

DISPOSAL REGULATIONS: REGISTRANT FACT SHEET

On September 8, 2014, the Drug Enforcement Administration (DEA) made available for public view a final rule regarding the disposal of pharmaceutical controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010 (“Disposal Act”). The final rule is available for public view at <http://www.federalregister.gov/public-inspection>. The final rule will officially publish in the *Federal Register* on September 9, 2014, and will be available on <http://www.regulations.gov>, and our website, <http://www.DEAdiversion.usdoj.gov>. This Registrant Fact Sheet contains a general summary of some of the effects of the new rule on registrants. For detailed information, please visit our website or contact your local DEA office.

1. What is the Disposal Act?

- The Disposal Act amended the Controlled Substances Act (CSA) to give the DEA authority to promulgate new regulations, within the framework of the CSA, that will allow ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities for disposal in a safe and effective manner consistent with effective controls against diversion. The goal of the Disposal Act is to encourage public and private entities to develop a variety of methods of collection and disposal in a secure, convenient, and responsible manner.

2. What do the implementing regulations do?

- Effective October 9, 2014, the implementing regulations allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect pharmaceutical controlled substances from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.
- The new regulations reorganize and consolidate previously existing regulations on disposal, including the role of reverse distributors. Effective October 9, 2014, the existing regulation on disposal of controlled substances, 21 C.F.R. 1307.21, will be removed. New requirements on proper disposal procedure and security will be in a new part 1317.
- As of October 9, 2014, all Memoranda of Agreement (MOA) and Memoranda of Understanding (MOU) issued pursuant to current 21 C.F.R. 1307.21 will be null and void. Registrants should consult 21 C.F.R. 1317.05(a) for information on new MOAs and MOUs for the disposal of controlled substances.
- Effective October 9, 2014, the existing regulation on return and recall, 21 C.F.R. 1307.12, will be removed. New return and recall requirements for registrants and non-registrants are incorporated into new 21 C.F.R. 1317.10 and 1317.85.
- Effective October 9, 2014, registrants must use DEA Form 41 to record the destruction of controlled substances. However, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains 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 (*e.g.*, 21 C.F.R. 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

3. Who is an “ultimate user”?

- The CSA defines an “ultimate user” 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.”

4. What is “collection”?

- “Collection” means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent’s property, or a long-term care facility on behalf of an ultimate user who resides or has resided at that facility. The term “collector” means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized to so receive a controlled substance for the purpose of destruction.

5. How can a registrant become an “authorized collector”?

- Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that desire to be collectors may do so by modifying their registration to obtain authorization to be a collector. Registrants may modify their registration online at <http://www.DEAdiversion.usdoj.gov>. Once authorized, these entities are “authorized collectors.”
- Eligible registrants must have authority to handle schedule II controlled substances.
- Collectors are not authorized to conduct take-back events. Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events.

6. Who can operate a collection receptacle for the collection of pharmaceutical controlled substances?

- Authorized collectors may maintain collection receptacles inside their registered location; and Federal, State, tribal, or local law enforcement may continue to maintain collection receptacles inside their physical location.
- Authorized hospitals/clinics with an on-site pharmacy, and retail pharmacies, may maintain collection receptacles at long-term care facilities.

7. Who can operate a mail-back program for the collection of pharmaceutical controlled substances?

- Authorized collectors with an on-site method of destruction may operate a mail-back program.

8. If I become an authorized collector and decide to stop, how do I do so?

- *Collection receptacle:* Authorized collectors maintaining a collection receptacle must dispose of all collected pharmaceutical controlled substances in their possession in accordance with the new rule, and notify the DEA that collection activities are ceasing, in writing or online at <http://www.DEAdiversion.usdoj.gov>.

- *Mail-back program:* Authorized collectors operating a mail-back program must make a reasonable effort to notify the public prior to discontinuing or ceasing collection; obtain the written agreement of another collector to receive all remaining mail-back packages; and notify the DEA that collection activities are ceasing, in writing or online at <http://www.DEAdiversion.usdoj.gov>.

9. What can I collect as an authorized collector?

- An authorized collector may collect pharmaceutical controlled substances and non-controlled substances. Controlled and non-controlled pharmaceuticals may be co-mingled in a single collection receptacle, however it is not required.
- Controlled substances that are collected from ultimate users shall not be co-mingled with a registrant's inventory/stock of controlled substances (*i.e.*, registrants shall not dispose of controlled substance inventory in a collection receptacle or mail-back package, or through a take-back event).

10. Can ultimate users dispose of illicit drugs through a collection receptacle, mail-back package, or take-back event?

- No. Ultimate users may not dispose of illicit drugs (*e.g.*, schedule I controlled substances such as marijuana, heroin, LSD) through any of the three disposal methods.

11. I am a pharmacist. If my pharmacy chooses to become an authorized collector, will we need to collect and retain information about persons who utilize the collection receptacle, such as a person's name, prescription information, or physician information?

- No. A collector shall not require any person to provide any personally identifying information.

12. How does a registrant dispose of controlled substances when 21 C.F.R. 1307.21 is removed?

- The authorized methods and procedures regarding disposal are outlined, in 21 C.F.R. 1317.05, according to whether the substances being disposed of are practitioner inventory, non-practitioner inventory, or collected controlled substances.

13. How can a registrant destroy controlled substances?

- The new regulations do not require a particular method of destruction, so long as the desired result is achieved. Pharmaceutical controlled substances must be rendered "non-retrievable" in compliance with all applicable Federal, State, tribal and local laws. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances.
- "Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.