Drug Enforcement Administration Rules on Pharmaceutical Drug Collection

Updated 8/20/2024

Effective October 9, 2014, Drug Enforcement Administration (DEA) regulations allow authorized manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies to collect controlled and non-controlled pharmaceutical drugs from ultimate users by voluntarily administering mail-back programs and maintaining collection receptacles. In addition, the regulations allow authorized hospitals/clinics with an on-site pharmacy and retail pharmacies to voluntarily maintain collection receptacles at long-term care facilities.

Approved entities that are licensed by the Ohio Board of Pharmacy are permitted to engage in the collection of pharmaceutical drugs from ultimate users if they comply with DEA and Board of Pharmacy regulations. To assist in the implementation of these rules, the Ohio Board of Pharmacy has developed the following guidance document.

Please be advised that this document provides general guidance on DEA and Board of Pharmacy regulations and that those entities wishing to collect pharmaceuticals from ultimate users should review all relevant Federal and State laws and regulations in their entirety. The complete text of the new federal rules can be accessed here: www.federalregister.gov/articles/2014/09/09/201420926/disposal-of-controlled-substances

This guidance document is broken down into several sections to assist in the implementation of these regulations.

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Section 1: Returning Unwanted, Expired or Unused Prescription Medications

1) How Does the DEA Define Ultimate User?

An “ultimate user” is defined as a person who has lawfully obtained, and who possesses, a pharmaceutical drug for their own use or for the use of a member of their household or for an animal owned by an individual or a member of their household.

You may dispose of a member of your household’s unused or unwanted pharmaceutical drugs. But, if they are not a member of your household, you may not dispose of their pharmaceutical drugs on their behalf. Only ultimate users may dispose of pharmaceutical drugs. The rule has the following exceptions:

- If someone dies while in lawful possession of pharmaceutical drug, any person lawfully entitled to dispose of the decedent’s property may dispose of the drugs; and

- A long-term-care facility may dispose of a current or former resident’s pharmaceutical controlled substances.

(§ 1317.30 Authorization to collect from non-registrants)

2) The DEA rules only specify controlled substances. Can I also return non-controlled and over the counter medications?

Yes. The DEA permits the co-mingling of controlled and non-controlled substances. In addition, Board of Pharmacy regulations also allow for the return of non-controlled prescription drugs to authorized collectors.

(§ 1317.70 Mail-back programs)
(§ 1317.75 Collection receptacles)
(Ohio Administrative Code Chapter 4729:10-1)

3) Do I have to follow DEA regulations if I operate a program that only collects noncontrolled drugs?

Yes. The Board reasonably expects that any program offering to collect prescription medications has the potential to inadvertently collect controlled substances. Therefore, programs that seek to only collect non-controlled prescription medications should adhere to DEA rules regarding the collection of controlled substances.

4) Are ultimate users permitted to destroy controlled substances by other methods (mixing with coffee grounds, kitty litter, etc.)?

Yes. Although the DEA has authorized more methods for drug collection, the rule does not prohibit ultimate users from using existing lawful methods. Such methods can be accessed here:
http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/ensuringsafeuse ofmedicine/safedisposalofmedicines/ucm186187.htm

5) Can ultimate users dispose of illicit drugs through a collection receptacle, mail-back package, or take-back event?

No. Ultimate users may not dispose of illicit drugs (e.g., schedule I controlled substances such as marijuana, heroin, LSD) via any of the approved disposal methods.

6) Do these rules allow for the return of recalled controlled substances by the ultimate user (i.e. the consumer)?

Yes. In the event of a product recall, an ultimate user in lawful possession of a controlled substance listed in Schedule II, III, IV, or V may deliver the recalled substance to the manufacturer of the substance, or another registrant authorized by the manufacturer to accept recalled controlled substances on the manufacturer's behalf. An ultimate user may also transfer recalled pharmaceutical drugs to authorized collectors or law enforcement via a collection receptacle, mail back package, or take-back event.

(§ 1317.85 Ultimate user delivery for the purpose of recall or investigational use of drugs)

7) Can a long term care facility dispose of pharmaceutical drugs on behalf of an ultimate user who resides, or has resided, at that facility?

Yes. Long term care facilities may dispose of pharmaceutical drugs on behalf of an ultimate user who resides, or has resided, at that facility through an authorized collection receptacle (maintained by an authorized hospital/clinic or retail pharmacy) located at the facility.

When disposing of such controlled substances by transferring those substances into a collection receptacle, such disposal must occur immediately, but no longer than three business days after the discontinuation of use by the ultimate user. Discontinuation of use includes a permanent discontinuation of use as directed by the prescriber, as a result of the resident's transfer from the long-term care facility, or as a result of death.

(§ 1317.80 Collection receptacles at long-term care facilities)
(§ 1317.30 Authorization to collect from non-registrants)

8) How Does the DEA Define Collection?

“Collection” means to receive a controlled substance for the purpose of destruction from an ultimate user, a person lawfully entitled to dispose of an ultimate user decedent’s property, or

a long-term care facility on behalf of an ultimate user who resides or has resided at that facility.

(§ 1300.01 Definitions relating to controlled substances)

9) Will the DEA continue to operate drug take-back events?

The DEA continues to sponsor take-back events in the Spring and Fall. For more information, visit: https://www.dea.gov/takebackday.

To locate collection receptacles around Ohio, please visit: www.pharmacy.ohio.gov/disposal.

Section 2: Authorized Collectors

10) How Does the DEA Define an Authorized Collector?

The term "authorized collector" means a registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an on-site pharmacy, or retail pharmacy that is authorized by the DEA to receive a controlled substance for the purpose of destruction.

11) How can a registrant become an "authorized collector"?

Manufacturers, distributors, reverse distributors, narcotic treatment programs, hospitals/clinics with an on-site pharmacy, and retail pharmacies that wish to be collectors may do so by modifying their registration to obtain authorization to be a collector. Registrants may modify their registration online at http://www.DEAdiversion.usdoj.gov. Once authorized, these entities are "authorized collectors."

Eligible registrants **must** have authority to handle Schedule II controlled substances.

If a hospital/clinic with an on-site pharmacy or retail pharmacy is applying for a modification in registration to authorize the registrant to be a collector to maintain a collection receptacle at a long-term care facility, the request shall also include the name and physical location of each long term care facility at which the hospital/clinic with an on-site pharmacy, or the retail pharmacy, intends to operate a collection receptacle.

Authorization to be a collector is subject to renewal. If a registrant that is authorized to collect ceases activities as a collector, such registrant shall notify the DEA in accordance with DEA rules (*See FAQ #13*).

