to conduct take-back events, administer mail-back programs, and maintain collection receptacles. These regulations also allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, and retail pharmacies to voluntarily administer mail-back programs and maintain collection receptacles. In addition, this rule expands the authority of authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long term care facilities and for long term care facilities to use collection receptacles on behalf of current or previous residents.

The Final Rule became effective October 9, 2014.

Collectors
- According to the Final Rule, the following groups may serve as “collectors” of controlled substances for the purpose of destruction:
  o Manufacturers
  o Distributors
  o Reverse distributors
  o Narcotic treatment programs
  o Hospitals/Clincs with an onsite pharmacy
  o Retail pharmacies (DEA states they intend “retail pharmacy” to include any entity registered with the DEA as a retail pharmacy as opposed to those entities registered as a hospital/clinic. Closed door pharmacies, long term care pharmacies, specialty pharmacies, are likely registered with the DEA as a “retail pharmacy”.
- In order to serve as a collector, the above groups must apply to modify their DEA registration to become and “authorized collector”. The registrant will need to specify which method(s) of collection will be used. No fee will be required for this registration modification. See www.DEAdiversion.usdoj.gov for information about modifying a DEA registration.
- Collectors may receive controlled substances for the purpose of destruction from the following:
  o “Ultimate user” defined 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 by a member of his household.”
  o Person lawfully entitled to dispose of an ultimate user decedent’s property
  o In the case of collection receptacles in long term care facilities, the long term care facility on behalf of an ultimate user who resides or has resided at that facility
Take-Back Programs
Bottom line: Pharmacists, pharmacy technicians and student pharmacists can continue to participate in take-back events in partnership with law enforcement, but ultimate users may only transfer controlled substances directly to law enforcement.
- DEA provides specific language that continues to authorize law enforcement, either independently or in partnership with private entities or community groups, to voluntarily hold take-back events. Only law enforcement can conduct take-back programs; other groups may assist.
- The Final Rule does not change existing law enforcement procedures regarding the handling, storage, transfer, or destruction of controlled substances, but it does outline procedures for take-back events themselves.
- Law enforcement that conduct take-back events need to appoint a law enforcement officer to oversee the collection at the event.
- According to the regulation, no other person such as a take-back event volunteer, can handle or touch the controlled substances prior to their transfer from the ultimate user to law enforcement. Only law enforcement can accept substances from community members.
- Nothing in the rule prohibits law enforcement from partnering with pharmacists, student pharmacists, or others to inventory or sort substances that have been collected by law enforcement provided that the collected substances remain under the control and custody of law enforcement. Law enforcement should provide adequate security to prevent diversion or theft.
- Specific recommendations for take-back event collection bins outlined on page 53568 of the Final Rule

Mail-Back Programs
Bottom line: Pharmacies may facilitate participation in mail-back programs in partnership with a reverse distributor, for example, but would likely not conduct the mail-back program themselves as onsite destruction of received controlled substances is required.
- The regulations contain specific language allowing law enforcement to voluntarily continue to conduct mail-back programs.
- DEA states that mail-back programs may be conducted by registered manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, or retail pharmacies that are (1) authorized as “collectors” and (2) have and utilize an “onsite” method of destruction at their registered location.
- Destruction must render the controlled substances “non-retrievable” (i.e. through incineration). Flushing controlled substances or mixing controlled substances with coffee grounds or kitty litter are examples of existing methods of destruction that do not meet the non-retrievable standard.
- DEA defines “onsite” as “located on or at the physical premises of the registrant’s registered location.” Specifically, a controlled substance is destroyed “onsite” when destruction occurs on the physical premises of the destroying registrant’s registered location.
- An authorized collector that wishes to conduct a mail-back program needs to produce and provide specified packages (at no cost or for a fee) to patients. The authorized collector may provide this packaging in partnership with a third party. For example, a reverse distributor (authorized as a collector by DEA) could produce mail-back packages and allow a pharmacy, hospital, or other group to provide these packages to patients. In this case, the reverse distributor would be responsible for operating the mail-back program and would receive the mail-back packages directly at its registered location for onsite destruction.
(Mail-Back Programs cont.)

- The authorized collector that is conducting the mail-back program is responsible for inventory/record keeping requirements. In the above example, the reverse distributor is responsible for the record keeping requirements outlined by the DEA. Further information about these inventory and record keeping requirements is available on pages 53563-53564 of the Final Rule.

- Mail-back packages need to be:
  - Postage paid and pre-addressed to the authorized mail-back location
  - Nondescript, tamper-evident, tear-resistant, water- and spill-proof, and sealable
  - Contain a unique identification number so that each package can be tracked
  - Contain instructions for the user that indicate the process for mailing back that package, permitted substances that can be sent, notice that packages may only be mailed from within the US, and notice that only packages provided by the authorized collector will be accepted for destruction
  - Patients cannot be required to provide any personally identifiable information when mailing back controlled substances to an authorized collector

- Mail-back packages received by the collector shall not be opened, x-rayed or otherwise penetrated, and the substances may not be individually handled, counted, inventoried, or otherwise discerned. The sealed mail-back packages must be destroyed onsite in a prompt manner.

