

# DEA Rule Changes: Impact on Industry Disposal Practices

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# The New DEA Disposal Regulation

- Requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users
- Regulations implement the Secure and Responsible Drug Disposal Act of 2010
- Expands options for take-back events, mail-back programs, and collection receptacle locations
- Law enforcement can remain involved at all 3 levels
- Authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, retail pharmacies and hospitals/clinics with on-site pharmacies can voluntarily participate
- Retail pharmacies and hospitals/clinics with on-site pharmacies are authorized to maintain collection receptacles at long term care facilities
- Reorganizes and consolidates regulations on disposal and role of reverse distributors

# Healthcare Sectors Impacted by Proposed DEA Changes

- **Registrant Disposal**
  - Hospitals, clinics, physicians, veterinarians, dentists
  - Retail Pharmacies including LTCF Provider Pharmacies
  - Reverse Distributors
- **Non-Registrant Disposal**
  - **“Ultimate User” collection programs, including law enforcement**
    - Mail-back
    - Receptacles (kiosks)
    - Single day events
  - **“Ultimate User” long term care facilities (LTCFs)**
    - Receptacles provided and managed by retail pharmacies and hospitals/clinics with on-site pharmacies

# Definition of Terms (1317.05(c) (iv))

**Registrant** means any person who is registered pursuant to either section 303 or section 1008 of the Act (21 U.S.C. 823 or 958).

**Practitioners:** retail pharmacies and hospitals/clinics (physicians, veterinarians, dentists)

**Non-practitioners:** manufacturers, distributors, narcotic treatment programs, reverse distributors (1317.05(c)(iv))

**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 by a member of his household. 21 U.S.C 802(27).

Also includes individuals lawfully entitled to dispose of an ultimate user decedent's property

# Definition of Terms 1300.05

**Non-retrievable:** the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes.

Cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue.

**Methods of Destruction (FR 53522 col1):** Intention to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible. Must also meet all other applicable Federal, State, tribal and local laws and regulations. **Once “non-retrievable,” no longer subject to DEA regulations.**

Supersedes all existing MOAs and MOUs.

Retains ability for practitioners to request assistance from the local special Agent in Charge (SAC). (1317.05(a)(5)).

# Definition of Terms

**Disposal and dispose:** to refer generally to the wide range of activities that result in CS being unavailable for further use or one entity ridding themselves of such substances (e.g., returns). (FR53547 col 2)

A controlled substance can be “disposed of” by destruction, return, recall, sale, or through the manufacturing process.

The new rule eliminates the authority of the SACs to individually authorize disposal methods for non-practitioners, and retains this option for practitioners (1317.05)

**Destruction (1317.90):** Must be rendered non-retrievable.

Incineration is the ONLY method currently accepted by DEA.

Sewering and landfill disposal (mixing with kitty litter, etc.) do not meet non-retrievable standard. (FR53547 col 3)

# Definition of Terms

**Reverse distribute (1300.01):** to acquire controlled substances from another registrant or law enforcement for the purpose of:

1. Return to the registered manufacturer or another registrant authorized by the manufacturer to accept returns on the manufacturer's behalf
2. Destruction

**Reverse distributor (1300.01):** a person registered with the Administration as a reverse distributor

# Definition of Terms 1300.01

**Collection:** to receive controlled substances for the purpose of destruction from an ultimate user, or a person so lawfully entitled, or managed by a pharmacy at a long-term care facility on behalf of ultimate user.

**Collector:** registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that has registered as a collector

# Definition of Terms 1300.05

**Employee:** as defined under the general common law of agency.

Criteria to determine employee status for the purpose of disposal:

- Directly paid by the registrant

- Subject to direct oversight by the registrant

- Required to follow the registrant's procedures etc. for handling controlled substances

- Subject to receive a performance rating or evaluation on a regular/routine basis

- Subject to disciplinary action by the registrant

- Required to render services at the registrant's registered location

**Challenge:** Hospitals where many nurses are employed by nursing agencies. Hospitals where the entire pharmacy may be outsourced. Physician clinics and some ambulatory surgery centers where registrant is the physician and is an employee, not an owner.

# Revised Form 41, Record of Destruction 1304.21(e)

- Purpose: To record destruction of controlled substances both within the closed system of distribution and to account for registrant destruction of collection from ultimate users and other non-registrants
- Name and signature of two employees who witnessed the destruction
- Wastage generated and destroyed in an institutional setting (e.g. remaining substance in a vial, transdermal patch, or syringe) must follow 1304.22(c) but need not be recorded on a DEA Form 41.
- No. of units or volume dispensed/administered, name of patient, date, initials of person dispensing/administering, etc.

# Revised Form 41 Example

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 |
|-----------------|---|--------------|-------------------|----------|----------|-----------|----------------------|--------------------|-----------------|
| <i>Examples</i> | 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.              |   |              |                   |          |          |           |                      |                    |                 |
| 3.              |   |              |                   |          |          |           |                      |                    |                 |
| 4.              |   |              |                   |          |          |           |                      |                    |                 |
| 5.              |   |              |                   |          |          |           |                      |                    |                 |
| 6.              |   |              |                   |          |          |           |                      |                    |                 |
| 7.              |   |              |                   |          |          |           |                      |                    |                 |

**2. Collected Substances**

|                 | Returned Mail-Back Package | Sealed Inner Liner | Unique Identification Number       | Size of Sealed Inner Liner | Quantity of Packages(s)/Liner(s) Destroyed |
|-----------------|----------------------------|--------------------|------------------------------------|----------------------------|--|
| <i>Examples</i> | X                          |                    | MBP1106, MBP1108 - MBP1110, MBP112 | N/A                        | 5  |
|                 |                            | X                  | CRL1007 - CRL1027                  | 15 gallon                  | 21   |
|                 |                            | X                  | CRL1201                            | 5 gallon                   | 1  |
| 1.              |                            |                    |                                    |                            |  |
| 2.              |                            |                    |                                    |                            |  |
| 3.              |                            |                    |                                    |                            |  |
| 4.              |                            |                    |                                    |                            |  |
| 5.              |                            |                    |                                    |                            |  |
| 6.              |                            |                    |                                    |                            |  |
| 7.              |                            |                    |                                    |                            |  |