(§ 1317.40 Registrants authorized to collect and authorized collection activities)
(§ 1301.51 Modification in registration)

12) What can I collect as an authorized collector?

An authorized collector may collect pharmaceutical controlled substances and non-controlled substances. Controlled and non-controlled pharmaceuticals may be co-mingled in a single collection receptacle, however it is not required.

Controlled substances that are collected from ultimate users shall not be co-mingled with a registrant's inventory/stock of controlled substances (i.e., registrants shall not dispose of controlled substance inventory in a collection receptacle or mail-back package, or through a take-back event).

Persons may not dispose of medical sharps and needles (e.g., insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), and compressed cylinders or aerosols (e.g., asthma inhalers).

Authorized collectors should be vigilant to prevent ultimate users from disposing of prohibited drugs. In addition to employee oversight (*See FAQ #20*a), collectors should also include proper instructions, signage and employee training to prevent unauthorized substances from being collected.

Authorized collectors are not permitted to review drugs collected as the DEA has concluded that allowing inspection of inner liners and mail-back packages presents an unacceptable risk of diversion.

13) If I become an authorized collector and decide to stop, how do I do so?

Collection receptacle: Authorized collectors maintaining a collection receptacle must dispose of all collected pharmaceutical drugs in their possession in accordance Federal and State laws and rules (*See Section 7: Destruction of Collected Pharmaceuticals*), and notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

Mail-back program: Authorized collectors operating a mail-back program must make a reasonable effort to notify the public prior to discontinuing or ceasing collection; obtain the written agreement of another collector to receive all remaining mail-back packages; and

notify the DEA that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov.

(§ 1301.52 Termination of registration; transfer of registration; distribution upon discontinuance of business)

14) I am a pharmacist. If my pharmacy chooses to become an authorized collector, will we need to collect and retain information about persons who utilize the collection receptacle, such as a person's name, prescription information, or physician information?

No. A collector shall not require any person to provide any personally identifying information. While an authorized collector is not permitted to collect information from an individual disposing of drugs, they should include proper instructions, signage and employee training to ensure that drugs are only disposed by individuals authorized by the DEA (*See FAQ #1*).

15) What is a narcotic treatment program?

Practitioners wishing to administer and dispense approved Schedule II controlled substances for maintenance and detoxification treatment must obtain a separate DEA registration as a Narcotic Treatment Program.

A narcotic treatment program can register with the DEA as an authorized collector to provide the opportunity for patients to dispose of unused pharmaceutical drugs, with certain enhanced security controls (*See FAQ #20*).

16) What are the employee security requirements for collectors and reverse distributors?

A collector or reverse distributor shall not employ, as an agent or 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 or who, 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.

(§ 1301.71 Security requirements generally)
(§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs)

17) How does the DEA define an employee?

"Employee" means an employee as defined under the general common law of agency. Some of the factors relevant to the determination of employee status include: The hiring party's right to control the manner and means by which the product is accomplished; the skill required; the source of the instrumentalities and tools; the location of the work; the duration of the relationship between the parties; whether the hiring party has the right to assign additional projects to the hired party; the extent of the hired party's discretion over when and how long to work; the method of payment; the hired party's role in hiring and paying assistants; whether the work is part of the regular business of the hiring party; whether the hiring party is in business; the provision of employee benefits; and the tax treatment of the hired party. Other applicable factors may be considered and no one factor is dispositive.

The following criteria will determine whether a person is an *employee* of a registrant for the purpose of disposal: The person is directly paid by the registrant; subject to direct oversight by the registrant; required, as a condition of employment, to follow the registrant's procedures and guidelines pertaining to the handling of controlled substances; subject to receive a performance rating or performance evaluation on a regular/routine basis from the registrant; subject to disciplinary action by the registrant; and required to render services at the registrant's registered location.

(§ 1300.05 Definitions relating to the disposal of controlled substances)

18) Do collectors and reverse distributors need to complete a DEA Form 222 or digitally signed electronic order for the purpose of collecting pharmaceuticals from ultimate users?

No. The following are exempt from completing this form when distributing controlled substances:

(1) Deliveries to an authorized DEA registrant by an ultimate user, a long-term care facility on behalf of an ultimate user who resides or has resided at that facility, or a person authorized to dispose of the ultimate user decedent's property.

(2) Distributions to reverse distributors and distributors by collectors and law enforcement.

(3) Deliveries of controlled substances from ultimate users for the purpose of recalls.

(**§ 1305.03 Distributions requiring a Form 222 or a digitally signed electronic order**)

Section 3: Drug Collection Receptacles

19) Who can operate a drug collection receptacle?

The following may operate drug collection receptacles:

- Authorized collectors (*See FAQ #10*) may maintain collection receptacles inside their registered location; and Federal, State, tribal or local law enforcement may continue to maintain collection receptacles inside their physical location (*See Section 8: Law Enforcement*).

- Authorized hospitals/clinics with an on-site pharmacy and retail pharmacies may maintain collection receptacles at long-term care facilities. Clinics that have a dispensing room that is not operated by a pharmacist are not considered entities with an on-site pharmacy.

(§ 1317.30 Authorization to collect from non-registrants)

20a) What are the collection receptacle location requirements?

Collection receptacles must be securely placed and maintained:

(1) Inside a collector's registered location, inside law enforcement's physical location, or at an authorized long-term care facility; and

(2) At a registered location, 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). Except as follows:

(i) At a hospital/clinic: A collection receptacle must be located in an area regularly monitored by employees, and shall not be located in the proximity of any area where emergency or urgent care is provided.

(ii) At a narcotic treatment program: A collection receptacle must be located in a room that does not contain any other controlled substances and is securely locked with controlled access.

(iii) At a long-term care facility: A collection receptacle must be located in a secured area regularly monitored by long-term care facility employees.

(§ 1317.75 Collection receptacles)

20b) Can a collector operate a drug collection receptacle where the receptacle is located inside the registered location, but the ultimate user is allowed to dispose of pharmaceuticals from the outside (i.e. bank deposit)?

No. According to the DEA, this is not permitted. Authorized collectors should adhere to the location requirements (*See FAQ #20a*).

21) Are there design specifications for collection receptacles?

According to the DEA rules, a collection receptacle must meet the following design specifications:

(1) Be securely fastened to a permanent structure so that it cannot be removed;

(2) Be a securely locked, substantially constructed container with a permanent outer container and a removable inner liner (*See FAQ #22*);

(3) The outer container must include a small opening that allows contents to be added to the inner liner, but does not allow removal of the inner liner's contents;

(4) The outer container must prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances, if a collector chooses to comingle substances, are acceptable substances (Schedule I controlled substances, controlled substances that are not lawfully possessed by the ultimate user, and other illicit or dangerous substances are not permitted); and

(5) Except at a narcotic treatment program, the small opening in the outer container of the collection receptacle must 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.

