



# *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

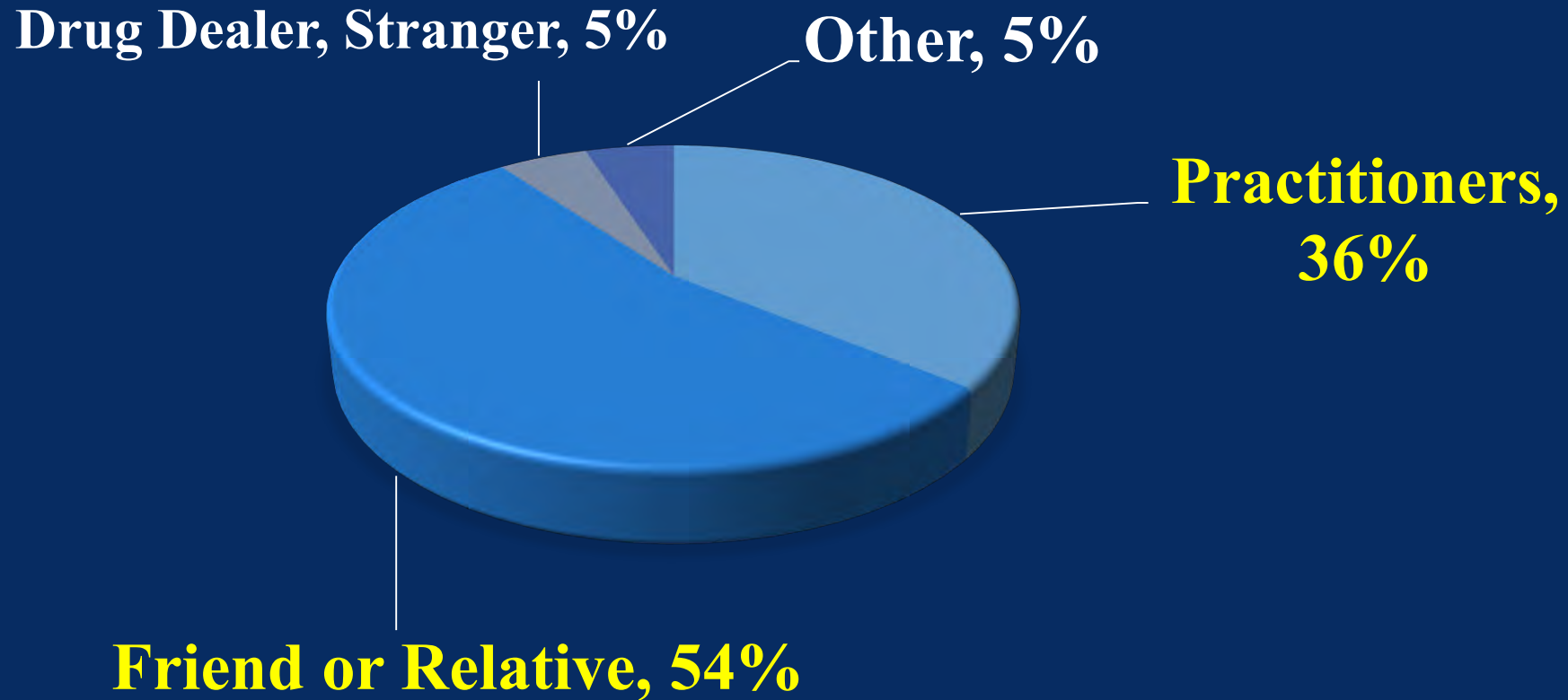
3. **What is DEA's current recommended method of disposal for practitioner inventory?**
4. **When is a DEA Form 41 required for the disposal of controlled substances.**
5. **What disposal methods are available for ultimate user's ?**