Form DEA-41

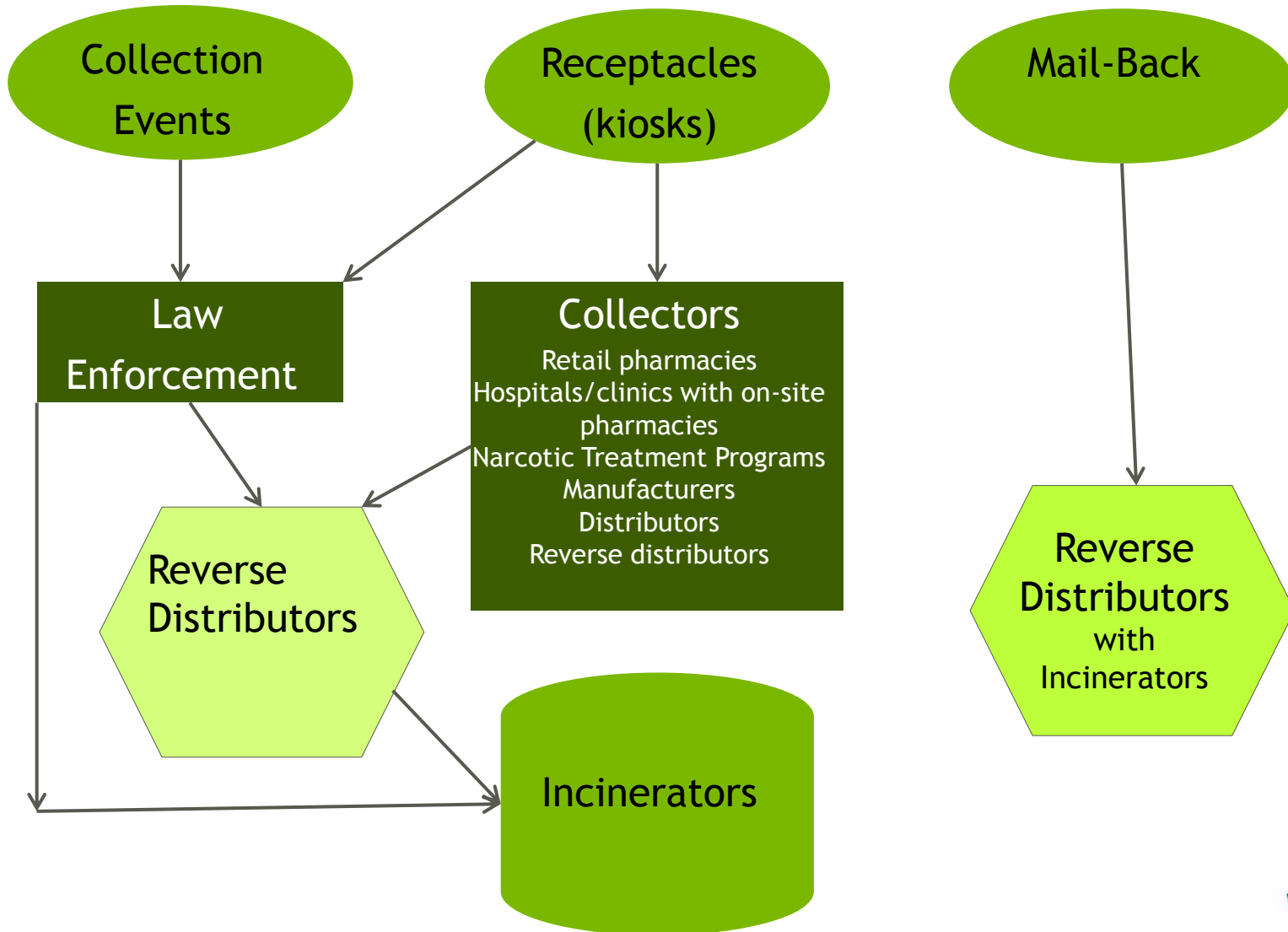
See instructions on reverse (page 2) of form.



# Impact on Hospitals/Clinics

- Decisions regarding ultimate user consumer collection programs
  - Risk (financial and regulatory), recordkeeping, cost
  - Long term care facilities
  - Public relations
- Disposal options for inventory of registrants
  - Reverse distribution of undispensed outdated controlled substances
  - Cannot use receptacles for the disposal of registrant inventory
  - Methods for managing disposal/destruction of “wastage” generated during the course of treatment, i.e. “dispensed” controlled substances
  - Methods for managing disposal of controlled substances brought in by patients (ultimate user consumer waste)

