KANSAS MEDICATION DRUG DISPOSAL PROGRAM
FREQUENTLY ASKED QUESTIONS (FAQs)

Kansas prescription medications often go unused or expire. The Kansas Medication Drug Disposal Program offers Kansans a convenient, safe and environmentally responsible option for disposing of unwanted medications. Proper disposal reduces accumulation in the home and the subsequent risk of unintentional poisoning, drug abuse and diversion. By utilizing a take-back location for your unused medications, you help us to limit the environmental impact that they may have on our surface and groundwater. Please join us in this important endeavor to safeguard our families and the environment.

https://www.deadiversion.usdoj.gov/pubdispsearch/spring/main?execution=e2s1

IF YOU ARE COLLECTING **CONTROLLED SUBSTANCES** YOU MUST ADHERE TO THE FOLLOWING:

ULTIMATE USERS

Who can turn in returned, unwanted, expired or unused medications including controlled substances?

An "ultimate user" is a person who has lawfully obtained, and who possesses, a controlled substance 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 a pharmaceutical drug, any person lawfully entitled to dispose of the decedent's property may dispose of the drugs
- A long-term-care facility (that has a pharmacy) may dispose of a current or former resident's pharmaceutical controlled substances using this program.

The DEA rules only specify controlled substances. Can I also return non-controlled and over the counter medications to an authorized collector?

Yes. The DEA permits the co-mingling of controlled and non-controlled substances.

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 found at: http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186187.htm

Can ultimate users dispose of illicit drugs or Schedule I controlled substances through a collection receptacle, mail-back package, or take-back event?

No, ultimate users may not dispose of illicit drugs or Schedule I controlled substances (i.e., marijuana, heroin, LSD) via any of the approved disposal methods. Persons may not dispose of any controlled substances they do not legally possess. This includes schedules II-V controlled substances that are illegally obtained or possessed.

DEA Fact Sheet for the Public/Ultimate Users:
http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_public.pdf

AUTHORIZED COLLECTORS

Who is an "authorized collector" of unwanted, expired or unused medications including controlled substances?

The term "authorized collector" means a Kansas Board of Pharmacy and DEA registered manufacturer, distributor, reverse distributor, narcotic treatment program, hospital/clinic with an onsite pharmacy, or retail pharmacy that is authorized by the DEA to receive controlled substances for the purpose of destruction. This means that anyone collecting drugs in Kansas must have a Kansas Board of Pharmacy registration to possess controlled substances and a corresponding DEA permit. Clinics that have a dispensing room that are not operated by a pharmacist are not considered entities with an on-site pharmacy.

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." Registrants must also notify the Board of Pharmacy by signing up for the Kansas Medication Disposal Program.

Eligible registrants **must** have authority to handle Schedule II controlled substances through the DEA and Kansas Board of Pharmacy.

If a hospital/clinic with an on-site pharmacy or retail pharmacy is applying for a modification in registration to become an authorized collector through 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 authorized collector intends to maintain a collection receptacle. This authorization is subject to renewal. If an authorized collector ceases collection, such entity shall notify the DEA.

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 with Federal and State laws and rules, and notify the DEA and Kansas Board of Pharmacy that collection activities are ceasing, in writing or online at http://www.DEAdiversion.usdoj.gov and through the Kansas Medication Disposal Program.

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 and through the Kansas Medication Disposal Program.

What can I collect as an authorized collector?

An authorized collector may collect 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.

Persons may not dispose of medical sharps and needles (insulin syringes), iodine-containing medications, mercury-containing thermometers, radiopharmaceuticals, antineoplastic agents (cancer chemotherapy drugs, cytotoxic drugs), or compressed cylinders or aerosols (asthma inhalers). Authorized collectors should be vigilant to prevent ultimate users from disposing of prohibited drugs in addition to employee oversight.

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. An authorized 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.

DEA Fact Sheet for Registrants/Authorized Collectors:
http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_registrant.pdf

LONG-TERM CARE FACILITIES

Can a long-term care facility 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?

Yes, long-term care facilities may dispose of pharmaceutical drugs on behalf of the ultimate user who resides, or has resided, at that facility through an authorized collection receptacle. The long-term care facility must have an authorized hospital/clinic or retail pharmacy located at the facility and be a DEA registrant and a Kansas Board of Pharmacy registrant.

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.

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 (a charge nurse or supervisor) designated by the authorized collectoror, 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.

What if my long-term care facility does not have a return receptacle? What are the requirements for drug destruction?

The licensing of long-term care facilities require a licensed pharmacist to identify any deteriorated, outdated, or discontinued drugs and biologicals and any drugs or biologicals that are unused remaining from a discharged or deceased resident during the monthly pharmacy services review. The licensed pharmacist shall destroy, if appropriate, any deteriorated, outdated, unused, or discontinued drugs and biologicals at the nursing facility and in the presence of one witness who is a licensed nurse employed by the facility. A record shall be on file in the facility

which contains the date, drug name, quantity of drugs and biologicals destroyed, and signatures of the pharmacist and licensed nurse. K.A.R. 28-39-156.

