Drug Disposal Resources for Terminal Distributors of Dangerous Drugs

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This guidance is intended to assist terminal distributors of dangerous drugs in the disposal of drug inventory. This document is reference material for licensees and applicants. For patient drug disposal resources visit: www.pharmacy.ohio.gov/disposal.

To assist licensees in the proper disposal of dangerous drugs, the Ohio Board of Pharmacy developed this guidance document. This guidance is broken down into the following sections:

Controlled Substances:

- How to Dispose of Controlled Substance Inventory
- Required Record Keeping for Disposal of Controlled Substance Inventory
- Disposal of Unused Portion of a Controlled Substance (Wastage)

Non-Controlled Substances:

- How to Dispose of Non-Controlled Substance Inventory
- Required Record Keeping for Disposal of Non-Controlled Substance Inventory
- Disposal of Unused Portion of a Non-Controlled Substance (Wastage)

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How to Dispose of Controlled Substance Inventory

NOTE: This section applies to the disposal of inventory. For the disposal of controlled substances resulting from wastage (e.g., administration, compounding, etc.) see this section.

OAC 4729:5-3-01 requires that a licensee dispose of all controlled substances in accordance with 21 CFR 1317. This federal regulation requires controlled substance disposal to occur using one of the following methods:

1) On-site destruction

A licensee may dispose of controlled substance inventory using an on-site method of destruction. Per federal regulations, the method of destruction must render the controlled substance(s) to a "non-retrievable" state to prevent diversion of any such substance for illicit purposes.

"Non-retrievable" means the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the dangerous drugs which are controlled substances unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A dangerous drug which is a controlled substance is considered non-retrievable when it cannot be transformed into a physical or chemical condition or state as a controlled substance or controlled substance analogue.

IMPORTANT NOTE ABOUT NON-RETRIEVABLE STANDARD AND COMMERCIAL PRODUCTS (ex. chemical digester disposal): Regardless of whether the product claims to render controlled substances non-retrievable, a licensee that disposes of a controlled substance must use a product or method that actually does render the controlled substance non-retrievable. The Ohio Board of Pharmacy, similar to the DEA, does not evaluate, review, or approve the processes or methods utilized to render a controlled substance "non-retrievable," as long as the desired result is achieved.

2) Deliver to a reverse distributor for disposal

Promptly deliver that controlled substance to a reverse distributor's registered location by either:

- Pick-up by a common or contract carrier; or
- Pick-up by a DEA-registered reverse distributor from the licensed location.

If a licensee needs assistance in finding a DEA-registered reverse distributor they may contact their Local Diversion Field Office for a current list.

NOTE: "*Common carrier"* means a person holding itself out to the general public to provide transportation for compensation (examples include FedEx, UPS, DHL, etc.).

"*Contract carrier"* means a person providing transportation for compensation under continuing agreements with one person or a limited number of persons (example may include a trucking company that only hauls goods for a single manufacturer).

3) Return to the manufacturer or distributor for the purpose of return or recall

For the purpose of return or recall, promptly deliver that controlled substance by common or contract carrier pick-up or pick-up by other authorized DEA registrants at the licensed location to either of the following:

- The DEA registered person from whom it was obtained; or
- The DEA registered manufacturer of the substance, or another registrant authorized by the manufacturer to accept returns or recalls on the manufacturer's behalf.

4) Request assistance from the DEA Special Agent in Charge

Request assistance from the DEA Special Agent in Charge of the Administration in the area in which the practitioner is located. For more information about this process, contact a Local Diversion Field Office.

IMPORTANT REMINDER: To prevent their use, OAC 4729:5-3-06 requires all adulterated or expired drugs to be stored in a separate and secure area apart from the storage of drugs used for dispensing, personally furnishing, compounding, and administration. Adulterated/expired drugs shall be stored no longer than one year from the date of adulteration or expiration by those holding a terminal distributor of dangerous drugs license. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

Required Record Keeping for Disposal of Controlled Substances from Inventory

OAC 4729:5-3-01 requires that all records of controlled substance destruction comply with 21 CFR 1304. Specifically, 21 CFR 1304.21(e) requires that any person that destroys a controlled substance or causes the destruction of a controlled substance shall maintain a record of destruction on a **DEA Form 41**.