NOTE: *A law enforcement agency is NOT required to have a collection receptacle that meets the DEA specifications. However, please see FAQ #50 for Ohio State Board of Pharmacy required specifications for law enforcement agencies.*

(§ 1317.75 Collection receptacles)

22) What are the requirements for the inner liner of collection receptacles?

An inner liner must meet the following requirements:

(1) The inner liner must be waterproof, tamper-evident, and tear-resistant;

(2) The inner liner must be removable and sealable immediately upon removal without emptying or touching the contents;

(3) The contents of the inner liner shall not be viewable from the outside when sealed;

(4) The size of the inner liner shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10gallon, etc.); and

(5) The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked.

(b) Access to the inner liner shall be restricted to employees of the collector.

(c) The 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. *For more information on the removal of the liner, please see FAQ #24*.

(§ 1317.60 Inner liner requirements)

NOTE: *While suggested, a law enforcement agency is NOT required to have an inner liner that meets the DEA specifications. However, please see FAQ #50 for Ohio Board of Pharmacy required specifications for law enforcement agencies.*

23) What are the record keeping requirements for DEA registrants for collection receptacles?

Authorized collectors are required to keep the following records:

(1) The date each unused inner liner is acquired, unique identification number and the size (e.g., 5-gallon, 10-gallon, etc.) of each unused inner liner acquired;

(2) The date each inner liner is installed, the address of the location where each inner liner is installed, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each installed inner liner, the registration number of the collector, and the names and signatures of the two employees that witnessed each installation;

(3) 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 (e.g., 5-gallon, 10-gallon, etc.) of each inner liner removed, the registration number of the collector, and the names and signatures of the two employees that witnessed each removal;

(4) The date each sealed inner liner is transferred to storage, the unique identification number and size (e.g., 5-gallon, 10-gallon, etc.) of each sealed inner liner stored, and the names and signatures of the two employees that transferred each sealed inner liner to storage;

(5) The date each sealed 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 (e.g., 5-gallon, 10-gallon, etc.) 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 or distributor; and

(6) For sealed inner liners destroyed on-site by the collector, the same information is required of reverse distributors (*See FAQ #53*).

It is up to the registrant to develop a system for inner liners that includes a unique identification number. The numbers may be added by the manufacturer of the liner or could be applied by the authorized collector.

Separate records should be kept for every drug collection receptacles operated by an authorized collector. The records should also be kept separate from the authorized collector's controlled substance stock.

(§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors)

NOTE: *A law enforcement agency is NOT required to maintain records as outlined above. However, please see FAQ #51 for Ohio State Board of Pharmacy required specifications for law enforcement agencies.*

24) What are the requirements for the installation and removal of the liner by employees?

The installation and removal of the inner liner of the collection receptacle must be performed by or under the supervision of at least two employees of the authorized collector. These employees must not have been convicted of any felony offense relating to controlled substances or who, 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.

For long term care facilities, the rules require 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, by or under the supervision of two employees of the authorized collector.

NOTE: *A law enforcement agency is NOT required to meet the removal requirements as outlined above. Any pharmaceutical drugs collected by law enforcement through a collection receptacle should be removed and stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.*

(§ 1317.75 Collection receptacles)
(§ 1317.80 Collection receptacles at long-term care facilities)

25) Are there inventory requirements for collectors that operate collection receptacles?

Yes. For the required DEA and Board of Pharmacy inventories, registrants authorized to collect via a collection receptacle, the record shall include the following information about each unused inner liner on hand and each sealed inner liner on hand awaiting destruction:

(1) The date of the inventory;

(2) The number and size of inner liners (e.g., five 10-gallon liners, etc.); and

(3) The unique identification number of each inner liner.

(§ 1304.11 Inventory requirements)

26) Can I count/inventory drugs collected?

No. Pharmaceutical substances collected cannot not be individually counted or inventoried. For hospitals and clinics with an on-site pharmacy and for retail pharmacy settings, pharmaceutical drugs should be placed directly into the collection receptacle by the ultimate user or another authorized individual (See FAQ #1).

NOTE: *According to the DEA, data collection is not impossible under the rule even though collected substances cannot be sorted or inventoried after they have been deposited into a collection receptacle or received by a collector through a mail-back package (unless the*

collection is conducted by law enforcement and the substances are within the custody and control of law enforcement). For example, authorized collectors may seek information voluntarily from ultimate users regarding the substances the ultimate user is disposing. And, data such as the weight of the inner liners, the number of ultimate users attending a take-back event, and the number of mail back packages received in relation to the number of packages disseminated, can be useful measures. The rule only prohibits authorized collectors from physically handling the substances, such as taking the substances from the ultimate user, or sorting substances after the ultimate user has deposited them into a receptacle or mail-back package.

(§ 1317.75 Collection receptacles)

27) Are there any special requirements for collection receptacles at long term care facilities?

Yes. A collection receptacle must be located in a secured area regularly monitored by long-term care facility employees.

Only authorized retail pharmacies and hospitals/clinics with an on-site pharmacy may install, manage, and maintain collection receptacles at long-term care facilities and 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 must 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, by or under the supervision of two 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 transferred from the facility (*See FAQ #46*).

NOTE: *Pharmacy employees cannot transfer sealed inner liners from a long-term care facility to a reverse distributor. Transportation to a reverse distributor must be done by common contract carrier (i.e. USPS, UPS or FEDEX) or must be picked up by the reverse distributor.*

(§ 1317.80 Collection receptacles at long-term care facilities)

28a) Can a law enforcement agency operate a collection receptacle at a retail pharmacy without the pharmacy having to register as an authorized collector?

No. The retail pharmacy must adhere to all DEA regulations, including registration as an authorized collector.

28b) Can a law enforcement agency collect and destroy drugs from a collection receptacle operated by an authorized collector (such as a pharmacy)?

No. According to the DEA, this practice is not permitted. The authorized collector must adhere to destruction procedures outlined in section 7 of this document.

Section 4: Mail-Back Programs

29) Do the rules authorize the collection of pharmaceutical drugs by mail?

Yes. However, only collectors with an on-site method of destruction may operate a mail-back program.

NOTE: *Law enforcement can destroy drugs collected by a mail-back program by transporting them to a reverse distributor or destroying the drugs in a method pursuant to Federal and State law (See FAQ #44).*

30) How does the DEA define on-site?