DEA Fact Sheet for Long-term Care Facilities:
http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_ltcf.pdf

TAKE BACK PROGRAMS

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

Yes, the next sponsored event is on October 22, 2016 from 10:00 am to 2:00 pm. For more information, visit http://www.deadiversion.usdoj.gov/drug_disposal/takeback/.

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.

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.

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

No. Authorized 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.

What are the requirements for drug take-back events?

Only federal, state, tribal, or local law enforcement may conduct a take-back event and collect controlled and non-controlled prescription medications from ultimate users and persons lawfully entitled to dispose of an ultimate user decedent's property.

The DEA regulations 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.

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.

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.

Collection receptacles shall not require any person to provide any personally identifying information or details concerning the substance collected.

NARCOTIC TREATMENT PROGRAMS

What is a narcotic treatment program and can they take back drugs?

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. For more information, please visit:
http://www.deadiversion.usdoj.gov/pubs/manuals/pract/section6.htm

A narcotic treatment program can register with the DEA and Kansas Board of Pharmacy as an authorized collector to provide the opportunity for patients to dispose of unused pharmaceutical drugs, with certain enhanced security controls.

COLLECTION RECEPTACLE REQUIREMENTS

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 registered 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).

Exceptions:

- 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.
- At a narcotic treatment facility: A collection receptacle must be located in a room that does not contain any other controlled substances and is securely locked with controlled access.
- At a long-term care facility: A collection receptacle must be located in a secured area regularly monitored by long-term care facility employees.

Are there design specifications for collection receptacles?

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

- Be securely fastened to a permanent structure so that it cannot be removed;
- Be a security locked, substantially constructed container with a permanent outer container and a removable inner liner.
- 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.
- The outer container must prominently display a sign indicating that only Schedule II-V controlled and non-controlled substances are acceptable substances, if a collector chooses to comingle 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.)
- 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.

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

An inner liner must meet the following requirements:

- The inner liner must be
    - waterproof, tamper-evident, and tear-resistant
    - removable and sealable immediately upon removal without emptying or touching the contents
- The contents of the inner liner shall not be viewable from the outside when sealed
- The size shall be clearly marked on the outside of the liner (e.g., 5-gallon, 10-gallon, etc.)
- The inner liner shall bear a permanent, unique identification number that enables the inner liner to be tracked
- Access to the inner liner shall be restricted to employees of the collector
- 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

What are the requirements for employee installation or removal of the inner liner?

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 surrendered a DEA registration for cause.

For long-term care facilities, the rules require the installation, removal, transfer, and storage of inner liners 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.

RECORD KEEPING REQUIREMENTS

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.

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.

Are there inventory requirements for collectors that operate collection receptacles?

Yes. For the required DEA and Kansas Board of Pharmacy inventories, authorized collectors shall include the following record-keepings information about each unused inner liner on hand and each sealed inner liner on hand awaiting destruction:

- The date of the inventory;
- The number and size of inner liners (e.g., five 10-gallon liners, etc.); and
- The unique identification number of each inner liner.

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.

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.

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

An authorized 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 surrendered a DEA registration for cause.

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:

- 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.
- Distributions to reverse distributors and distributors by authorized collectors and law enforcement.
- Deliveries of controlled substances from ultimate users for the purpose of recalls.

MAIL-BACK PROGRAMS

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

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

How does the DEA define on-site?

“On-site” means located on or at the physical premises of the authorized collector’s registered location. A pharmaceutical drug is destroyed on-site when destruction occurs on the physical premises of the registered location. A hospital/clinic has an on-site pharmacy when it has a pharmacy located on the physical premises of the registered location.

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 authorized collector. An authorized collector conducting a mail-back program shall have and utilize at their registered location a method of destruction consistent with the DEA regulations. 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. 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:

- The package must be nondescript and shall not include any markings or other information that might indicate that the package contains pharmaceutical drugs;
- The package must be water- and spill-proof, tamper-evident, tear-resistant, and sealable;

- The package must be preaddressed with and delivered to the authorized collector's registered address or the participating law enforcement agency's physical address;
- The cost of shipping the package shall be postage paid;
- The package must have a unique identification number that enables the package to be tracked; and
- 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 authorized 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 agency 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 agency that they are sending one of the designated packages by giving the unique identification number on the package.

An authorized collector that conducts a mail-back program must:

1. Accept only those pharmaceutical drugs contained within packages that the authorized 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 authorized collector did not make available or did not agree to receive.

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

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.

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

Yes. For each authorized collector operating 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:

- date of the inventory;
- number of mail-back packages; and

- unique identification number of each package, whether unused or awaiting destruction

I don't have a mail-back package, but I remember the address from the last mail-back 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, including 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. If persons would like to use a mail-back package and don't possess one, they may contact an authorized collector to obtain one.

