Overview of Secure and Responsible Drug Disposal Act of 2010

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Office of Diversion Control

- Is to Prevent, Detect, and Investigate the Diversion of Pharmaceutical Controlled Substances and Listed Chemicals from Legitimate Channels.

- While Ensuring an Adequate and Uninterrupted Supply of Controlled Substances to Meet Legitimate Medical, Commercial, and Scientific Needs.

UNIFORM CONTROLLED SUBSTANCES ACT OF 1970 (CSA)
Closed System of Distribution

- Importer
- Manufacturer
- Practitioner
- Distributor
- Pharmacy
- End User

Obvious Problem: Opiates

**CDC:**

- Drug overdose was the leading cause of injury death in 2011. Among people 25 to 64 years old, drug overdose caused more deaths than motor vehicle traffic crashes.
- Of the 41,340 drug overdose deaths in the United States, 22,810 (55%) were related to pharmaceuticals.

Teens and Their Attitudes

- 20% of teens report abusing Rx medications to get high.
- 3 in 10 teens believe Rx pain relievers are not addictive.
- 40% of teens believe that Rx meds are “much safer” than illegal drugs.
USE -> ABUSE -> ADDICTION

Figure 2.16 Source Where Pain Relievers Were Obtained for Most Recent Nonmedical Use among Past Year Users Aged 12 or Older: 2012-2013

Source: CDC/NCHS, NVSS

Note: The percentages do not add to 100 percent due to rounding.

Rx Narcotic Overdose deaths are Greater than Heroin + Cocaine Combined

Source: CDC/NCHS, NHAM
Prior to October 9, 2014

Ultimate users had no authority to distribute controlled substance to others.

Secure and Responsible Drug Disposal Act

- October 12, 2010, signed into law
- Published in federal register September 9, 2014
- Went into effect October 9, 2014

What is the Disposal Act?

- Amended the CSA
- Allows ultimate users to deliver unused pharmaceutical controlled substances to appropriate entities.
- Goal: Encourage the development of collection and disposal in a secure, convenient, and responsible manner.
Who is an “Ultimate User”?  

- A person who has lawfully obtained, and who possesses, a controlled substance for his own use,
- Or for a member of his household,
- Or for an animal owned by him or a member of his household.


Options for Ultimate User Disposal  

- Collection Receptacles
- Mail-Back Programs
- Take-Back Events

Who Can Collect from Ultimate Users?  

- DEA Registrant authorized to be a collector
- Person lawfully entitled to dispose of Ultimate Users property (death)
- Law Enforcement  
  - Federal, State, Tribal or local LE acting in the course of official duties

C.F.R. Section 1317.30
Other Options for Ultimate Users

- Any method of pharmaceutical disposal prior to the new regulations is still valid
- FDA and EPA Guidelines are still valid

EPA/FDA Guidelines for Ultimate Users:

- Suggests you don’t flush
- Suggests you use Take-back program or household disposal.
- Household disposal:
  - Remove from original containers
  - Mix with undesirable substance
  - Place in disposable container

FDA.gov

FDA recommends disposal by flushing for certain narcotic controlled substances.
FDA Recommends Flushing

Medicines Recommended for Disposal by Flushing

Listed by Medicine and Active Ingredient

There is a small number of medicines that may be especially harmful, and in some cases, fatal when just one dose if they are used by someone other than the patient for whom the medicine was prescribed. This list from FDA tells you exactly expirable, outdated, or unused medicines you should flush down the sink or toilet to help prevent danger to people and pets in the home.

<table>
<thead>
<tr>
<th>Medicine</th>
<th>Active Ingredient</th>
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Which DEA registrants can be a collector?

- Manufacturers
- Distributors
- Reverse Distributors
- Narcotic Treatment Programs
- Hospital/Clinic with an on-site pharmacy
- Retail Pharmacies

C.F.R. Section 1317.40
Modification Process

- Must be authorized to handle Schedule II's
- Modify Registration on line at http://www.DEAdiversion.usdoj.gov

Who can maintain a Collection Receptacle?

- All DEA Collectors
  - Hospitals/Clinics with on-site pharmacy and retail pharmacies may maintain at a LTCF
- Law Enforcement

12 CURRENT COLLECTORS IN WI
Where can Collection Receptacles be located?

- Securely maintained at:
  - DEA Collectors registered location
  - LE facility
  - Authorized Long Term Care Facilities

Collection Receptacles for DEA Registrants

Physical specifications for DEA Collectors:
- Securely fastened to permanent structure
- Securely locked
- Substantially constructed container

- Section 1317.75
Collection Receptacles for Law Enforcement

- Maintained inside the physical location
- C.F.R. Section 1317.75(d)

Mail-back Programs

Who can run a Mail-back Program?

- DEA Authorized collectors with an on-site destruction method that is non-retrievable.
- Law Enforcement

C.F.R. Section 1317.70
Mail-Back Packaging Specifications

- Packages may be made available for sale or free of charge;
- Any person may partner with a collector or law enforcement to make packages available to the public;
- Nondescript and no markings that indicate it contains controlled substances

   21 CFR § 1317.70 (c)

Mail-Back Packaging Specifications

- Water- and spill-proof, tamper-evident, tear-resistant, and sealable;
- Pre-addressed with the collector’s registered address;
- Pre-paid postage;
- Unique ID number so package can be tracked; and
- Instructions for mailing.

   21 CFR § 1317.70 (c)

Take-back Events
Who can conduct a Take-back Event?

• Law Enforcement may conduct Take-Back events.
• Any person or community group, registrant or non-registrant can partner with LE to conduct a Take-Back event.

Law Enforcement

• Law enforcement continues to have autonomy with respect to how they collect controlled substances from ultimate users, including:
  - maintaining collection receptacles
  - conducting mail-back programs
  - conducting take-back events

21 CFR § 1317.35

Take Back Program Requirements:

• Law Enforcement MUST be present

• Law Enforcement MUST take possession of controlled substances

• Law Enforcement MUST maintain possession and take drugs to destruction site.
Take Back Program Requirements:

- LE shall appoint a LE officer employed by Agency to oversee collection.

- Should have at least one collection receptacle.

- Collection receptacle should be securely locked, substantially constructed with an outer container and removable liner.

Take Back Program Requirements:

- Outer container should include a small opening that allows contents to be added but not removed.

- Controlled and non-controlled substances can be co-mingled

- Only Ultimate Users and persons entitled to dispose on behalf of Ultimate User may transfer to LE

Questions?
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