

Brief Overview of the DEA's Final Rule for the Disposal of Controlled Substances

On September 8, 2014, the Drug Enforcement Administration (DEA) released a final Rule to implement the Secure and Responsible Drug Disposal Act, which was signed into law in October 2010.

The final Rule defines protocols for take-back of leftover controlled substances from any person the drug is prescribed to, any member of that person's household, and from individuals lawfully entitled to dispose of a deceased person's property. Controlled drugs for pets can also be disposed of by household members.

The final Rule takes effect on October 9, 2014. It will take some time to fully implement because potential collectors as allowed under the Rule must apply to DEA to amend their controlled substances registration if they wish to provide medicine take-back and disposal services.

Take-back methods that are allowed in accordance with protocols in the Rule include:

- 1. Collection receptacle locations** (i.e., permanent drop-off boxes) – operated by authorized drug manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment centers, or law enforcement agencies.
- 2. Take-back events** – conducted by law enforcement agencies only.
- 3. Mail-back programs** – operated by authorized drug manufacturers, distributors, reverse distributors, retail pharmacies, hospitals/clinics with an on-site pharmacy, narcotic treatment centers, or law enforcement agencies.

Long-term care facilities: The new Rule also allows for operation of collection receptacles at these facilities by an authorized retail pharmacy or by an authorized hospital/clinic with an on-site pharmacy.

Security: All collection methods must be conducted under specific security protocols that ensure safe handling of collected medicines to prevent diversion.

Comingling of medicines: By any of these collection methods, controlled substances may be co-mingled with other consumer medications. So consumers can place all leftover medicines into one collection box or one mail-back envelope without having to attempt to identify and separate different medications.

Final destruction: The proposed rule makes it simpler for authorized collectors to send drugs away to final destruction through existing providers of pharmaceutical waste disposal. The Rule does not limit the specific destruction method, but requires that drugs must be rendered non-retrievable and the disposal method must comply with federal, tribal, state, local laws. DEA specifically says flushing and trash disposal do not meet the non-retrievable standard for collected medicines.

Background: Public comment on a draft of the Rule was conducted between December 2012 and February 2013. Currently, leftover or expired controlled substances - such as prescription narcotics and stimulants - can only be collected from residents by law enforcement, at take-back events or drop-off programs. The Rule expands allowed options for collecting controlled substances from individuals and their family members for safe destruction by secure medicine return programs. The new options will be more convenient for residents and even more effective in reducing misuse or improper disposal of leftover household medicines. The 2010 federal law amended the Controlled Substances Act and authorized the DEA to develop the new Rule, but the law does not mandate the creation of any medicine take-back programs, nor does it provide any funding for those programs.

Link to DEA Final Rule: _

<https://www.federalregister.gov/articles/2014/09/09/2014-20926/disposal-of-controlled-substances>