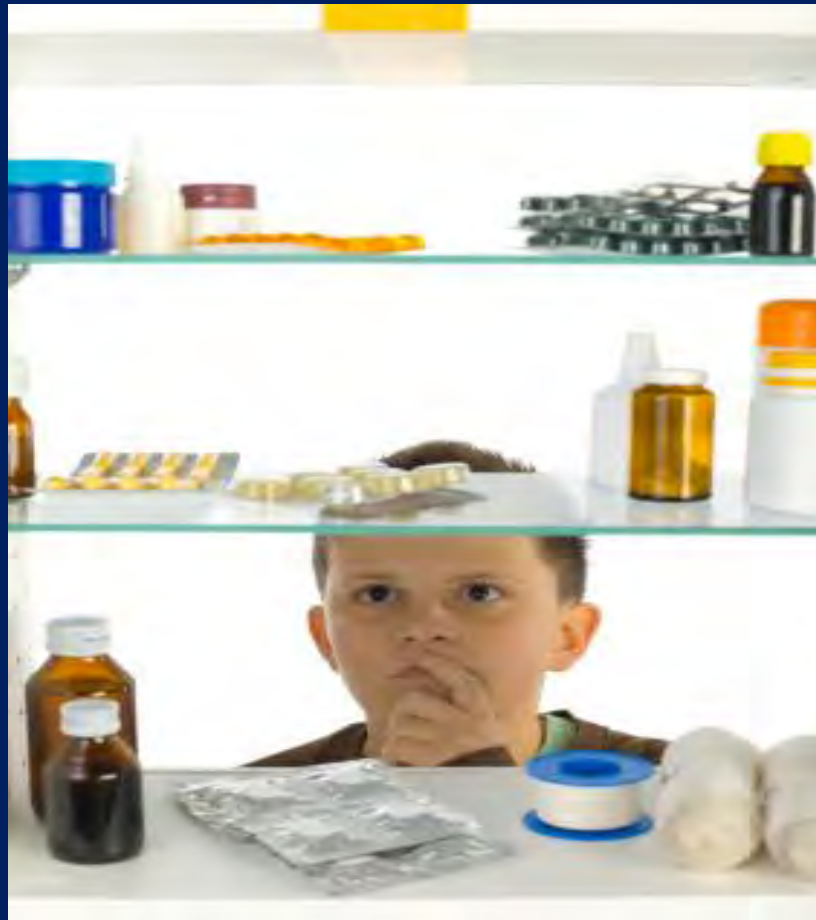
# Where Do They Come From?



Source: Department of Health and Human Services



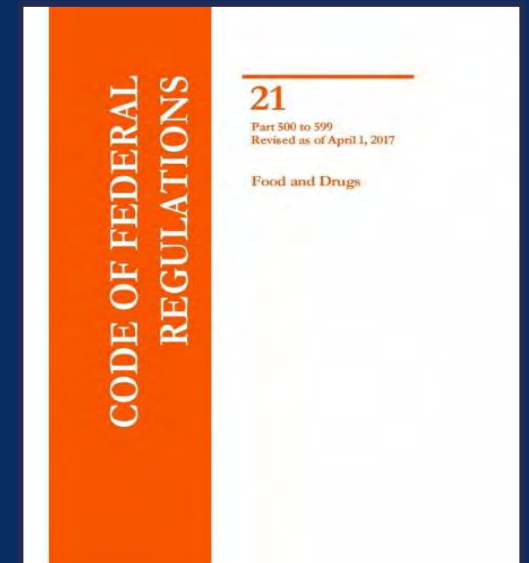
# The Medicine Cabinet and Pharmaceutical Controlled Substance Disposal





# 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:

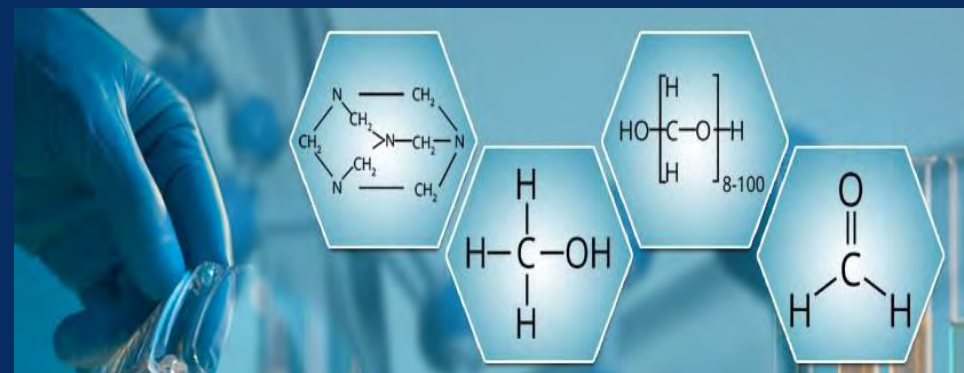
- **Decrease the supply** of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
- **Protect the environment** from potentially harmful contaminants by providing alternate means of disposal for ultimate users.



# 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.



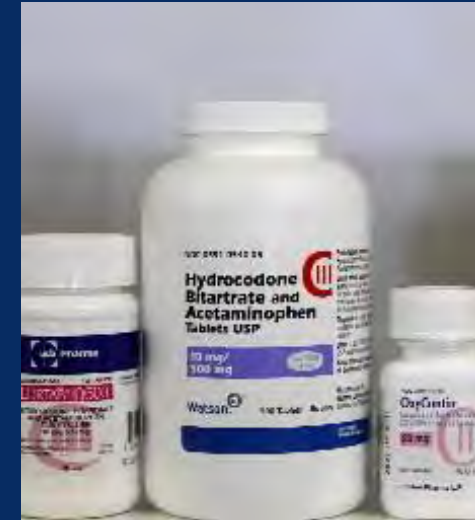
**These methods  
do not meet the  
standard**

[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.)





