



## Pharmacy Quality Assurance Commission Guidance Document

<b>Title:</b>	Secure and Responsible Drug Disposal Program
<b>Reference:</b>	Title 21 CFR § 1317 and WAC 246-869-130
<b>Contact:</b>	Executive Director
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<b>Approved:</b>	
	Chair, Pharmacy Quality Assurance Commission

While the Washington State Pharmacy Quality Assurance Commission has no specific statutory authority to permit the take back of medications, *RCW 18.64.005* provides general statutory authority to enforce *WAC 246-869-130 – Return or exchange of drugs*. This rule allows for drugs to be returned to a Washington State pharmacy for destruction in accordance with the Drug Enforcement Administration (DEA) regulations. The Drug Enforcement Administration *Title 21 Code of Federal Regulation (CFR) – Part 1317* fully details the Drug Enforcement Administration’s regulations on secure and responsible drug disposal.

Pharmacy Commission approvals for individual pharmacy drug disposal programs are no longer necessary. Any authorized DEA collector licensed under the authority of the WA State Pharmacy Commission must at a minimum, comply with all DEA requirements set forth in *Title 21 CFR Part 1317*. This document is the Washington State Pharmacy Quality Assurance Commission’s interpretation of *Title 21 CFR Part 1317*. It is designed only as a tool to assist and outline appropriate steps for the following Washington State entities to become DEA authorized collectors:

1. Retail Pharmacies;
2. Hospital/Clinics with on-site pharmacies; and
3. Long-Term Care Facilities the pharmacies above choose to register as a collection site.

**\*Disclaimer\*** - Each entity participating in a secure and responsible drug disposal program is responsible for ensuring that it fully complies with all DEA regulations. This document is intended as a resource and overview but cannot be relied upon or used as a substitute for ensuring that each entity is aware of and compliant with all DEA regulations.



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## **I. REGISTER AS A DEA AUTHORIZED COLLECTOR; COLLECTION SITE**

- A. The collector is authorized by the DEA to receive controlled substances from the ultimate user for the purpose of destruction.
- B. The registrant must obtain authorization to be a collector in accordance with *CFR 1301.51*.
- C. Registrant may go to [http://www.deadiversion.usdoj.gov/drug\\_disposal/](http://www.deadiversion.usdoj.gov/drug_disposal/) and click on *Registration for Disposal of Controlled Substances* to modify eligible DEA registration to collect pharmaceutical controlled substances from ultimate users.
- D. Registrant must provide name, address, and registration number as well as the method of collection the registrant intends to conduct (collection receptacles).
- E. Signature is required in accordance with *CFR 1301.13(j)*.
- F. Once authorized, entity is called "Authorized Collector".
- G. Authorized collectors may collect *pharmaceutical* non-controlled and *pharmaceutical* controlled substances which may be co-mingled in a single collection receptacle (*see DEA Registrant Fact Sheet*).

## **II. WASHINGTON STATE PHARMACY QUALITY ASSURANCE COMMISSION REQUESTS NOTIFICATION OF AUTHORIZED DEA COLLECTOR STATUS**

- A. Once DEA Authorized Collector Status is obtained, Washington State Pharmacy Quality Assurance Commission requests notification by completing the *Notice of DEA Authorized Collector Status* Form that includes the following:
  - 1. Name of pharmacy and collection site(s)
  - 2. Washington State issued pharmacy license number
  - 3. DEA Registration number
  - 4. Physical address of pharmacy and collection site(s)
  - 5. Effective date of active DEA Collector status (or date DEA Collector Status Inactive)
- B. See *Notice of DEA Collector Status Form – Appendix A*

## **III. INDIVIDUALS PERMITTED TO DISPOSE OF DRUGS IN COLLECTION RECEPTACLES (ultimate user 21 USC 802 (27))**

- A. *Ultimate user* refers to a person who has lawfully obtained and who possesses *pharmaceutical* non-controlled and *pharmaceutical* controlled substances for his own use or for the use of a member of the household or for an animal owned by him or a member of his household. This includes a household member of the person or a pet who was prescribed the medication.
- B. If an ultimate user dies while lawfully in possession of a controlled substance for personal use, any person lawfully entitled to dispose of a decedent's property may deliver the pharmaceutical controlled substance to an authorized collection site.
- C. A long-term care facility on behalf of an ultimate user who resides or resided at such long-term care facility and is/was in lawful possession of a controlled substance, in accordance with *CFR 1317.80*.
- D. Pharmaceutical waste from ANY business, commercial institution, or other individual other than listed above shall NOT be accepted. Pharmaceutical waste from origins other than household waste fall under far more restrictive environmental waste disposal regulations.

