8/13/2026

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess, and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

Amend

- **4729:5-14-01 – Emergency medical services - definitions.** Rescinds and replaces current definition rule. Defines terms related to emergency medical service (EMS) organizations and adds terms from newly adopted DEA regulations on emergency medical services.
- **4729:5-14-02 – Licensure and procurement of dangerous drugs.** Establishes licensure and procurement requirements for EMS organizations. Adds section requiring compliance with DEA requirements and registration of an EMS headquarters. Adds the types of terminal distributors of dangerous drugs (TDDDs) from which an EMS organization can obtain dangerous drugs. Adds requirements for records of delivery and drug acquisition/transport. Requires DEA registration in accordance with federal law.
- **4729:5-14-03 – Security and control of dangerous drugs.** Establishes requirements for the security and storage of dangerous drugs by EMS organizations. Adds section about storing controlled substances and requirements for carrying drugs on their person. Updates reference for the section on requirements for securing drugs. Updates paragraph (I) to mention requirements in CFR 1301.20.
- **4729:5-14-04 – Record keeping.** Establishes record keeping requirements for emergency medical service organizations. Updates the requirements for records of receipt, acquisitions, or delivery of dangerous drugs, as well as records of controlled and non-controlled substance dangerous drugs that were administered or disposed of. Adds the requirement for records of acquisition or verbal orders to be kept by the EMS organization. Adds that records must be documented using a form approved by the DEA and what must be included in the records.

77 S. High Street, 17th Floor
Columbus, OH 43215 U.S.A.

Phone: 614 | 466 4143
Fax: 614 | 752 4836

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- **4729:5-14-05 – Protocols and verbal orders for drug administration.** Establishes requirements for administering a dangerous drug by an EMS organization. Authorizes the administration of medication for opioid use disorder by EMS personnel. Adds the requirement to maintain records of verbal orders and what must be included.

To access the rule text and accompanying business impact analysis, visit the following link: www.pharmacy.ohio.gov/EMSrules.

Comments on the proposed rules will be accepted until close of business on **September 14, 2026**. Please send all comments to the following email address: rulecomments@pharmacy.ohio.gov.

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov.

Common Sense Initiative

Mike DeWine, *Governor*
Jim Tressel, *Lt. Governor*
Joseph Baker, *Director*

Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy

Rule Contact Name and Contact Information: Summer Reyburn, summer.reyburn@pharmacy.ohio.gov

Regulation/Package Title (a general description of the rules' substantive content):

Emergency Medical Services

Rule Number(s): 4729:5-14-01, 4729:5-14-02, 4729:5-14-03, 4719:5-14-04, 4729:5-14-05

Date of Submission for CSI Review: 8/13/2026

Public Comment Period End Date: 9/14/2026

Rule Type/Number of Rules:

New/___ rules

No Change/____ rules (FYR? ___)

Amended/__5__ rules (FYR? _Y_)

Rescinded/__1__ rules (FYR? _Y_)

Common Sense Initiative

Mike DeWine, *Governor*
Jim Tressel, *Lt. Governor*
Joseph Baker, *Director*

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☒ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. Please briefly describe the draft regulation in plain language.
Please include the key provisions of the regulation as well as any proposed amendments.

- 4729:5-14-01 – Rescinds and replaces current definition rule. Defines terms related to emergency medical service (EMS) organizations and adds terms from newly adopted DEA regulations on emergency medical services.
- 4729:5-14-02 – Establishes licensure and procurement requirements for EMS organizations. Adds section requiring compliance with DEA requirements and registration of an EMS headquarters. Adds the types of terminal distributors of dangerous drugs (TDDDs) from which an EMS organization can obtain dangerous drugs. Adds requirements for records of delivery and drug acquisition/transport. Requires DEA registration in accordance with federal law.
- 4729:5-14-03 – Establishes requirements for the security and storage of dangerous drugs by EMS organizations. Adds section about storing controlled substances and requirements for carrying drugs on their person. Updates reference for the section on requirements for securing drugs. Updates paragraph (I) to mention requirements in CFR 1301.20.
- 4729:5-14-04 – Establishes record keeping requirements for emergency medical service organizations. Updates the requirements for records of receipt, acquisitions, or delivery of dangerous drugs, as well as records of controlled and non-controlled substance dangerous drugs that were administered or disposed of. Adds the requirement for records of acquisition or verbal orders to be kept by the EMS organization. Adds that records must be documented using a form approved by the DEA and what must be included in the records.
- 4729:5-14-05 – Establishes requirements for administering a dangerous drug by an EMS organization. Authorizes the administration of medication for opioid use disorder by EMS personnel. Adds the requirement to maintain records of verbal orders and what must be included.