- If a collector receives a mail-back package that they did not provide, the collector must notify the DEA Field Division Office in their area within three business days. This would apply to a pharmacy that receives a sealed mail-back package if they themselves are not the authorized mail-back collector even if they provided the mailer on behalf of a reverse distributor.

- Pharmacies cannot receive sealed mail-back packages for disposal unless they will be destroying the sealed mail-back package onsite.

Collection Receptacles

Bottom line: This is the most likely method pharmacies would provide to their patients for disposal of controlled substances.

- The regulation contains specific language allowing Federal, State, tribal, and local law enforcement to voluntarily maintain collection receptacles at the law enforcement’s physical location.

- DEA authorizes manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an onsite pharmacy, and retail pharmacies to be “collectors” with authorization to maintain collection receptacles at their registered location. With the exception of long term care facilities (see below), collection receptacles are not allowed at other locations like community centers, schools, churches, etc.

- Only ultimate users and person lawfully entitled to dispose of an ultimate user decedent’s property may deposit controlled substances in a collection receptacle. An individual may not gather controlled substances from friends, neighbors for bringing into the pharmacy, for example.

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

- DEA registrants cannot use the collection receptacles to dispose of unused controlled substances in their inventory or stock.
(Collection Receptacles cont.)

- Collection receptacle requirements include:
  - The receptacle must be securely placed and maintained inside the collector’s registered location
  - The receptacle must be located within 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)
  - The receptacle must be securely fastened to a permanent structure so that it cannot be removed
  - The receptacle must be a securely locked, substantially constructed container with a permanent outer container and removable inner liner
  - The receptacle must prominently display a sign indicting that only non-controlled drugs and Schedule II, III, IV or V controlled substances are acceptable for collection
  - The opening must be capable of being locked at times when an employee is not present (e.g., when the pharmacy department is closed) or not being regularly monitored by an LTCF employee

- Inner liner requirements include:
  - The inner liner must be waterproof, tamper-evident, and tear-resistant
  - The liner must be removable and sealable immediately upon removal without emptying or touching the contents
  - The contents of the inner liner shall not be viewable from the outside when sealed
  - The size of the inner liner must be clearly marked on the outside of the liner (e.g., 5-gallon)
  - The inner liner must bear a permanent, unique identification number that enables the liner to be tracked
  - Only employees of the collector shall have access to inner liners

- The inner liner shall be installed by or under the supervision of at least two employees of the authorized collector.

- The inner liner shall be sealed by two employees of the authorized collector immediately upon removal from the permanent outer container. The sealed inner liner shall not be opened or contents analyzed.

- Upon removal of the inner liner, a hospital/clinic with an onsite pharmacy or a retail pharmacy must do one of the following:
  - Promptly destroy the inner liner and its contents “on site”, rendering it “non-retrievable”
  - Promptly deliver the inner liner and its contents to a distributor’s or reverse distributor’s registered location by common or contract carrier pick-up or by distributor or reverse distributor pick-up at the registrant’s registered location
  - Request assistance from the Special Agent in Charge of the Administration in the area in which the authorized hospital/clinic or pharmacy is located. More information about requesting this assistance is available on page 53565 of the Final Rule.
  - Securely store the sealed inner liner and its contents at the collector’s registered location in either a securely locked, substantially constructed cabinet or a securely locked room with controlled access until prompt destruction can occur
Additional Information for Hospitals/Clinics with an Onsite Pharmacy

Bottom line: Hospital/Clinics with onsite pharmacies may maintain collection receptacles in non-urgent/emergency care areas that are regularly monitored by employees.

- DEA states that a hospital/clinic has an “onsite pharmacy” when it has a pharmacy located on the physical premises of the registrant’s registered location.
- Hospitals/Clinics that are collectors must place collection receptacles in locations that are regularly monitored by employees, but not in proximity of any area where emergency or urgent care is provided.
- Controlled substances dispensed pursuant to a medication order by a practitioner in a hospital or clinic for immediate administration at the practitioner’s registered location remain under the custody and control of the DEA registrant. Therefore, if that substance is not fully used (e.g. some of the substance remains in the vial, syringe, etc. after administration but cannot be further utilized), the DEA registrant must destroy the remaining, unusable controlled substance in accordance with 1317.90 and 1317.95 and record the destruction in accordance with 1304.22(c). A collection receptacle may not be used.

