

# *Practitioner Diversion Awareness Conference*

**Disposal and Returns of Patient Controlled  
Substance Medications**

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# Course Objectives

- § **Discuss the Secure and Responsible Drug Disposal Act of 2010, and the implementing regulations of 2014.**
- § **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?



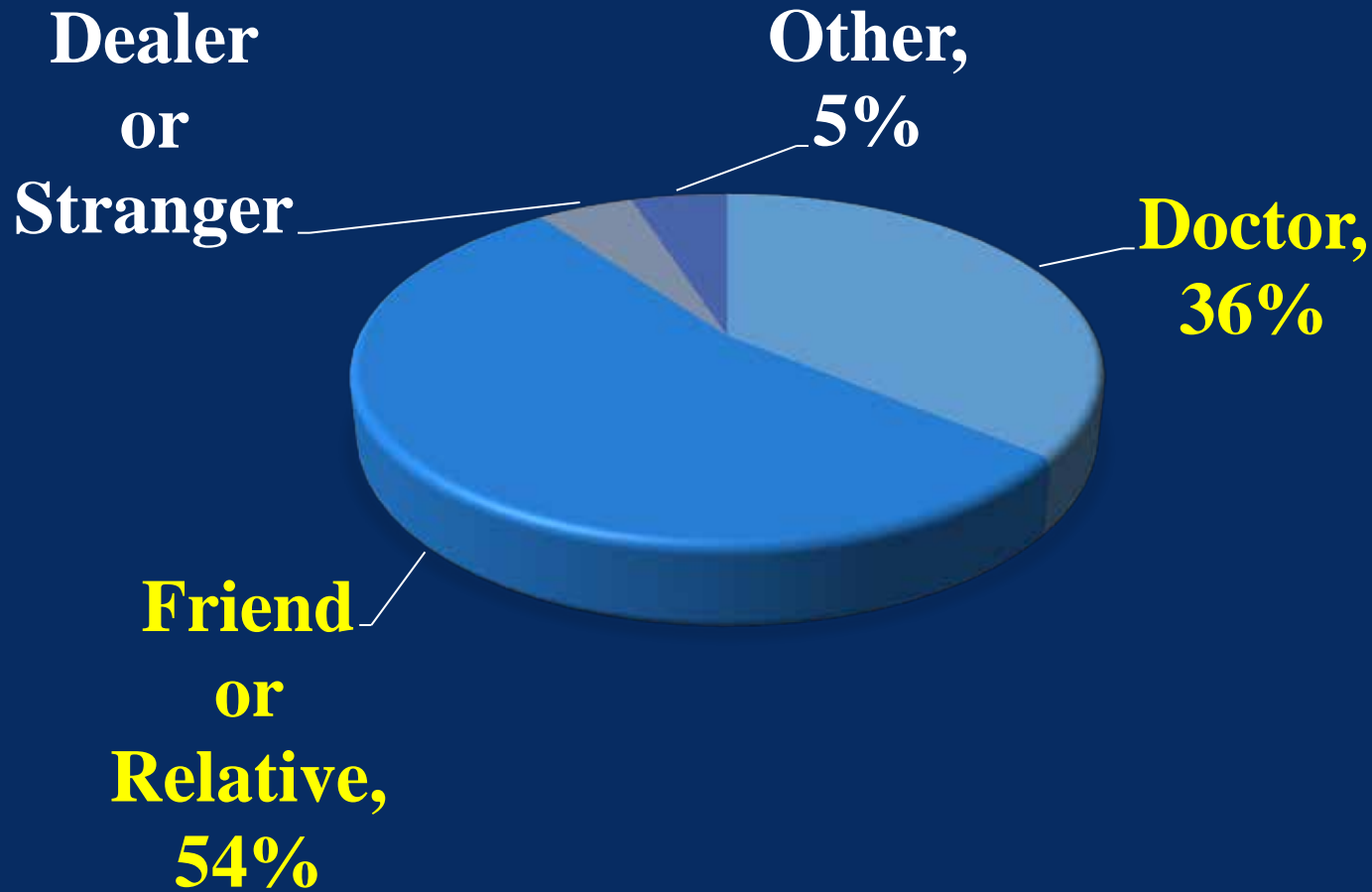
# Questions To Discuss

- 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?



Source: Department of Health and Human Services





# Secure and Responsible Drug Disposal Act of 2010

§ Authorized the DEA to promulgate regulations that allow ultimate users to transfer pharmaceutical controlled substances to authorized entities for disposal.





# Ultimate User

§ 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.**





# Secure and Responsible Drug Disposal Act of 2010

- § Created an exception for **LTCFs** to transfer pharmaceutical controlled substances for disposal on behalf of patients who reside or have resided at that facility.