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rules are authorized by sections 4729.26 and 3719.28 of the Ohio Revised Code. In addition, section 4729.54 authorizes the Board of Pharmacy to license EMS organizations as terminal distributors of dangerous drugs.

4. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**
If yes, please briefly explain the source and substance of the federal requirement.

These rules implement newly enacted DEA regulations (effective 2.5.26) governing the operation of emergency medical service organization.

5. **If the regulation implements a federal requirement, but includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.**

Not applicable.

6. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

Section 4729.26 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing the practice of pharmacy and the distribution of dangerous drugs.

Section 3719.28 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules prescribing the manner of keeping and the form and content of records to be kept by persons authorized to manufacture, distribute, dispense, conduct research in, prescribe, administer, or otherwise deal with controlled substances.

7. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?**

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**
If applicable, please include the date and medium by which the stakeholders were initially contacted.

The rules in this package were distributed for public comment to all EMS licensees between 6/24/2026-7/29/2026.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

10. What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?

Paragraph (J) in 4729:5-14-02 was updated after a stakeholder asked about the provision of additional non-controlled medication by a transferring hospital to EMS personnel during an inter-facility transport when the patient is at risk of exhausting their supply while en route. The Board updated this paragraph to allow this under the amended rule.

A stakeholder had comments about 4729:5-14-02 paragraph (H) appearing to limit hospital involvement to one-for-one replacement following an emergency response, and noted it does not address other legitimate operational needs, such as establishing initial inventory for a new EMS organization. The Board added references to 21 CFR 1307.11, showing the DEA still authorizes wholesale sales. This stakeholder also asked to bring back paragraph (I) of 4729:5-14-03, saying it preserved existing practices for EMS organizations operating under common ownership with hospitals and health systems. The Board ended up restoring this paragraph with an added cross-reference to the DEA regulation on hospital registration for EMS.

Finally, a few stakeholders had comments on language that was directly taken by the Board from the new DEA regulations and incorporated into the rules. The Board did not make any updates to these comments to ensure the wording of the rules and the new DEA regulations are the same to avoid EMS organizations running afoul of the DEA regulations.

11. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

Scientific data was not used to develop or review these rules.

12. What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives? ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use***

to comply.

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the operation of EMS and the distribution of dangerous drugs, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

13. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rules to ensure that the regulations do not duplicate another Ohio Board of Pharmacy regulation.

14. Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the regulated community.

The rules will be posted on the Board of Pharmacy's web site; information concerning the rules will be included in materials e-mailed to licensees; and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rules. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates, webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

Emergency medical service organizations

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

The adverse impact can be quantified in terms of dollars, hours to comply, or other factors; and may be estimated for the entire regulated population or for a representative business. Please include the source for your information/estimated impact.

In general, violation of these rules may result in administrative discipline for a licensee. Discipline might include reprimand, denial of a license, suspension of a license, monetary fine, and/or revocation of a license.

- 4729:5-14-01: Defines terms related to emergency medical service organizations. This should have no adverse impact as this is a definitional section.
- 4729:5-14-02: Establishes licensure requirements for emergency medical service organizations. This rule requires organizations that possess dangerous drugs to become licensed as a terminal distributor of dangerous drugs. To do so, they will need to submit three documents which each require 30 minutes to complete and pay a license fee of either $160.00 or $360.00/$460.00 (depending on if the license is Category II or Category III). EMS Satellite license fees are $160.00. They are also required to register with the DEA, which will cost $888 for a three-year license. Some fees can be waived; more information on this can be found on our website at www.pharmacy.ohio.gov/EMSDEA.
- 4729:5-14-03: Establishes requirements for the security and storage of dangerous drugs by an emergency medical service organization. Costs of compliance will vary based upon the method an EMS organization chooses to utilize.
- 4729:5-14-04: Establishes record keeping requirements for emergency medical service organizations. Requires maintaining drug records for up to three years. All records except for drug administration must be recorded using positive ID. This can vary from a manual signature on a paper record to a more sophisticated method such as a fingerprint scan. Cost of compliance will vary based upon the method an EMS organization chooses to utilize.
- 4729:5-14-05: Establishes that an EMS professional can administer, but not prescribe, dangerous drugs. The rule also authorizes EMS professionals to administer medication for opioid use disorder. If an EMS organization chooses to provide this service, it will incur costs to ensure that the patient receives follow-up care and other administrative costs to comply with the rule. Requires maintaining verbal orders for up to three years. Cost of compliance for keeping records will vary based upon the method an EMS organization chooses to utilize.