Additional Information Regarding Collection Receptacles in LTC Facilities

Bottom line: Hospitals/Clinics with an onsite pharmacy and retail pharmacies may maintain collection receptacles in long term care facilities. Long term care facilities may dispose of residents’ or prior residents’ controlled substances in collection receptacles under certain circumstances.

- “Long term care facility” is defined as “a nursing home, retirement care, mental care, or other facility or institution which provides extended health care to resident patients.”
- DEA authorizes that hospitals/clinics with an onsite pharmacy and retail pharmacies may maintain collection receptacles at long term care facilities (LTCFs). The authorized hospital/clinic with an onsite pharmacy or authorized retail pharmacy is responsible for:
  o Installation, management, and maintenance of the collection receptacle
  o Removal and sealing of inner liners or supervision of this activity
  o Transferring and storage of sealed inner liners or supervision of this activity
- Registrants that wish to maintain collection receptacles at LTCFs must include the name and physical location of each LTCF at which they intend to operate a collection receptacle in their application for a modified registration with the DEA. This means that if a pharmacy wants to add additional facilities to their list of LTCFs where they maintain a collection receptacle, they will have to further modify their registration with the DEA. If an LTCF changes ownership and changes its name, the authorized collector must modify its registration with DEA.
- Pharmacies that provide collection receptacles at LTCFs do not need to provide medications for the LTCF or have any other relationship with them.
- In addition to meeting the requirements for all collection receptacles (above), a receptacle in an LTCF needs to be located in a secured area monitored by LTCF employees. The authorized collector (e.g., pharmacy) is responsible for ensuring the regular monitoring of LTCF personnel and ensuring the appropriate security procedures are in place at LTCFs in the event of suspected tampering or diversion.
- As long as the regulations are followed, there can be more than one authorized collection receptacle at an LTCF.
- LTCFs may dispose of controlled substances on behalf of ultimate users who reside, or have resided, at LTCF. Controlled substances should be transferred into the receptacle immediately, but no longer than three business days after it’s determined that the patient no longer needs the controlled substance (medication discontinued by prescriber, resident transferred from the LTCF, resident’s death).
(LTCF Receptacles cont.)

- Inner liner installation, removal, storage, and transfer at LTCFs may be done by either of the following:
  - A designated supervisor-level employee of the LTCF (e.g. charge nurse, supervisor, or similar employee) AND one employee of the collector (authorized hospital/clinic or retail pharmacy)
  - Two employees of the authorized collector
- DEA permits authorized hospitals/clinics and retail pharmacies to store inner liners that have been sealed upon removal from a collection receptacle at an LTCF in a securely locked, substantially constructed cabinet or a securely locked room with controlled access for up to three business days until the liners can be transferred for destruction.
- Hospitals/Clincs and retail pharmacies must not transfer sealed inner liners from LTCFs to their primary registered location. Collectors should deliver sealed inner liners to distributor’s or reverse distributor’s registered location by common or contract carrier pick-up or by distributor or reverse distributor pick-up at LTCF. Practitioners may not transport collected substances to destruction location.
- LTCF residents may also request that LTCF personnel place the resident’s unwanted medication in a mail-back package, seal the mail-back package, and deposit that package in the facility’s outgoing mail. However, the LTCF should ensure that the individual patient is the disposer and should be wary of establishing any protocols whereby the facility itself is engaging in collection activities.
- Records related to collection receptacles at LTCFs must be maintained at the authorized collector’s registered location and not at the LTCF.
- DEA provides guidance related to use of automated dispensing systems on page 53545 of Final Rule.

Record Keeping Requirements for Collectors Maintaining Collection Receptacles

Bottom line: Pharmacies must have a complete, accurate record of each inner liner, sealed inner liner.

- Collectors maintaining collection receptacles need to keep inventory of unused inner liners on hand and sealed inner liners on hand awaiting destruction. This inventory must include:
  - Date of the inventory
  - Number and size of inner liners (e.g., five 10-gallon liners)
  - Unique identification number of each inner liner
- When unused inner liners are acquired, the following information must be recorded:
  - Date each unused inner liner is acquired
  - Unique identification number and size of each liner
- When installing each inner liner, the following information must be recorded:
  - Date inner liner is installed
  - Address of the location where installed
  - Unique identification number and size of liner installed
  - Registration number of the collector
  - Names and signatures of the two employees that witnessed the installation
- When removing an inner liner from a collection receptacle and sealing, the following information must be recorded:
  - Date inner liner is removed and sealed
  - Address of the location from which the inner liner is removed
  - Unique identification number and size of removed liner
  - Registration number of the collector
  - Names and signatures of the two employees that witnessed the removal
(Record Keeping cont.)

