Board of Pharmacy

INSPECTION GUIDE

Terminal Distributor of Dangerous Drugs

Emergency Medical Service Organization

Updated 3/27/2026

To review updates, please see the update history section at the end of this document.

This document is reference material for licensees and applicants. The document does not bind the Ohio Board of Pharmacy, and does not confer any rights, privileges, benefits, or immunities for or on any person, applicant, or licensee.

Applicability

This guide applies only to locations licensed as a terminal distributor of dangerous drugs that meet the following definition of an emergency medical services organization (EMS organization) in rule 4729:5-14-01 of the Ohio Administrative Code:

> *"Emergency medical service organization" means a public or private organization using first responders, EMTs-basic, EMTs-I, or paramedics, or a combination of first responders, EMTs-basic, EMTs-I, and paramedics, to provide emergency medical services.*

REMINDER: This inspection guide **does not apply** to pharmacies, institutional facilities, or any of the following license types that have their own corresponding chapter of the Ohio Administrative Code:

- Pain Management Clinics – 4729:5-11
- First Aid Departments – 4729:5-13
- Animal Shelters – 4729:5-15
- Laboratories – 4729:5-16
- Clinic and Prescriber Offices – 4729:5-19
- Veterinary Clinics – 4729:5-20
- Opioid Treatment Programs – 4729:5-21
- Non-Limited Facilities – 4729:5-22
- Limited Facilities – 4729:5-23

Inspection Authority

Pursuant to section 3719.13 of the Revised Code and rule 4729:5-3-03 of the Administrative Code, a location licensed by the State Board of Pharmacy as a terminal distributor of dangerous drugs is subject to an on-site inspection by the Board. An authorized Board agent may, without notice, carry out an on-site inspection or investigation of an entity licensed by the Board.

Upon verification of the Board agent's credentials, the agent shall be permitted to enter the licensed entity.

Submission of an application for a license as a terminal distributor of dangerous drugs with the State Board of Pharmacy constitutes permission for entry and on-site inspection by an authorized Board agent.

After the completion of the inspection, the authorized Board agent will provide an inspection report for review and any corrective actions required. If the inspection report requires a written response, responses must be mailed within 30 days of the inspection to writtenresponse@pharmacy.ohio.gov.

Applicable Rules

The following provides a general list of rule chapters that apply to EMS organizations licensed as terminal distributor of dangerous drugs:

- **4729:5-1 – Definitions**
- **4729:5-2 – Licensing**
- **4729:5-3 – General Terminal Distributor Provisions**
- **4729:5-4 – Disciplinary Actions**
- **4729:5-14 – Emergency Medical Service Organizations**
  - 4729:5-14-01 – Emergency medical services - definitions.
  - 4729:5-14-02 – Licensure.
  - 4729:5-14-03 – Security and control of dangerous drugs.
  - 4729:5-14-04 – Record keeping.
  - 4729:5-14-05 – Protocols and verbal orders for drug administration.

Health Insurance Portability and Accountability Act (HIPAA)

Upon inspection, Board staff may ask to review patient records to determine compliance with Ohio laws and rules. To address concerns regarding compliance with HIPAA, the Board has developed the following FAQ to assist licensees.

What is HIPAA?

- HIPAA is a federal privacy rule created to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically.

Why does the HIPAA privacy rule not apply to the Ohio Board of Pharmacy?

- HIPAA applies to health plans, health clearinghouses, and to any health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted standards under HIPAA, known as "covered entities" and to their business associates.
    - The Board of Pharmacy does not fit the definition of a covered entity because:
        1) The Board does not provide or pay for the cost of medical care;
        2) The Board is not a health care provider; and
        3) The Board does not process health information on behalf of other organizations (billing, community health management information systems, etc.).
- In addition, the Board is not considered a "business associate" because it does not perform activities on behalf of or provide services to a covered entity (as described in 1-3 above) that involves the use or disclosure of identifiable health information.
- Examples of a business associate include, but are not limited to, the following: third-party administrators that assist with claims processing or a consultant that performs utilization review for a hospital.

How can a licensee be assured the Board will protect patient information?

- The Board's confidentiality statute, ORC 4729.23, provides that any information provided to the Board in the course of an investigation is confidential and is not a public record.
- In addition, there are exemptions in Ohio's Public Records law that exempt medical records/patient information from being released in response to a public record request (ORC Section 149.43(A)(1)(a)).

For more information about the HIPAA Privacy Rule, visit: https://www.hhs.gov/hipaa/for-professionals/privacy/index.html

Positive Identification Guidance

"Positive identification" means a method of identifying a person that does not rely on the use of a private personal identifier such as a password, but must use a secure means of identification that includes any of the following:

(1) A manual signature on a hard copy record;

(2) A magnetic card reader;

(3) A bar code reader;

(4) A biometric method;

(5) A proximity badge reader;

(6) A board approved system of randomly generated personal questions;

(7) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who performed the action requiring positive identification. The printout must be maintained for three years and made readily retrievable; or

(8) Other effective methods for identifying individuals that have been approved by the board.

NOTE: A method relying on a magnetic card reader, a bar code reader, a proximity badge reader, or randomly generated questions for identification must also include a private personal identifier.

REMINDER: Positive identification should be at the conclusion of a drug transaction. For electronic systems, positive identification required at log-in does not document the specific drug transaction and causes other security problems. For example, a nurse does not document the administration of a medication when they log in to an electronic drug record keeping system.

SPECIAL NOTICE FOR EMS ORGANIZATIONS: The use of electronic signatures is permissible to capture drug administration by EMS personnel. An electronic signature means any of the following:

(1) A private, unique personal identifier and secure passcode consisting of a combination of letters, numbers, and symbols that is adapted or executed by an individual as that individual's electronic signature.

(2) An electronic image of an individual's handwritten signature that is captured following drug administration and is created by using a writing apparatus (i.e., stylus). The signature shall be legible and include the person's first name, last name, and credentials.

Distribution of Overdose Reversal Medications by EMS Personnel (e.g., Naloxone)

Ohio law (ORC 3715.50) permits any person or government entity to purchase, possess, personally furnish, and distribute an overdose reversal drug (ORD) without a prescriber-authorized protocol if all the following conditions are met:

(1) The overdose reversal drug is in its original manufacturer's packaging.

(2) The overdose reversal drug's packaging contains the manufacturer's instructions for use.

(3) The overdose reversal drug is stored in accordance with the manufacturer's or distributor's instructions.

Per Board Resolution (Adopted February 2023), an EMS organization is not required to maintain any patient-specific record keeping requirements for the distribution of naloxone and other overdose reversal drugs.

For additional information on distribution of overdose reversal drugs in Ohio, visit: www.pharmacy.ohio.gov/ORD.