16. **Are there any proposed changes to the rules that will reduce a regulatory burden imposed on the business community? Please identify.** ***(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

Not Applicable.

17. **Why did the Agency determine that the regulatory intent justifies the adverse impact to the regulated business community?**

The Board determined that the regulatory intent justifies the impact on business because the regulations protect and promote public safety by ensuring uniform licensing, drug storage, and record keeping standards.

Regulatory Flexibility

18. **Does the regulation provide any exemptions or alternative means of compliance for small businesses? Please explain.**

These rules do not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. **How will the agency apply Ohio Revised Code section 119.14 (waiver of fines and penalties for paperwork violations and first-time offenders) into implementation of the regulation?**

The Ohio Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations.

20. What resources are available to assist small businesses with compliance of the regulation?

Board of Pharmacy staff is available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Rule 4729:5-14-01 | Emergency medical services - definitions. (NEW / RESCIND 4729:5-14-01)

As used in Chapter 4729:5-14 of the Administrative Code:

(A) “Actively in use” means the emergency medical services vehicle is currently engaged in responding to an emergency call, is transporting patients, or is on call.

(B) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(C) "Certificate to practice" means the certificate to practice as an emergency medical responder, emergency medical technician, advanced emergency medical technician, or paramedic issued by the division of emergency medical services within the department of public safety pursuant to section 4765.30 of the Revised Code and Chapter 4765-8 of the Administrative Code.

(D) "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.

(E) "Electronic signature" means any of the following attached to or associated with an electronic drug administration record by EMS organization personnel to authenticate the drug administration record:

(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.

(3) Any other method approved by the board.

(F) “Emergency medical service” has the same meaning as in section 4765.01 of the Revised Code.

(G) "Emergency medical service organization" or "EMS organization" has the same meaning as in section 4765.01 of the Revised Code and shall include any emergency medical services provided by ground, air, or otherwise.

(H) “Emergency medical services vehicle” means an ambulance, fire apparatus, supervisor truck, or other vehicle used by an emergency medical services organization for the purpose of providing or facilitating emergency medical care and transport or transporting controlled substances and other dangerous drugs to and from licensed locations.

(I) “Hospital” has the same meaning as in rule 4729:5-9-01 of the Administrative Code.

(J) "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 pursuant to 21 U.S.C. 823 (June 11, 2026).

(K) “On call” means that the emergency medical services vehicle and its personnel are ready and available to respond but may not be responding to an emergency at that precise moment.

(L)

(1) "Positive identification" means a method of identifying EMS personnel that does not rely solely on the use of a private personal identifier such as a password, but must also include a secure means of identification such as the following:

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

(b) A magnetic card reader;

(c) A bar code reader;

(d) A biometric method;

(e) A proximity badge reader;

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

(g) A printout of every transaction that is verified and manually signed within a reasonable period of time by the individual who prescribed, administered, or dispensed the dangerous drug. The printout must be maintained for three years and made available on request to those individuals authorized by law to review such records; or

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

(2) 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.

(M) "Protocol" or "standing order" means a definitive set of written treatment guidelines that include definitive orders for drugs and their specified dosages which have been authorized and signed by the EMS organization's medical director. A protocol may be used only by licensed or certified EMS personnel or individuals licensed in accordance with Chapter 4723. of the Revised Code, in accordance with the individual's scope of practice, when providing limited medical services to individuals in an emergency.

(N) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that they can be separated out from all other records and, upon request, produced for review no later than three business days to an agent, officer or inspector of the board.

(O) "Responsible person" has the same meaning as defined in agency 4729 of the Administrative Code and is responsible for the supervision and control of dangerous drugs as required in division (B) of section 4729.55 of the Revised Code, adequate safeguards as required in division (C) of section 4729.55 of the Revised Code, security and control of dangerous drugs and maintaining all drug records otherwise required.

(P) "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.