"On-site" means located on or at the physical premises of the registrant's registered location. A pharmaceutical drug is destroyed on-site when destruction occurs on the physical premises of the destroying registrant's registered location. A hospital/clinic has an on-site pharmacy when it has a pharmacy located on the physical premises of the registrant's registered location.

(§ 1300.05 Definitions relating to the disposal of controlled substances)

31) If I operate a mail-back program, can I charge a fee for the packages?

Yes. The rules state that if a registrant chooses to establish a mail-back program they must provide specific mail-back packages to the public, either at no cost or for a fee.

32) What are the requirements for a mail-back program?

A mail-back program may be conducted by Federal, State, tribal or local law enforcement or any collector. A collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with the DEA regulations (*See FAQ #44*).

NOTE: *A law enforcement agency that operates a mail-back program is not required to have a method of destruction on site (See FAQ #29).*

Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person lawfully entitled to dispose of an ultimate user decedent's property may be collected (*See FAQ #1*). Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

Collectors or law enforcement that conduct a mail-back program shall make packages available (for sale or for free) to ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property, for the collection of pharmaceutical drugs by common or contract carrier. Any person may partner with a collector or law enforcement to make such packages available in accordance with this section. The packages made available must meet the following specifications:

(1) The package must be nondescript and shall not include any markings or other information that might indicate that the package contains pharmaceutical drugs;

(2) The package must be water- and spill-proof; tamper-evident; tear-resistant; and sealable;

(3) The package must be preaddressed with and delivered to the collector's registered address or the participating law enforcement's physical address;

(4) The cost of shipping the package shall be postage paid;

(5) The package must have a unique identification number that enables the package to be tracked; and

(6) The package must include instructions for the user that indicate the process for mailing back the package, the substances that can be sent, notice that packages may only be mailed from within the customs territory of the United States (the 50 States, the District of Columbia, and Puerto Rico), and notice that only packages provided by the collector will be accepted for destruction.

Ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property shall not be required to provide any personally identifiable information when

mailing back pharmaceutical drugs to a collector. The collector or law enforcement may implement a system that allows ultimate users or persons lawfully entitled to dispose of an ultimate user decedent's property to notify the collector or law enforcement that they are sending one of the designated packages by giving the unique identification number on the package.

A collector that conducts a mail-back program must:

(1) Accept only those pharmaceutical drugs contained within packages that the collector made available for the collection of drugs by mail.

(2) Within three business days of receipt, notify the DEA Field Division Office in their area of the receipt of a package that likely contains controlled substances that the collector did not make available or did not agree to receive (*See Section 10: Reporting Theft or Loss and Additional Information*).

NOTE: *The DEA does not permit pharmacies to advertise on the mail-back packages. Such advertising would indicate that the package contains pharmaceutical drugs.*

(§ 1317.70 Mail-back programs)

33) How do I discontinue the operation of a mail-back program?

If discontinuing activities as an authorized mail-back program, the DEA rules require the following:

(1) Make a reasonable effort to notify the public prior to discontinuing such activities or ceasing the authorized mail-back program; and

(2) Obtain the written agreement of another collector that has and utilizes at its registered location a method of destruction to receive all remaining mail-back packages that were disseminated but not returned and arrange for the forwarding of only such packages to that location.

(§ 1317.70 Mail-back programs)

34) Who is authorized to handle mail-back packages from ultimate users?

Only law enforcement officers employed by the law enforcement agency or law enforcement component of a Federal agency and employees of the collector shall handle packages received through an authorized mail-back program. Upon receipt of a mail-back package by a collector conducting a mail-back program, the package shall not be opened, x-rayed, analyzed, or otherwise penetrated.

(§ 1317.70 Mail-back programs)

35) What are the record keeping requirements for DEA registrants to collect mail-back packages?

For unused packages that the collector makes available to ultimate users and other authorized non-registrants at the collector's registered address: the date made available, the number of packages, and the unique identification number of each package;

For unused packages provided to a third party to make available to ultimate users and other authorized non-registrants: the name of the third party and physical address of the location receiving the unused packages, date sent, and the number of unused packages sent with the corresponding unique identification numbers;

For sealed mail-back packages received by the collector: date of receipt and the unique identification number on the individual package; and

For sealed mail-back packages destroyed on-site by the collector: number of sealed mail-back packages destroyed, the date and method of destruction, the unique identification number of each mail-back package destroyed, and the names and signatures of the two employees of the registrant who witnessed the destruction.

The records should also be kept separate from the authorized collector's controlled substance stock.

(§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors)

36) Are there inventory requirements for collectors that operate mail-back programs?

Yes. For each registrant authorized to collect through a mail-back program, the record shall include the following information about each unused mail-back package and each returned mail back package on hand awaiting destruction:

(1) The date of the inventory;

(2) The number of mail-back packages; and

(3) The unique identification number of each package on hand, whether unused or awaiting destruction.

(§ 1304.11 Inventory requirements)

37) I don't have a mail-back package, but I remember the address from the last mailback package I used. Can I mail pharmaceutical drugs to that address without an official mail-back package?

No. Persons must use the mail-back package that was provided by an authorized collector or one of their partners. The mail-back package must meet certain specifications, to include having a unique identification number. If an authorized collector receives a sealed mail-back package that they did not provide, the collector must reject it, or if they inadvertently accept it, they must notify the DEA (*See Section 10: Reporting Theft or Loss and Additional Information*).

If persons would like to use a mail-back package and don't possess one, they may contact an authorized collector to obtain one.

Section 5: Take-Back Events

38) Can an authorized collector conduct a drug-take back event?

No. Collectors are not authorized to conduct take-back events. Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events.

(§ 1317.65 Take-back events)

39) What are the requirements for drug take-back events?

Federal, State, tribal, or local law enforcement may conduct a take-back event and collect controlled and non-controlled drugs from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property (*See FAQ #1*).

Collectors are *NOT* authorized to conduct take-back events. Law enforcement may continue to conduct take-back events at any time. Any person or community group, registrant or non-registrant, may partner with law enforcement to conduct take-back events.

The DEA regulations and Ohio Administrative Code Chapter 4729:10-1 require law enforcement to appoint a law enforcement officer employed by the agency to oversee the collection. Law enforcement officers employed and authorized by the law enforcement agency or law enforcement component of a Federal agency conducting a take-back event shall maintain control and custody of the collected substances from the time the substances are collected from the ultimate user or person authorized to dispose of the ultimate user decedent's property until secure transfer, storage, or destruction of the controlled substances has occurred.

Each take-back event *should* have at least one receptacle for the collection of pharmaceutical drugs. The collection receptacle should be a securely locked, substantially constructed container with an outer container and a removable inner liner. The outer container should include a small opening that allows contents to be added to the inner liner, but that does not allow removal of the inner liner's contents.