Required Notifications or Document Submissions

Links to instructions and forms can be found in the table below and can also be accessed on the Board's terminal distributor licensing page: https://www.pharmacy.ohio.gov/Licensing/TDDD.aspx

Ohio Board of Pharmacy rules require the following notifications to the Board:

Notification/Submission Requirement	How to Submit
Change in Business Description *OAC 4729:5-2-03* Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted **within thirty days** of any change in the ownership, business or trade name, category, or address.	A change of business description must be completed online using Ohio's eLicense system. Instructions on submitting this information can be accessed **here**.
Discontinuation of Business *OAC 4729:5-2-04* A terminal distributor of dangerous drugs who plans to discontinue business activities shall file a notice with the Board of Pharmacy. The notice shall be submitted, in a manner determined by the Board, **within thirty days of discontinuation of business** as a terminal distributor of dangerous drugs.	Requires submission of a **Written Notice of Discontinuing Business Form**.
Change of Responsible Person/Medical Director *OAC 4729:5-2-01* A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified **within ten days** of the effective date of the appointment of the new responsible person. ***Notification shall include a current drug list signed by the new medical director.***	Requires submission of a **Change of Responsible Person Request in eLicense Ohio.**

Drug List Modifications OAC *4729:5-14-02* An EMS organization may only possess those controlled substances and dangerous drugs that are on the drug list submitted to the Board at the time of application. The EMS organization's medical director may modify the drugs that may be possessed and administered by the EMS organization by submitting a new drug list in a manner determined by the Board. **REMINDER:** A modification to the drug list shall require an update to the EMS organization's protocols. Any updates or changes to the protocols shall only be submitted to the Board upon request. **IMPORTANT:** When uploading a drug list, it will replace the current drug list on file. The list should include all drugs (not just updates) that may be purchased and possessed by the licensee. Click here to review a licensee's current drug list.	Requires electronic submission of a signed drug list. A sample drug list along with instructions for submission can be accessed **here**. A licensee may submit drug list using a different format but it must include all of the components of the **sample drug list** provided by the Board.
Storage of Records at EMS Organization Headquarters *OAC 4729:5-14-04* Records from EMS satellites may be stored at the EMS organization headquarters if prior approval is obtained by the EMS organization.	Requires submission of a **EMS Request for Satellite Record Storage at Headquarters Form**.
Theft or Significant Loss of Dangerous Drugs and Drug Documents *OAC 4729:5-3-02* Licensees are required to report the theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) and drug documents.	For more information on this requirement, the Board developed this guidance document.

Important Terms

- **"Controlled substance"** means a drug, compound, mixture, preparation, or substance included in Schedule I, II, III, IV, or V.

- **"Dangerous drug"** means any of the following:

  (1) Any drug to which either of the following applies:

  (a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

  (b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

  (2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

  (3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body;

  (4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

- **"Direct supervision"** or **"personal supervision"** means EMS organization personnel shall be physically present at the licensed location or within the immediate proximity of an EMS unit to deter and detect the diversion of dangerous drugs.

- **"Distributor of dangerous drugs"** or "drug distributor" means the following persons licensed in accordance with section 4729.52 of the Revised Code:

  (1) Wholesale distributors of dangerous drugs, including:

  (a) Brokers; and

(b) Virtual wholesalers.

(2) Manufacturers of dangerous drugs.

(3) Outsourcing facilities.

(4) Third-party logistics providers.

(5) Repackagers of dangerous drugs.

- **"Medical director"** means a physician to whom an EMS organization has designated, pursuant to section 4765.42 of the Revised Code, to perform the duties of medical director including establishing medical protocols that must be followed in the delivery of emergency medical services. The program medical director shall be registered with the United States Drug Enforcement Administration (DEA) pursuant to 21 U.S.C. 823.

- **"Readily retrievable"** means that records maintained in accordance with this division shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer, or inspector of the Board.

- **"Personally furnish"** or "personally furnishing" means the final association of a drug with a patient by a prescriber prior to the distribution to a patient for use outside the prescriber's practice setting.

- **"Satellite"** means a location licensed by the State Board of Pharmacy as a terminal distributor of dangerous drugs that is separate from the licensed headquarters of the EMS organization.

- **"Tamper-evident"** means a package, storage container, or other physical barrier that is sealed or secured in such a way that access to the drugs stored within is not possible without leaving visible proof that such access has been attempted or made.

Inspection Guide Table of Contents

Section Title	Page No.
Licensing, Responsible Person, & Medical Director	15
Personnel	16
Drug List & Protocols	19
Record Keeping System	21
Drug Administration Records & Oxygen Transfilling	23
Drug Purchases & Hospital Drug Exchanges	24
Drug Disposal	27
Drug Security & Expired/Adulterated Drugs	32
Drug Storage & Temperature Control	37
Theft or Significant Loss of Drugs and Drug Documents	40
Controlled Substance Inventory	42
Recall Procedures	44
Buprenorphine Administration to Treat Opioid Use Disorder	46
Additional Frequently Asked Questions for EMS	48

Emergency Medical Service (EMS) Organization - Inspection Guide

OAC = Ohio Administrative Code / ORC = Ohio Revised Code / CFR = Code of Federal Regulations

Licensing, Responsible Person, & Medical Director

Question	Description / Guidance	Law/Rule
Have there been any changes in the licensee's ownership, business name or trade name, category, or address without submitting a new application to the Board?	Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application, required fee, and license. The new application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.	OAC 4729:5-2-03
Does the responsible person/medical director match what is indicated in eLicense?	A location licensed as a terminal distributor of dangerous drugs must have a responsible person at all times. When there is a change of responsible person, the Board must be notified within ten days of the effective date of the appointment of the new responsible person. A new responsible person must be designated using eLicense. For detailed instructions, use this link: **Change of Responsible Person Request in eLicense Ohio**.	OAC 4729:5-2-01
Does the EMS organization have a medical director that possesses a valid DEA registration?	An EMS organization medical director shall be registered with the United States Drug Enforcement Administration.	OAC 4729:5-14-01

Personnel

Question	Guidance	Law/Rule
Does the EMS organization have a current personnel list?	As part of the initial licensing process, an EMS organization is required to submit a list of personnel employed, including volunteers, by the EMS organization who may access and administer dangerous drugs, which includes the name of each employee or volunteer, level of certification, certification number, and expiration date. Any change of the EMS organization's personnel list shall be updated within thirty days of a change of personnel. An EMS organization is required to maintain a current copy or have access to a current copy of the organization's personnel list at each licensed location. Updated personnel lists should not be submitted to the Board.	OAC 4729:5-14-02
Have any licensed/registered employees at the EMS organization with access to drug stock ever been disciplined by an Ohio licensing agency?	"Access to drug stock" includes not only physical access, but also any influence over the handling of dangerous drugs such as purchases, inventories, issuance of medical orders, etc. It does not include employees or contractors such as maintenance, janitorial, IT, or other staff that may need limited supervised access to areas where dangerous drugs or DEA controlled substance order forms are kept. Disciplinary action means any of the following, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement: (1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration, or certification;	OAC 4729:5-1-01 OAC 4729:5-4-01

	(2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action; (3) An administrative fine or money penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration, or certification actions, such as revocation, suspension, censure, reprimand, or probation; (4) An action to reprimand or place the license, registration, or certification holder on probation; (5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration, or certification actions, such as revocation, suspension, reprimand, probation, or surrender; (6) The withdrawal of a renewal application for licensure, registration, or certification while under investigation; (7) The non-renewal of a license, registration, or certification while under investigation or to avoid an investigation; (8) The surrender or other relinquishment of a license, registration, or certification in lieu of a formal sanction against a person's license, registration, or certificate, whether permanent or temporary;	

	(9) In lieu of an adverse licensure, registration, or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license, registration, or certification in the future; (10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.	

