

How to Start a Drug Take-Back Program at Your Pharmacy

Continuing Pharmacy Education (CPE) Information

- This CPE program is approved for 0.5 hours of home study CPE in Pharmacy Law for Idaho pharmacists
- To satisfactorily complete this program, a pharmacist must:
 - Fully read the CPE monograph and complete the accompanying post-test evaluation
 - Mail the post-test answer sheet, postmarked no later than December 31, 2018 to:
 - Idaho State Board of Pharmacy
Home Study CPE Program
1199 Shoreline Lane, Suite 303
Boise, Idaho 83702-0067
 - Pass the post-test with a score of at least 80%; and
 - Include a self-addressed stamped envelope (SASE) for the return of a statement of credit. No statement of credit will be awarded unless a SASE is provided by the pharmacist.

Background

Unused and unwanted medications are often stockpiled within a person's home. These supplies are vulnerable to theft, abuse and diversion, contributing to the epidemic of prescription drug abuse. To help facilitate safe removal and disposal of such medications, the Drug Enforcement Administration (DEA) finalized rules in 2014 authorizing "ultimate users" to transfer controlled substances to an "authorized collector." Retail pharmacies, hospitals and clinics with on-site pharmacies, among others, may become authorized collectors of controlled substances under these rules. In order to participate, such pharmacies must follow specific requirements related to collection receptacle placement, use of inner liners, and reverse distribution, among others. This CPE program will:

- Describe the necessary requirements prior to starting a drug take-back program;
- Describe the materials that are needed to start and maintain a drug-take back program; and
- Describe recordkeeping requirements of medications collected within a drug take-back program.

Definitions

The following terms will be used throughout this CPE Program:

The Disposal Act: An amendment to the Controlled Substance Act that gave the DEA authority to promulgate new rules that allow for "ultimate users" to deliver unused medications -- both controlled and non-controlled -- for safe disposal.

Ultimate User: A person who has lawfully obtained, and who possesses, a controlled substance for his/her own use or for the use of a member of his/her household or for an animal owned by him or a member of his household.

Authorized Collector: The entity in which the take-back receptacle is placed, managed, and supervised. It is also the entity responsible for following the law set forth by the DEA and responsible for the handling and coordination with the reverse distributor.

Reverse Distributor: The person/company registered with the DEA to acquire controlled substances from another registrant (e.g., a pharmacy) or law enforcement agency for the purpose of safe destruction. There are at least three companies as of present who are legally able to reverse distribute. Licensed reverse distributors as of November 2016 include, but may not be limited to:

- Assured Waste Solutions
- Sharps Compliance Inc.
- Med Return, LLC

Getting Started

How do I modify my DEA registration to become an authorized collector? If a pharmacy desires to become an authorized collector, it must modify its DEA registration. There is no cost to modify an eligible DEA registration to become an authorized collector. You may modify your registration here: <https://apps.deadiversion.usdoj.gov/webforms2/spring/disposalLogin?execution=e3s1>.

To register as an authorized collector, the following information must be provided to DEA on the aforementioned form:

- The registrant's name, address, and registration number as printed on the current certificate of registration;
- The method(s) of collection the registrant intends to conduct (collection receptacle and/or mail back program); and
- A signature of one of the following:
 - The applicant, if an individual; or
 - A partner of the applicant, if a partnership; or
 - An officer of the applicant, if a corporation, corporate division, association, trust or other entity; or
 - An authorized power of attorney of the applicant.

Eligible registrants must have authority to handle schedule II controlled substances. If the modification of registration is approved, the DEA will issue a new certificate of registration to the registrant, and it must be maintained with the original certificate of registration until expiration.

What is allowed as a collection receptacle?

A collection receptacle must be located in the immediate proximity of a designated area where controlled substances are stored and at which an employee is present (e.g., can be seen from the pharmacy counter).

The DEA has specific requirements that must be followed. Pharmacies are encouraged to work closely with a reverse distributor to ensure the right materials are obtained. Specifically a collection receptacle shall meet the following design specifications:

- 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 that allows content to be added to the inner liner, but does not allow removal of the inner liner's contents
- The outer container shall prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances are allowed
- The small opening in the outer container of the collection receptacle shall be locked or made otherwise inaccessible to the public when an employee is not present (e.g., when the pharmacy is closed), or when the collection receptacle is not being regularly monitored by long-term care facility employees. There is an exception to this for narcotic treatment programs.
- The installation and removal of the inner liner of the collection receptacle shall be performed by or under the supervision of at least **two (2)** employees of the authorized collector.

A collector shall not employ, as an agent or as an employee who has access to or influence over controlled substances acquired by collection, any person who:

- Has been convicted of any felony offense relating to controlled substances;
- Has, at any time, had an application for registration with DEA denied;
- Had a DEA registration revoked or suspended; or
- Has surrendered a DEA registration for cause.

