

medsafe
Safe Collection Proper Destruction

***Management of
Unused Patient
Dispensed
Medications***

SHARPS
Compliance, Inc.

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Disposal Options

- Sewer
- Trash
- DEA Takeback days
- Receptacles and mailbacks
 - Non-controls
 - Non-controls and controls

DEA Rule

- On October 8, 2014, the Drug Enforcement Administration (DEA) released its final rule regarding the disposal of pharmaceutical controlled substances in accordance with the Controlled Substance Act, as amended by the Secure and Responsible Drug Disposal Act of 2010.

Collection Challenges

- Even though controlled substances are 5 to 10% of medications collected, but are the larger problem
- Ultimate users need easy access to environmentally safe and systems they can feel confident about
- DEA take-back days have been limited with the hope of receptacle placement and mailback usage
- State rules
- Long-term care collectors
- Funding



DEA-Compliant Receptacle ***It Starts with Security***

Instructions for Use

Small lockable opening that allows contents to be added without removal

Substantially constructed container with a permanent outer shell, e.g. 14-gauge powder-coated steel construction (UL Tested 291)

Securely fastens to the floor or wall

Compliant signage

Two ultra high-security padlocks secure main door



DEA-Compliant Inner Liner Containment and Transport

- Waterproof, tamper-evident, and tear-resistant
- Double 200lb opaque corrugated boxes
- 4mil plastic liner with zip-tie and absorbent
- DOT drop/leak tested
- Removable without touching contents
- Size, unique ID, barcode - traceable
- Pre-paid, pre-addressed to reverse distributor with onsite destruction
- Instructions for use and step log



Instructions for Use and Steps to Compliance

Sharps Compliance is a DEA registered reverse distributor. All MedSafe inner liners will be transported and transferred to its DEA registered facility, Sharps Environmental Services via common carrier in compliance with all applicable sections of § 1317.

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Pharmacy shall modify its DEA registration to become an authorized collector, and list locations of collection receptacles.

01

The MedSafe receptacle shall be securely fastened to a permanent structure so that it cannot be removed and can be seen from the pharmacy counter. Two authorized pharmacy employees shall install the Inner liner, and both sign the Step Log. Two authorized employees shall maintain keys for the receptacle in a safe location.

02

When the receptacle Inner liner is full, two authorized pharmacy employees shall remove, seal and package the liner immediately upon removal without emptying or touching the contents; and both shall sign the Step Log.

07

The Inner liner may be stored by two authorized employees in a securely locked, substantially constructed cabinet or securely locked room if necessary prior to transferring for disposal. Both employees shall sign the Step Log.

08

Proper Documentation

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**Inner Liner
Step Log
38-Gallon**

1. INSTALLATION (Place Inner Liner into Receptacle)

Date Inner Liner Received: _____ Inner Liner NO: _____

Date Inner Liner Installed into Receptacle: _____

Address where Inner liner Installed:

Collector (Pharmacy) Registration NO: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

2. REMOVAL (Remove and Seal Inner Liner)

Date Inner Liner Removed from Receptacle and Sealed: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

3. STORAGE (Transfer to Storage)

Date Inner Liner Transferred to Storage: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

4. DESTRUCTION (Ship for Destruction)

Date Inner Liner Transferred/Shipped for destruction: _____

1st Employee Name: _____

1st Employee Signature: _____

2nd Employee Name: _____

2nd Employee Signature: _____

Address (Reverse Distributor to which Inner Liner Transferred):

Sharps Environmental Services

1544 NE Loop, Carthage, TX 75633

Reverse Distributor Registration NO: R50365800

100939 REV A

Who Can Collect?