Drug List & Protocols

Question	Guidance	Law/Rule
Does the EMS organization's drug list match the list on-file with the Board?	An EMS organization may only possess drugs that are on the drug list submitted to the Board and signed by the EMS organization's medical director. An EMS organization is required to maintain a current copy or have access to a current copy of the organization's drug list at each licensed location. The drug list on file can be accessed here: www.pharmacy.ohio.gov/DL	OAC 4729:5-14-02
Does the EMS organization possess any dangerous drugs that are not on the drug list on file with the Board?	An EMS organization may only possess drugs that are on the drug list submitted to the Board and signed by the EMS organization's medical director. The medical director may modify the drugs that may be possessed and administered by EMS organization personnel by submitting a new drug list to the Board. For each drug possessed and administered, the EMS organization must list the brand/generic name of the drug, strength to be stocked, and the dosage form. While not required to be used, a drug list template can be accessed here: www.pharmacy.ohio.gov/druglist.	OAC 4729:5-14-02 ORC 4729.54
Does the EMS organization have protocols signed by the medical director?	As part of the initial licensing process, an EMS organization is required to submit a copy of the organization's protocols signed by the medical director.	OAC 4729:5-14-02 ORC 4729.54

	Any modification to the EMS organization’s drug list requires an update to the EMS organization's protocols. Updates to protocols **ARE NOT REQUIRED** to be submitted to the Board. An EMS organization is required to maintain a current copy or have access to a current copy of the organization's protocols at each licensed location.	

Record Keeping System

Question	Guidance	Law/Rule
Does the EMS organization use a manual, computerized, or combination of both to maintain drug records?	Describe what type of system (manual, electronic, or both).	
If using a computerized record keeping system, does the system have effective security controls to prevent unauthorized access?	All computerized systems must contain security features to prevent unauthorized access. Such features may include unique usernames and passwords, biometrics (i.e., fingerprint), or any other method that ensures only authorized users may obtain access. All methods for accessing electronic records must be user-specific (i.e., no shared usernames or passwords).	OAC 4729:5-14-04
If using a computerized system, are records backed up daily to prevent record loss?	Licensee should provide documentation demonstrating that computerized records are backed up daily.	OAC 4729:5-14-04
If using computerized record keeping system, is it stand-alone or able to be shared or accessed by another location?	If shared access, confirm that security features are in place to prevent unauthorized access from other locations.	OAC 4729:5-14-04
Does the EMS organization scan and electronically maintain paper records?	All paper records shall be scanned in full color via technology designed to capture information in one form and reproduce it in an electronic medium presentable and usable to an end user.	OAC 4729:5-14-04

Are records maintained at the licensed location for three years?	All records of receipt, distribution, administration, selling, disposing, destroying, or using dangerous drugs shall be maintained for a period of three years at the place where the dangerous drugs are located. Records from satellites may be stored at the EMS organization headquarters if prior approval is obtained by the EMS organization.	OAC 4729:5-14-04
FOR SATELLITE SITES ONLY: Is the satellite site approved to maintain records at the EMS organization headquarters?	Records from satellites may be stored at the EMS organization headquarters if prior approval is obtained by the EMS organization.	OAC 4729:5-14-04
Are all required records uniformly maintained and readily retrievable?	All drug records must be uniformly maintained and readily retrievable (e.g., can be produced for review no later than three business days to an agent, officer, or inspector of the Board.)	OAC 4729:5-14-04

Drug Administration Records & Oxygen Transfilling

Question	Guidance	Law/Rule
Does the EMS organization maintain records of drug administration containing the required information?	Records of administering drugs must be legible and shall contain the first and last name of the EMS personnel who administered the drug, name of the EMS organization, name and strength of the drug administered, date of administration, time of administration, amount of the drug administered, and the name or other means of identifying the patient, such as medical record number or run number.	OAC 4729:5-14-04
Does the EMS organization capture the identification of the administering EMS personnel?	Records of administering drugs must capture the identification of the individual administering the drug using either of the following methods: (1) An electronic signature in a computerized recordkeeping system; or (2) Any form of positive identification.	OAC 4729:5-14-04
Do records of oxygen transfilling include manufacturer's lot number?	Records of oxygen transfilling shall include the manufacturer's lot number of the oxygen used for transfilling the portable oxygen tanks. **REMINDER:** If there is a recall of oxygen by the manufacturer, all portable oxygen tanks affected by the recall shall be handled in accordance with the manufacturer's recall instructions.	OAC 4729:5-14-04

Drug Purchases & Hospital Drug Exchanges

Reminder on Verification of Licensure by an Institutional Pharmacy or Facility: *In lieu of requiring an EMS organization to maintain a copy of its protocol and personnel list with the institutional pharmacy or institutional facility (e.g., free standing emergency department), the Board permits an institutional pharmacy/facility to satisfy this requirement by conducting an annual query to ensure the EMS organization is properly licensed as a terminal distributor of dangerous drugs. This also satisfies the licensure verification requirements of OAC 4729:5-3-04. See OAC 4729:5-3-04 (D)(3).*

Question	Guidance	Law/Rule
Does the licensee maintain complete and accurate records of drugs purchased/received?	Records of receipt/purchase shall contain the name, strength, dosage form, and quantity of the dangerous drugs received; the name and address of the seller; the name and address of the recipient; and the date of receipt. An invoice from a drug distributor (e.g., wholesaler) licensed in accordance with division 4729:6 of the Administrative Code or a hospital pharmacy or facility owned by a hospital (e.g., freestanding emergency department) providing drugs on a "replacement basis" (sometimes referred to as a 1:1 exchange) containing the required information may be used to meet this requirement. Records must be maintained for a period of three years. Board staff will review records of receipt to determine compliance.	OAC 4729:5-14-04
Has the licensee performed and documented an annual query of eLicense prior to purchasing drugs at wholesale?	Before a terminal distributor of dangerous drugs may purchase dangerous drugs at wholesale (including samples), the terminal distributor shall query the Board's online roster to confirm any of the following:	OAC 4729:5-3-04

	(1) The seller is licensed to engage in the sale of dangerous drugs in accordance with section 4729.52 of the Revised Code (i.e., wholesaler, manufacturer, repackager, outsourcing facility, or 3PL); or (2) The seller is licensed to engage in the occasional sale or distribution of dangerous drugs at wholesale in accordance with rule 4729:5-3-09 of the Administrative Code (i.e., pharmacies or other terminal distributors). If a licensed terminal distributor of dangerous drugs conducts a documented query at least annually and relies on the results of the query in purchasing dangerous drugs, the terminal distributor shall be deemed not to have violated section 4729.51 of the Revised Code in making the purchase. Documented queries must be maintained for three years. Board staff will review drug invoices and compare them to documented queries of eLicense.	
Does the licensee engage in the occasional sale of dangerous drugs?	If yes, records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code must contain the name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold; the address of the location where the drugs were transferred or sold; and the date of transfer or sale. **NOTE:** This includes intracompany transfers/sales and occasional sales.	OAC 4729:5-3-09 ORC 4729.51 OAC 4729:5-14-04

	Occasional sales by EMS organizations (i.e., sales outside of a commonly owned company/organization) are limited to overdose reversal drugs (e.g., naloxone) and drugs that are in shortage. "Drug shortage," with respect to an occasional sale, means a drug on the United States Food and Drug Administration's drug shortage list that is not commercially available regardless of the reason that the drug is not available, including the absence of a manufacturer for the drug or the lack of a readily available supply of the drug from a manufacturer or wholesaler. Board staff will review records to determine compliance.	

