

Practitioner Diversion Awareness Conference

Disposal and Returns of Patient Controlled
Substance Medications

Marsha L.D. Ikner, Staff Coordinator





LEGAL DISCLAIMER

The following presentation was accompanied by an oral presentation on **February 4 & 5, 2019**, 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.**



Fair Use Act Disclaimer

This presentation is for educational purposes only. This presentation may not be further copied or used, with the embedded images and videos, without an independent analysis of the application of the Fair Use doctrine.

Fair Use

Under section 107 of the Copyright Act of 1976, allowance is made for “Fair Use” for purposes such as criticism, comment, news reporting, teaching, scholarship, education and research.

Fair Use is a use permitted by the copyright statute that might otherwise be infringing. Any potentially copyrighted material used in this presentation has been reviewed and found to be used in a manner consistent with Fair Use. A completed Fair Use checklist is attached.



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?



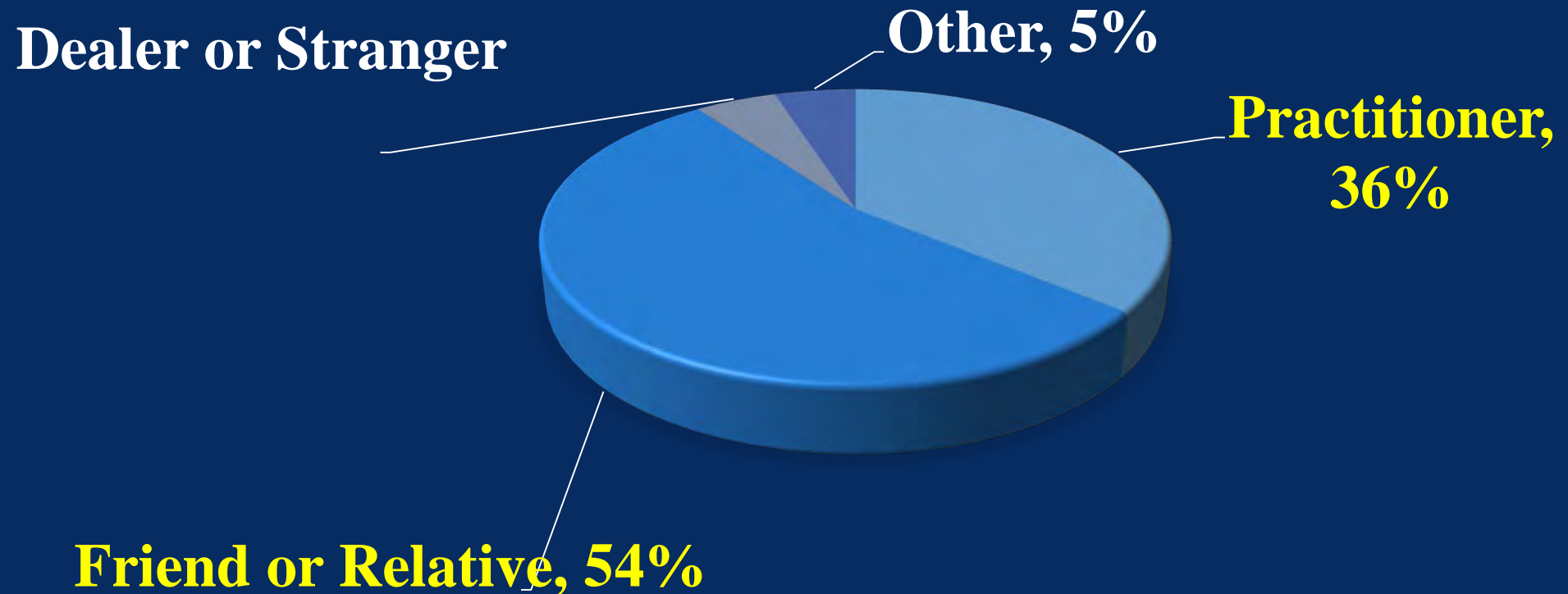
Questions To Discuss

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?

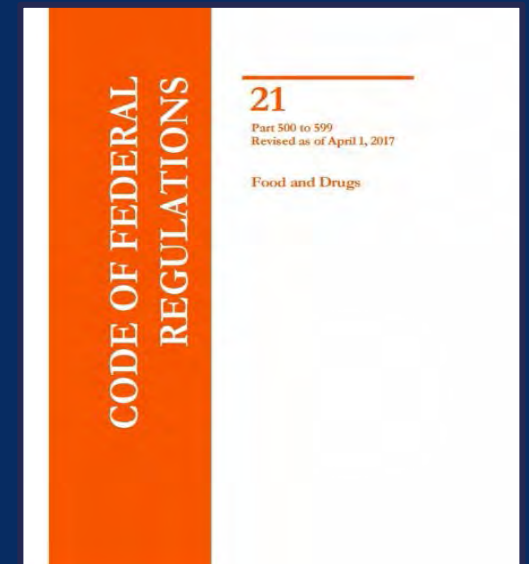


Source: Department of Health and Human Services



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:

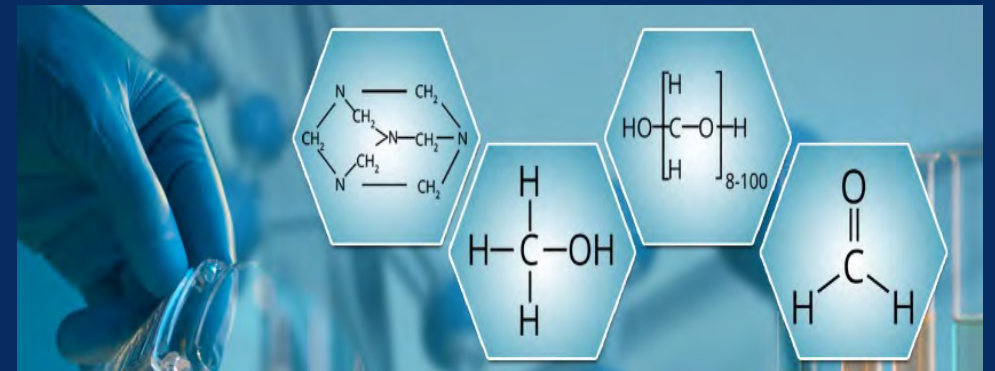
- **Decrease the supply** of pharmaceutical controlled substances available for misuse, abuse, diversion, and accidental ingestion; and
- **Protect the environment** from potentially harmful contaminants by providing alternate means of disposal for ultimate users.