#### **IV. GENERAL COLLECTION RECEPTACLE REGULATIONS (CFR 1317.75)**

- A. Only Ultimate Users and other authorized non-registrant persons in lawful possession of *pharmaceutical* controlled substances scheduled II, III, IV, or V or *pharmaceutical* non-controlled medications shall be permitted to deposit these substances into the collection receptacle.
- B. Once a substance has been deposited into a collection receptacle, the substance shall not be counted, sorted, inventoried, or otherwise individually handled.
- C. Receptacle shall be securely placed and maintained. Receptacle shall be securely fastened to a permanent structure so it cannot be removed.
- D. Receptacle shall be a securely locked, substantially constructed container with a permanent outer container with a removable inner liner as specified in *CFR 1317.60*.
- E. The outer container shall include a small opening that allows contents to be added to the inner liner but does not permit the removal of inner liner contents.
- F. The outer container shall prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances, if a collector chooses to commingle substances, shall be acceptable substances. One example of the signage could state, "Lawfully possessed federally Scheduled II through V Pharmaceutical Controlled Substances and Pharmaceutical Non-controlled Substances only." The DEA does not accept Schedule I controlled substances, illicit or dangerous substances, or controlled substances not lawfully possessed by the ultimate user. Despite what Washington State law may be regarding marijuana, the DEA considers marijuana to be a Schedule I controlled substance and disposal of this substance is not permitted.
- G. The small opening in the outer container (receptacle) shall be locked or made otherwise inaccessible to the public when an employee is not present or the pharmacy is closed. The hours of drop off are based on the hours of the host location.
- H. The installation and removal of the inner liner shall be performed by or under the supervision of at least two employees of the authorized collector.
- J. Pharmacy shall NOT use receptacle to dispose of unused controlled or non-controlled substances in their inventory or stock (*CFR 1317.05* and *1317.75*).
- K. *Pharmaceutical* non-controlled and *pharmaceutical* controlled substances returned for destruction shall not be sold, given away, re-packaged or re-dispensed for use by another patient.

#### **V. ADDITIONAL COLLECTION RECEPTACLE REGULATIONS AT HOSPITAL/CLINIC PHARMACIES (CFR 1317.75(c)(2)(i))**

**Must follow all general collection receptacle regulations as well as the following:**

- A. The collection receptacle shall be located in an area regularly monitored by employees.
- B. The collection receptacle shall NOT be located in the proximity of any area where emergency or urgent care is provided.

#### **VI. ADDITIONAL COLLECTION RECEPTACLE REGULATIONS AT RETAIL PHARMACIES (CFR 1317.75(c)(2))**

**Must follow all general collection receptacle regulations as well as the following:**

- A. The collection receptacle shall be securely placed and maintained in 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).

## VII. ADDITIONAL COLLECTION RECEPTACLE REGULATIONS AT LONG-TERM CARE FACILITIES (LTC)

**(CFR 1317.80) Must follow all general collection receptacle regulations as well as the following:**

- A. The collection receptacle shall be located in a secured area regularly monitored by long-term care facility employees.
- B. LTC facility may dispose of controlled substances in schedule II, III, IV, V on behalf of ultimate user who resides or has resided at such long term care facility by transferring the controlled substances into an authorized collection receptacle at the LTC facility.
- C. Disposal must occur immediately, but no longer than 3 business days after the discontinuation of use by an ultimate user. (discontinuation per a physician's order, a transfer out of the facility, or as a result of death)
- D. Only authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may install, manage, and maintain collection receptacles. Must comply with all requirements of *CFR 1317* including *CFR 1317.60, 1317.75, 1317.80*.
- E. Installation, removal, transfer and storage of inner liners shall be performed by:
  - i. One employee of the authorized collector and one supervisor-level employee of LTC
  - ii. Two employees of authorized collector
- F. Sealed and removed inner liners may only be stored at the LTC for up to 3 business days and may only be stored in a securely locked, substantially constructed cabinet or a securely locked room with controlled access until transfer in accordance with *CFR 1317.05(c)(2)(iv)*.
- G. The hospital/clinic with an on-site pharmacy or retail pharmacy is not permitted to become a collector until a modification to the DEA registration is complete. When modifying registration, the pharmacy shall include the name and physical location of each long term care facility at which the pharmacy intends to operate the collection receptacle. (*CFR 1301.51*)