Drug Disposal

Question	Guidance	Rule/Law
Does the EMS organization return controlled substance inventory that is expired or otherwise adulterated back to the institutional pharmacy or facility where it was obtained for disposal?	Unless the EMS organization is registered with the United States Drug Enforcement Administration (DEA), any controlled substance that is expired or otherwise adulterated shall be returned to the institutional pharmacy or facility that is owned or operated by a hospital where the EMS organization originally procured the drugs. This does not apply to the disposal of unused portions of controlled substances resulting from patient administration.	OAC 4729:5-14-03
Does the EMS organization maintain the required records for the return of dangerous drugs back to the institutional pharmacy or facility where it was originally obtained?	All EMS organizations shall keep a record of all dangerous drugs transferred. Records shall include name, strength, dosage form, and quantity of the dangerous drug transferred for disposal. It shall also include the name and address of the institutional pharmacy or facility accepting the drugs for return and disposal and the date the transfer was conducted. **NOTE:** While not required to return non-controlled drugs for disposal, an EMS organization may utilize an institutional pharmacy and facility for disposal of non-controlled drugs if those drugs were obtained from that pharmacy or facility. All records must be maintained for a period of three years.	OAC 4729:5-14-03
IF EMS ORGANIZATION HAS A DEA REGISTRATION: Does the licensee dispose of controlled substances on-site using a method that	Any person legally authorized under Chapters 3719. and 4729. of the Revised Code to possess dangerous drugs which are controlled substances shall dispose of such drugs in accordance with 21 C.F.R. 1317. The method of destruction must render the dangerous drugs which are controlled substances to a state of non-retrievable. Records	OAC 4729:5-3-01

renders the drug non-retrievable?	of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (1/1/2016) shall be maintained for a minimum of three years and made available to the Board of Pharmacy upon request. "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 to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes. **NOTE:** Per the Drug Enforcement Administration, flushing (i.e., drain or toilet) does not meet the definition of non-retrievable. A licensee is responsible for maintaining documentation demonstrating that the method of disposal meets the requirement to render controlled substances non-retrievable. All records must be maintained for a period of three years.	
IF EMS ORGANIZATION HAS A DEA REGISTRATION: Does	If yes, Board staff will document the name of the reverse distributor.	OAC 4729:5-14-03

the licensee use a reverse distributor for the disposal of controlled substances?	**NOTE:** This is only permissible if the EMS organization has a registration with the Drug Enforcement Administration (DEA).	
IF EMS ORGANIZATION HAS A DEA REGISTRATION: Does the licensee maintain complete and accurate records of the disposal of controlled substances?	A licensee must use a DEA Form 41 to document the disposal of controlled substances. **NOTE:** Use of the DEA Form 41 does not apply to the disposal of an unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply. If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification on the DEA Form 41 of two licensed/certified healthcare professionals conducting and witnessing the disposal. The disposal of controlled substances shall be conducted by two licensed or certified EMS personnel, one of whom shall be: ▪ 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	OAC 4729:5-3-01 OAC 4729:5-14-04 OAC 4729:5-14-03

	▪ A licensed prescriber, registered nurse, or pharmacist who is employed or affiliated with the EMS organization. All records must be maintained for a period of three years. Board staff will review records of disposal to determine compliance.	
Does the licensee maintain complete and accurate records of the disposal of unused portions of controlled substances resulting from patient administration?	Records for the disposal or destruction of the unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed; the date disposed; the method of disposal; and the positive identification of the two EMS personnel who disposed of the drugs. **NOTE:** At least **one** of the EMS personnel witnessing the disposal must be authorized to administer controlled substances under their professional license (paramedic, advanced emergency medical technician, prescriber, nurse, pharmacist). 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. Board staff will review records of disposal to determine compliance.	OAC 4729:5-3-01 OAC 4729:5-14-03 OAC 4729:5-14-04
Does the licensee dispose of non-controlled drugs using a method that prevents the	Methods of disposal of non-controlled dangerous drugs must prevent the possession or use of the drugs by unauthorized persons.	OAC 4729:5-3-06

possession or use of the drugs by unauthorized persons?		
Does the licensee maintain complete and accurate records of the disposal of non-controlled dangerous drugs?	Records of disposal of dangerous drugs from inventory, other than controlled substances, shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed; the date of disposal; the method of disposal; and the positive identification of the EMS personnel that performed the disposal. **NOTE:** This does not apply to wastage from administration. For non-controlled drugs, such documentation is not required. To assist licensees in complying with the record keeping requirements for the disposal of non-controlled drugs from inventory, the Board developed a sample form that can be accessed by visiting: www.pharmacy.ohio.gov/NCdispose All records must be maintained for a period of three years.	OAC 4729:5-14-04

Drug Security & Expired/Adulterated Drugs

Question	Guidance	Law/Rule
Are all controlled substances physically secured with access limited to authorized EMS personnel?	All controlled substance dangerous drugs maintained by the EMS organization shall be physically secured with access limited to the following persons: ▪ 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. **NOTE:** A certified emergency medical responder or emergency medical technician (e.g., EMT-B) may have access to controlled substances **only** under the direct supervision of the individuals listed above and **only** for the following purposes: ▪ For the purpose of documenting the disposal of an unused portion of a controlled substance resulting from administration to a patient; or ▪ For the purpose of documenting the disposal of controlled substances.	OAC 4729:5-14-03