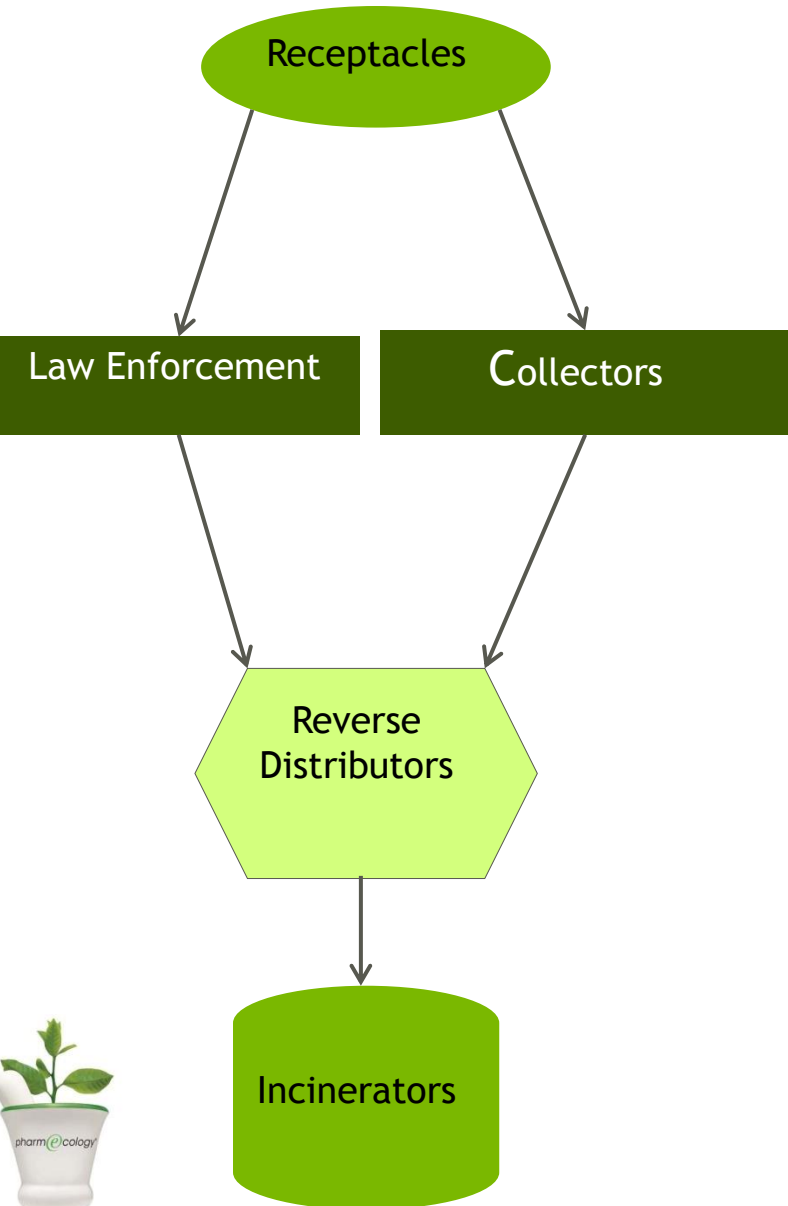
# Impact on Ultimate User Options



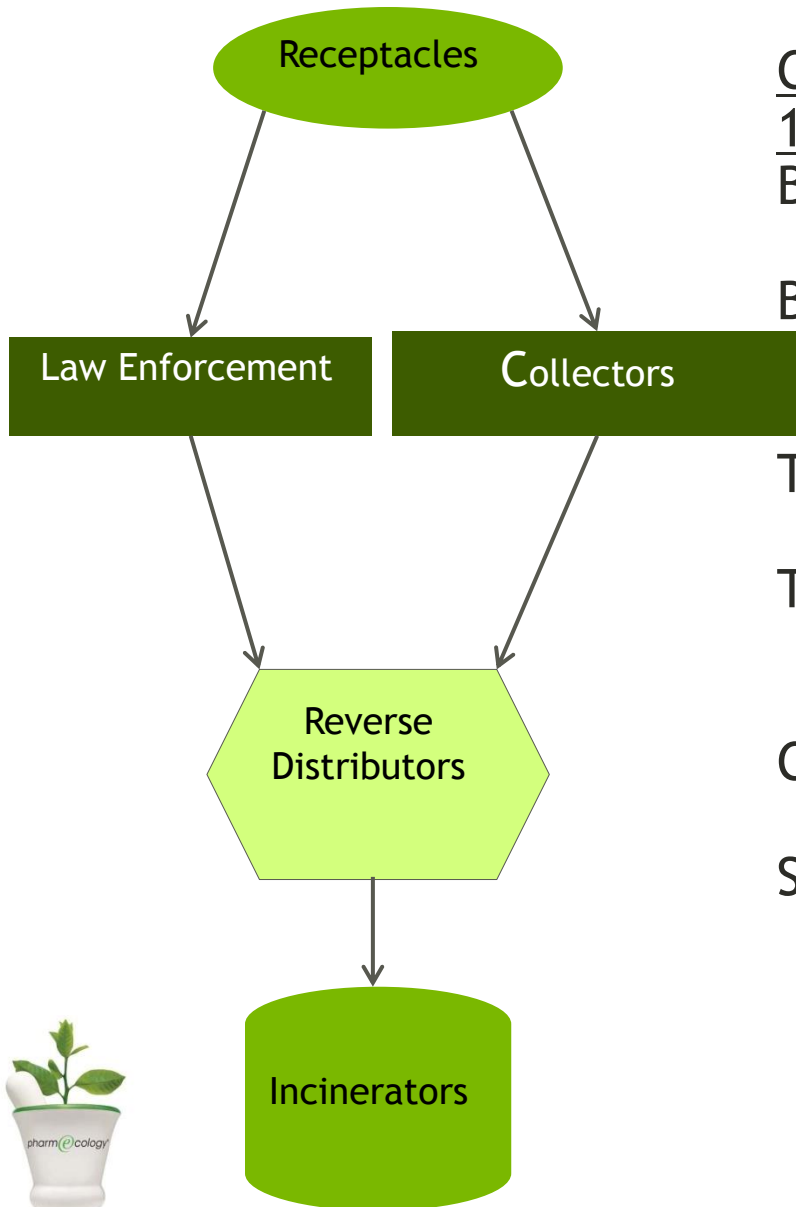
# Collection Receptacles

Registrants authorized to collect controlled substances from ultimate users: 1317.40

Retail pharmacies,  
Hospitals/clinics with an on-site pharmacy,  
Narcotic treatment programs,  
Manufacturers,  
Distributors,  
Reverse distributors,  
Long term care facilities at which registered hospitals/clinics with an on-site pharmacy or retail pharmacies are authorized to maintain collection receptacles



# Collection Receptacles



## Collection Receptacle Requirements: 1317.75(e)

Be securely fastened to a permanent structure so that it cannot be removed

Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner

The outer container shall include a small opening to allow contents to be added

The outer container shall prominently display that only Schedules II-V are acceptable (no illicit drugs)

Collector may choose to accept non-controlled substances also

Small opening shall be locked or made inaccessible when an employee is not present (e.g. when pharmacy is closed)

# Collection Receptacles

## Inner liner requirements 1317.60

Waterproof, tamper-evident, tear-resistant  
Removable and sealable immediately upon  
removal with no touching of contents

Contents not viewable from outside

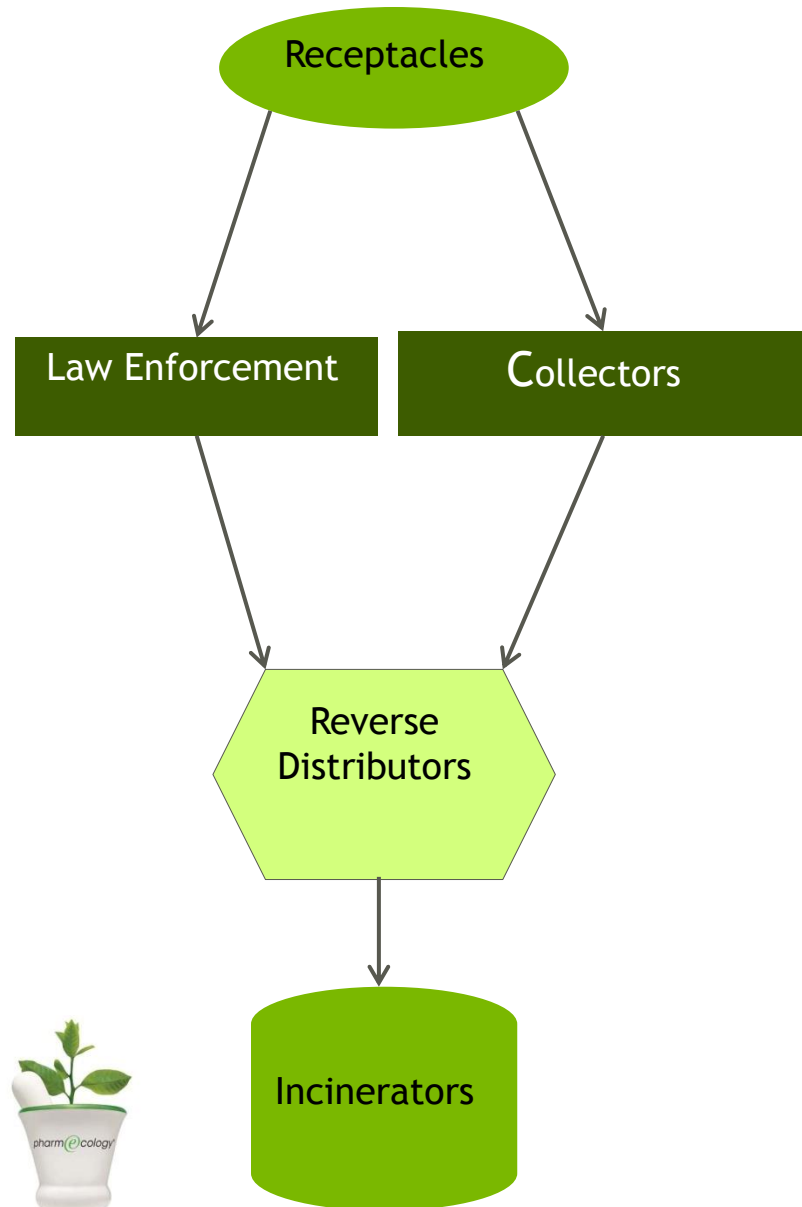
Size of the inner liner clearly marked  
e.g. 5 gallon, 10 gallon, etc.