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.



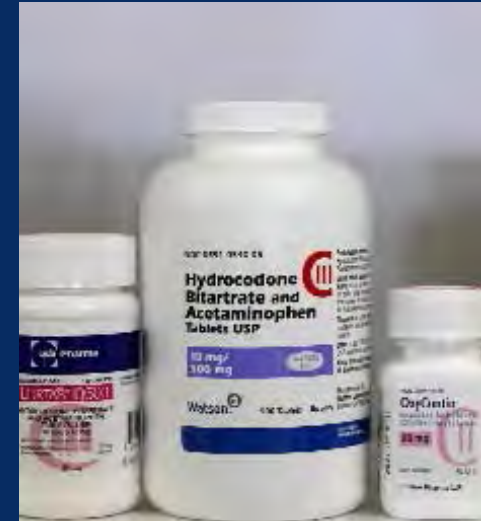
**These methods
do not meet the
standard**

[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.)





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\(e\)](#)

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 | 83 | 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 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**

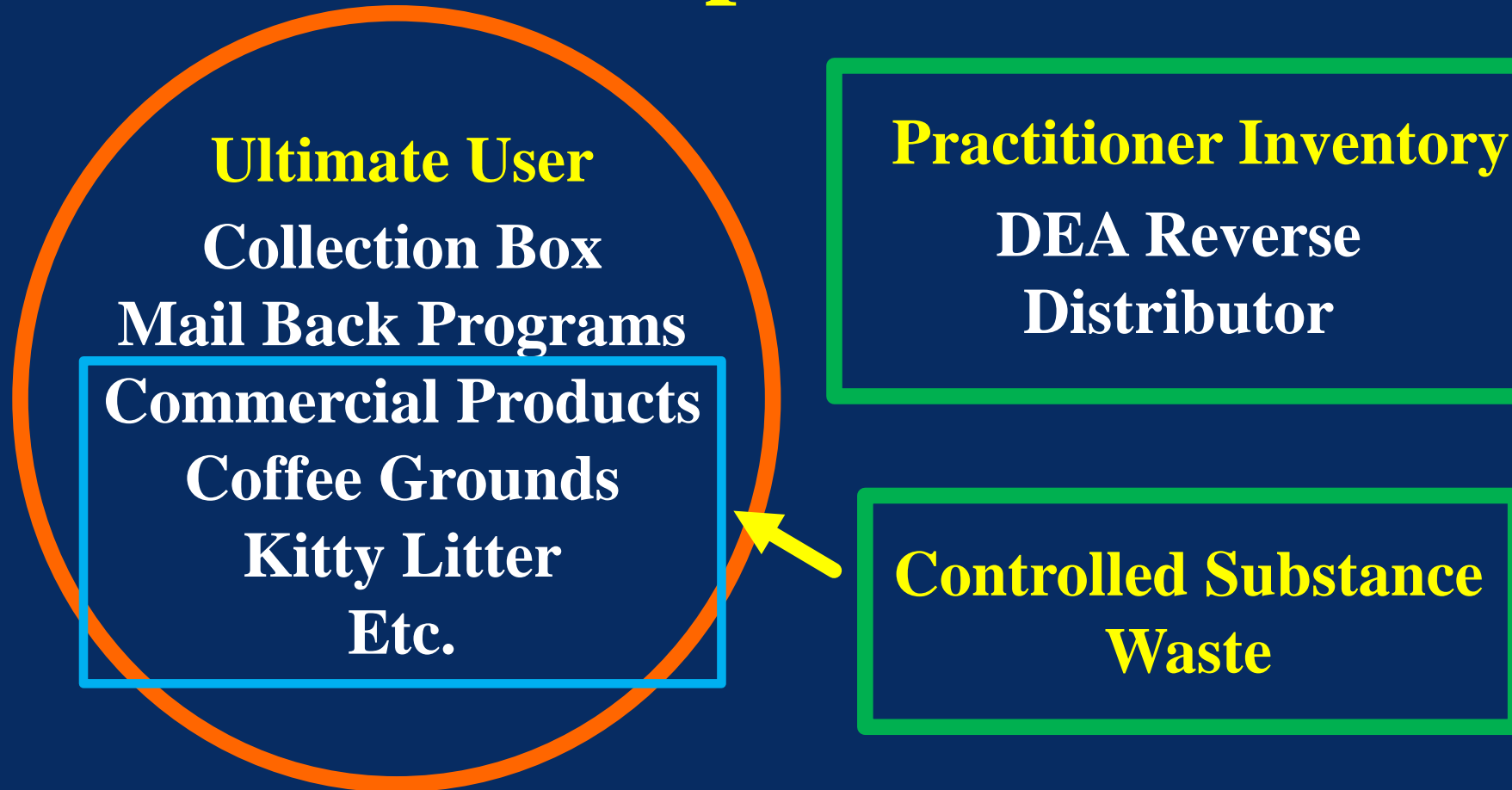
**Practitioner CS Waste
Ultimate Users**

**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

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 | 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 !*