	REMINDER: An emergency medical technician (e.g., EMT-B) may also have access to a supply of buprenorphine. See Buprenorphine Administration to Treat Opioid Use Disorder section for more information.	
Are non-controlled drugs maintained by the EMS organization under direct supervision of licensed or certified EMS personnel?	All non-controlled dangerous drugs maintained by the EMS organization shall be maintained under the direct supervision of licensed or certified EMS personnel employed or affiliated with the EMS organization to deter and detect the diversion of dangerous drugs.	OAC 4729:5-14-03
Are non-controlled drugs physically secured when direct supervision is not possible?	If direct supervision is not possible, the licensed location is not currently in use, or the facility is being utilized to hold an event attended by persons other than licensed or certified EMS personnel, all non-controlled dangerous drugs shall be physically secured with access limited to licensed or certified EMS personnel, except for the following if stored in a sealed, tamper-evident manner: ▪ Solutions labeled for irrigation use; ▪ Dextrose solutions; ▪ Saline solutions; ▪ Lactated ringers; ▪ Sterile water; and ▪ Naloxone hydrochloride or other overdose reversal drug as defined in rule 4729-8-01 of the Administrative Code.	OAC 4729:5-14-03
Are multi-dose vials properly labeled?	Upon the initial puncture of a multiple-dose vial containing a drug, the vial shall be labeled with a beyond-use date or date opened. The beyond-use date for an opened or entered (e.g., needle punctured)	OAC 4729:5-14-03

	multiple-dose container with antimicrobial preservatives is twenty-eight days, unless otherwise specified by the manufacturer. A multiple-dose vial that exceeds its beyond-use date shall be deemed adulterated.	
Are there expired/adulterated drugs present in the licensee's active drug stock?	Board staff will conduct a check for expired drugs/adulterated drugs, including, but not limited to, the following: ▪ Expired drugs in common stock areas. ▪ Multidose vials that have been opened/punctured and exceed twenty-eight days from the date of puncture, unless otherwise specified by the manufacturer. ▪ Adulterated drugs in common stock areas (partial vials of single-dose injectable drugs). If the vial says single use, and it has been punctured/used, it must be discarded and may not be used again. ▪ **NOTE:** The following are also considered expired or adulterated and should not be present in a licensee's active drug stock: o A device containing dangerous drugs must be used by the date/time indicated on the manufacturer's labeling or, if no such date exists, may only be used for up to six hours following preparation.	OAC 4729:5-3-06 OAC 4729:5-14-03

	○ A conventionally manufactured sterile dangerous drug product that is reconstituted must be used by the date/time indicated on the manufacturer's labeling or, if no such date exists, may only be used for up to six hours following preparation. ○ A conventionally manufactured sterile dangerous drug product that is diluted (i.e., diluting or mixing into a syringe to administer directly to a patient) must be used within six hours of preparation.	
Are expired/adulterated drugs appropriately segregated from the licensee's active drug stock?	Expired/adulterated drugs must be stored separately from active drug stock in a manner that prohibits access by unauthorized persons. Expired/adulterated controlled substances that are segregated must be secured in the same manner as active controlled substance stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored where active controlled substance stock is maintained but segregated in a manner that is clear to all who see it that the drugs may not be used. Expired/adulterated non-controlled substance drugs must be segregated from the active drug stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored in common stock areas but segregated in a manner that is clear to all who see it that the drugs may not be used.	OAC 4729:5-3-06 OAC 4729:5-14-03

Are expired/adulterated drugs stored no longer than one year from the date of expiration/adulteration?	Expired/adulterated drugs shall be stored no longer than one year from the date of expiration/adulteration by those holding a terminal distributor of dangerous drugs license. Board staff will review expired/adulterated drugs to confirm.	OAC 4729:5-3-06

Drug Storage & Temperature Control

Question	Guidance	Law/Rule
Are areas where dangerous drugs are stored dry, well-lit, well-ventilated, and maintained in a clean and orderly condition?	All areas where dangerous drugs are stored must be dry, well-lit, well-ventilated, and maintained in a clean and orderly condition.	OAC 4729:5-14-03
Are drug storage areas maintained at temperatures and conditions which will ensure the integrity of the drug stock?	Storage areas must be maintained at temperatures and conditions which will ensure the integrity of the drugs prior to use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling. There is not a requirement for monitoring room temperature; however, Board staff may document temperature readings if storage areas are excessively hot or cold.	OAC 4729:5-14-03
Are refrigerators and/or freezers used for the storage of drugs maintained at the proper temperature?	The facility must maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained: (1) Temperature logs with, at a minimum, daily observations; or (2) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion. Records of temperature control monitoring for refrigerators and freezers used for the storage of drugs must include any of the following: (1) For temperature logs, either:	OAC 4729:5-14-03

	(a) The date and time of observation, the full name or the initials of the individual performing the check, and the temperature recorded; or (b) For systems that provide automated temperature monitoring, maintain a report that provides, at a minimum, the date and time of observation and the temperature recorded. (2) For temperature monitoring systems capable of detecting and alerting staff of a temperature excursion, maintain reports that provide information on any temperature excursion that includes the date, time, temperature recorded, and length of each excursion. **NOTE:** A licensee may select the appropriate method for monitoring temperature (i.e., electronic, manual, etc.). Temperature readings should be available for review by Board staff.	
Does the licensee have a policy to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs?	A licensee is required to develop and implement policies and procedures to respond to any out-of-range individual temperature readings or excursions to ensure the integrity of stored drugs. The policy should be made available for review upon inspection and should describe, at a minimum, all the following: ▪ The actions to be taken in the event of temperature excursions outside the labelled storage conditions.	OAC 4729:5-14-03

	▪ The process for appropriately investigating, documenting, and assessing temperature excursions outside the labelled storage conditions to ensure the integrity of the drug stock (for example, stability data or technical justification).	
Are refrigerators and/or freezers used for the storage of drugs free of food or beverage products?	A licensee is required to develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs. The policy should be made available for review upon inspection and all refrigerators and freezers used for drug storage will be examined to ensure compliance. **NOTE:** Licensees may keep unopened bottled water in the refrigerator doors to help maintain consistent temperatures.	OAC 4729:5-14-03

Theft or Significant Loss of Drugs and Drug Documents

Question	Guidance	Law/Rule
Has the licensee experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?	A licensee is required to notify the Board of any theft or significant loss of dangerous drugs (controlled and non-controlled prescription drugs) immediately upon discovery of the theft or significant loss. This includes dangerous drugs in transit that were either shipped from or to a prescriber, terminal distributor, or drug distributor. In addition to the initial notification requirements, a licensee is required to submit a detailed report of the theft or significant loss to the Board using the online portal within thirty days following the discovery of such theft or significant loss. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	OAC 4729:5-3-02
Has the licensee experienced any theft or loss of uncompleted prescription blank(s), written prescription order(s) not yet dispensed, or DEA controlled substance order forms in the past twenty-four months?	A licensee is required to report, immediately upon discovery, to the Board any theft or loss of uncompleted prescription blank(s) used for writing a prescription, DEA controlled substance order forms (Form 222), written prescription order(s) not yet dispensed, and original prescription order(s) that have been dispensed. Unlike dangerous drugs, a licensee is not required to submit a detailed follow-up report within thirty days of the initial report of theft or loss of drug documents.	OAC 4729:5-3-02

	NOTE: Unlike dangerous drugs, drug documents do not have a significant loss threshold. Therefore, all losses (in addition to thefts) must be reported to the Board. **REMINDER:** For more information on reporting theft or loss, visit: www.pharmacy.ohio.gov/theft	

Controlled Substance Inventory

Question	Guidance	Law/Rule
Does the licensee conduct an annual inventory of controlled substances that includes all the required information?	All Category III licensees must complete an annual inventory **even if drugs are not on-site** (zero balance). Records of inventories must be maintained for at least three years. Inventories must follow the process established by the Drug Enforcement Administration (DEA) for conducting a controlled substance inventory. Each inventory must contain a complete and accurate record of all controlled substances on hand the date the inventory is conducted. **IMPORANT:** According to the DEA, controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the TDDD, including controlled substances that are expired or adulterated controlled substances awaiting disposal. The inventory must have the names of the controlled substances, each finished form, the number of units, and/or the number of commercial containers of each finished form. If listed in Schedules I or II, make an exact count or measure of the contents. If listed in Schedule III, IV, or V, make an estimated count or measure of the contents, unless the container holds more than 1,000 tablets or capsules, in which case the licensee must make an exact count of the contents.	OAC 4729:5-14-04 OAC 4729:5-3-07

	NOTE: The annual inventory may be taken on any date which is within thirteen months of the previous inventory date. Board staff will review records to determine compliance.	
How does the licensee monitor its inventory of controlled substances?	Board staff will review and document how the licensee monitors its inventory of controlled substances (e.g., daily count, perpetual inventory, etc.).	