The installation, removal, transfer, and storage of inner liners shall be performed by either:

- One employee of the authorized collector and one supervisor-level employee (in the case of a long-term care facility) designated by the authorized collector; or
- Under the supervision of two (2) employees of the authorized collector.

Are collection receptacles at long-term care facilities legal?

A long-term care facility may dispose of controlled substances in Schedules II, III, IV, and V on behalf of an ultimate user who resides, or has resided, at such long-term care facility by transferring those controlled substances into an authorized collection receptacle located at that long-term care facility.

Only authorized retail pharmacies and hospitals or clinics with an on-site pharmacy may install, manage, and maintain collection receptacles at long-term care facilities. The retail pharmacy, hospital, or clinic is responsible to remove, seal, transfer, and store, or supervise the removal, sealing, transfer, and storage of sealed inner liners at long-term care facilities.

The installation, removal, transfer, and storage of inner liners shall be performed either:

- By or under the supervision of one employee of the authorized collector and one supervisor-level employee of the long-term care facility (e.g., a charge nurse or supervisor) designated by the authorized collector; or
- Under the supervision of two (2) employees of the authorized collector.

Upon removal, sealed inner liners may only be stored at the long-term care facility for up to three business days in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer.

Materials for Starting

What are some expected costs associated with starting a drug take-back program?

Pharmacies are encouraged to work with a reverse distributor to obtain an up-to-date estimate. For the purposes of this CE, we will use one example of costs as quoted from a reverse distributor on November 1, 2016. Highlighting this example is designed to provide an illustrative example only; it does not imply endorsement of any company or product, and it may not be current as markets are always dynamic:

- \$1,550 - collection receptacle.
 - Includes collection signage for consumers and direction to what is allowed and not allowed to go in the receptacle.
 - Includes a removable shelf.
 - Includes a drill template which is used to assist registrant with installation.
 - Hardware (3 sleeve anchors to secure unit to floor, 2 bolts/nuts to secure sign to top of receptacle).
- \$400 – Shipping: a one-time cost to ship receptacle and all materials to each location. If a pharmacy has four different locations, there would be four one-time charges to ship to each location.
- \$140 – Liner Bundle.
 - (1) 16" x 16" x 20" cardboard/fiberboard box meets PG II standards.
 - (1) 40 gallon liner opaque (non-see through), tear resistant, leak resistant, individually serialized for traceability.
 - (4) Absorbent Pads.
 - (1) Serialized zip tie which is used to seal the liner once full.
 - (1) Set of instructions for bundle set up and shipping.
 - (1) Set of instructions for installation for initial shipment.
 - (1) Return Shipping Document.
 - (1) Prepaid UPS return shipping label.
 - Each refill bundle (which includes shipping) is \$140

This cost of the bundle also includes destruction as this is all in one. Once the reverse distributor receives the first bundle back at its site, they auto-reload a replacement bundle to keep the pharmacy whole.

The continued costs once the preparation has occurred essentially lie in the cost of the liner bundle.

Maintaining a Drug Take-Back Program

Who can place medications within the receptacle?

Authorized collectors may only allow ultimate users and other authorized non-registrant persons in lawful possession of a controlled substance in Schedule II, III, IV, or V – or non-controlled medications -- to deposit such substances in a collection receptacle at a registered location.

Collectors shall not permit an ultimate user to transfer such substance to any person for any reason. Once a substance has been deposited into a collection receptacle, the substance shall **not** be counted, sorted, inventoried, or otherwise individually handled. It is important to note that this drug take-back program is designed for ultimate users, not prescribers or pharmacies. Disposal from such entities are not authorized in a drug take-back program.

What types of medications can be placed within the receptacle?

An authorized collector may collect controlled substances and non-controlled medications. Illicit drugs (schedule 1 controlled substances) are not allowed through this disposal method. In addition, the following may not be added to a receptacle: insulin syringes, products containing iodine and mercury-containing thermometers, or compressed cylinders or aerosols (e.g., asthma inhalers).

What happens once the drugs are within the receptacle?

Once the medications are placed within the receptacle, the medications cannot be counted, sorted, or handled in any way by the pharmacy staff. The only monitoring that is required is determining whether or not the liner is full and in need of disposal by the pharmacy's DEA-registered reverse distributor.

There is to be **no** inventory kept of the medications collected through the receptacle. A good practice suggestion to measure success would be to keep track of the weight of disposed product, a value which can be provided by a reverse distributor upon receipt.

How do I handle the medications once the liner is full?