- **Collection Receptacles**

- Retail Pharmacies, hospitals/clinics with onsite pharmacies, drug treatment facilities, LTCF (managed by pharmacy)
- Law Enforcement
- Can install, maintain and manage a collection receptacle program

- **Mailbacks**

- Reverse distributor can be a registrant collector (Sharps Compliance)
- Can partner with others to provide mailbacks
- Reverse distributor must have onsite treatment where mailbacks are directly sent

Pharmacy

- Update DEA registration to collector status
- Secure inside pharmacy but not behind counter
- Drop-slot locked when closed
- Two employees place, package, and transfer inner liner
- Document management
- May store in locked room or cabinet

Law Enforcement

- Collectors or Federal, State, tribal, or local law enforcement may manage and maintain collection receptacles for disposal
- Secured LE physical location
- Storage and records same as for illicit controlled substances evidence
- When ship inner liner to RD (Sharps via UPS), document the unique identification number and size of inner liner transferred

Mailback Program

- A mail-back program may be conducted by Federal, State, tribal, or local law enforcement or any collector
- Envelopes can be handed out to citizens (free of charge or for a cost)
 - At a pharmacy; hospice
 - By law enforcement
 - If controls are brought to a city facility for disposal
 - Do not handle the drugs; hand envelopes to citizen

Mailback

- Any person may partner with a mailback collector
- Collector must have onsite treatment, e.g. incineration
- Mailbacks must be:
 - Nondescript
 - Water- and spill-proof; tamper-evident; tear-resistant; and sealable;
- Prepaid and preaddressed with and delivered to the collector's registered address
- Unique ID # for tracking
- Instructions
- No personally identifiable information can be required

Mailback



- Reverse Distributor (RD) receives approval for packaging from common carrier/USPS
- RD updates registrant status with DEA to be collector
- Mailbacks purchased from RD
 - Documentation maintained by RD
 - Inventory maintained by organization
- Give/sell to ultimate user (UU)
- UU mails to RD when full for disposal
- Documentation/reconciliation

Destruction

- Pre-addressed, pre-paid inner liner and/or mailback is returned via common carrier
- At the treatment center, 2 employees from manage the process (once again, limits diversion)
- Inner liners and mailbacks are scanned, weighed and stored in Schedule II vault.
- Destroyed to the point of being unidentifiable and irretrievable within 30 days of receipt

Tracking Documentation

- Secure, proprietary online data warehouse, unique for each client
 - DEA compliant
 - Outbound inventory
 - Returned inventory
 - Date of return
 - Condition of return
 - Weight of return
 - Current status of return (stored)
 - Date of destruction
 - Effectiveness check

Choosing a Reverse Distributor

Experience and Expertise

- History with pharmaceuticals and mailback
- History with dealing with materials from ultimate users – uncontrolled environment
- Processes in place
- Working a current program
- Hundreds of units currently in place collection controlled substances from ultimate users

Discussion



Envelope Pricing

<i>TakeAway Medication Recovery Systems</i>	
Item	Price
TakeAway Medication Recovery System Envelope (case of 12) with display box	\$75.00 (plus S&H)
TakeAway Medication Recovery System Envelope (25ct w/ POP)	\$124.50 (plus S&H)
TakeAway Medication Recovery System Envelope, case of 50	\$249.00 (plus S&H)
TakeAway Medication Recovery System Envelope, case of 250	\$1050.00 (plus S&H)

MedSafe Pricing

F.O.B. Destination

Item	Description	State and Local Government Pricing
17818	18 Gal MedSafe Receptacle with Liner, Standard Header. For collection and disposal of ultimate user medications, INCLUDING SCHEDULE II-V CONTROLLED SUBSTANCES. Must be utilized in conjunction with 18 Gal MedSafe Liners (Item # 17418).	\$1,458.00
17838	38 Gal MedSafe Receptacle with Liner, Standard Header. For collection and disposal of ultimate user medications, INCLUDING SCHEDULE II-V CONTROLLED SUBSTANCES. Must be utilized in conjunction with 38 Gal MedSafe Liners (Item # 17438).	\$1,620.00
17418	18 Gal MedSafe Liner, case of 4. For collection and disposal of ultimate user medications, INCLUDING SCHEDULE II-V CONTROLLED SUBSTANCES. Must be utilized in conjunction with 18 Gal MedSafe Receptacle (Item # 17818). Each liner is serialized and includes pre-paid return via common carrier.	\$540.00
17438	38 Gal MedSafe Liner, case of 4. For collection and disposal of ultimate user medications, INCLUDING SCHEDULE II-V CONTROLLED SUBSTANCES. Must be utilized in conjunction with 38 Gal MedSafe Receptacle (Item # 17838). Each liner is serialized and includes pre-paid return via common carrier.	\$765.00