## VIII. APPROVED CONTENT OF COLLECTION RECEPTACLES

**Collection Receptacles may only contain *pharmaceutical* controlled and *pharmaceutical* non-controlled substances and may only be deposited by an ultimate user or other authorized non-registrant person entitled to dispose of household pharmaceutical waste.**

- A. Receptacles (or mailer packages) **may** accept the following:
  - i. Pharmaceutical non-controlled prescriptions
  - ii. Pharmaceutical controlled substance prescriptions (Federally Scheduled II through V only)
  - iii. Pharmaceutical over-the-counter medications that residents use in their homes, residential settings or long-term care facilities
  - iv. Only medications used for residential use may be accepted
- B. Receptacles (or mailer packages) **may NOT** accept the following:
  - i. Vitamins and supplements
  - ii. Herbal-based remedies and homeopathic drugs, products or remedies
  - iii. Cosmetics, shampoos, sunscreens, toothpaste, lip balm, antiperspirants
  - iv. Personal care products that are regulated as both cosmetics and nonprescription drugs under the *FDA Act Title 21 U.S.C. Chapter 9*
  - v. Schedule 1 illegal substances



- vi. Marijuana – this is a federally scheduled 1 illegal controlled substance
- vii. Pharmaceutical waste from ANY business or commercial institution
- viii. Medical sharps and needles
- ix. Compressed cylinders or aerosols (ie. Inhalers)
- x. Iodine-containing medications
- xi. Mercury containing thermometers

**IX. MAIL-BACK PROGRAMS (1317.70)**

- A. A mail-back program may be conducted by any collector with an on-site method of destruction. The collector shall have and utilize at their registered location a method of destruction consistent with *CFR 1317.90*.
- B. Collectors conducting mail-back programs shall make packages available (for sale or for free).

**X. MAILER PACKAGE REGULATIONS (CFR 1317.70 and 1317.90)**

Any person may partner with a collector or law enforcement to make mailer packages available. The mailer packages shall meet the following specifications:

- a. Package shall be non-descript and shall not include any markings or information that may indicate the package contains controlled substances.
- b. Package shall be water and spill proof; tamper-evident; tear-resistant and sealable.
- c. Package shall be preaddressed with and delivered to the collector's registered address.
- d. Cost of shipping the package shall be postage paid.
- e. Package shall have unique identification number that enables the package to be tracked.
- f. Package shall include instructions for the user that indicates the following:
  - 1. Process for mailing back
  - 2. The substances that can be mailed
  - 3. Notice that packages may only be mailed from within the United States, District of Columbia and Puerto Rico
  - 4. Notice that only packages provided by the collector will be accepted for destruction
- g. Ultimate user must use an official mail-back package envelope.
- h. Authorized collector must reject any mail-back package that they did not provide or if inadvertently accepted, they must notify the DEA. (*see DEA Public Fact Sheet*)

**XI. INNER LINER REGULATIONS (CFR 1317.60, 1317.75(g))**

- A. Access to the inner liner shall be restricted to employees of the collector.
- B. Two authorized employees will install, remove, and seal the inner liners in preparation for disposal.
- C. Inner liner shall be waterproof, tamper-evident, and tear-resistant.
- D. Inner liner shall be removable and sealable immediately upon removal without emptying or touching the contents.
- E. Inner liner shall be sealed by two employees immediately upon removal from the permanent outer container and the sealed inner liner shall not be opened, x-rayed,



- analyzed or otherwise penetrated.
- E. Contents of the inner liner shall not be viewable from the outside when sealed.
- F. The size of the inner liner shall be clearly marked on the outside of the liner (ie. 5 gallon, 10 gallon, etc.).
- G. The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked from time of shipment to the pharmacy until ultimate destruction.  
(CFR 1317.60(5))