NOTE: *Law enforcement is not required to utilize collection receptacles at take-back events. The text of the final rule states, "[e]ach take-back event should have at least one receptacle for the collection of permitted substances . . ." 21 CFR 1317.65. Thus, law enforcement should have some type of receptacle at take-back events.*

Only those controlled substances listed in Schedule II, III, IV, or V that are lawfully possessed by an ultimate user or person entitled to dispose of an ultimate user decedent's property may be collected. Controlled and non-controlled substances may be collected together and be comingled, although comingling is not required.

OAC 4729:10-1-03 also prohibits the collection of radiopharmaceuticals, needles, syringes or lancets. When applicable, a bulk sharps disposal container may be provided at each collection event for the disposal of sharps.

Only ultimate users and persons entitled to dispose of an ultimate user decedent's property in lawful possession of a controlled substance in Schedule II, III, IV, or V may transfer such substances to law enforcement during the take-back event. No other person may handle the controlled substances at any time.

Ohio regulations also require that a law enforcement agency must ensure that the confidentiality of the individual disposing of a drug is maintained pursuant to applicable State and Federal laws, rules, and regulations.

NOTE: *While it is considered best practice, there is NO DEA requirement to notify the local DEA Resident Office prior to conducting a take-back event.*

(§ 1317.65 Take-back events)
(Ohio Administrative Code 4729:10-1-03)

40) How does the DEA define law enforcement officer?

The DEA defines a law enforcement officer as any of the following:

(1) Meets all of the following criteria:

- Employee of either a law enforcement agency, or law enforcement component of a Federal agency;
- Is under the direction and control of a Federal, State, tribal, or local government;
- Acting in the course of his/her official duty; and
- Duly sworn and given the authority by a Federal, State, tribal, or local government to carry firearms, execute and serve warrants, make arrests without warrant, and make seizures of property;

(2) A Veterans Health Administration (VHA) police officer authorized by the Department of Veterans Affairs to participate in collection activities conducted by the VHA; or

(3) A Department of Defense (DOD) police officer authorized by the DOD to participate in collection activities conducted by the DOD.

(§ 1300.05 Definitions relating to the disposal of controlled substances)

Section 6: Storage of Collected Pharmaceuticals

41) What are the storage requirements for liners removed from collection receptacles at retail pharmacies, hospitals and long-term care facilities?

Sealed inner liners can only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.

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.

(§ 1301.75 Physical security controls for practitioners)
(§ 1317.80 Collection receptacles at long-term care facilities)

42) What are the storage requirements for sealed mail-back packages?

Sealed mail-back packages collected can only be stored at the registered location in a securely locked, substantially constructed cabinet or a securely locked room with controlled access.

(§ 1301.75 Physical security controls for practitioners)

43) What are the storage requirements for sealed mail-back packages and inner liners collected by manufacturers, distributors, narcotic treatment programs, and reverse distributors?

Sealed mail-back packages and inner liners collected by manufacturers, distributors, narcotic treatment programs, and reverse distributors shall be stored in one of the following secured areas:

(1) Where small quantities permit, a safe or steel cabinet;

(i) Which safe or steel cabinet shall have the following specifications or the equivalent: 30-man minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(ii) Which safe or steel cabinet, if it weighs less than 750 pounds, is bolted or cemented to the floor or wall in such a way that it cannot be readily removed; and

(iii) Which safe or steel cabinet, if necessary, depending upon the quantities and type of controlled substances stored, is equipped with an alarm system which, upon attempted unauthorized entry, shall transmit a signal directly to a central protection company or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve.

(2) A vault constructed before, or under construction on, September 1, 1971, which is of substantial construction with a steel door, combination or key lock, and an alarm system; or

(3) A vault constructed after September 1, 1971:

(i) The walls, floors, and ceilings of which vault are constructed of at least 8 inches of reinforced concrete or other substantial masonry, reinforced vertically and horizontally with \1/2\-inch steel rods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;

(ii) The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes against surreptitious entry, 10 man-minutes against forced entry, 20 man-hours against lock manipulation, and 20 man-hours against radiological techniques;

(iii) Which vault, if operations require it to remain open for frequent access, is equipped with a "day-gate" which is self-closing and self-locking, or the equivalent, for use during the hours of operation in which the vault door is open;

(iv) The walls or perimeter of which vault are equipped with an alarm, which upon unauthorized entry shall transmit a signal directly to a central station protection company, or a local or State police agency which has a legal duty to respond, or a 24-hour control station operated by the registrant, or such other protection as the Administrator may approve, and, if necessary, holdup buttons at strategic points of entry to the perimeter area of the vault;

(v) The door of which vault is equipped with contact switches; and

(vi) Which vault has one of the following: Complete electrical lacing of the walls, floor and ceilings; sensitive ultrasonic equipment within the vault; a sensitive sound accumulator system; or such other device designed to detect illegal entry as may be approved by the Administration.

(§1301.72 Physical security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs; storage areas)

Section 7: Destruction of Collected Pharmaceuticals

44) How can a registrant destroy collected pharmaceuticals?

The new regulations do not require a particular method of destruction, so long as the desired result is achieved. Pharmaceuticals must be rendered "non-retrievable" in compliance with all applicable Federal, State, tribal and local laws. This standard is intended to allow public and private entities to develop a variety of destruction methods that are secure, convenient, and responsible, consistent with preventing the diversion of such substances.

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

When the actual substances collected for destruction are unknown but may reasonably include controlled substances, the method of destruction shall be sufficient to render non-retrievable any controlled substance likely to be present.

Currently, the only acceptable method of destruction that DEA recognizes is incineration. If another method is considered by a registrant (for example, chemical destruction), it should ensure that it renders pharmaceutical drugs as non-retrievable.

NOTE: *Ohio regulations regarding the destruction of collected drugs require all drugs collected (controlled and non-controlled) to be rendered non-retrievable.*

Additionally, the Ohio regulations require the method of destruction to ensure that the confidentiality of the individuals disposing of drugs is maintained pursuant to applicable Federal and State laws, rules, and regulations.

(§ 1300.05 Definitions relating to the disposal of controlled substances)
(§ 1317.90 Methods of destruction)
(Ohio Administrative Code 4729:10-1-04)

45) What are the disposal requirements for collected drugs?

Any collector in lawful possession of a pharmaceutical drug acquired by collection from an ultimate user or other authorized non-registrant person shall dispose of that substance in the following ways:

Mail-back program

Upon receipt of a sealed mail-back package, the collector shall promptly:

(1) Destroy the package using an on-site method of destruction; or

(2) Securely store the package and its contents at the collector's registered location in a manner consistent with rules for practitioners (*See FAQ #42*), or in a manner consistent with the security requirements for Schedule II controlled substances (*See FAQ #43*) until prompt on-site destruction can occur.