Recall Procedures

For more information on this rule, see our Recall Procedures for Terminal Distributors document: www.pharmacy.ohio.gov/recalls

Question	Description / Guidance	Law/Rule
Does the licensee have written procedures in place to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee?	An EMS organization licensed as a terminal distributor of dangerous drugs is required to develop and implement a written procedure to manage recalls for the dangerous drugs stocked, dispensed, or personally furnished by the licensee. Such procedures must be regularly updated as necessary and must be readily retrievable (e.g., produced within three business days) upon request.	OAC 4729:5-3-18
Does the licensee's written recall procedures include all the requirements established in rule?	The written recall procedures must include all of the following: 1. The terminal distributor must, where appropriate, contact patients to whom the recalled drug products have been dispensed or personally furnished. 2. The terminal distributor must make a reasonable attempt to ensure that a recalled drug has been removed from inventory no later than the next business day after receipt of the recall notice by the terminal distributor's responsible person or the responsible person's designee, and quarantined until proper disposal, destruction, or return of the drug. **IMPORTANT:** If a drug that is subject to a recall is maintained by the terminal distributor in a container without a lot number, the terminal distributor shall consider this drug included in the recall.	OAC 4729:5-3-18

	3. Maintaining all required documentation and records for activities taken by the terminal distributor in relation to a drug recall. **NOTE:** All records documenting recall activities shall be maintained for three years and shall be made readily retrievable.	
Does the licensee maintain records documenting recall activities in a readily retrievable manner?	All records documenting recall activities shall be maintained for three years and shall be made readily retrievable (e.g., produced within three business days).	OAC 4729:5-3-18

Buprenorphine Administration to Treat Opioid Use Disorder

The administration of an initial dose of buprenorphine by EMS are often referred to as "Bridge Programs." For more information on the operation of Bridge Programs by EMS, see the State Board of Emergency Medical, Fire, and Transportation Services' Guidelines: https://ems.ohio.gov/about-us/state-board-of-emfts/state-board-guidelines

Question	Description / Guidance	Law/Rule
Does the EMS organization's protocol permit the administration of buprenorphine?	An emergency medical services professional with a certificate to practice and acting within their scope of practice may administer directly (but not prescribe) an initial dose of buprenorphine, or another medication for opioid use disorder approved by the Board, to a patient who is experiencing opioid use disorder in accordance with a protocol approved by the organization's medical director. **NOTE:** Any buprenorphine administered in accordance with a protocol authorized by the medical director is exempted from reporting to the drug database (i.e., OARRS). Currently, no other medications have been approved by the Board other than buprenorphine. All formulations of the medication are permissible under this rule if authorized under the protocol signed by the EMS organization's medical director.	OAC 4729:5-14-05
Does the EMS organization's protocol ensure that the EMS organization is able to provide a direct linkage to a program or prescriber who will continue the patient's therapy?	If the EMS organization has a buprenorphine administration protocol to treat opioid use disorder, the protocol must ensure that the EMS organization is able to provide a direct linkage to a program or prescriber who will continue the patient's therapy.	OAC 4729:5-14-05

Are emergency medical technicians (EMT-B) authorized to administer buprenorphine pursuant to a protocol?	If yes, buprenorphine must be stored in a manner that does not permit an emergency medical technician access to other controlled substance dangerous drugs maintained by the EMS organization.	OAC 4729:5-14-05

Additional Frequently Asked Questions for EMS

1. What does the term “controlled substance” mean?

“Controlled substance” as defined in ORC 3719.01 means a drug, compound, mixture, preparation, or substance included in Schedule I, II, III, IV, or V.

2. What does the term “dangerous drug” mean?

The term dangerous drug means **any** of the following:

(1) Any drug to which either of the following applies:

(a) Under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, the drug is required to bear a label containing the legend "Caution: Federal law prohibits dispensing without prescription" or "Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian" or any similar restrictive statement, or the drug may be dispensed only upon a prescription;

(b) Under Chapter 3715. or 3719. of the Revised Code, the drug may be dispensed only upon a prescription.

(2) Any drug that contains a schedule V controlled substance and that is exempt from Chapter 3719. of the Revised Code or to which that chapter does not apply;

(3) Any drug intended for administration by injection into the human body other than through a natural orifice of the human body;

(4) Any drug that is a biological product, as defined in section 3715.01 of the Revised Code.

3. What is a responsible person?

A "responsible person" is responsible for the compliance with all state and federal laws, regulations, and rules governing the distribution of drugs.

Per OAC 4729:5-14-03: *The security and control of dangerous drugs is the responsibility of the responsible person on the terminal distributor of dangerous drugs license. The responsible person may delegate the day-to-day tasks to EMS organization personnel who hold appropriate certification/licensure to access the dangerous drugs for which the personnel are responsible.*

4. What are the requirements for the storage of controlled substances by an EMS organization?

All controlled substance dangerous drugs maintained by an EMS organization shall be physically secured with access limited to the following persons:

- 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.

NOTE: A certified emergency medical responder or emergency medical technician (e.g., EMT-B) may have access to controlled substances **only** under the direct supervision of the individuals listed above and **only** for the following purposes:

- For documenting the disposal of an unused portion of a controlled substance resulting from administration to a patient; or
- For documenting the disposal of controlled substances.

REMINDER: An emergency medical technician (e.g., EMT-B) may also have access to a supply of buprenorphine. See Buprenorphine Administration to Treat Opioid Use Disorder section for more information.

5. What are the requirements for the storage of non-controlled drugs by an EMS organization?

All non-controlled dangerous drugs maintained by the EMS organization shall be maintained under the direct supervision of licensed or certified EMS personnel employed or affiliated with the EMS organization to deter and detect the diversion of dangerous drugs.

If direct supervision is not possible, the licensed location is not currently in use, or the facility is being utilized to hold an event attended by persons other than licensed or certified EMS personnel, all non-controlled dangerous drugs shall be physically secured with access limited to licensed or certified EMS personnel, except for the following if stored in a sealed, tamper-evident manner:

- Solutions labeled for irrigation use;
- Dextrose solutions;
- Saline solutions;
- Lactated ringers;
- Sterile water; and
- Naloxone hydrochloride or other overdose reversal drug as defined in rule 4729-8-01 of the Administrative Code.