## **XII. DESTRUCTION PROCEDURES**

- A. All controlled substances to be destroyed shall be rendered non-retrievable. Collectors shall dispose of sealed inner liners and their contents by utilizing one of these methods:
  - a. Prompt destruction in the presence of an agent of the Drug Enforcement Administration or other authorized person.
  - b. Prompt delivery of controlled substance to a reverse distributor's registered location by common or contract carrier pick-up or by distributor pick-up at the registrant's registered location. **(THIS IS MOST COMMON METHOD)**
  - c. Request assistance from the Special Agent in Charge of the Drug Enforcement Administration in the area in which the pharmacy/collection site is located. The request shall be made using the DEA Form 41.
- B. If the controlled substances are transferred to a person registered or authorized to accept the controlled substances for the purpose of destruction, two employees of the transferring registrant shall load and unload or observe the loading and unloading of any controlled substances until transfer is complete.

## **XIII. STORAGE AND RECORD KEEPING (CFR 1317.95)**

- A. The sealed inner liner and its contents shall be securely stored at the collector's registered location in a manner consistent with *CFR 1301.75(c)* until prompt destruction can occur. (*CFR 1317.05(c)(2)(ii)*). Sealed liners shall be stored in a securely locked, substantially constructed cabinet or a securely locked room with controlled access, except as authorized by *CFR 1317.80(d)* for long term care facilities.
- B. Pharmacies will keep records of all transactions with the transporter and file reports as required by *21 CFR Part 1304*.

## **XIV. REVERSE DISTRIBUTOR**

A reverse distributor is authorized to acquire controlled substances through a collection receptacle in accordance with *CFR 1317.75* and *CFR 1317.80*.

- A. Any person that reverse distributes a controlled substance shall be registered with the Drug Enforcement Administration.
- B. Reverse Distributor shall acquire controlled substances from a registrant pursuant to *CFR 1317.05* and *1317.55(a)(c)* and in the following manner:
  - 1. Reverse Distributor may pick up controlled substances from a registrant at registrant's location or authorized collection site.
  - 2. Reverse Distributor may receive controlled substances delivered by common or contract carrier



- C. Reverse Distributor shall destroy or cause destruction of any controlled substance received for the purpose of destruction no later than 30 calendar days after receipt.

## XVI. CONTACTS AND RESOURCES

- A. Contact the DEA's Registration Call Center at 1-800-882-9539 to find a collection receptacle near you.
- B. Visit the DEA website at [http://www.deadiversion.usdoj.gov/drug\\_disposal/](http://www.deadiversion.usdoj.gov/drug_disposal/) for drug disposal information including the September 9, 2014 Final Rule and *Drug Disposal Fact sheets* for registrants, general public, and long term care facilities.
- B. Contact the Washington State Pharmacy Quality Assurance Commission for general questions at [WSPQAC@doh.wa.gov](mailto:WSPQAC@doh.wa.gov)
- C. Visit the Washington State Pharmacy Quality Assurance Commission website for Secure Drug Disposal Guidance document and *Notice of DEA Authorized Collector Status Form*.

<http://www.doh.wa.gov/LicensesPermitsandCertificates/ProfessionsNewReneworUpdate/PharmacyCommission>

# APPENDIX A



Pharmacy Quality Assurance Commission  
PO Box 47877  
Olympia, WA 98504-7877  
360-236-4700

## Notice of DEA Authorized Collector Status

Please send notice of DEA Collector Status to the Pharmacy Quality Assurance Commission at:

Email: [WSPQAC@doh.wa.gov](mailto:WSPQAC@doh.wa.gov)

Fax: 360-236-4626

Pharmacy Name (Printed):		Pharmacy License Number:	
Pharmacy Physical Address:		DEA Registration Number:	
Effective Date of Active DEA Collector Status:	Effective Date of Inactive DEA Collector Status : (Complete only if ceasing collection activities):		
1. Name of Collection Site:			
Collection Site Physical Address (if different from Pharmacy address):			
2. Name of Collection Site (multiple sites may be applicable if long-term care facilities are registered as collection sites):			
Collection Site Physical Address (multiple sites may be applicable if long-term care facilities are registered as collection sites):			