(Q) "Scope of practice" has the same meaning as defined as in section 4765.35 of the Revised Code and Chapter 4765-12 of the Administrative Code for an emergency medical responder or first responder, section 4765.37 of the Revised Code and Chapter 4765-15 of the Administrative Code for an emergency medical technician or emergency medical technician-basic, section 4765.38 of the Revised Code and Chapter 4765-16 of the Administrative Code for an advanced emergency medical technician or emergency medical technician-intermediate, and section 4765.39 of the Revised Code and Chapter 4765-17 of the Administrative Code for a paramedic or emergency medical technician-paramedic.

(R) "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.

(S) "Verbal order" means an oral directive that is given through any method of communication including by radio or telephone, directly to an emergency medical services professional, to contemporaneously administer a dangerous drug, including a controlled substance, to individuals in

need of emergency medical services outside the physical presence of the medical director or authorizing medical professional.

Rule 4729:5-14-02 | Licensure and procurement of dangerous drugs.

(A) An EMS organization that possesses dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs with an emergency medical services classification.

(1) The location that serves as the main station of the EMS organization will be deemed the headquarters. The headquarters shall be the location where records and drugs for distribution to satellite locations are maintained.

(2) Any satellite location associated with the headquarters of the EMS organization where dangerous drugs will be stored must be licensed as a terminal distributor of dangerous drugs.

(B) An application for licensure shall include all the following:

(1) A completed application;

(2) A copy of the organization's protocols signed by the medical director;

(3) A list of the dangerous drugs, or drug list, that may be possessed and administered by EMS organization personnel, expressed in standard dose units, signed by the medical director;

(4) 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; and

(5) The fee for the appropriate category of licensure.

(C) Each location, headquarters and satellite, may only possess those dangerous drugs that are on the drug list submitted to the board pursuant to paragraph (B)(3) of this rule and only at locations licensed by the state board of pharmacy.

(1) A medical director may modify the drugs that may be possessed and administered by EMS organization personnel by submitting a new drug list to the state board of pharmacy in a manner determined by the board.

(2) 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.

(D) If there is a change of the medical director of an EMS organization, the new medical director shall submit notification, in a manner determined by the board, no later than five business days following the change. Notification shall include a current drug list signed by the new medical director.

(E) Any change of the EMS organization's personnel list shall be updated within thirty days of a change of personnel. Any change of personnel shall only be submitted to the board upon request.

(F) An EMS organization shall maintain a current copy or have access to a current copy of the organization's protocols, personnel list**,** and drug list at each licensed location **for immediate inspection by an agent, inspector, or employee of the board**.

(G) An EMS organization shall comply with drug enforcement administration registration requirements pursuant to 21 CFR 1301.20 (February 5, 2026). An EMS organization may register its headquarters with the drug enforcement administration in lieu of a separate registration for each satellite location.

(H) Notwithstanding any other provision of the Administrative Code, an EMS organization may obtain dangerous drugs from one or more of the following:

(1) A drug distributor pursuant to division 4729:6 of the Administrative Code.

(2) A hospital or freestanding emergency department owned and operated by a hospital for purposes of restocking an emergency medical services vehicle following an emergency response in accordance with 21 CFR 1307.14 (February 5, 2026) and 21 CFR 1307.15 (February 5, 2026).

(3) A hospital pharmacy conducts an occasional wholesale in accordance with rule 4729:5-3-09 of the Administrative Code and 21 CFR 1307.11 (July 11, 2003).

(I) All drug acquisitions conducted in accordance with paragraph (H) shall be documented as follows:

(1) The EMS organization operating the vehicle maintains the record of such receipt in accordance with paragraph (B) of rule 4729:5-14-04 of the Administrative Code.

(2) The drug distributor, hospital, or institutional facility owned and operated by a hospital maintains a record of such delivery to the EMS organization that contains all of the following:

(a) Name of the drug;

(b) Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(c) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(d) Number of commercial containers distributed;

(e) Date of the distribution;

(f) Name and address of the person to whom the dangerous drug was distributed;

(g) If acquiring controlled substances, the drug enforcement administration (DEA) registration number of the person to whom the dangerous drug was distributed; and

(h) Name and title of the person in receipt of the distributed dangerous drugs.

(J) Dangerous drugs dispensed by an institutional pharmacy pursuant to a prescriber's order to treat patients being transported by an EMS organization does not constitute drug acquisition pursuant to this rule.