Inner liner bears a permanent, unique ID  
number that can be tracked

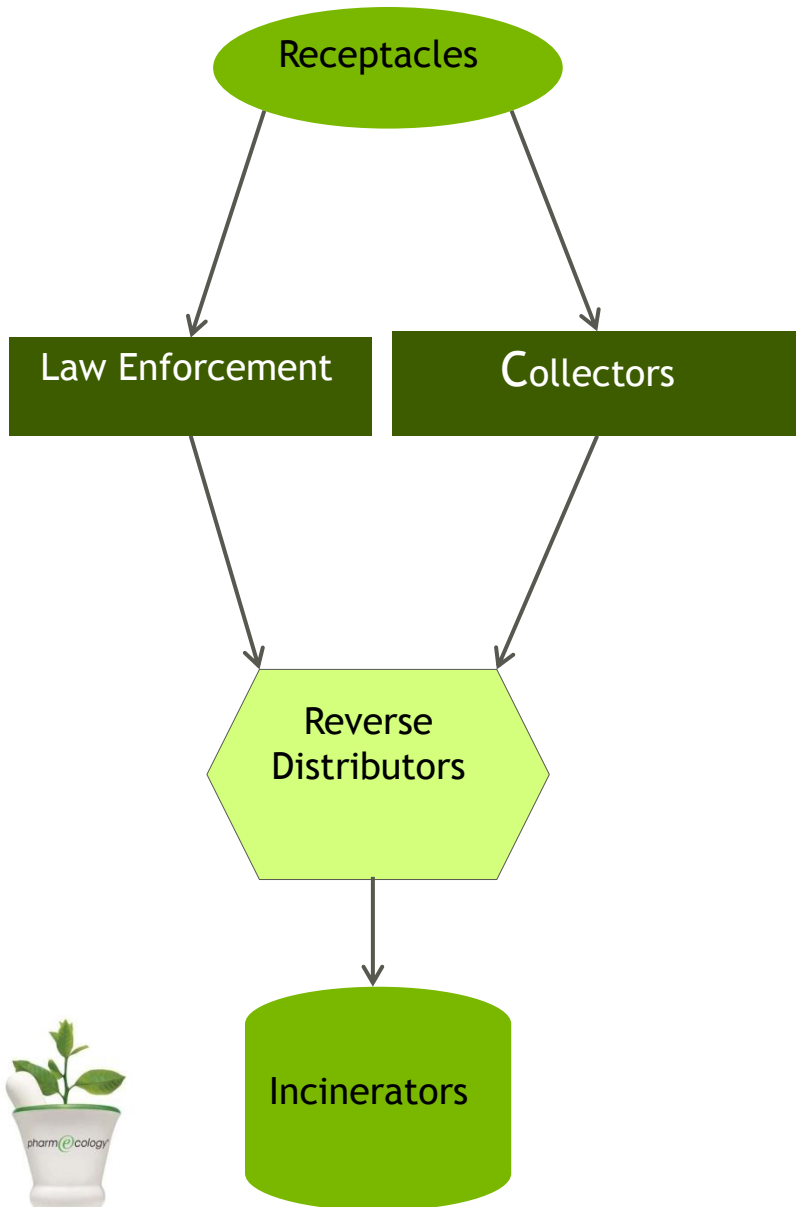
Access restricted to employees of the  
collector

Sealed by two employees immediately  
upon removal

Shall not be opened, x-rayed, analyzed  
or otherwise penetrated



# Collection Receptacles



## Collection Receptacle Usage: 1317.75

Only schedule II, III, IV & V in lawful possession can be accepted

Non-controlled drugs may be commingled  
Only ultimate users and other authorized non-registrants can use

No counting, sorting, inventorying or handling once deposited

## Collection Placement: 1317.75

Retail pharmacy: immediate proximity of pharmacy inventory and at which an employee is present

Hospital/clinic: Area regularly monitored by employee; NOT in emergency or urgent care area

Narcotic treatment program: securely locked room with no other CS

Long term care facility: secured and regularly monitored by employees

Inside law enforcement's physical location



# Collection Receptacles

Long Term Care Facility requirements: 1317.80

Within 3 days of “discontinuation of use”

Permanent DC by prescriber,  
resident’s transfer, death

Pharmacy/Hospital/Clinic with pharmacy may  
install, manage, maintain receptacle

Installation, removal, transfer, storage of

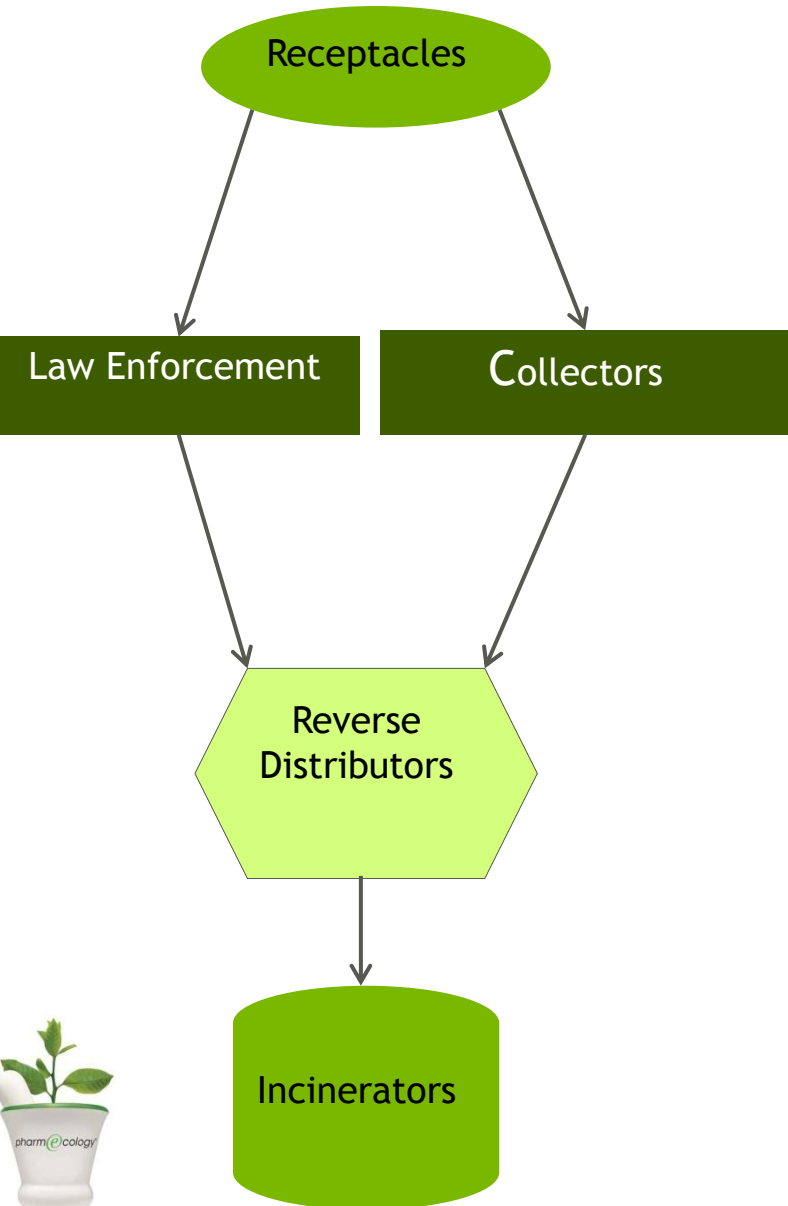
inner liner by either: 2 pharmacy  
employees or 1 pharmacy employee  
and 1 supervisor-level LTCF employee