- When transferring a sealed inner liner to storage, the following information must be recorded:
  - Date of move to storage
  - Unique identification number and size of sealed liner
  - Names and signatures of the two employees that transfer the sealed liner to storage

- When transferring a sealed inner liner for destruction, the following information must be recorded:
  - Date sealed liner is transferred for destruction
  - Address and registration number of distributor or reverse distributor to whom the sealed inner liner was transferred
  - Unique identification number and size of sealed liner
  - Names and signatures of two employees that transferred the sealed inner liner to the distributor or reverse distributor.

Special Note for Hospice Patients

Bottom line: Home hospice and homecare personnel cannot collect controlled substances from patients or their families for the purpose of disposal.

- Home hospice and homecare personnel are often challenged by disposal of controlled substances after a patient dies. In the Final Rule, the DEA clarifies that home hospice and homecare personnel may not dispose of the deceased patients’ controlled substances.

- Options for disposal of controlled substances when a patient dies at home include:
  - A person “lawfully entitled to dispose of the decedent’s property” OR a member of the deceased patient’s household may deliver the controlled substance(s) to an authorized collector (take-back event, mail-back program, collection receptacle)
  - A person “lawfully entitled to dispose of the decedent’s property” OR a member of the deceased patient’s household may flush the substance(s) or mix with kitty litter or coffee grounds and throw the substance(s) away
  - The hospice or homecare organization can partner with an authorized collector to provide mail-back packages for the person “lawfully entitled to dispose of the decedent’s property” OR a member of the deceased patient’s household

Employees of Collectors

- The following criteria will determine whether a person is an employee of a registrant for the purpose of disposal:
  - Persons who are directly paid by the registrant
  - Persons who are subject to direct oversight by the registrant
  - Persons who are required, as a condition of employment, to follow the registrant’s procedures and guidelines pertaining to the handling of controlled substances
  - Persons who receive a performance rating or performance evaluation on a regular/routine basis from the registrant
  - Persons who are subject to disciplinary action by the registrant
  - Persons who render services at the registrant’s registered location

- Pharmacies serving as collectors cannot employ anyone with access to collected substances who has been convicted of a felony offense related to controlled substances or who has had an application for registration with the DEA denied, revoked, suspended, or surrendered.
**General Notes**

- All proposed collection methods are voluntary. Further, DEA does not prohibit collectors from refusing to collect any certain specified controlled substances.
- Any registrant that has been authorized as a collector and who desires to discontinue their collection of controlled substances must notify the DEA. See [www.DEAdversion.usdoj.gov](http://www.DEAdversion.usdoj.gov)
- DEA allows all controlled substances collected through take-back events, mail-back programs, and collection receptacles to be comingled with non-controlled substances although that comingling is not required.
- Controlled substances collected by collectors through mail-back programs and collection receptacles cannot be individually counted or inventoried.
- Controlled substances collected from ultimate users would not be part of a registrant's inventory and would not be counted as such. Pharmacies, physicians, or other practitioner registrants may not dispose of items from their inventory using take-back events, mail-back programs, or collection receptacles.
- Onsite destruction requirements are outlined on pages 53569-53570 of the Final Rule.
- Destruction must render the controlled substances “**non-retrievable**” (i.e. through incineration). Flushing controlled substances or mixing controlled substances with coffee grounds or kitty litter are examples of existing methods of destruction that do not meet the non-retrievable standard.
- All registrants are required to report theft and significant loss of controlled substances within one business day of discovery.
- DEA suggests that those ultimate users without access to take-back programs, mail-back programs, or collection receptacles may still use existing disposal methods (e.g. flushing, mixing with kitty litter or coffee grounds).
- DEA states that it “understands that there may be circumstances where there is no authorized person to dispose of the controlled substances, such as when controlled substances are abandoned at a school or summer camp, and return to the ultimate user is not feasible. In such instances, the affected entities should contact local law enforcement or their local DEA office for guidance on proper disposal procedures.”
Destruction of Controlled Substances in Hospitals
Bottom line: With the DEA updated definition of destruction as rendering a controlled substance “non-retrievable”, the health care community has been left with no real options for “wasting” controlled substances (as is current standard of practice). PSW expects the DEA will provide clarification very soon.

- Controlled substances that have been dispensed for immediate administration pursuant to an order for medication in an institutional setting have remained under the custody and control of that registered institution even if the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as “drug wastage” and “pharmaceutical wastage”). Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations, and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

- **21 CFR 1317.90 and 1317.95** outline the requirements for destruction of controlled substances
- As DEA registrants, DEA states that hospitals shall select a method outlined in **21 CFR 1317.95** for destroying controlled substances that are considered “waste”. Although other options are listed in 1317.95, the following would be the most likely options for a hospital.
  - **Option 1:** Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction (like a reverse distributor). Two hospital employees shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.
  - **Option 2:** Onsite destruction. Two hospital employees shall handle or observe the handling of any controlled substance until it’s rendered non-retrievable. In addition, two hospital employees shall personally witness the destruction until it’s rendered non-retrievable.