



DEA Releases New Rules for Safe and Secure Prescription Drug Disposal

October 7, 2014

Summary at a Glance:

The DEA has published a final rule on disposal of controlled substances. The DEA suggests three possible options for disposal:

1. Drug take-back programs
2. Mail-back programs
3. Collection receptacles for drug disposal

However, the rule does not require use of any of these methods, and notes that it does not prohibit use of any existing lawful method of disposal. The final rule has specific guidance for hospice employees. Hospice staff should carefully read the section on hospice specific issues.

This final rule will take effect on October 9, 2014.

DEA Releases New Rules for Safe and Secure Prescription Drug Disposal

On September 9, 2014, the U.S. Drug Enforcement Administration released a final rule for the disposal of controlled substances by publication in the Federal Register. A copy of the final rule can be found in the [Federal Register](#) (PDF). The final rule will go into effect on October 9, 2014. NHPCO submitted comments on the [proposed DEA drug disposal rule](#) (PDF), which appeared in the Federal Register on December 12, 2012.

The DEA administrator stated, "These new regulations will expand the public's options to safely and responsibly dispose of unused or unwanted medications... The new rules will allow for around-the-clock, simple solutions to this ongoing problem. Now everyone can easily play a part in reducing the availability of these potentially dangerous drugs."

Prior to the passage of the Secure and Responsible Drug Disposal Act of 2010, the Controlled Substances Act (CSA) made no legal provisions for patients to rid themselves of unwanted pharmaceutical controlled substances except to give them to law enforcement, and it banned pharmacies, doctors' offices, and hospitals from accepting them. Most people flushed their unused drugs down the toilet, threw them in the trash, or kept them in the household medicine cabinet.

Hospice Specific Issues

This DEA final rule does not provide any new authorization for hospices or hospice employees to handle controlled substances. Hopefully, the expansion of mail-back programs and collection receptacles outlined below will increase the options available to patients and families to dispose of unwanted controlled substances. Hospice employees will continue to have an important responsibility to educate patients and families about the importance of safe disposal of unwanted controlled substances, and how to use the options available to them.

In the final rule, DEA responded to some hospice-specific questions:

1. How should a hospice handle drug disposal in the home?

(This answer is taken from the DEA discussion on the issue in the final rule in its entirety.)

Detail on Issue: The DEA received a number of comments regarding the lack of provisions for hospice and other homecare programs to dispose of controlled substances on behalf of patients. According to the commenters, many hospices have written policies and procedures in place for the management and disposal of controlled substances in the patient's home. Given the available options for ultimate user disposal, commenters expressed concern that hospices may no longer be able to assist families in disposing of a deceased patient's drugs. Commenters suggested that the DEA allow hospice staff to dispose of a decedent's controlled substances by sewerage or landfill disposal.

A: The DEA appreciates the difficulties facing home hospice staff with regard to the disposal of pharmaceutical controlled substances. The Disposal Act provides that "if a person dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of the decedent's property may deliver the controlled substance to another person for the purpose of disposal under the same conditions as provided" for ultimate users. 21 U.S.C. 822(g)(4). Otherwise, home hospice and homecare personnel are not authorized to receive pharmaceutical controlled substances from ultimate users for the purpose of disposal. In addition, an ultimate user includes "a person who has lawfully obtained, and possesses, a controlled substance for his own use or *for the use of a member of his household.*" 21 U.S.C. 802(27). Accordingly, a member of the hospice patient's household may dispose of the patient's pharmaceutical controlled substances, but the home hospice or homecare provider cannot do so unless otherwise authorized by law (for example, under state law) to dispose of the decedent's personal property.