# Disposal of Controlled Substances Final Rule of 2014

**Benefits** to the public are:

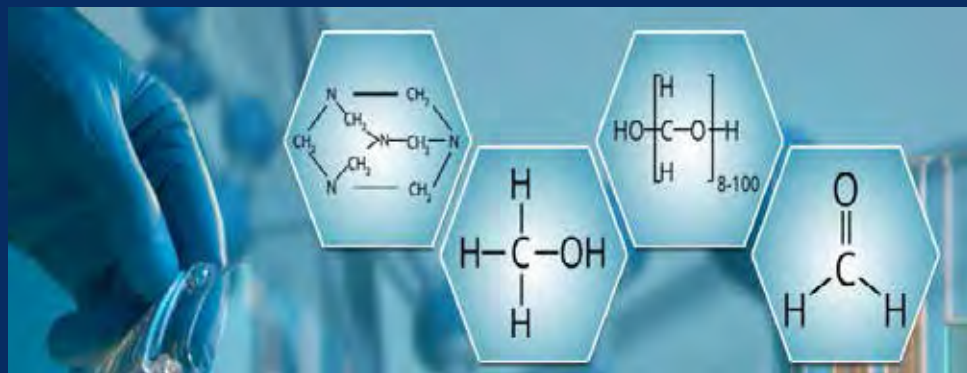
- § **Decrease the supply** of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
- § **Protect the environment** from potentially harmful contaminants by providing alternate means of disposal for ultimate users.



# Non-Retrievable

§ 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







# Non-Retrievable

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.



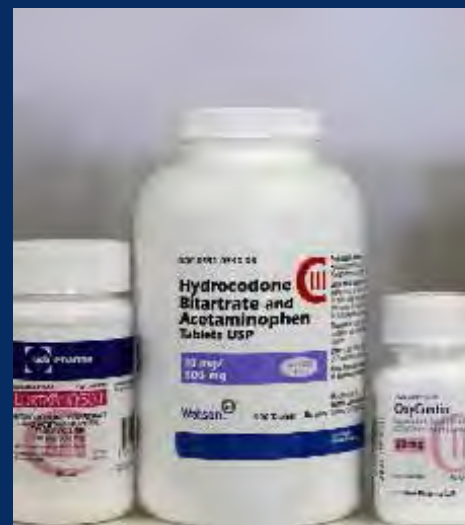
**These methods  
do not meet the  
standard**

[21 CFR § 1300.05](#)





# Disposal of Practitioner Controlled Substance Inventory and Controlled Substance Waste





# 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)**





# Disposal of Controlled Substance Inventory

## 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)**



# Disposal of Controlled Substance Inventory

§ A practitioner may also request assistance from the Special Agent in Charge.

[21 C.F.R. § 1317.05\(a\) and \(b\)](#)





# Products That Advertise They are Non-Retrievable

- § 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

**NOT APPROVED**



# 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 states 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.
- § Two employees witness the handling and the destruction of the controlled substances.

21 C.F.R. § 1317.95(c) and (d)

21 C.F.R. § 1304.21(e)

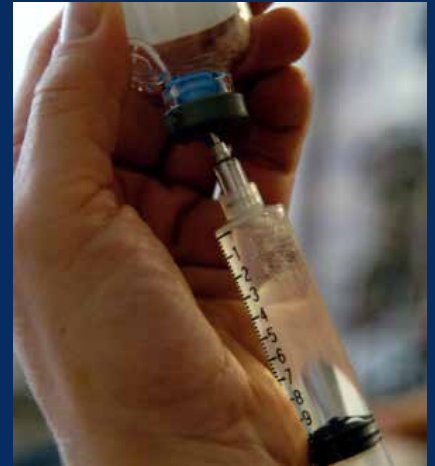




# Disposal of Controlled Substance Waste

**Record of waste disposal must include:**

- § **Name of Substance**
- § **Form**
- § **Quantity**
- § **Date of Disposal**
- § **Manner of Disposal**
- § **Registrants Name, Address, DEA number**



**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 User” Destruction

“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.





# Collection at LTCFs

§ 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**





# Preventing Diversion

- § **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.**



# Post Questions

**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**





# Post Questions

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

- a. True
- b. False

OMB APPROVAL NO. 1117-0007 Expiration Date 9/30/2017

**U. S. DEPARTMENT OF JUSTICE – DRUG ENFORCEMENT ADMINISTRATION**  
**REGISTRANT RECORD OF CONTROLLED SUBSTANCES DESTROYED**  
**FORM DEA-41**

**A. REGISTRANT INFORMATION**

Registered Name: \_\_\_\_\_ DEA Registration Number: \_\_\_\_\_

Registered Address: \_\_\_\_\_

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip Code: \_\_\_\_\_

Telephone Number: \_\_\_\_\_ Contact Name: \_\_\_\_\_

**B. ITEM DESTROYED**

**1. Inventory**

	National Drug Code or DEA Controlled Substances Code Number	Batch Number	Name of Substance	Strength	Form	Pkg. Qty.	Number of Full Pkgs.	Partial Pkg. Count	Total Destroyed
Examples	16590-598-60	N/A	Kadian	60mg	Capsules	60	2	0	120 Capsules
	0555-0767-02	N/A	Adderall	5mg	Tablet	100	0	83	83 Tablets
	9050	B02120312	Codine	N/A	Bulk	1.25 kg	N/A	N/A	1.25 kg
1.									
2.									



# Post Questions

**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 !*