6. What EMS personnel may administer dangerous drugs?

An emergency medical services professional with a certificate to practice and ***acting within their scope of practice*** may administer directly (but not prescribe) a dangerous drug outside the physical presence of a medical director or authorizing prescriber in accordance with the following:

(A) A protocol or standing order that is issued and adopted by one or more medical directors of the EMS organization; or

(B) A verbal order that is:

(1) Issued in accordance with a policy of the organization; and

(2) Provided by a medical director or an authorizing prescriber in response to a request by the emergency medical services professional with respect to a specific patient in any of the following circumstances:

(a) In the case of a mass casualty incident; or

(b) To ensure the proper care and treatment of a specific patient.

For more information on EMS personnel scope of practice, visit: www.pharmacy.ohio.gov/EMSpractice

7. What should I do with medications that have expired?

OAC 4729:5-14-03 requires all drugs that are stored improperly, expired, damaged, tampered, or otherwise adulterated be separated from active stock to prevent possible administration to patients. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by the EMS organization. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

For Controlled Substances: Expired/adulterated controlled substances that are segregated must be secured in the same manner as active controlled substance stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored where active controlled substance stock is maintained but segregated in a manner that is clear to all who see it that the drugs may not be used.

For Non-Controlled Drugs: Expired/adulterated non-controlled substance drugs must be segregated from the active drug stock. This can be a bin/bag clearly marked "outdated/do not use" or a similar statement that is stored in common stock areas but segregated in a manner that is clear to all who see it that the drugs may not be used.

8. How do I dispose of non-controlled dangerous drugs?

A non-controlled dangerous drug that is expired may be returned to the supplier where the drug was obtained or may be disposed of in a manner that renders the drug unavailable and unusable.

OAC 4729:5-14-04 requires records of disposal of dangerous drugs from inventory, other than controlled substances, to contain the name, strength, dosage form, and quantity of the dangerous drug disposed; the date of disposal; the method of disposal; and the positive identification of the EMS personnel that performed the disposal.

9. How do I dispose of controlled substance dangerous drugs?

Unless the EMS organization is registered with the United States Drug Enforcement Administration (DEA), any controlled substance that is expired shall be returned to the hospital where the EMS organization obtained the controlled substances.

If the disposal of controlled substance drug inventory is performed on-site, records shall also include the positive identification on the DEA Form 41 of two licensed/certified healthcare professionals conducting and witnessing the disposal. The disposal of controlled substances shall be conducted by two licensed or certified EMS personnel, one of whom shall be:

- 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.

All records must be maintained for a period of three years.

10. How do I dispose of partially-used controlled substances (a.k.a. waste)?

Records for the disposal or destruction of the unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply shall contain the name, strength, dosage form, and quantity of the dangerous drug

disposed; the date disposed; the method of disposal; and the positive identification of the two EMS personnel who disposed of the drugs.

NOTE: At least **one** of the EMS personnel witnessing the disposal must be authorized to administer controlled substances under their professional license (paramedic, advanced emergency medical technician, prescriber, nurse, pharmacist).

The disposal method does not have to render the unused portion of the drug non-retrievable.

All records of disposal must be maintained for a period of three years.

11. What does the term "positive identification" mean?

"Positive identification," as defined in OAC 4729:5-14-01, means a method of identifying EMS personnel. Positive identification includes a manual signature on a hard copy record or report, a biometric method, or a private personal identifier such as a password with an additional secure means of identification such as a bar code reader, a magnetic card reader, a proximity badge reader, a Board of Pharmacy-approved system of randomly generated personal questions, or other effective method approved by the Board of Pharmacy.

Positive identification should be at the conclusion of a drug transaction. For electronic systems, positive identification required only at log-in does not meet the requirements of the rule because it does not document the specific drug transaction and causes other security problems.

12. Do I need to document drug administration using positive identification?

No. OAC 4729:5-14-04 requires the identification of the individual administering the drug using either of the following methods:

(1) An electronic signature in a computerized recordkeeping system; or

(2) Any form of positive identification.

NOTE: An electronic signature may include any of the following:

- A private, unique personal identifier and secure passcode consisting of a combination of letters, numbers, and symbols that is adapted or executed by an individual as that individual's electronic signature.

- An electronic image of an individual's handwritten signature that is captured following drug administration and is created by using a writing apparatus (i.e., stylus). The signature shall be legible and include the person's first name, last name, and credentials.

13. What should I do if drugs are missing, lost, or stolen?

Any theft or significant loss of dangerous drugs must be reported immediately upon discovery. More information on theft or significant loss can be accessed here: www.pharmacy.ohio.gov/theft

14. What should I do if drugs appear to be damaged or tampered with?

OAC 4729:5-14-03 requires any dangerous drug that is stored improperly, expired, damaged, tampered, or otherwise adulterated to be separated from active stock to prevent possible administration to patients. Adulterated drugs shall be stored no longer than one year from the date of adulteration or expiration by the EMS organization. Adulterated drugs shall be stored in a manner that prohibits access by unauthorized persons.

NOTE: Tampering with dangerous drugs is a criminal act and must be reported to the Board of Pharmacy. If a dangerous drug is suspected of being tampered with, it is to be secured as evidence and held for investigation.

15. When an EMS vehicle is removed from any licensed facility for service or maintenance, should all the drug stock be removed?

Yes. All dangerous drugs shall be removed from the vehicle and properly secured at the licensed facility.

16. What are the record retention requirements for drug accountability and security?

All records of receipt, distribution, administration, selling, disposing, destroying, or using dangerous drugs shall be maintained for a period of three years at the place where the dangerous drugs are located.

Records from satellites may be stored at the headquarters if a prior written request is sent to the Board of Pharmacy and approved. The request must be submitted electronically using the form "EMS Request for Satellite Record Storage at Headquarters" that is posted on the terminal distributor licensing page.

All records must be uniformly maintained and readily retrievable. This means that records maintained by EMS agencies must be kept in such a manner that they can be separated out from all other records and, upon request, produced for review in no later than three business days to an agent, officer, or inspector of the Board.

Records of oxygen transfilling shall include the manufacturer's lot number of the oxygen used for transfilling the portable oxygen tanks. If there is a recall of oxygen by the manufacturer, all portable oxygen tanks affected by the recall shall be handled in accordance with the manufacturer's recall instructions.

17. What information must be included in my records?

OAC 4729:5-14-04 of the Ohio Administrative Code requires the following:

- **Records of receipt** shall contain the name, strength, dosage form, and quantity of the dangerous drugs received; the name and address of the seller; the name and address of the recipient; and the date of receipt. An invoice from a drug distributor licensed in accordance with division 4729:6 of the Administrative Code containing the required information may be used to meet this requirement.

- **Records of administering dangerous drugs** shall be legible and shall contain the first and last name of the EMS personnel who administered the drug; name of the EMS organization; name and strength of the drug administered; date of administration; time of administration; amount of the drug administered; the name or other means of identifying the patient, such as medical record number or run number; and the identification of the individual administering the drug

using either of the following methods: (1) An electronic signature in a computerized recordkeeping system; or (2) Any form of positive identification.