(1) Administration or disposal of the unused portion of a dangerous drug resulting from administration shall be documented in the same manner as drugs administered from the inventory of the EMS organization in accordance with rule 4729:5-14-04 of the Administrative Code.

(2) Dangerous drugs dispensed, but not utilized as part of the patient transport, shall not be returned to inventory and shall be disposed of in accordance with the requirements of this chapter.

Rule 4729:5-14-03 | Security and control of dangerous drugs.

(A) 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.**~~ A responsible person shall comply with the requirements set forth in rule 4729:5-2-01 of the Administrative Code.

(B) A licensed EMS organization shall provide effective controls and procedures to deter and detect the diversion of dangerous drugs.

(1) Except as provided in paragraph (B)(2) of this rule, only the following may have access to controlled substance dangerous drugs maintained by the EMS organization:

(a) A paramedic (emergency medical technician-paramedic) certified in accordance with Chapter 4765. of the Revised Code;

(b) An advanced emergency medical technician (emergency medical technician-intermediate) certified in accordance with Chapter 4765. of the Revised Code; and

(c) A licensed prescriber, registered nurse, or pharmacist who is employed or affiliated with the EMS organization.

(2) An emergency medical technician (emergency medical technician-basic) certified in accordance with Chapter 4765. of the Revised Code may have access to buprenorphine to administer an initial dose pursuant to paragraph (C) of rule 4729:5-14-05 of the Administrative Code. Buprenorphine maintained in accordance with this paragraph shall:

(a) Be ~~**physically**~~ secured **in accordance with paragraph (D) of this rule** with access limited to persons listed in paragraphs (B)(1) and (B)(2) of this rule.

(b) **Be s**tored in a manner that does not permit an emergency medical technician access to other controlled substance dangerous drugs maintained by the EMS organization.

(3) A certified emergency medical responder (emergency medical responder) and emergency medical technician certified in accordance with Chapter 4765. of the Revised Code may have supervised access to controlled substance dangerous drugs as follows:

(a) For the purpose of documenting the disposal of an unused portion of a controlled substance resulting from administration to a patient in accordance with paragraph (~~K~~ J) of this rule and only under the direct supervision of the persons listed in paragraph (B)(1) of this rule.

(b) For the purpose of documenting the disposal of controlled substances in accordance with paragraph (~~J~~ I) of this rule and only under the direct supervision of the persons listed in paragraph (B)(1) of this rule.

(C)

(1) 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.

(2) 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:

(a) Solutions labeled for irrigation use;

(b) Dextrose solutions;

(c) Saline solutions;

(d) Lactated ringers;

(e) Sterile water; and

(f) Naloxone hydrochloride or other overdose reversal drug as defined in rule 4729-8-01 of the Administrative Code.

(D) ~~Except as provided in paragraph (B)(2) of this rule,~~ All controlled substance dangerous drugs maintained by the EMS organization shall be ~~physically~~ secured **pursuant to paragraph (D)(1) of this rule** with access limited ~~to persons listed~~ **in accordance with** ~~in~~ paragraph (B)~~(1)~~ of this rule.

(1) Except when emergency medical services personnel are carrying controlled substances on their person or in a jump bag as set forth in paragraph (D)(2) of this rule, an EMS organization shall store controlled substances in a storage component that is identified as:

(a) A securely locked, substantially constructed cabinet or safe that cannot be readily removed, which shall be located in accordance with 21 CFR 1301.80 (February 5, 2026);

(b) An automated dispensing machine as defined in 21 CFR 1300.01 (April 28, 2026), which shall comply with the requirements of 21 CFR 1301.80 (February 5, 2026).

(2) EMS organization personnel, in accordance with their applicable scope of practice, may carry controlled substances on their person or in a jump bag instead of storing the controlled substances in a safe when responding to an emergency. The controlled substances shall be returned to a storage component as described in paragraph (D)(1) when EMS organization personnel are not currently engaged in responding to an emergency.

(E) All areas where dangerous drugs and devices are stored shall be dry, well-lit well-ventilated, and maintained in a clean and orderly condition. Storage areas shall be maintained at temperatures which will ensure the integrity of the drugs prior to their use as stipulated by the USP/NF and/or the manufacturer's or distributor's labeling unless otherwise directed by the board. Refrigerators and freezers used for the storage of drugs and devices shall comply with the following:

(1) Maintain either of the following to ensure proper refrigeration and/or freezer temperatures are maintained:

(a) Temperature logs with, at a minimum, daily observations; or

(b) A temperature monitoring system capable of detecting and alerting staff of a temperature excursion.