Please be advised that while federal regulations require the name and signatures of the two employees of the registrant that witnessed the destruction to be documented on a **DEA Form 41**, Ohio regulations require the following witnesses employed by the terminal distributor of dangerous drugs to be listed on a **DEA Form 41**:

License Type	Witnesses Required on DEA Form 41
Pharmacy (Institutional, Outpatient, etc.)	Two licensed or registered healthcare professionals that witnessed the disposal (including a nurse, pharmacy technician, and technician trainee), one of whom shall be a pharmacist. **NOTE:** Institutional facilities that have patient specific medications (nursing homes, corrections, etc.) should refer to OAC 4729:5-3-01.
Clinic, First-Aid, Pain Management Clinic, Opioid Treatment Program, Limited Facility, Non-Limited Facility	Two licensed/registered health care professionals that witnessed the disposal (e.g., nurse, respiratory care therapist, MD/DO, PA, APRN, pharmacist, dentist, hygienist, etc.), one of whom shall be the responsible person or the responsible person's designee.
Veterinary Clinic	Two licensed/registered* health care professionals that witnessed the disposal (e.g., veterinarian or veterinary technician), one of whom shall be the responsible person or the responsible person's designee. *A veterinarian may use an animal aide in lieu of one of the licensed or registered healthcare professionals

	required to conduct and witness the disposal of controlled substances.
EMS	Two EMS certified personnel who witnessed the disposal. Certified emergency medical responders and emergency medical technicians may serve as a witness to the disposal but only if under the direct supervision of any of the following: ▪ A paramedic (emergency medical technician-paramedic) certified in accordance with Chapter 4765. of the Revised Code; ▪ An advanced emergency medical technician (emergency medical technician-intermediate) certified in accordance with Chapter 4765. of the Revised Code; or ▪ A licensed prescriber, registered nurse, or pharmacist who is employed or affiliated with the EMS organization.
Animal Shelters/WARFs/Dog Wardens	Two persons that witnessed the disposal, one of whom shall be the responsible person or a veterinarian, registered veterinary technician, county dog warden, or certified euthanasia technician. The other witness must be an employee or volunteer of the animal shelter, WARF, or dog warden.
Laboratories	Two laboratory employees that witnessed the disposal, one of whom shall be the responsible person or the responsible person's designee.

This chart is a summary. Licensees should review the applicable inspection guide and associated record keeping rule to ensure compliance.

RECORD RETENTION REMINDER: DEA Form 41 and all other records associated with the disposal of dangerous drugs must be maintained for ***three years*** from the date of destruction. Terminal distributors of dangerous drugs are generally required to keep required records for three years. This differs from DEA requirements, which only require records to be maintained for two years.

Disposal of Unused Portion of a Controlled Substance (Wastage)

The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized) may be destroyed using an on-site method. The on-site method **does not** have to meet the definition of non-retrievable but must render the drug unavailable and unusable.

FOR COMPOUNDERS: The disposal of unused controlled substances resulting from the compounding process are also required to be documented in accordance with section.

Records for disposal of an unused portion of a controlled substance must include the name of the drug, the quantity disposed, the date and manner of disposal, and the positive identification of two persons conducting and witnessing the disposal. Documentation of disposal may be maintained in the patient record (i.e., with administration record). **NOTE:** Federal regulations do not require this information to be documented on a **DEA Form 41**.