Inner liners may be stored up to 3 business  
days in a securely locked cabinet or  
room with controlled access

Inner liners may be shipped to a reverse  
distributor (RD) or picked up by a RD

All records to be retained by registrant

Pharmacy personnel CANNOT return the  
inner liner to the pharmacy



# Specific LTCF Issues

- The location of the collection receptacle at an LTCF is both a registered location of the pharmacy managing the receptacle and a controlled premise
- As a “controlled premise,” the DEA may enter LTCFs and conduct administrative inspections
- Rule provides “additional options for disposal and does not prohibit any methods currently used by LTCFs that are consistent with Federal, State, tribal, and local laws and regulations” (FR 35341 col 2)
- LTCFs are not prohibited from destroying patients’ unwanted CS on behalf of the resident
- “Non-retrievable” language applies only to DEA registrants, not to ultimate users



# Collection Receptacles

## Reverse Distributors and Distributors authorized to acquire CS from collection Receptacles 1317.55

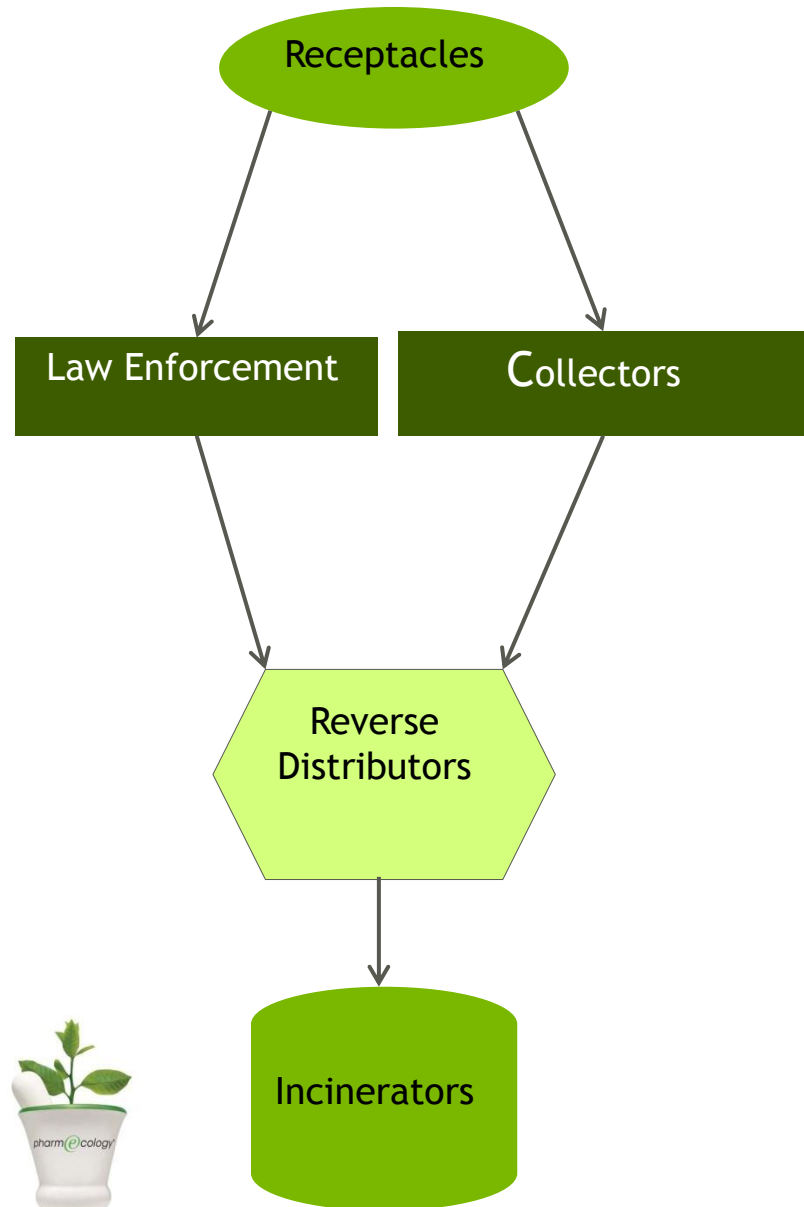
May pick up CS from a registrant or collection site or receive CS delivered by common or contract carrier, or delivered directly by non-practitioner registrant 1317.15

