Practitioner Diversion Awareness Conference

Disposal and Returns of Patient Controlled Substance Medications

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Course Objectives


- Discuss how to properly dispose of practitioner inventory.

- Discuss how to properly dispose of controlled substance waste.
Course Objectives

- Discuss the disposal of controlled substances by the patient “ultimate user.”

- Discuss the disposal of patients’ controlled substances at long term care facilities.
Questions To Discuss

At the completion of this block of instruction you will be able to answer the following questions:

1. Which method of destruction for controlled substance practitioner inventory is not allowed?

2. Can a practitioner take back a controlled substance that was already prescribed or dispensed to a patient?
Questions To Discuss

3. What is DEA’s current recommended method of disposal for practitioner inventory?

4. When is a DEA Form 41 required for the disposal of controlled substances.

5. What disposal methods are available for ultimate user’s?
Where Do They Come From?

- Practitioners: 36%
- Dealer or Stranger: 54%
- Other: 5%

Source: Department of Health and Human Services
Authorized the DEA to promulgate regulations that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal.
A person who has lawfully obtained, and who possesses, a controlled substance for their own use, or for the use of a member of their household, or for an animal owned by them or a member of their household.

21 USC § 802(27)
What is a “Collector”

- A registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on site pharmacy, or retail pharmacy that is authorized to so receive a controlled substance for the purpose of destruction.

- The registrant has a modified registration authorizing the collection of controlled substances from the “ultimate user.”

21 C.F.R. § 1300.01(b)
Secure and Responsible Drug Disposal Act of 2010

- This did not change existing methods of disposal of controlled substances, for ultimate users but expanded the options.

- Ultimate users now have more locations where they can securely, safely, responsibly, and conveniently dispose of their unwanted pharmaceutical controlled substances.
Secure and Responsible Drug Disposal Act of 2010

- The regulations continue to allow Federal, State, tribal, and local law enforcement to maintain collection receptacles at the law enforcement’s physical location;
- And either independently or in partnership with private entities or community groups, to voluntarily hold take-back events and administer mail-back programs.

U.S. Drug Enforcement Administration
Diversion Control Division
Created an exception for LTCFs to transfer pharmaceutical controlled substances for disposal on behalf of patients who reside or have resided at that facility.
Benefits to the public are:

- Decrease the supply of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and

- Protect the environment from potentially harmful contaminants by providing alternate means of disposal for ultimate users.
A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue...

21 CFR § 1300.05
The purpose of this destruction standard is to:

- Permanently render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

These methods do not meet the standard

21 CFR § 1300.05
Disposal of Controlled Substance Inventory

Practitioner options to dispose of inventory are:

- Prompt on-site destruction if proper method.
- Prompt delivery to a DEA registered reverse distributor by common carrier or reverse distributor pick-up.

21 C.F.R. § 1317.05(a) and (b)
Returned or Recalled Controlled Substances

- Prompt delivery by common or contract carrier or pick-up at the registered location by:
  - Registrant from whom it was obtained.
  - Registered manufacturer of the substance.
  - Another registrant authorized by the manufacturer to accept returns or recalls on the manufacturers behalf.

21 C.F.R. § 1317.05(a) and (b)
A practitioner may also request assistance from the Special Agent in Charge.

21 C.F.R. § 1317.05(a) and (b)
DEA is aware that there are companies that claim that their products can render controlled substance inventories non-retrievable, and have DEA approval.

DEA has not approved any such products for the disposal of practitioner inventory.

21 CFR § 1300.05
Disposal of Controlled Substance Inventory

- Controlled substance practitioner inventory cannot go to a collector.

- Collectors can only receive controlled substances from the “ultimate users.”

21 C.F.R. § 1317.05(a) and (b)  21 C.F.R. § 1317.75(c)
Disposal of Controlled Substance Waste

DEA allows disposal of controlled substance waste if:

- It is **authorized** under your state’s laws… and

- It is the **remaining portion** of used needles, syringes, or other injectable products in a practitioner environment (hospital, clinic, physicians office, etc.)

*21 C.F.R. § 1304.21(e)*
Disposal of Controlled Substance Waste

Recordkeeping for disposal of controlled substance waste:

- No DEA Form 41 required.
- Recommended that two employees witness the handling and the destruction of the controlled substance waste.

21 C.F.R. § 1317.95(c) and (d)
21 C.F.R. § 1304.21(e)
Disposal of Controlled Substance Waste

Record of waste disposal must include:

- Name of Substance
- Form
- Quantity
- Date of Disposal
- Manner of Disposal

21 CFR § 1304.22(c)
Disposal of Controlled Substance Waste

- Records must be maintained at the practitioner’s registered location for a minimum of two years.
- Longer if required by state laws or regulations.

21 CFR § 1304.04(a)
Patient’s Controlled Substances

- A physician **cannot** take back controlled substances that have been administered, prescribed, or dispensed to the “ultimate user.

- It is **not authorized** by Federal Laws and Regulations.

- Do not put **yourself or your practice** in harms way by ignoring this.
Disposal of Ultimate User’s Controlled Substances
“Ultimate User” Destruction

- DEA recommends that “ultimate users” do not flush their expired or unwanted prescriptions and over-the-counter drugs down the toilet or drain unless the label or accompanying patient information specifically instructs you to do so.

- Be aware the FDA posted instructions to flush certain types of controlled substances.
“Ultimate users” can now return unwanted or expired prescription and over-the-counter drugs to:

- Law enforcement supported drug take-back program or collection box.
- DEA registered collector that has an on-site collection receptacle.
- DEA registered mail back program.
LTCFs may dispose of a current or former resident’s unwanted or unused controlled substances in a collection receptacle located at the LTCF.

21 C.F.R. § 1317.80(a)
Summary of Destruction Standards

Not Required to Comply with Non-Retrievable Standard
- Practitioner CS Waste
- Ultimate Users

Non-Retrievable Standard
- Practitioner CS Inventory
Summary of Disposal Options

Ultimate User
- Collection Box
- Mail Back Programs
- Commercial Products
- Coffee Grounds
- Kitty Litter
- Etc.

Practitioner Inventory
- DEA Reverse Distributor

Controlled Substance Waste
Do not allow patients to bring their previously prescribed or dispensed controlled substances to your facility prevents diversion.

Timely proper disposal of inventory prevents diversion.

Timely witnessing and documenting the disposal of controlled substance waste prevents diversion.
Post Questions

1. Which method of destruction of controlled substance practitioner inventory is not allowed?

   a. Return to whomever it was purchased from.
   b. Send the controlled substances to a reverse distributor.
   c. Return to a DEA registered “collector” or a take back location.
   d. Destroy the controlled substances on-site.
2. Can a practitioner take back a controlled substance that was already prescribed or dispensed to a patient?

a. Yes
b. No
Post Questions

3. DEA’s recommended way of destruction is by incineration.

a. True
b. False
4. Controlled substance waste must always be reported on a DEA Form 41 ( Destruction of Controlled Substances).

a. True
b. False
5. A Practitioner can destroy controlled substance inventory (expired) by placing them into kitty litter or coffee grinds.

a. True
b. False
Thank-you for your time and attention!

U.S. Drug Enforcement Administration
Diversion Control Division