Collection receptacles.

Upon removal from the permanent outer container, the collector shall seal it and promptly:

(1) Destroy the sealed inner liner and its contents;

(2) Securely store the sealed inner liner and its contents at the collector's registered location in a manner consistent with rules for practitioners (*See FAQ #41*), or in a manner consistent with the security requirements for Schedule II controlled substances (*See FAQ #43*) until prompt destruction can occur;

(3) Securely store the sealed inner liner and its contents at a long-term care facility according to DEA regulations (*See FAQ #41*).

(§ 1317.05 Registrant disposal.)

46) What are the approved methods of destruction for drugs collected by practitioners (i.e., retail pharmacies and hospitals/clinics)?

Collectors that are practitioners (i.e., retail pharmacies and hospitals/clinics) shall dispose of sealed inner liners and their contents by utilizing any of the following methods:

- Promptly destroy that pharmaceutical drug using an on-site method of destruction (required for mail-back programs);
- Promptly deliver that pharmaceutical drug to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) pick-up or by reverse distributor pick-up at the registrant's registered location;
- Request assistance from the DEA Special Agent in Charge in the area in which the practitioner is located; or
- Deliver the sealed inner liners and their contents to a distributor's registered location by common or contract carrier pick-up (such as UPS, FEDEX or USPS) or by distributor pick-up at the collector's authorized collection location.

NOTE: *Practitioner employees are not permitted to transport drugs. Transportation to a reverse distributor must be done by common contract carrier or must be picked up by the reverse distributor.*

(§ 1317.05 Registrant disposal)

47) What are the approved methods of destruction drugs collected by non-practitioners (i.e., manufacturers, distributors, narcotic treatment programs, and reverse distributors)?

Collectors that are non-practitioners (i.e., manufacturers, distributors, narcotic treatment programs, and reverse distributors) shall dispose of sealed inner liners and their contents by utilizing any of the following methods:

- Promptly destroy the controlled substance using an on-site method of destruction (required for mail-back programs);

- Promptly deliver the controlled substance to a reverse distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by reverse distributor pick-up at the registrant's registered location;

- Promptly transport the controlled substance by its own means to the registered location of a reverse distributor, the location of destruction, or the registered location of any person authorized to receive that controlled substance for the purpose of return or recall; or

- Deliver the sealed inner liners and their contents to a distributor's registered location by common or contract carrier (such as UPS, FEDEX or USPS) or by distributor pick-up at the collector's authorized collection location for destruction. Freight forwarding facilities may not be utilized to transfer sealed inner liners and their contents.

(§ 1317.05 Registrant disposal)

48) What are the procedures for destroying collected pharmaceutical drugs?

The DEA includes the following procedures based on a number of different destruction scenarios:

Transfer to a person registered or authorized to accept controlled substances for the purpose of destruction. If the pharmaceutical drugs 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 drugs until transfer is complete.

Transport to a registered location. If the pharmaceutical drugs are transported by a registrant to a registered location for subsequent destruction, the following procedures must be followed:

(1) Transportation shall be directly to the registered location (the substances shall be constantly moving towards their final location and unnecessary or unrelated stops and stops of an extended duration shall not occur).

(2) Two employees of the transporting registrant shall accompany the controlled substances to the registered location.

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances until transfer is complete.

Transport to a non-registered location. If the pharmaceutical drugs are transported by a registrant to a destruction location that is not a registered location (i.e. an incineration facility approved by the Ohio EPA for the destruction of drugs), the following procedures must be followed:

(1) Transportation shall be directly to the destruction location (the substances shall be constantly moving towards their final destruction location and unnecessary or unrelated stops and stops of an extended duration shall not occur);

(2) Two employees of the transporting registrant shall accompany the controlled substances to the destruction location;

(3) Two employees of the transporting registrant shall load and unload or observe the loading and unloading of the controlled substances;

(4) Two employees of the transporting registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(5) Two employees of the transporting registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

On-site destruction. If the controlled substances are destroyed at a registrant's registered location utilizing an on-site method of destruction, the following procedures must be followed:

(1) Two employees of the registrant shall handle or observe the handling of any controlled substance until the substance is rendered non-retrievable; and

(2) Two employees of the registrant shall personally witness the destruction of the controlled substance until it is rendered non-retrievable.

NOTE: *These procedures only apply to registrants and NOT law enforcement agencies.*

(§ 1317.95 Destruction procedures)

49) If I am a registrant, do I need to use a special form to record the destruction of drugs collected?

Registrants must use DEA Form 41 (https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/surrend.html) to record the destruction of controlled substances collected from ultimate users as well as the destruction of controlled substances that remain in the closed system of distribution.

However, a controlled substance dispensed for immediate administration pursuant to an order for medication in an institutional setting remains under the custody and control of that registered institution even if the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, transdermal patch, or syringe after administration but cannot or may not be further utilized, commonly referred to as "drug wastage" and "pharmaceutical wastage"). Such remaining substance must be properly recorded, stored, and destroyed in accordance with DEA regulations (e.g., 21 C.F.R. 1304.22(c)), and all applicable Federal, State, tribal, and local laws and regulations, although the destruction need not be recorded on a DEA Form 41.

(§ 1304.21 General requirements for continuing records)

Section 8: Law Enforcement

50) Does a law enforcement agency have to comply with the DEA requirements for drug collection receptacles?

No. Law enforcement agencies are not required to have a collection receptacle that meets all of the specifications required by the DEA for registrants (i.e. removable liners that are uniquely identifiable), and the text of the rule is amended to clarify that the specifications apply to authorized collectors and not law enforcement.

However, Ohio Administrative Code rule 4729:10-1-03 does require a law enforcement collection receptacle to meet certain requirements.

(Ohio Administrative Code 4729:10-1-03)

51) What are the requirements for law enforcement to collect controlled substances from ultimate users?

The rules permit any Federal, State, tribal or local law enforcement to collect controlled substances from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property using the following collection methods:

(1) Take-back events (*See Section 5: Take-Back Events*);

(2) Mail-back programs (*See Section 4: Mail-Back Programs*);

(3) Collection receptacles located inside law enforcement's physical address (*See FAQ #50*).

According to the DEA, law enforcement agencies that conduct a take-back event or a mail-back program or maintains a collection receptacle should maintain any records of removal, storage, or destruction of the drugs collected in a manner that is consistent with that agency's recordkeeping requirements for illicit controlled substances evidence.

