



**Disposal of Controlled Substances
DEA Notice of Proposed Rulemaking**

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Presentation Objective

Background - Why do we need a regulation for the disposal of controlled substances.

Outline the current practices for the collection and disposal of Controlled Substances from Ultimate Users.

Understand the requirements for the secure disposal of controlled substances by DEA registrants and ultimate users in DEA's notice of proposed rulemaking.

Discussion of some of the concerns voiced by interested parties submitting comments on the notice of proposed rulemaking.

Prescription Drug Abuse Statistics

Statistics from the National Institute of Drug Abuse

In 2010, approximately 7 million people were current users of prescription drugs taken non-medically.

The most commonly abused chemicals are:

- Pain Relievers – 5.1 million
- Tranquillizers – 2.2 million
- Stimulants – 1.1 million
- Sedatives – 0.4 million

Prescription Drug Abuse Statistics

Among High School Seniors, prescription and over-the-counter medications account for most of the commonly abused illicit drugs.

- 1 in 12 High School Seniors Reported Non-Medical Use of Vicodin
- 1 in 20 Reported Abuse of OxyContin
- 70% stated that they obtained the prescription narcotics from a friend or relative

Prescription Drug Abuse Statistics

Between 1991 and 2010, prescriptions for opioid drugs increased from approximately 75.5 million to 209.5 million (an increase of greater than 200%).

Over the same time period stimulant prescriptions increased from 5 million to 45 million (a 900% increase).

Between 1999 and 2008 prescription drug overdose deaths increased over 400%, while cocaine and heroin deaths increased by less than 50%.

In 2008 there were approximately 12,000 prescription drug deaths, while there were approximately 7,000 combined deaths attributed to cocaine and heroin.

Pharmaceutical Drugs and the Environment

Information from EPA's Pharmaceuticals and Personal Care Products Website.

Studies have shown that Pharmaceuticals are present in US waterways. How did they get there?

- Medication residues pass through the body and into sewer lines.
- Unused or expired medications that are placed in the trash or flushed.

Pharmaceutical Drugs and the Environment

Sewerage systems are not designed to treat or remove pharmaceuticals from the waste stream.

Pharmaceuticals have been identified in most of the water bodies that have been sampled.

EPA is currently working on numerous research projects to quantify the environmental and health risks from pharmaceuticals in the environment.

Current Controlled Substances Disposal Practices

The Controlled Substances Act (CSA) was implemented by DEA in 1970.

The CSA was designed to prevent, detect, and eliminate the diversion of controlled substances.

To accomplish this DEA developed a closed loop system of distribution from manufacture to the pharmacy. Each handler of the Controlled Substance must be registered and document the movement of materials.

Current Controlled Substances Disposal Practices

The closed loop distribution ends when the controlled substance is issued to the ultimate user (the person whose name is on the prescription).

DEA did not account for instances where the ultimate user did not fully use all of the drugs in a prescription.

The CSA did not authorize the ultimate user to transfer unused controlled substances to another person for disposal.

Initial Guidance to ultimate users was to dispose excess medications by flushing. This guidance has been updated. Ultimate user is now advised to wrap in coffee grounds and dispose in the trash.

Current Controlled Substances Disposal Practices

On October 12, 2010, The Secure and Responsible Drug Disposal Act was enacted.

The Disposal Act amended the CSA to allow an ultimate user to "deliver" a controlled substance "to another person for the purpose of disposal" if the person receiving the controlled substance is authorized to receive the substance.

At this time, ultimate users may only deliver controlled substances to a law enforcement official under the direction of DEA.

Current Controlled Substances Disposal Practices

DEA has established National Take-Back Days

These are one-day collection events.

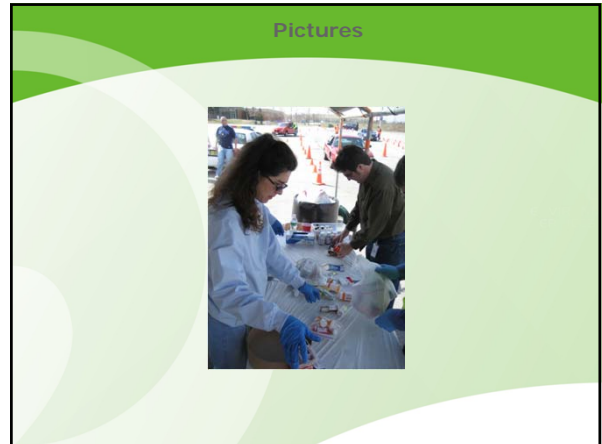
Conducted by Law Enforcement Agencies. Often with assistance from hazardous waste management companies.

Controlled substances are segregated from non-controlled substances for destruction or disposal. A pharmacist is on-site to perform the segregation.

Law enforcement takes ownership of the controlled substances and escorts the waste for destruction or places the materials in secure storage until escorted for destruction.