Ohio rules require the following witnesses to document (using positive identification) the disposal of an unused portion of a controlled substance:

License Type	Witnesses Required for On-Site Disposal of Unused Portion of a Controlled Substance
Pharmacy (Institutional, Outpatient, etc.)	Two licensed or registered healthcare professionals that witnessed the disposal (including nurse, pharmacy technicians, and technician trainees)
Clinic, First-Aid, Pain Management Clinic, Opioid Treatment Program, Limited Facility, Non-Limited Facility	Two licensed/registered health care professionals that witnessed the disposal (e.g., nurse, respiratory care therapist, MD/DO, PA, APRN, pharmacist, dentist, hygienist, etc.).
Veterinary Clinic	Two licensed/registered* health care professionals that witnessed the disposal (e.g., veterinarian or veterinary technician). *A veterinarian may use an animal aide in lieu of one of the licensed or registered healthcare

	professionals required to conduct and witness the disposal of controlled substances.
EMS	Two EMS certified personnel who witnessed the disposal. Certified emergency medical responders and emergency medical technicians may serve as a witness to the disposal but only if under the direct supervision of any of the following: ▪ A paramedic (emergency medical technician-paramedic) certified in accordance with Chapter 4765. of the Revised Code; ▪ An advanced emergency medical technician (emergency medical technician-intermediate) certified in accordance with Chapter 4765. of the Revised Code; or ▪ A licensed prescriber, registered nurse, or pharmacist who is employed or affiliated with the EMS organization.
Animal Shelters/WARFs/Dog Wardens	Two persons witnessing the disposal, one of whom shall be the responsible person or a veterinarian, registered veterinary technician, or certified euthanasia technician.
Laboratories	Two laboratory employees that witnessed the disposal.

This chart is a summary. Licensees should review the applicable inspection guide and associated record keeping rule to ensure compliance.

REMINDER: The disposal method does not have to render the unused portion of the drug non-retrievable. All records must be maintained for a period of three years.

How to Dispose of Non-Controlled Substance Inventory

NOTE: This section applies to the disposal of inventory. For the disposal of non-controlled substances resulted from wastage (e.g., administration, compounding, etc.) see this section.

OAC 4729:5-3-06 (B) requires that a licensee dispose of all non-controlled substances using a method of disposal that prevents the possession or use of the drugs by unauthorized persons.

This does not require a licensee to dispose of non-controlled drugs in the same manner as controlled substances (i.e. non-retrievable). However, the method utilized should reasonably ensure that no one would be able to utilize the medication following disposal.

Healthcare facilities and healthcare-related businesses that generate pharmaceutical waste are responsible for appropriately managing such waste in accordance with all local, state, and federal regulations. This includes RCRA regulations for managing hazardous waste pharmaceuticals, if the pharmaceuticals generated are hazardous waste. For additional information, visit:

- Ohio EPA - Hazardous Waste Pharmaceuticals
- Managing Pharmaceutical Waste in US Healthcare Facilities

Required Record Keeping for Disposal of Non-Controlled Substance Inventory

All terminal distributors are required to keep the following records of all non-controlled dangerous drugs that are disposed from a licensee's inventory:

- Name, strength, dosage form, and quantity of the dangerous drug disposed;
- The date of disposal
- The method of disposal; and
- The identification of the licensed health care professional that performed the disposal.
    - **IMPORTANT:** Positive identification is only required if non-controlled destruction is occurring at a pharmacy (outpatient or institutional) or an institutional facility.

NOTE: The above information is a summary. Licensees should review the applicable inspection guide and associated record keeping rule to ensure compliance.

To assist licensees in complying with these record keeping requirements, the Ohio Board of Pharmacy developed this ***sample*** form, which can be found here: www.pharmacy.ohio.gov/NCdispose.

RECORD RETENTION REMINDER: All records associated with the disposal of non-controlled drugs must be maintained for ***three years*** from the date of destruction. Terminal distributors of dangerous drugs are generally required to keep required records for three years.

Disposal of Unused Portion of a Non-Controlled Substance (Wastage)

Unlike controlled substances, the Ohio Board of Pharmacy **does not** have any record keeping requirements to document the disposal of wastage from administration.

FOR COMPOUNDERS: The disposal of unused non-controlled drugs resulting from the compounding process is **NOT required** to be documented.