Personally received by RD employees at registered location

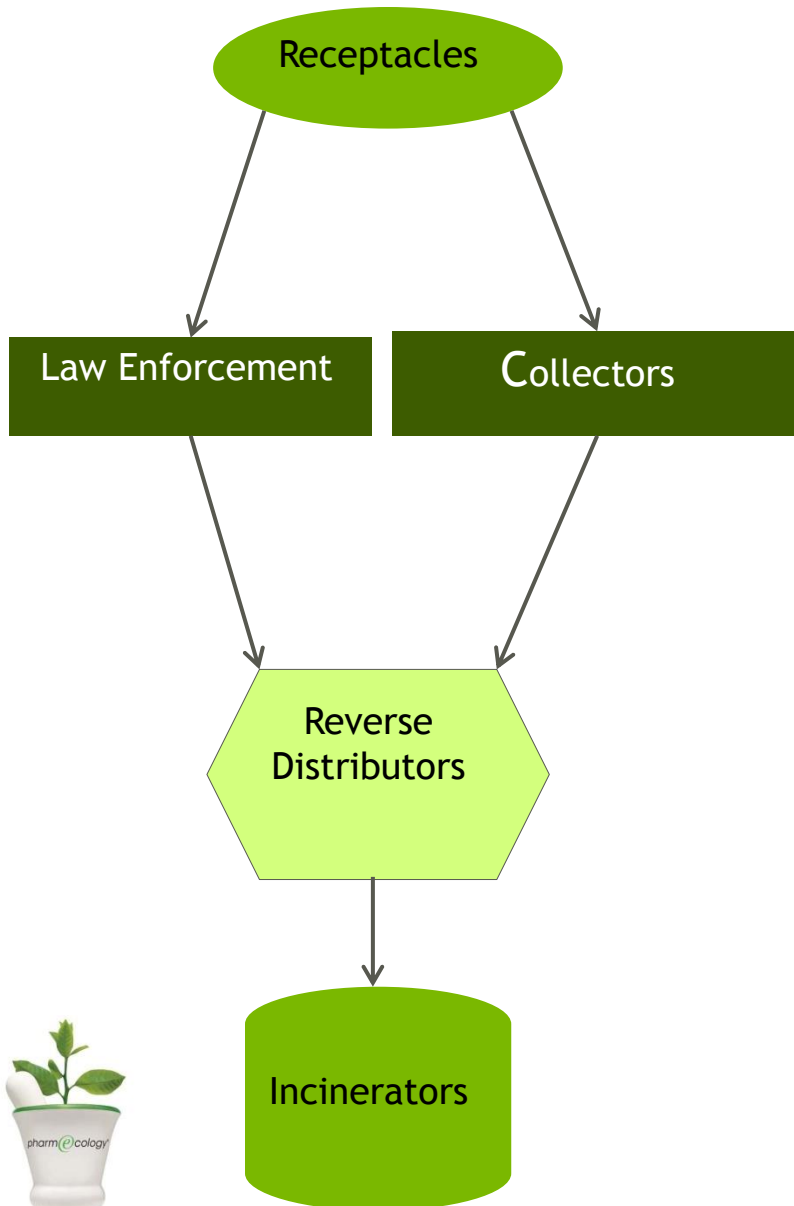
Immediately store in accordance with security controls

Timely destroy CS or cause destruction no later than 30 calendar days after receipt

Record of destruction to include DEA Form 41 1304.21



# Collection Receptacles



## Records for Collectors: 1304.22

Date each unused inner liner acquired,  
Unique ID number, size

Date liner is installed,  
address of location, unique ID number,  
size, registration number of collector,  
names and signatures of 2 employees  
witnessing installation

Date liner is removed and sealed, address of  
location, ID number, size,  
registration number, names and  
signatures of 2 employees witnessing  
removal

Date, etc. that liner is transferred to storage  
Date, etc. that each liner is transferred for  
destruction, address and registration  
number of reverse distributor to  
whom transferred, unique ID number,  
size of liner, names and signatures of  
2 employees



# Summary Table of Recordkeeping for Collectors Using Receptacles/Inner Liners

| Inner Liner Records              | Acquisition | Installation | Removal & Sealing | Transfer to Storage | Transfer for Destruction |
|----------------------------------|-------------|--------------|-------------------|---------------------|--------------------------|
| Date                             | X           | X            | X                 | X                   | X                        |
| Unique ID #                      | X           | X            | X                 | X                   | X                        |
| Size                             | X           | X            | X                 | X                   | X                        |
| Address of Registrant            |             | X            | X                 |                     |                          |
| Registration # of Collector      |             | X            | X                 |                     |                          |
| Names/<br>Signatures 2 employees |             | X            | X                 | X                   | X                        |
| Address of RD                    |             |              |                   |                     | X                        |
| Registration # of RD             |             |              |                   |                     | X                        |



# Collection Receptacles

Recordkeeping Requirements: 1304.04

Reverse Distributors: 1304.22

Number of sealed inner liners acquired from other persons,

date of acquisition.

number and size,

unique ID number,

Name, Address and registration

number of person from whom acquired

Date, place and method of destruction;