Two (2) pharmacy employees must remove, seal and package the liner immediately upon removal without emptying or touching the contents. A complete log as described below is necessary. The full liner may be stored by two employees in a securely locked, substantially constructed cabinet or securely locked room with restricted access. If no such space is available, schedule an appointment with a collector and remove the liner when the reverse distributor arrives.

Recordkeeping Requirements

What records must be kept in a take-back program?

Each inner liner comes with a unique identification number which is used for tracking purposes. The collection receptacle inner liners require a very accurate log of acquisition, installation, removal, transfer to storage, and transfer for distribution. The following records must be kept:

- The date each unused inner liner is acquired, including the unique identification number and the size of each unused inner liner acquired;
- The date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size of each installed inner liner, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation;
- The date each inner liner is removed and sealed, the address of the location from which each inner liner is removed, the unique identification number and size of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removed;
- The date each sealed inner liner is transferred to storage, the unique identification number and size of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage; and
- The date each inner liner is transferred for destruction, the address and registration number of the reverse distributor or distributor to whom each sealed inner liner was transferred, the unique identification number and the size of each sealed inner liner transferred, and the names and signatures of the two employees that transferred each sealed inner liner to the reverse distributor.

What do I need to do to discontinue my take-back program?

Any registrant that has been authorized as a collector and desires to discontinue its collection of controlled substances from ultimate users shall notify the DEA of its intent by submitting a written notification to the Registration Unit at the DEA.

For more information, the final DEA rules can be found online at:

https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf

References:

1. Drug Enforcement Administration.
https://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf. Accessed November 1, 2016.
2. US Department of Justice. Drug Enforcement Administration. Diversion Control Division.
https://www.deadiversion.usdoj.gov/drug_disposal/takeback/. Accessed November 1, 2016.
3. Assured Waste Solutions. <http://www.assuredwaste.com/>. Accessed November 1, 2016.

Acknowledgements:

This CPE program was developed by Jennifer Ruwo, PharmD candidate at Idaho State University. This resource is provided for general education purposes and does not constitute legal advice. The official drug take-back program provisions are contained in federal law, regulations, and rulings.

Post-Test Questions

1. The Disposal Act allows for _____ substances to be placed within a receptacle.
 - A. Non-controlled
 - B. Controlled
 - C. Illicit
 - D. A and B
 - E. All of the Above
2. An example of an ultimate user would include a person who has lawfully obtained, and who possess, a controlled substance for:
 - A. Their friend who lives next door
 - B. Their own use
 - C. Their grandmother who lives at a skilled nursing facility who stopped taking their medication
 - D. A medication found in the parking lot that was brought in by an associate
3. What website would you go to modify your DEA registration to become an authorized collector?
 - A. bop.idaho.gov
 - B. nabp.pharmacy
 - C. fda.gov
 - D. deadiversion.usdoj.gov
4. The cost to modify my DEA registration for a take-back program is:
 - A. \$0
 - B. \$100
 - C. \$500
 - D. \$1000
5. The collection receptacle must be located:
 - A. In eye sight of an employee of the collector
 - B. In the immediate proximity where controlled substances are stored
 - C. Secured to a permanent structure
 - D. All of the above
6. Installation, removal, transfer and storage of the liners is to be done by:
 - A. The PIC only
 - B. The store manager only
 - C. Two employees designated by the authorized collector
 - D. Only an employee of the reverse distributor
7. The initial cost of the receptacle and shipping of the receptacle to your pharmacy is estimated to be roughly:
 - A. \$2,000
 - B. \$3,000
 - C. \$4,000
 - D. \$5,000

8. Items that can be placed within the receptacle include
 - A. Norco
 - B. Used insulin syringe
 - C. Cocaine
 - D. Mercury thermometer

9. Items should be sorted base on their level of control prior to shipping
 - A. True
 - B. False

10. Records related to inner liners must be kept for the following activities:
 - A. Acquisition of inner liner
 - B. Installation of inner liner
 - C. Removal of inner liner
 - D. Transfer of inner liner to storage
 - E. Transfer of inner liner to DEA reverse distributor
 - F. All of the Above
 - G. None of the Above

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Post-Test Answer Sheet

- Mail the post-test answer sheet, postmarked no later than December 31st, 2018 to:
 - Idaho State Board of Pharmacy
Home Study CPE Program
1199 Shoreline Lane, Suite 303
Boise, Idaho 83702-0067
- Include a self-addressed stamped envelope (SASE) for the return of a statement of credit. No statement of credit will be awarded unless a SASE is provided by the pharmacist.

Pharmacists Name _____

Idaho License Number _____

Answers:

1. _____

6. _____

2. _____

7. _____

3. _____

8. _____

4. _____

9. _____

5. _____

10. _____

Feedback on this CPE Program:

Ideas for future Board-approved home study CPE programs: