Federal Regulations and the Disposal of Controlled Substances

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Legal Disclaimer

The following presentation was accompanied by an oral presentation on December 13, 2017, and does not purport to establish legal standards that are not contained in statutes, regulations, or other competent law. Statements contained in this presentation that are not embodied in the law are not binding on DEA. Summaries of statutory and regulatory provisions that are summarized in this presentation do not purport to state the full extent of the statutory and regulatory requirements of the cited statutes and regulations. I have no financial relationships to disclose.
The Medicine Cabinet and Pharmaceutical Controlled Substances
Study: Sharing of Medication

1. University of Pennsylvania Dental School Study:

More than half of the narcotics prescribed for wisdom teeth removal go unused... findings suggest that more than 100 million pills prescribed go unused... leaving the door open for possible misuse or abuse.

Study: Sharing of Medication

2. John Hopkins Study:
   - 60% had leftover opioids they hung on for “future use”
   - 20% shared their medications
   - 8% likely will share with a friend
   - 14% likely will share with a relative
   - 10% securely lock their medication

Secure and Responsible Drug Disposal Act of 2010

P.L. 111-273

October 12, 2010

Federal Register

September 9, 2014
Secure and Responsible Drug Disposal Act of 2010

Legislation that provides Ultimate Users and LTCF with additional methods to dispose of unused, unwanted or expired controlled substance medication in a secure, safe and responsible manner.
Secure and Responsible Drug Disposal Act of 2010

- Authorized DEA to promulgate regulations that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal in a safe and effective manner consistent with effective controls against diversion.
Regulations do not limit the ways that ultimate users may dispose of pharmaceutical controlled substances—they expand them.
Participation is voluntary

DEA may not require any person to establish or operate a disposal program.
Secure and Responsible Drug Disposal Act of 2010

Ultimate Users may continue to utilize the FDA and EPA guidelines for the disposal of medicines, available at:

www.fda.gov

www.epa.gov
**Ultimate User:** “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 a member of his household.”

*21 USC § 802(27)*
Got Drugs?
Oct. 22ND
10AM - 2PM
Turn in your unused or expired medication.
For Drop off Locations Visit DEA.gov
14th National Take Back Day
October 28, 2017

DRUG ENFORCEMENT
ADMINISTRATION
DIVERSION CONTROL PROGRAM
14th National Take Back Day: October 28, 2017
Total Law Enforcement Participation: 4,274

Drug Enforcement Administration
Diversion Control Program

*American Indian and Alaskan Native Communities: 64 Partners
14th National Take Back Day: October 28, 2017
Total Collection Sites: 5,321

Drug Enforcement Administration
Diversion Control Program

*American Indian and Alaskan Native Communities: 115 sites
14th National Take Back Day: October 28, 2017

Total Weight Collected (pounds): 912,305 lbs. (456 Tons)

*American Indian and Alaskan Native Communities: 1507 lbs.
National Take Back I-XIV Totals:
Total Weight Collected (pounds): 9,015,668 (4,508 Tons)
14th National Take Back Day
American Indian and Alaskan Native Communities Participation
October 28, 2017

DRUG ENFORCEMENT ADMINISTRATION
DIVERSION CONTROL PROGRAM
14th National Take Back Day: October 28, 2017
Total American Indian and Alaskan Native Communities
Law Enforcement Participation: 64
14th National Take Back Day: October 28, 2017
Total American Indian and Alaskan Native Communities Collection Sites: 115
14th National Take Back Day: October 28, 2017

Total American Indian and Alaskan Native Communities

Weight Collected (pounds): 1507 lbs. (.754 Tons)
Authorized to Collect

Following persons are authorized to collect from ultimate user and other non-registrants for destruction:

– Any DEA registrant authorized pursuant to § 1317.40

– Federal, State, tribal, or local law enforcement when in the course of official duties and pursuant to § 1317.35

21 CFR § 1317.30
Authorized to Collect

DEA Registrants authorized to collect:

– Manufacturers
– Distributors
– Reverse Distributors
– Narcotic Treatment Programs
– Hospitals with an on-site pharmacy
– Retail Pharmacies

21 CFR § 1317.40
New Authorized Methods of Collection

Lawful collection/possession of controlled substances acquired from ultimate users or other non-registrant persons shall be disposed of in the following ways:

Mail-back Programs
Collection Receptacles
Collection Receptacles
Collection Receptacle Location

Must be securely placed and maintained:

• Inside collector’s registered location
• Inside law enforcement’s physical location, or
• Inside an authorized LTCF
Design of Collection Receptacle

- Securely fastened to a permanent structure.

- Securely locked, substantially constructed container with permanent outer container and removable inner liner.

- Outer container must have small opening that allows for contents to be added, but does not allow for removal of contents.

21 CFR § 1317.75(e)
Mail-Back Programs
Mail-Back Program – Who is Authorized to Operate?

Any **authorized** collector that has and utilizes at its registered location (on-site) a method of destruction consistent with § 1317.90

21 CFR § 1317.70
Mail-Back Program

Requirements of mail-back program

– Only **lawfully-possessed** Schedules II-V controlled substances may be collected

– Controlled and non-controlled substances may be collected and **comingled**

**21 CFR § 1317.70 (b)**
Mail-Back Packaging

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

21 CFR § 1317.70 (c)
Mail-Back Package Specifications

Packages may only be mailed from the customs territory of the United States:

• 50 States
• District of Columbia
• Puerto Rico

21 CFR § 1317.70

Personally identifiable information **shall not be required** when using mail-back package.
Inventory vs Waste
Disposal of Inventory By Practitioners
21 CFR § 1317.05

(a) Practitioner inventory. Any registered practitioner in lawful possession of a controlled substance in its inventory that desires to dispose of that substance shall do so in one of the following ways:
(1) Promptly destroy that controlled substance in accordance with subpart C of this part using an on-site method of destruction;
Disposal for Practitioners

(2) Promptly deliver that controlled substance to a Reverse Distributor (registered location) by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location.
Disposal for Practitioners

(3) For the purpose of return or recall, promptly deliver that controlled substance ... to ... (T)he registered person from whom it was obtained, the registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf.
(4) Request assistance from the Special Agent in Charge of the Administration in the area in which the practitioner is located.
Non-retrievable ... a process that permanently alters the substance’s physical or chemical condition or state through irreversible means, and thereby renders the controlled substance unavailable and unusable for all practical purposes.

21 CFR § 1300.05(b)
Destruction of Controlled Substances

All controlled substances destroyed by a registrant, or caused to be destroyed by a registrant, shall be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations and shall be rendered non-retrievable.

21 CFR § 1317.90
Disposal of Waste By Practitioners
Destruction of Controlled Substances

All controlled substances destroyed by a registrant, or caused to be destroyed by a registrant, shall be destroyed in compliance with applicable Federal, State, tribal, and local laws.

See “Dear Practitioner” Letter, Destruction of Pharmaceutical Waste

October 17, 2014.
Records: Destruction of Inventory

21 CFR § 1304.21 (e)

- DEA Form 41
- Complete and Accurate Record
- Name and Signature of the Two Employees who Witnessed the Destruction
Records: Destruction of Waste

21 CFR § 1304.21 (e)

No DEA Form 41

21 CFR § 1304.22(a)(2)(ix)

Date, Quantity, and Manner of Disposal
Drug Recall
or
Investigational Drug Return
Drug Recall: Ultimate User Return

If controlled substances are recalled, ultimate users may deliver the recalled substance to the manufacturer, or another registrant authorized to accept recalled substances on the manufacturer’s behalf.

21 CFR § 1317.85(a) & (b)
Termination of Ability to Collect

Registrant shall notify the DEA in writing or online.

21 CFR § 1301.52(f)

21 CFR § 1317.70 (e)(3)
Patient Resources for Disposal (Anytime of the Year)

https://apps.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e1s1
(Disposal location search tool, for disposal of medications)

www.rxdrugdropbox.org
(Police Department Locations, for disposal of medications)

www.disposemymeds.org
(Pharmacy Locations, for disposal of medications)

www.fda.gov (Search: Disposal)


Contact Information
DEA Diversion Control Division
Attn: Liaison and Policy Section
8701 Morrissette Drive
Springfield, VA 22152
Phone: 202-307-7297
E-mail: ODLP@usdoj.gov
DIVERSION OF THE DISPOSED

• PRACTITIONERS
  - Using unapproved destruction devices
  - Take drugs from patients

• REVERSE DISTRIBUTORS
  - Failure to have two employees handle the drugs including transportation and destruction

A PATIENT CURED IS A CUSTOMER LOST.
DIVERSION OF THE DISPOSED

• PHARMACY
  - Take drugs from patients
  - Do not complete records accurately with reverse distributors

• Others
  - Stealing from Sharps Containers
  - LTC Facilities stealing deceases patient’s drugs
  - LTC Facilities – own pharmacy (use left over meds)
Officer Accused Of Stealing Painkillers From Evidence Room, Drug Drop Box
Aberdeen, Maryland

Meeker County deputy is accused of stealing drugs from a drop box and toys from a holiday toy drive
Litchfield, Minnesota

Vineland officer charged with taking meds from prescription drop box
Bridgeton, New Jersey
Questions / Thank You