Pictures





State Prescription Drug Take-Back Programs

Several States have passed legislation, or have bills that are currently being debated on take-back programs, mail-back programs, and reuse/recycling programs for prescription drugs.

Washington State Take-Back Program

Law Enforcement Agencies Accept Controlled Substances

Pharmacies accept prescription drugs that are NOT controlled substances, over the counter medicines, pet medicines, inhalers, and more.

Drop Boxes set up at Pharmacies.

Website Established – www.takebackyourmeds.org

Proposed Rules

DEA Proposed 3 Options for the collection of Controlled Substances from ultimate users:

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

Reverse Distributor

Revised the definition of reverse distributor - "to acquire controlled substances from another DEA registrant or a law enforcement agency for the purpose of (1) Return to the manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf, or (2) destruction.

A reverse distributor would be required to destroy CSA received for destruction within 14 calendar days of taking possession of the Controlled Substance.

Proposed Rules

Take-Back Programs

- Law Enforcement Agencies can continue to conduct Take-Back Programs
- Only the Ultimate User can handle the Controlled Substance at the event (no sorting)
- A "Full-Time" Law Enforcement Officer must oversee the collection
- Collected Controlled Substances may be transferred to a Reverse Distributor

Proposed Rules

Mail-Back Programs

Mail-Back programs can be conducted by registered manufacturers, distributors, reverse distributors, or pharmacies.

Mail-back packages MUST be received at a facility that has an on-site method of destruction.

Mail-back packages cannot be opened, x-rayed, or otherwise penetrated prior to destruction (e.g., the contents of the package may not be handled, counted, or inventoried).

Proposed Rules

Mail-Back Programs (Continued)

The Mail-Back Packages must be:

- Postage Paid
- Pre-addressed to the authorized mail-back location
- Non-descript
- Tamper-evident and Tamper-resistant
- Waterproof
- Contain a unique identification number so that each package can be tracked
- Contain instructions on the substances that can be sent, the process for mailing back the package, and a notice that only packages provided by the authorized collector will be accepted for destruction

Proposed Rules

Collection Receptacles

Collection receptacles may be located at registered manufacturers, distributors, reverse distributors, retail pharmacies, long-term care facilities with a pharmacy on-site, and at law enforcement facilities. The collection receptacle must:

- Have a permanent outer container with a removable inner liner
- The outer container must have an opening big enough to allow contents to be added, but small enough to prevent removal
- The opening must be capable of being locked
- The container must display a sign indicating that only non-controlled drugs and Schedule II, III, IV, or V controlled substances may be placed in the container
- The container must be securely fastened to a permanent structure
- The container must be located in the immediate proximity of a designated controlled substances storage area

Proposed Rules

Collection Receptacles (Continued)

- The inner liner must be waterproof, tamper-evident, and tear resistant
- The liner must be removable and sealable without emptying or touching the contents
- The contents of the inner liner shall be viewable when sealed
- The size of the liner must be marked on the liner
- The liner must be marked with a permanent, unique identification number

The removal of the inner liner must be performed under the supervision of at least two authorized employees.

Proposed Rules

Collection Receptacles at Long-Term Care Facilities

An authorized pharmacy located at a long-term care facility may install a collection receptacle under the control of the pharmacy.

The long-term care facility may deposit the controlled substances into the collection receptacle on behalf of a patient.

The controlled substances must be transferred into the collection receptacle within three business days after the controlled substances are no longer needed by the patient.

Proposed Rules

Methods of Destruction

DEA has proposed "NON-RETRIEVABLE" as the standard of destruction and is not requiring a particular method of destruction.

However, in a September 26, 2012, memorandum titled "Recommendation on the Disposal of Household Pharmaceuticals Collected by Take-Back Events, Mail-Back, and Other Collection Programs" Suzanne Rudzinski, Director of the Office of Resource Conservation and Recovery at EPA, states that EPA recommends that household pharmaceuticals collected at these programs be incinerated.

"EPA's preference is that they be sent to a permitted hazardous waste combustor, but when that is not feasible, at a minimum, they should be sent to a large or small municipal waste combustor."

Comments Received by DEA

DEA Received 194 Sets of Comments

Issues included in the comments

- Increased cost of disposal of controlled substances if materials could not be segregated or removed from packaging and all wastes must be managed as controlled substances
- The cost to have 2 employees service drug boxes and drug transports
- Mail-Back Packages must be inspected prior to disposal
- Reverse distributors need more than 14 days for efficient destruction
- Non-Retail pharmacies at long-term care facilities should be allowed to manage and maintain collection receptacles
- DEA should allow collectors to compile data on the types and quantities of medications collected
- "Non-Retrievable" as Method of Destruction

Final Rule

No information has been published regarding DEA's response to comments.

The Docket indicates that DEA intends to publish the Final Rule in November 2013.

QUESTIONS?