This rule provides a number of options for ultimate users and persons lawfully entitled to dispose of a deceased ultimate user's property to safely and securely dispose of pharmaceutical controlled substances, yet the DEA does not require ultimate users to utilize these options. However, it is unlawful for ultimate users to transfer pharmaceutical controlled substances to unauthorized persons, and it is unlawful for unauthorized persons to receive such substances. It is also unlawful for any person to possess a controlled substance unless authorized to do so under the CSA (i.e., an

ultimate user, an entity registered with the DEA, or an entity exempt from registration with the DEA). 21 U.S.C. 844(a). Home hospice and other homecare providers are encouraged to assist their patients, and their patients' families, in disposing of pharmaceutical controlled substances in accordance with the CSA and its implementing regulations. While education is paramount, home healthcare agencies are also encouraged to partner with authorized collectors to promote or jointly conduct mail-back programs.

2. Can a hospice employee utilize a LTCF's collection receptacle for disposal of controlled substances for a LTCF resident who is also a patient of the hospice?

A: No. Congress specifically allowed the Attorney General to consider permitting LTCFs to dispose of pharmaceutical controlled substances on behalf of LTCF residents. This allowance did not extend to other persons who are simply attending to a person who is resident of the LTCF. As such, a hospice employee is not authorized to dispose of pharmaceutical controlled substances on behalf of a person who resides or has resided at a LTCF. However, LTCF employees may do so on behalf of ultimate users who reside, or have resided, at the LTCF.

3. Is a hospice facility considered a Long Term Care Facility (LTCF)?

A: LTCF is defined at § 1300.01(b) and “means a nursing home, retirement care, mental care or other facility or institution which provides extended health care to resident patients.”

Other Provisions of DEA Final Rule on Disposal of Controlled Substances

The DEA has worked to develop and implement these regulations to curb prescription drug abuse and diversion by allowing for methods for safe drug disposal. In the final rule, three voluntary options are suggested for ultimate user disposal:

- Drug take-back events
- Mail back programs
- Collection receptacles for drug disposal

Drug take-back events: As a temporary measure, DEA began hosting National Prescription Drug Take-Back events in September 2010. Since then, the DEA has sponsored eight take-back days. Enormous public participation in those events resulted in the collection of more than 4.1 million pounds (over 2,100 tons) of medication at over 6,000 sites manned by law enforcement partners throughout all 50 states, the District of Columbia, and several U.S. territories.

While DEA will no longer sponsor drug take-back days, local law enforcement may schedule drug take-back days at any time and may partner with any person or entity to sponsor and hold a day.

Mail-back programs: The rule designates certain DEA registrants as “collectors” that are authorized to conduct a mail-back program. They include:

- Manufacturers
- Distributors
- Reverse distributors
- Narcotic treatment programs (NTPs)
- Hospitals/clinics with an on-site pharmacy
- Retail pharmacies

All collectors who establish a mail-back program must provide specific mail-back packages to the public, either at no cost or for a fee. These collectors must also have and use an on-site method of destruction to destroy returned packages of controlled substances.

Collection receptacles: Authorized DEA collectors also may maintain a collection receptacle at their registered location. This could include law enforcement, hospitals and clinics with an onsite pharmacy, and retail pharmacies. Ultimate users (the patient, family member or authorized representative) will be able to carry their unwanted pharmaceutical controlled substances to an authorized retail pharmacy or other authorized collector location and deposit those controlled substances in a secure container for disposal. Retail pharmacies and hospitals/clinics with an onsite pharmacy may operate collection receptacles at long-term care facilities. Collectors with an on-site means of destruction may operate a mail-back program.

The public may find authorized collectors in their communities by calling the DEA Office of Diversion Control’s Registration Call Center at 1-800-882-9539

Drug disposal guidelines: Patients and families may also use the guidelines for the disposal of pharmaceutical controlled substances listed by the [Food and Drug Administration](#) (PDF) on their website.

Any method of disposal that was valid prior to these new regulations being implemented continues to be valid.

Ultimate user: An ultimate user is defined by the Controlled Substances Act (CSA) 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.” 21 U.S.C. 802(27).

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Members with questions following review of this Regulatory Alert should contact regulatory@nhpco.org.