Ohio regulations also require that a law enforcement agency must ensure that the confidentiality of the individual disposing of a drug is maintained pursuant to applicable state and federal laws, rules, and regulations.

Any pharmaceutical drugs collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be stored in a manner that prevents the diversion of controlled substances and is consistent with that agency's standard procedures for storing illicit controlled substances.

Any pharmaceutical drugs collected by law enforcement through a take-back event, mail-back program, or collection receptacle should be transferred to a destruction location in a manner that prevents the diversion of pharmaceutical drugs and is consistent with that agency's standard procedures for transferring illicit controlled substances.

(§ 1317.35 Collection by law enforcement)
(Ohio Administrative Code 4729:10-1-03)

Section 9: Reverse Distributors

52) How does the DEA define a reverse distributor and reverse distribute?

A "reverse distributor" is a person registered with the DEA as a reverse distributor. A reverse distributor is also required to be licensed by the Ohio State Board of Pharmacy as a Wholesale Distributor of Dangerous Drugs.

"Reverse distribute" means to acquire pharmaceutical drugs from another registrant or law enforcement for the purpose of: (1) Return to the registered manufacturer or another registrant authorized to accept returns on the manufacturer's behalf; or (2) Destruction.

(§ 1300.01 Definitions relating to controlled substances)

53) What are the reverse distributor record keeping requirements for collected pharmaceutical drugs?

For each sealed inner liner acquired by a reverse distributor from collectors or law enforcement and each sealed mail-back package acquired from law enforcement:

(1) The number of sealed inner liners acquired from other persons, including the date of acquisition, the number and, for sealed inner liners the size (e.g., five 10-gallon liners, etc.), of all sealed inner liners and mail-back packages acquired to inventory, the unique identification number of each sealed inner liner and mail-back package, and the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; and

(2) The date, place, and method of destruction; the number of sealed inner liners and mail-back packages destroyed; the name, address, and, for registrants, the registration number of the person from whom the sealed inner liners and mail-back packages were received; the number and, for sealed inner liners the size (e.g., five 10-gallon liners, etc.), of all sealed inner liners and mail-back packages destroyed; the unique identification number of each sealed inner liner and sealed mail back package destroyed; and the name and signatures of the two employees of the registrant that witnessed the destruction.

For all records, the record of receipt shall be maintained together with the corresponding record of return or destruction – DEA Form 41 (*See FAQ #49*).

(§ 1304.22 Records for manufacturers, distributors, dispensers, researchers, importers, exporters, registrants that reverse distribute, and collectors)

54) What are the requirements for reverse distributors?

Any person that reverse distributes a controlled substance must be registered with the DEA as a reverse distributor, unless exempted by law or otherwise authorized by DEA regulations.

A reverse distributor shall acquire pharmaceutical drugs from a registrant pursuant to § 1317.05 and 1317.55(a) and (c) in the following manner:

(1) Pick-up controlled substances from a registrant at the registrant's registered location or authorized collection site; or

(2) Receive pharmaceutical drugs delivered by common or contract carrier or delivered directly by a non-practitioner registrant.

- Delivery to the reverse distributor by an authorized registrant directly or by common or contract carrier may only be made to the reverse distributor at the reverse distributor's registered location. Once enroute, such deliveries may not be re-routed to any other location or person, regardless of registration status.

- All drug deliveries to a reverse distributor must be personally received by an employee of the reverse distributor at the registered location.

Upon acquisition of a controlled substance by delivery or pick-up, a reverse distributor must:

(1) Immediately store the controlled substance, in accordance with the DEA required security controls (S*ee FAQ #43 and #16*) at the reverse distributor's registered location or immediately transfer the controlled substance to the reverse distributor's registered location for secure storage, in accordance with the DEA required security controls (*See FAQ #43 and #16*), until timely destruction or prompt return of the pharmaceutical drugs to the registered

manufacturer or other registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf;

(2) Promptly deliver the controlled substance to the manufacturer or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf; or

(3) Timely destroy the controlled substance in a manner authorized by the DEA (*See FAQ #47 and #44*). A reverse distributor must destroy or cause the destruction of any drug received for the purpose of destruction no later than 30 calendar days after receipt.

(§ 1317.15 Reverse distributor registration requirements and authorized activities)
(§ 1301.74 Other security controls for non-practitioners; narcotic treatment programs and compounders for narcotic treatment programs)

55) Reverse distributor/distributor requirements for law enforcement?

A reverse distributor or distributor is authorized to acquire pharmaceutical drugs from law enforcement that collected the substances from ultimate users through collection receptacles.

A reverse distributor or a distributor must adhere to the following:

(1) Acquire the pharmaceutical drugs in the manner authorized for reverse distributors (*See FAQ #54*);

(2) Dispose of the controlled substances in the manner authorized for reverse distributors (*See FAQ #47 and #44*); and

(3) Securely store the controlled substances in a manner consistent with the security requirements for Schedule II controlled substances until timely destruction can occur (*See FAQ #43 and #16).*

(§ 1317.55 Reverse distributor and distributor acquisition of controlled substances from collectors or law enforcement.)

Section 10: Reporting Theft or Loss and Additional Information

56) Do I have to report the theft or loss of collected pharmaceutical drugs?

Yes. Any theft or loss, including sealed inner liners and returned mail-back packages, should be immediately reported to the Ohio State Board of Pharmacy and local law enforcement. In addition, loss or theft of collected pharmaceuticals should be reported to the DEA and the Ohio State Board of Pharmacy through DEA Form 106 within 30 days. This form has been updated to include the collection of information relevant to lost or stolen sealed inner liners and returned mail-back packages. The form can be accessed here: https://www.deadiversion.usdoj.gov/webforms/dtlLogin.jsp.

57) What are the contact numbers for the DEA and Ohio Board of Pharmacy?

The Ohio State Board of Pharmacy is committed to providing its licensees assistance in complying with all Federal and State laws and regulations. If you have questions, please do not hesitate to call the Board at 614-466-4143 or via email by visiting: http://www.pharmacy.ohio.gov/contact.aspx

Additionally, DEA registrants may also contact Ohio's DEA Resident Offices:

CINCINNATI RESIDENT OFFICE
36 East 7th Street, Suite 1900
Cincinnati, OH 45202
Diversion Number: (513) 684-3671
Diversion Fax: (513) 684-3080
Jurisdiction: Southern Ohio

CLEVELAND RESIDENT OFFICE
Courthouse Square
1375 East 9th Street Suite 700
Cleveland, OH 44114
Diversion Number: (216) 274-3600
Diversion Fax: (216) 664-1307

Jurisdiction: Northern Ohio

COLUMBUS RESIDENT OFFICE
500 South Front Street, Suite 612
Columbus, OH 43215
Diversion Number: (614) 255-4200
Diversion Fax: (614) 469-5788
Jurisdiction: Central and Southern Ohio

58) What are the contact numbers for the DEA registered reverse distributors?