STORAGE OF COLLECTED PHARMACEUTICALS

What are the storage requirements for inner 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.

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.

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;
    a. 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;
    b. 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
    c. 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:
    a. 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 steelrods tied 6 inches on center, or the structural equivalent to such reinforced walls, floors, and ceilings;
    b. The door and frame unit of which vault shall conform to the following specifications or the equivalent: 30 man-minutes

DESTRUCTION OF COLLECTED PHARMACEUTICALS

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.

What are the disposal requirements for collected drugs?

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

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

- Destroy the package using an on-site method of destruction; or
- Securely store the package and its contents at the collector's registered location in a manner consistent with rules for practitioners, or in a manner consistent with the security requirements for Schedule II controlled substances until prompt on-site destruction can occur.

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

- Destroy the sealed inner liner and its contents;
- Securely store the sealed inner liner and its contents at the collector's registered location in a manner consistent with rules for practitioners, or in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur; or
- Securely store the sealed inner liner and its contents at a long-term care facility according to DEA regulations.

What are the approved methods of destruction for drugs collected by practitioners 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 pick-up (such as UPS, FEDEX or USPS) or by reverse distributor pick-up at the registrant's registered location;
- Request assistance from the Kansas Board of Pharmacy Inspector 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.

Please note: Practitioner employees are not permitted to transport drugs. Transportation to a reverse distributor must be done by common contract carrier or by reverse distributor pick-up.

What are the approved methods of destruction for drugs collected by 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.

What are the procedures for destroying collected pharmaceutical drugs?

The DEA includes the following procedures based on 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), 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 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.

If I am an authorized collector, do I need to use a special form to record the destruction of drugs collected?

Registrants must use DEA Form 41 (http://www.deadiversion.usdoj.gov/21cfr_reports/surrend/) 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.

REVERSE DISTRIBUTORS

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 Kansas Board of Pharmacy.

"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.

What are the record-keeping requirements for reverse distributors?

For each sealed inner liner acquired by a reverse distributor from authorized 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.

What are the collection requirements for reverse distributors?

A reverse distributor shall acquire pharmaceutical drugs from a registrant in the following manner:

1. Pick-up controlled substances from an authorized collector at the 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.
    a. 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 en route, such deliveries may not be re-routed to any other location or person, regardless of registration status.
    b. 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 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, 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 no later than 30 calendar days after receipt.

Reverse Distributor and Distributor requirements for receiving from 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;
2. Dispose of the controlled substances in the manner authorized for reverse distributors; 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.

REPORTING THEFT OR LOSS AND ADDITIONAL INFORMATION

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 DEA and copied to the Kansas State Board of Pharmacy and local law enforcement. The DEA 106 form has been updated to include the collection of information relevant to lost or stolen sealed inner liners and returned mail-back packages.

CONTACT INFORMATION

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785-296-4056
785-296-8420 fax
pharmacy@ks.gov

Kansas DEA Resident Offices:
Kansas City District Office
7600 College Blvd., Ste. 100
Overland Park, KS 66210
Registration Assistance: (888) 803-1179
Investigative Matters/Diversion Number: (913) 951-4100
Investigative Matters/Diversion Fax: (913) 951-3684

IF YOU ARE COLLECTING ONLY **NON-CONTROLLED MEDICATIONS** YOU MUST ADHERE TO THE FOLLOWING:

KANSAS NON-CONTROLLED MEDICATION DISPOSAL PROGRAM.

What if I do not want to collect controlled substances under the DEA rules? Can I collect non-controlled medications only?

Yes, you can collect non-controlled substances through the Kansas Medication Disposal Program by filling out an application with Kansas Department of Health and Environment (KDHE). The application is on the Board of Pharmacy webpage under the link for Kansas Medication Disposal Program.

If I wish to collect controlled medications under the DEA rules, can I still fill out a Kansas application so that my location is placed on the Kansas map and consumers know that they can bring their drugs in for disposal?

Absolutely. The Kansas program identifies each pharmacy on a map that can be found on both the Board of Pharmacy and the KDHE webpage, and provides a list and location of participating pharmacies.

What medications are accepted?
Uncontrolled prescription medications
Over the counter medications
Medication samples
Pet medications
Vitamins
Liquid medications in glass or leak-proof containers
Medicated ointments and lotions
Inhalers

Sources:

http://www.fda.gov/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/EnsuringSafeUseofMedicine/SafeDisposalofMedicines/ucm186188.htm

http://www.deadiversion.usdoj.gov/

http://www.deadiversion.usdoj.gov/drug_disposal/index.html

http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm101653.htm

http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_registrant.pdf

http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_public.pdf

http://www.deadiversion.usdoj.gov/drug_disposal/fact_sheets/disposal_ltcf.pdf