- **Records for the disposal of controlled substance drugs** shall be maintained in accordance with OAC 4729:5-3-01 and, if disposal is performed on-site, the positive identification of the EMS personnel who disposed of the drugs. The rule requires maintaining the same records for controlled substance disposal as is required by the Drug Enforcement Administration, which requires the completion of Form 41 (https://www.deadiversion.usdoj.gov/21cfr_reports/surrend/41_form.pdf).

- **Records for the disposal or destruction of the unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply** shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed; the date disposed; the method of disposal; and the positive identification of the two EMS personnel who disposed of the drugs.

- **Records of the disposal or destruction of non-controlled dangerous** drugs shall contain the name, strength, dosage form, and quantity of the dangerous drug disposed; the date of disposal; the method of disposal; and the positive identification of the EMS personnel that performed the disposal.

- **Records of sale or transfer conducted in accordance with OAC 4729:5-3-09** shall contain the name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold; the address of the location where the drugs were transferred or sold; and the date of transfer or sale.

18. What type of license does an EMS organization need to possess dangerous drugs? (UPDATED 3/18/2026)

Ohio Licensure: All EMS physical locations that possess dangerous drugs must obtain a license as a terminal distributor of dangerous drugs (TDDD) from the Board of Pharmacy and each satellite location that possesses dangerous drugs, whether stored in a squad vehicle or on the physical premises, must have a satellite TDDD license. The license issued will be a limited license that includes a drug list. The drug list will list the specific drugs (along with emergency drug protocols) that an EMS organization may possess as approved by the organization's medical director.

DEA Registration: The Drug Enforcement Administration (DEA) officially published its final **rule** implementing the Protecting Patient Access to Emergency Medications Act of 2017 (PPAEMA) on February 5, 2026. The rule, effective March 9, 2026, requires all EMS agencies that are not owned or operated by a hospital to obtain a controlled substance registration from the DEA.

DEA created a new "Emergency Medical Services Agency" registration category, with a three-year fee equal to other dispenser registrations ($888). ***Please be advised that there are fee waivers for EMS agencies operated by state and local governments.*** The rule also includes federal requirements for the security and recordkeeping of controlled substances by EMS agencies. To apply for a new EMS registration, visit: **https://deadiversion.usdoj.gov/drugreg/registration.html**

19. If our EMS organization does not have a DEA registration, how do we get start up drug stock, utilizing a "1:1 drug exchange" system?

An EMS organization is required to have an agreement with a hospital acting as its responsible DEA registrant. An EMS organization must provide their responsible DEA registrant with a copy of the following documents: TDDD license with drug addendum and a copy of the organization's drug protocols signed by the medical director. The specific responsible DEA registrant's pharmacist will fill your initial drug order or release a new drug box and keep copies of the above documents. You should be prepared to show your employee identification and any other information the hospital deems necessary for security and accountability.

20. What if the receiving hospital/facility will not do a 1:1 exchange?

If a receiving hospital will not do a 1:1 exchange, the EMS organization is to return to their specific responsible DEA registrant hospital with a properly completed run sheet and any other documentation required by the hospital to replace their used drug stock.

21. In a 1:1 exchange system, what if the patient refuses transportation after we have administered dangerous drugs?

If a patient refuses transport after drugs were used, the EMS organization is to return to their specific responsible DEA registrant hospital with a properly completed run sheet to replace their used drug stock.

22. In a 1:1 exchange system, what should we do with dangerous drug stocks that are expired or about to expire?

Soon to be outdated: Try to use this stock before it expires date or have your DEA registrant hospital replace your short-dated drug stock.

Individual outdates: Return them to your DEA registrant hospital and have them replaced.

Outdates of items in boxes: Return to DEA registrant hospital and have a new box issued.

23. My EMS organization has a DEA registration; can we still utilize a 1:1 drug exchange with a medical control pharmacy? (UPDATED 3/18/2026)

Yes.

24. While on a call for service, can an EMS unit do a drug transfer or exchange with another EMS unit (a.k.a. curbside exchange)?

It depends on the circumstance.

No, if the EMS organization is utilizing 1:1 drug exchange with a hospital or if the EMS units are from different companies or governmental entities. A curbside exchange shall not occur under any circumstances.

Yes, if the EMS units are owned and operated by a single entity and the drug stock is under common EMS ownership. The exchange must be accompanied by proper documentation. Example: Acme EMS Squad #1 may perform a curbside exchange with Acme EMS Squad #2 with proper documentation of the transfer.

25. If two EMS units from different agencies both administer drugs to the same patient, who is required to complete a run sheet?

Both EMS units must complete a run sheet documenting their own administration of drugs.

26. Does the hospital need a completed run sheet at the time of the 1:1 drug exchange?

It is strongly recommended that a completed run sheet be presented at the time of the 1:1 drug exchange. However, if this is not possible and the hospital permits it, the EMS organization can use an alternate drug report at the time of the exchange. The EMS must follow up by sending a completed run sheet to the exchange hospital at some point and within a reasonable time period (i.e., end of shift). The hospital must then compare the drug use documented on the alternate drug report form to that on the completed run sheet. If there are discrepancies, the hospital must investigate and contact the Board of Pharmacy, and if appropriate the DEA, if it is determined that a theft or loss exists.

27. What records do I need to maintain if utilizing a 1:1 drug exchange?

OAC 4729:5-14-04 requires the following records to be maintained by the EMS organization:

- **Record of receipt from the hospital:** Records of receipt shall contain the name, strength, dosage form, and quantity of the dangerous drugs received; the name and address of the seller; the name and address of the recipient; and the date of receipt.

- **Record of transfer back to the hospital (e.g., for disposal or replacement):** Records of transfers shall contain the name, strength, dosage form, national drug code, and quantity of the dangerous drug transferred or sold; the address of the location where the drugs were transferred or sold; and the date of transfer or sale.

28. If there is a modification to my organization's drug list, am I required to notify the Board?

Yes. You are required to update your drug list and submit the entire list (not just the changes) electronically. Your drug list must be signed by the EMS organization's medical director and uploaded in .PDF format by visiting www.pharmacy.ohio.gov/upload. A sample drug list form and submission instructions are available on the TDDD licensing page or can be accessed directly by visiting: www.pharmacy.ohio.gov/druglist

NOTE: If your drug list has not changed, you are not required to submit a new list upon renewal.

29. If there is a modification to my organization's protocol or personnel list, am I required to notify the Board?

No. An organization should not submit any changes to their protocol or personnel list. However, such documentation should be updated and made available upon inspection.

*NOTE: **DO NOT** submit your personnel list or protocols upon renewal, even if there was a change.*

Emergency Medical Services - Update History

Update Date	Section Update	Update
3/18/2026	Additional Frequently Asked Questions for EMS	Updated guidance to permit an EMS organization that holds a DEA registration to also continue to procure controlled substances using a hospital drug exchange.
3/27/2026	Controlled Substance Inventory	Clarifies for the purposes of conducting a controlled substance inventory that controlled substances shall be deemed to be "on hand" if they are in the possession of or under the control of the TDDD, including controlled substances that are personally furnished but not yet distributed to the patient (e.g., prescriptions waiting to be picked up), complimentary samples, and expired or adulterated controlled substances awaiting disposal.