# 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\(e\)](#)

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: \_\_\_\_\_ 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	City	Number of Full Pkgs	Partial Pkg Count	Total Destroyed
16590-598-60	N/A	Kadian	60mg	Capsules	60	2	0	120 Capsules
0555-07	N/A	Adderall	5mg	Tablet	100	0	23	83 Tablets
0000	B02120312	Codeine	N/A	Bulk	1.25 kg	N/A	N/A	1.25 kg



# 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 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.



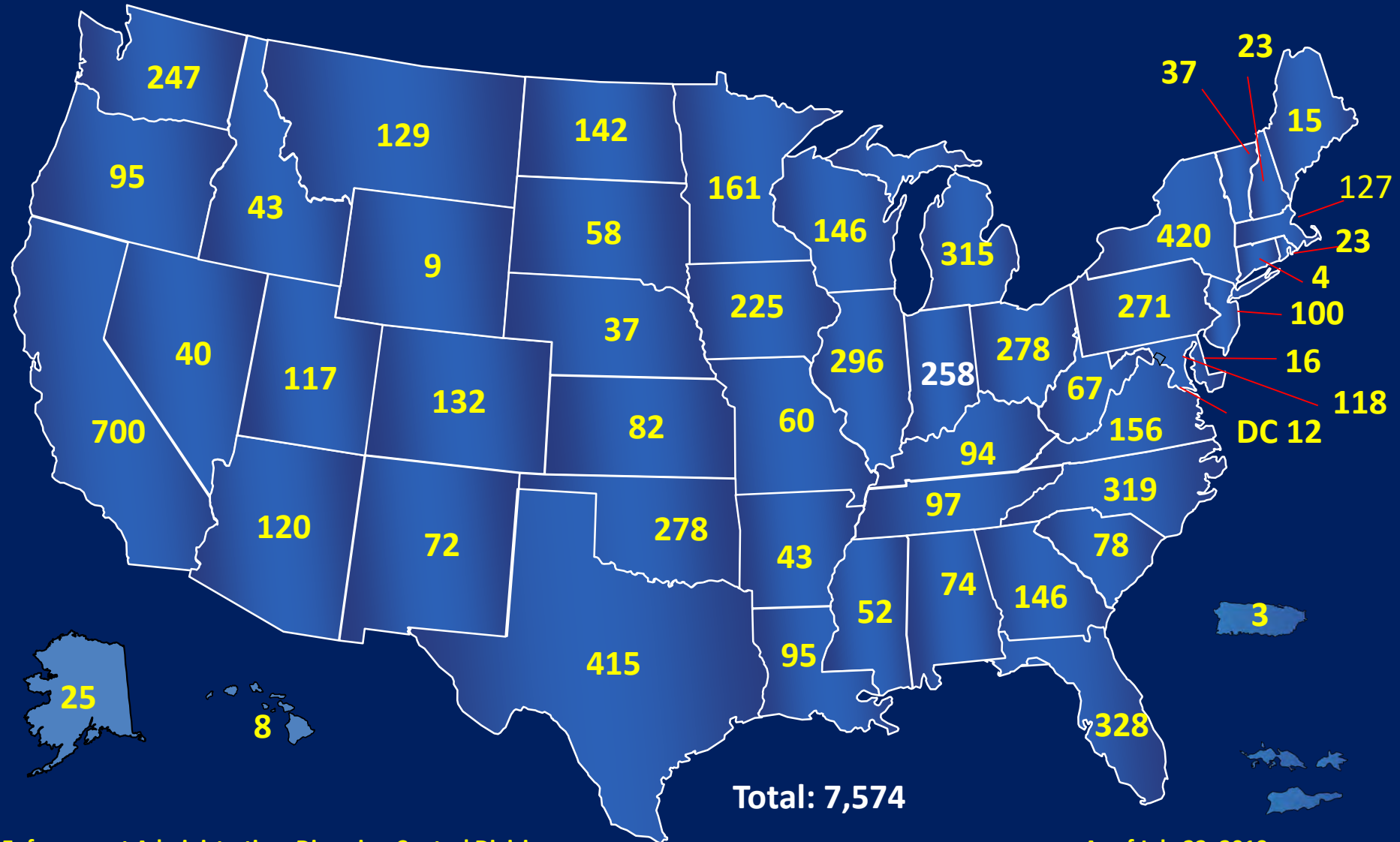


# Collection Receptacles



# DEA Registrants Only

## All Year Collection Sites (99% Pharmacies)



Guam 1





# 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)**





# New Disposal Law Passed

- On 10-23-2018 the SUPPORT for Patients and Communities Act was signed into law
- Under certain conditions, an employee of a **qualified hospice program** may handle and dispose of, without being registered by DEA, a controlled substances lawfully dispensed to the person receiving hospice care, as long as ...