Number of sealed inner liners,

name, address, registration number of

person from whom acquired,

number and size of all inner liners,

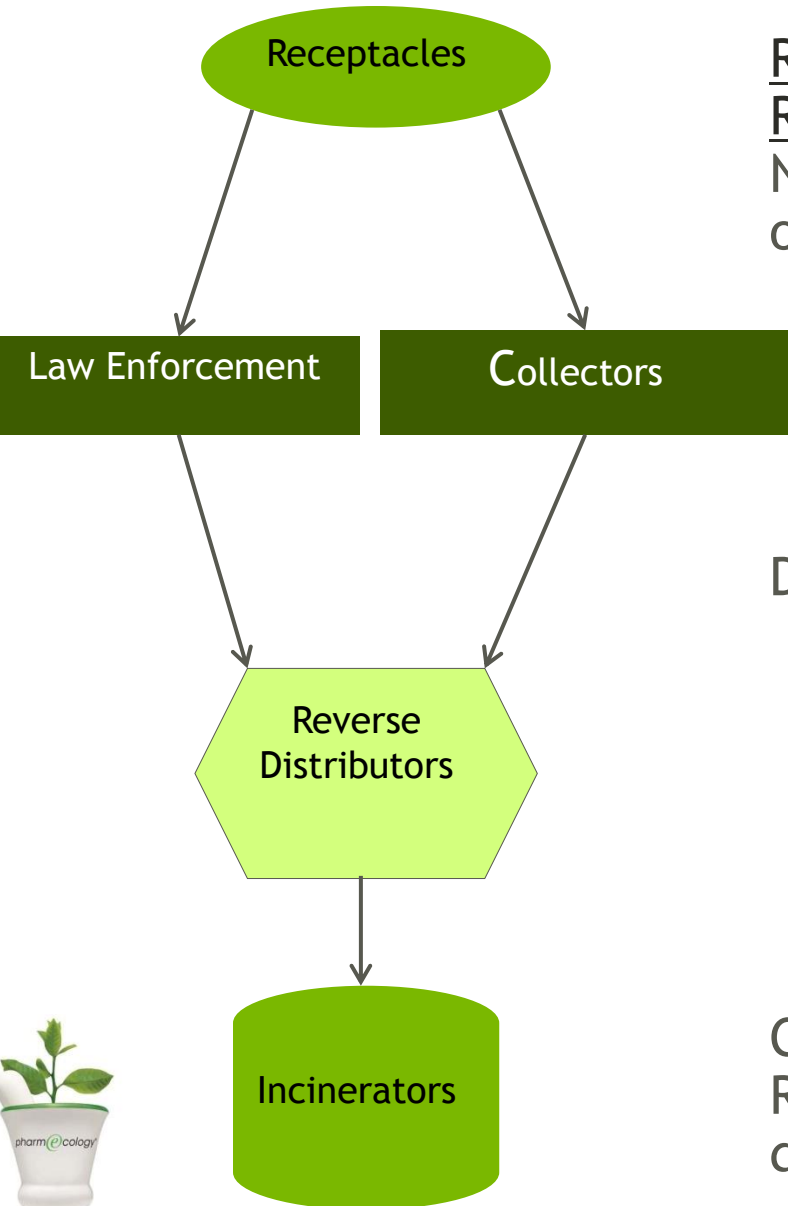
ID number,

name and signature of 2 employees

witnessing destruction

Completed DEA Form 41

Record of receipt maintained with record of destruction



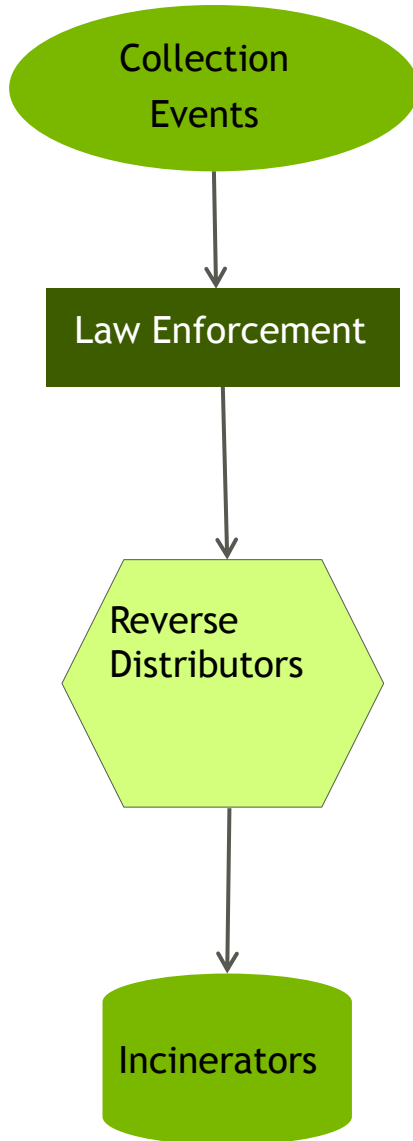
# Summary Table of Recordkeeping for Reverse Distributors Receiving Inner Liners

| Inner Liner Records           | Acquisition | Witnessed Destruction |
|-------------------------------|-------------|-----------------------|
| Date                          | X           | X                     |
| # of Liners                   | X           | X                     |
| Unique ID #                   | X           | X                     |
| Size                          | X           | X                     |
| Name of Registrant            | X           | X                     |
| Address of Registrant         | X           | X                     |
| Registration # of Collector   | X           | X                     |
| Names/ Signatures 2 employees |             | X                     |
| DEA Form 41                   |             | X                     |

Record of receipt maintained with record of destruction



# Collection Events: 1317.65



Only law enforcement officer can handle controlled substances

Other organizations may partner with Law enforcement to sponsor the event

Law enforcement shall appoint a law enforcement officer employed by the agency to oversee the collection

Law enforcement officers shall maintain control and custody of the collected substances from the ultimate user or authorized representative until secure transfer, storage, or destruction has occurred

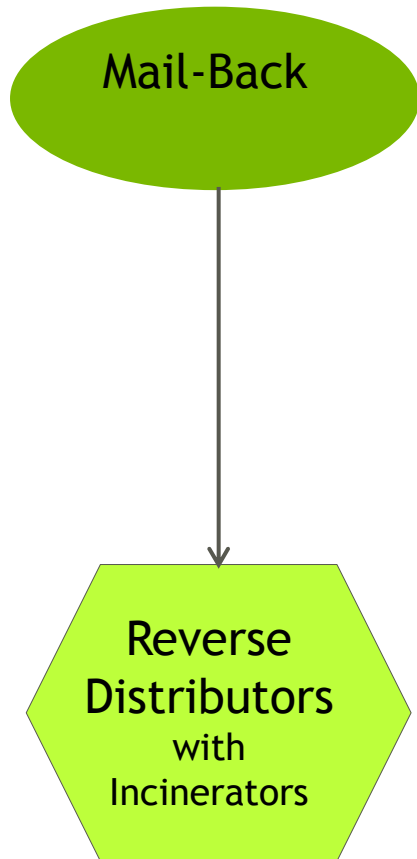
At least one receptacle for the collection of controlled substances is recommended but not required at each event (1317.60)

Only Schedules II, III, IV, V plus other non-controlled drugs if desired

No other persons may handle the controlled substances at any time (other than ultimate user or authorized person and law enforcement)



# Mail-back Programs



May be conducted by law enforcement or any collector that has at their registered location a method of destruction  
Limits non-law enforcement to a few RDs with on-site incinerators

Common or contract carriers may be used  
Any person may partner with law enforcement or an appropriate collector

Packages must be made available (free or for sale)  
Packaging must be nondescript  
Water- and spill-proof, tamper evident, tear-resistant, sealable

Packages must be pre-addressed with address of collector or law enforcement

Cost of shipping shall be postage paid

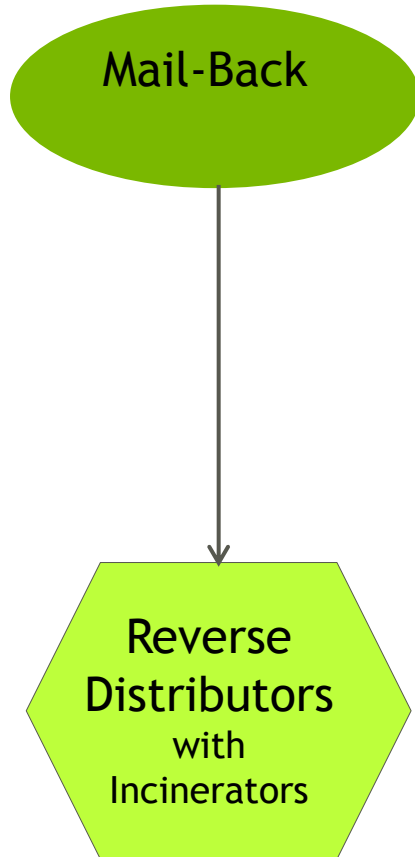
Package shall have unique identification number enabling tracking

Shall include instructions for user

No personal information required



# Mail-back Programs



## Responsibilities of Collector: 1317.70

Accept CS only within specified packages

Notify DEA of receipt of unsolicited package within 3 days

Make a reasonable effort to notify the public prior to discontinuing mail-back program