This list of reverse distributors does not constitute an endorsement by the DEA or the Ohio Board of Pharmacy of these companies or their products or services.

Ohio (Also Licensed by the OBP)
ACHIEVA GROUP RETURNS, INC. – 513-474-9900
HERITAGE – WTI – (330) 385-7337

Arizona
ENVIRONMENTAL PHARMACEUTICALS, LLC – 480-659-9611

California
EXP PHARMACEUTICAL SERVICES CORP. – 1-800-350-0397 or 510-476-0909
VEOLIA ES TECHNICAL SOLUTIONS, LLC – 626-945-6003
FAR WEST RETURNS – 530-872-1758

Florida
ARX RETURNS, INC. – 727-919-2527
PHARMACY RETURNS LOGISTICS – 386-935-0876
PHARMALINK, INC. – 727-669-8187
CAVU MEDICAL PRODUCTS & SERVICES – 813-749-7113
RX REVERSE DISTRIBUTORS, INC. – 772-388-1212
WOODFIELD DISTRIBUTOR LLC – 561-998-3885

Georgia

BURKE HORTON, INC DBA THE RX EXCHANGE – 687-306-1866
DANOX ENVIRONMENTAL SERVICES INC – 404-671-9163
MAXIMUM RX CREDIT, INC – 770-985-2136
PHARMAMATE dba RETURN CO – 727-867-1100
RETURN LOGISTICS – 912-748-5100
STERICYCLE, INC – 707-409-1500

Illinois

PHARMA LOGISTICS, LTD. 1-888-729-7427 or 847-837-1224
PHARMACEUTICAL RETURNS SERVICES – 1-800-215-5878 or 630-892-8740
PROGRESSIVE RETURNS, INC. – 773-622-9584
QUALANEX – 847-775-7256

Indiana

STERICYCLE, INC – 317-860-1200

Michigan

DRUG AND LABORATORY DISPOSAL, INC. – 1-800-685-9824 or 269-685-9824
EQ DETROIT, INC. – 313-347-1350
NORTRU, LLC – 313-824-5840
US INDUSTRIAL TECHNOLOGIES, INC. – 734-462-4100

Minnesota

EZ PHARMACY RETURNS, LCC – 1-800-440-0613

New Jersey

ADVANCED RX RETURNS – 201-222-3800

New York

ARK BUSINESS SERVICES, INC. – 347-590-2779
DEVOS, LTD. Dba GUARANTEED RETURNS – 1-800-473-2138 or 631-689-0191

North Carolina

ALMAC CLINICAL SERVICES, INC. – 919-479-8853
ASSURED WASTE SOLUTIONS, LLC – 704-224-6083
PHARMACEUTICAL DIMENSIONS – 336-664-5287

Oklahoma

TOTAL RETURNS – 580-276-3056

Pennsylvania

CHESAPEAKE WASTE SOLUTIONS, INC. – 717-653-8882
HDS RETURNS LLC – 724-658-0206
PHARMARETURNS – 215-653-7400
REPUBLIC ENVIRONMENTAL SYSTEMS, LLC – 215-822-8995
PRESTIGIOUS RX RETURNS DBS PRX RETURNS – 570-578-0136

South Carolina

ADVANCED ENVIRONMENTAL OPTIONS, INC. – 864-488-9111

Tennessee

MEDSAFE WASTE LLC – 615-829-8985
PHARMACEUTICAL CREDIT CORP. – 615-373-4262
QUALITY RX RETURNS – 865-660-6558
RELIABLE PHARMACEUTICAL RETURNS, LLC – 615-361-8856
RETURN SOLUTIONS, INC. – 865-675-1355

Texas

MED-TURN, INC. – 817-868-5300
PHILIP RECLAMATION SERVICES – 651-645-7509
SHARPS COMPLIANCE, INC. – 903-693-2525

Utah

CLEAN HARBOR ARAGONITE, LLC – 435-884-8100
NATIONAL PRODUCTS SALES – 801-972-4132

Washington

P.S. INDUSTRIES, INC. – 206-749-0739

Wisconsin

CAPITAL RETURNS, INC. – 1-800-950-5479 or 414-967-2800

VEOLIA ES TECHNICAL SOLUTIONS, LLC – 262-255-6655

NOTE: *This list is subject to change. Please contact your local DEA Resident Office for more information (See FAQ #57).*

Section 11: Home Hospice Care Programs

Ohio Revised Code 3712.062 requires the following of a licensed hospice care program that provides hospice care and services in a patient's home with respect to controlled substances that contain opioids:

- Establish a written policy and adopt certain practices for preventing the diversion of controlled substances containing opioids.

- Report to local law enforcement the quantity and type of controlled substances not relinquished to the program and requires the law enforcement agency to investigate and dispose of those controlled substances.

- To request, in writing, that the hospice patient or family relinquish any controlled substances containing opioids included in the patient's plan of care that are no longer needed by the patient. The request is to be made after the patient's death or when the drugs are no longer needed by the patient.

The law also requires that the disposal of controlled substances containing opioids must be documented by a program employee and performed in any of the following ways:

1. Performed by a program employee and witnessed by the patient or patient's family member;
2. Performed by the patient or patient's family member and witnessed by a program employee;
3. Performed by a program employee and witnessed by another program employee.

Staff from the Board of Pharmacy recently met with Ohio DEA representatives and received confirmation that the three options listed above are acceptable for the destruction of controlled substances within a patient's home. Please be advised that hospice staff are not permitted to remove any drugs from a patient's home but are permitted to witness a family member depositing controlled substances at a local take back receptacle. If available, hospice staff could also utilize a mail-back program. Hospice staff should assist the family member or patient with filling, sealing and ensuring the envelope is picked up by a common carrier.

If not utilizing a mail-back envelope or collection receptacle, a hospice care program should adhere to FDA guidelines for home disposal of controlled substances. Guidelines can be accessed here: https://www.fda.gov/drugs/safe-disposal-medicines/disposal-unused-medicines-what-you-should-know

Additionally, the FDA recognizes that there are a small number of medicines that may be especially harmful and, in some cases, fatal with just one dose if they are used by someone other than the person for whom the medicine was prescribed. Therefore, they have compiled a list of specific medications (many include controlled substance containing opioids) that should be flushed down the sink or toilet to help prevent diversion. The list can be accessed here: https://www.fda.gov/media/85219/download