# New Disposal Law Passed

- **The controlled substances are destroyed on-site and**
- **In compliance with all Federal, state, and local laws.**





# Summary of Destruction Standards

**Not Required to  
Comply with  
Non-Retrievable  
Standard**

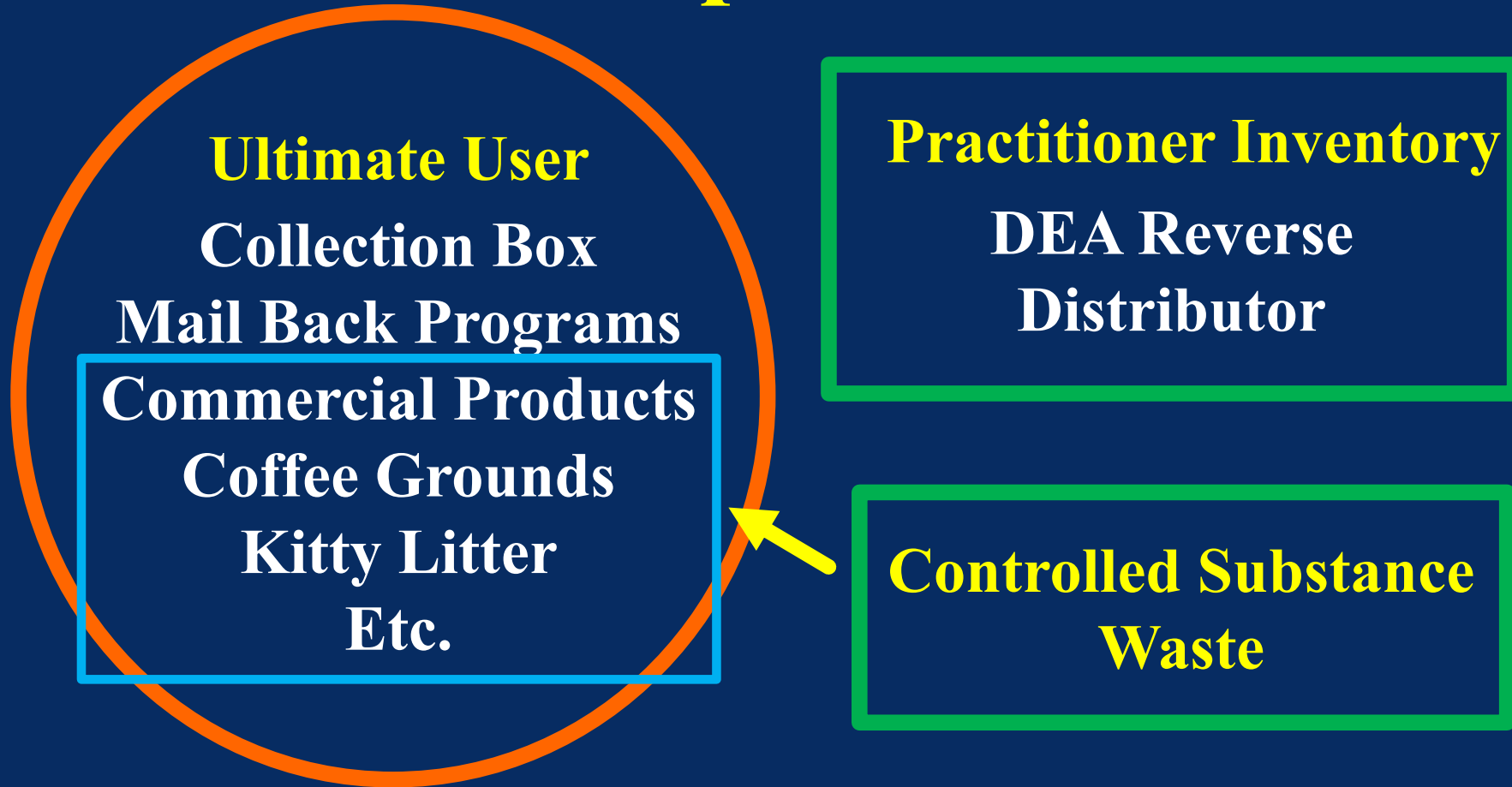
**Practitioner CS Waste  
Ultimate Users**

**Non-Retrievable  
Standard**

**Practitioner CS  
Inventory**



# Summary of Disposal Options





# 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

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**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	Codeine	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 !*