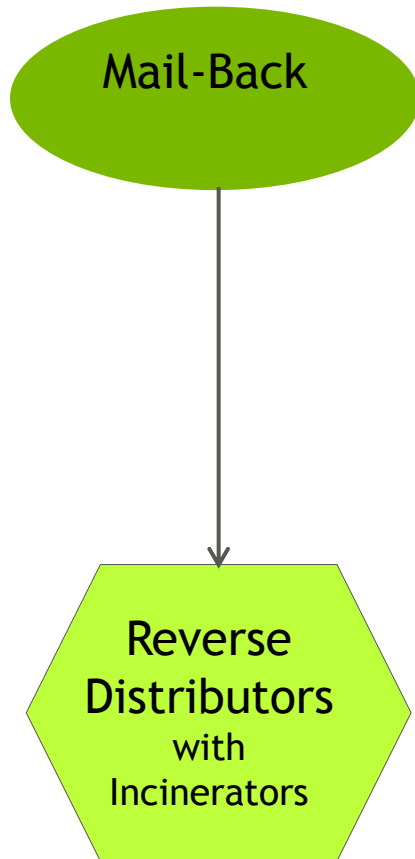
Obtain written agreement of another collector who meets the requirements of on-site destruction to receive remaining packages

Only law enforcement and employees of collector shall handle packages

No packages received shall be opened, x-rayed, analyzed, or otherwise penetrated



# Mail-back Programs



## Recordkeeping Requirements 1304.322

Unused packages at collector's address:

Date made available, number of packages, unique ID number

Unused packages provided to a 3<sup>rd</sup> party to make available: Name of 3<sup>rd</sup> party, physical address, date sent, number of unused packages with corresponding unique ID numbers

Sealed mail-back packages received by collector:

Date of receipt, ID #

Sealed mail-back packages destroyed by collector:

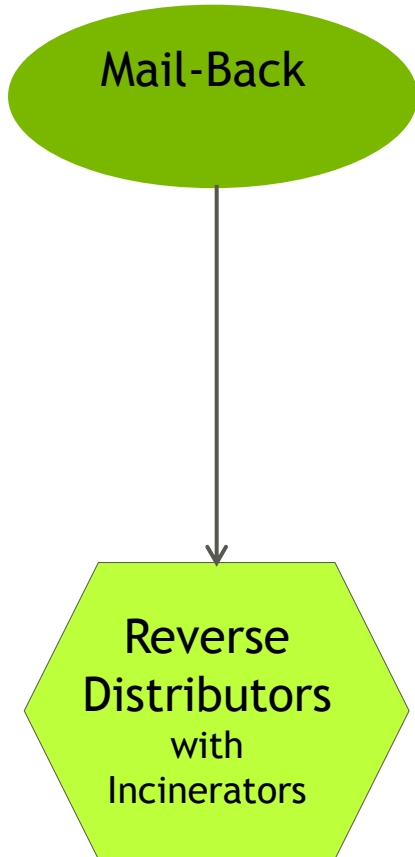
Number destroyed, date and method of destruction, unique ID number of each, names and signatures of 2 employees who witnessed destruction



# Mail-back Programs

## Additional Disposal Requirements 1317.05

Upon receipt the collector shall promptly:  
Destroy the package using an on-site method  
or securely store the package consistent with  
security requirements for schedule II CS  
until on-site destruction can occur



# Evaluating Risks as a Hospital Collector

- Is your facility prepared to comply with the recordkeeping requirements?
- Does your facility have an appropriate location that is available to the public and constantly monitored by employees?
- Have you analyzed the implementation and management costs?
  - Cost of kiosk, inner liners, publicity
  - Cost of inventory management, shipping, destruction
- How will you insure only controlled substances in schedules II through V will be placed into the kiosk?
- Where will you store the inner liners prior to shipment?



# Registrant Disposal: What Are Your Options?



# Registrant Disposal 1317.05

- Promptly destroy in accordance with subpart C of this part using an on-site method of destruction
- Promptly deliver to a reverse distributor's registered location by common or contract carrier pick-up or by reverse distributor pick-up at the registrant's registered location.
- Return or recall
- Request assistance from the Special Agent in Charge in the area
  - One copy of DEA Form 41 listing CS for disposal:
    - Transfer to a registrant for transport and destruction
    - Delivery to DEA
    - Destruction in the presence of a DEA agent

# Routine disposal 1317.05(a)(5)

- Special Agent in Charge may authorize practitioner to dispose of such substance, without prior application in each instance, on the condition that the practitioner keep records and file periodic reports.
- Apparently no new MOAs or MOUs will be issued.

# Methods of destruction 1317.90

- Must be destroyed in compliance with applicable Federal, State, tribal, and local laws and regulations
- Shall be rendered non-retrievable
- Where multiple controlled substances are comingled, the method of destruction must render all non-retrievable
- Also applies to reasonable assumption controlled substances may be present

# Destruction Procedures: On-Site

- Two employees shall handle or observe the handling of CS until rendered non-retrievable
- Two employees shall personally witness the destruction of the CS until rendered non-retrievable
- Two witnessing employees shall personally sign the completed Form 41
  
- EXCEPT: this does not apply to wastage generated when a CS has been dispensed to a patient

# Destruction Procedures

- Transfer to a person registered or authorized to accept CS for the purpose of destruction
  - Two employees of transferring registrant shall load and unload or observe the loading and unloading until transfer is complete
- Transport to a registered location
  - Directly to registered location
  - Two employees of transporting registrant shall accompany the CS to the registered location
  - Two employees of transporting registrant shall load and unload or observe loading and unloading of CS

# Destruction Procedures

- Transport to a non-registered location
  - Directly to destruction location
  - Two employees of transporting registrant shall accompany to the destruction location
  - Two employees of transporting registrant shall load and unload or observe the loading and unloading
  - Two employees of transporting registrant shall handle or observe handling until CS is rendered non-retrievable
  - Two employees of transporting registrant shall personally witness the destruction until CS rendered non-retrievable
  - Two employees of transporting registrant shall personally sign the completed Form 41

# Record of Destruction 1304.21(e)

- Maintain record of destruction on DEA Form 41 (complete, accurate, name and signature of two employees who witnessed destruction)
- EXCEPT “destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner’s registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with 1304.22(c) and such record need not be maintained on a DEA Form 41.”
- No. of units or volume dispensed/administered, name of patient, date, initials of person dispensing/administering, etc.

# Registrant Disposal Concerns

- Ability to render a drug “non-retrievable” in an institutional setting
- Ability to transfer drug wastage to a reverse distributor from an institutional setting
- Restrictive definition of “employee”
  - May not have two nurses available to witness the destruction who are “employees” of the hospital
  - May not have any pharmacists who are “employees” of the hospital due to outsourcing of departments
  - Clinics may have no one who is an employee of the Registrant, who is the physician
- Requirement to double witness the destruction of the CS until it is rendered non-retrievable

# Areas needing Clarification

- How should a healthcare facility handle “wastage” of a dispensed dose that is not entirely used?
  - Partial IVs, gels, tablets, vials, etc.
- How can the facility render the drugs non-retrievable?
- Are two witnesses still required if “wasting” is not considered “destruction”?
- Need clarification of “wasting” activity

# Questions?

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