DEA Rule Changes: Impact on Industry Disposal Practices

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Practice Greenhealth
October 15, 2014
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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.
## A. Registrant Information

<table>
<thead>
<tr>
<th>Registrant Name</th>
<th>DEA Registration Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Registrant Address</th>
<th>Contact Name</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zip Code</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Telephone Number</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
</tr>
</tbody>
</table>

## B. Item Destroyed

### 1. Inventory

<table>
<thead>
<tr>
<th>National Drug Code or DEA Controlled Substance Code Number</th>
<th>Batch Number</th>
<th>Name of Substance</th>
<th>Strength</th>
<th>Form</th>
<th>Pack QTY</th>
<th>Number of Full Packs</th>
<th>Partial Pack Count</th>
<th>Total Destroyed</th>
</tr>
</thead>
<tbody>
<tr>
<td>10586-5364-60</td>
<td>N/A</td>
<td>Kadian</td>
<td>80mg</td>
<td>Capsule</td>
<td>60</td>
<td>2</td>
<td>0</td>
<td>120 Capsules</td>
</tr>
<tr>
<td>0555-0787-03</td>
<td>N/A</td>
<td>Adderall</td>
<td>30mg</td>
<td>Tablet</td>
<td>100</td>
<td>0</td>
<td>83</td>
<td>83 Tablets</td>
</tr>
<tr>
<td>3050</td>
<td>B02150012</td>
<td>Cocaine</td>
<td>N/A</td>
<td>Bulk</td>
<td>1.25 kg</td>
<td>N/A</td>
<td>N/A</td>
<td>1.25 kg</td>
</tr>
</tbody>
</table>

### 2. Collected Substances

<table>
<thead>
<tr>
<th>Returned Mail Back Packages</th>
<th>Sealed Inner Liner</th>
<th>Unique Identification Number</th>
<th>Size of Sealed Inner Liner</th>
<th>Quantity of Packages(s), (s) Liners(s) Destroyed</th>
</tr>
</thead>
<tbody>
<tr>
<td>X</td>
<td></td>
<td>MBP1196, MBP119, MBP119, MBP12</td>
<td>N/A</td>
<td>5</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td>CRL1097, CRL1097</td>
<td>15 gallon</td>
<td>21</td>
</tr>
<tr>
<td>X</td>
<td></td>
<td>CRL1204</td>
<td>5 gallon</td>
<td>1</td>
</tr>
</tbody>
</table>

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 Events

Law Enforcement

Reverse Distributors

Collectors
- Retail pharmacies
- Hospitals/clinics with on-site pharmacies
- Narcotic Treatment Programs
- Manufacturers
- Distributors
- Reverse distributors

Mail-Back

Reverse Distributors with Incinerators

Incinerators
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

<table>
<thead>
<tr>
<th>Inner Liner Records</th>
<th>Acquisition</th>
<th>Installation</th>
<th>Removal &amp; Sealing</th>
<th>Transfer to Storage</th>
<th>Transfer for Destruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Unique ID #</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Size</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Address of Registrant</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Registration # of Collector</td>
<td>X</td>
<td>X</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Names/Signatures 2 employees</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Address of RD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>Registration # of RD</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

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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

<table>
<thead>
<tr>
<th>Inner Liner Records</th>
<th>Acquisition</th>
<th>Witnessed Destruction</th>
</tr>
</thead>
<tbody>
<tr>
<td>Date</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td># of Liners</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Unique ID #</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Size</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Name of Registrant</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Address of Registrant</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Registration # of Collector</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>Names/Signatures 2 employees</td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>DEA Form 41</td>
<td></td>
<td>X</td>
</tr>
</tbody>
</table>

Record of receipt maintained with record of destruction
Collection Events: 1317.65

- **Collection Events**
  - Only law enforcement officer can handle controlled substances
  - Other organizations may partner with law enforcement to sponsor the event

- **Law Enforcement**
  - 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

- **Reverse Distributors**
  - 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

- **Incinerators**
  - 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 3rd party to make available:
- Name of 3rd 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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