

DISPOSAL ACT: LONG-TERM CARE FACILITY 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 Long-Term Care Facility Fact Sheet contains a general summary of some of the effects of the new rule on Long-Term Care Facilities (LTCFs). 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. Can a LTCF dispose of pharmaceutical controlled substances on behalf of a person who resides or has resided at their facility?

- Yes. Beginning October 9, 2014, a LTCF may dispose of a current or former resident’s pharmaceutical controlled substances by depositing those substances into an authorized collection receptacle located at the facility.
- If someone dies while in lawful possession of pharmaceutical controlled substances, any person lawfully entitled to dispose of the decedent's property may dispose of the decedent’s pharmaceutical controlled substances.

3. How can my LTCF get a collection receptacle installed at my location?

- An authorized retail pharmacy or a hospital/clinic with an on-site pharmacy may install, manage and maintain a collection receptacle at a long-term care facility.

4. What can be placed in a collection receptacle?

- Pharmaceutical controlled substances and non-controlled substances may be placed in the receptacle.

5. How long does an LCTF have to dispose of a current or former resident’s unwanted or unused pharmaceutical controlled substances in an authorized collection receptacle?

- When disposing of pharmaceutical controlled substances by transferring those substances into a collection receptacle, such disposal shall occur immediately, but no longer than three business days after discontinuation of use by the LTCF resident.

- Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the long-term care facility, or as a result of death.

6. Can LTCF personnel help with disposal activities by handling collection receptacle inner liners?

- One supervisor-level employee of the LTCF (*e.g.*, charge nurse or supervisor), designated by the authorized collector, may assist in changing the collection receptacle inner liner under the supervision of one employee of the authorized collector.

7. How long can inner liners be stored at the LTCF?

- Upon removal, sealed inner liners may be stored at the LTCF for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.

8. What happens to a person's pharmaceuticals after they are placed in a collection receptacle? Can they be sold, given away, re-packaged, or re-dispensed for use by another patient? Can they be otherwise recycled?

- Pharmaceutical controlled substances transferred from ultimate users to authorized collectors via either collection receptacles or mail-back programs shall be securely stored or transferred until rendered non-retrievable. They may not be re-sold, donated, repackaged, or re-dispensed. Currently, the most common method of rendering pharmaceutical controlled substances non-retrievable is incineration.

9. No retail pharmacy or hospital/clinic with an on-site pharmacy will install or maintain a collection receptacle at my LTCF. How can the LTCF dispose of the residents' pharmaceutical controlled substances without a collection receptacle?

- There may be some LTCFs that will not have a collection receptacle, and there may be instances where LTCF residents are incapable of disposing of their own unused or unwanted medication. As ultimate users, LTCF residents may use any of the disposal options afforded other ultimate users (*e.g.*, mail-back programs), in addition to the disposal options currently available to other ultimate users (*e.g.*, flushing or otherwise discarding) that will remain options even after the new regulations are in effect.