(2) The terminal distributor shall 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.

(3) The terminal distributor shall develop and implement a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store drugs.

(F) 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) 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.

(G) A dangerous drug that is stored improperly, expired, damaged, tampered, or otherwise adulterated shall 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 as required by this rule.

(H) A non-controlled dangerous drug that is expired or adulterated shall be disposed of in a manner that renders the drug unavailable and unusable.

(I) 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**~~ **the** hospital acting as the EMS organization's ~~**responsible**~~ DEA registrant **in accordance with 21 CFR 1301.20 (February 5, 2026)**.

(J) Except as provided in paragraph (K) of this rule, the disposal of controlled substances shall be conducted ~~**in accordance**~~ **utilizing a non-retrievable method as defined in** ~~**with**~~ rule 4729:5-3-01 of the Administrative Code. **Except as provided in paragraph (I) of this rule. t**he disposal of controlled substances shall be conducted by two licensed or certified EMS personnel, one of whom shall meet the qualifications listed in paragraph (B)(1) of this rule.

(K) The unused portion of a controlled substance resulting from administration to a patient from a licensee's stock or emergency supply may be destroyed using an on-site method. The on-site method does not have to meet the definition of non-retrievable in rule 4729:5-3-01 of the Administrative Code but must render the drug unavailable and unusable.

The destruction of partially used controlled substances shall be conducted by two licensed or certified EMS personnel, one of whom shall meet the qualifications listed in paragraph (B)(1) of this rule.

(L) 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.

Rule 4729:5-14-04 | Record keeping.

(A) All EMS organizations shall keep a record of all dangerous drugs received, **acquired,** administered, sold, transferred, destroyed, or disposed.

~~**(B) 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.**~~

(B) Records of receipt or acquisition of dangerous drugs shall contain all of the following:

(1) Name of the drug.

(2) Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter).

(3) Number of units or volume of finished form in each commercial container.

(4) Number of commercial containers acquired (e.g., 100-tablet bottle or 3-milliliter vial).

(5) Date of the acquisition.

(6) Name and address of the person from whom the drug was acquired.

(7) If acquiring controlled substances, the drug enforcement administration registration of the person from whom the drug was acquired.

(8) Name and title of the person acquiring the drug.

(C) All records of receipt, **acquisition,** distribution, **verbal orders,** 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, in a manner determined by the board, is obtained by the EMS organization.

~~**(D) 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.~~

(D) An EMS organization shall maintain records for each dose of a controlled substance dangerous drug administered or disposed of in the course of providing emergency medical services (e.g., disposal of the unused portion of a controlled substance resulting from administration to a patient). The following information shall be included in each record:

(1) Name of the drug.

(2) Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter).

(3) Date administered or disposed of.

(4) Identification of the patient (consumer), which may include a medical record number or run number.

(5) Amount administered.

(6) Last name or initials of the medical director or authorizing medical professional issuing the standing or verbal order. This information may be pre-populated or autogenerated by the EMS organization's record keeping system.

(7) Whether a standing or verbal order was issued and adopted.

(8) Except as provided in paragraph (D)(9) of this rule, last name or initials of the person who administered the controlled substance, which shall be documented using either:

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

(b) Any form of positive identification.

(9) In the event that a controlled substance is administered by certified EMS personnel during an emergency response that are not directly employed or do not otherwise have access to the record keeping system operated by the EMS organization who own the drug, the personnel of the EMS organization who own the controlled substance being administered shall document the administration as follows:

(a) Last name or initials of the EMS organization personnel who witnessed the administration, which shall be documented using either:

(i) An electronic signature in a computerized record keeping system; or

(ii) Any form of positive identification.

(b) The last name or initials of the certified EMS personnel administering the controlled substance and the name of the EMS organization for which they are employed or under contract.

(10) Amount disposed of, if applicable.

(11) Manner disposed of.

(12) Last name or initials of the two EMS personnel who disposed of and witnessed the disposal, if applicable. This shall be documented using either:

(a) An electronic signature in a computerized record keeping system; or

(b) Any form of positive identification.

(E) An EMS organization shall maintain records for each dose of a non-controlled dangerous drug administered in the course of providing emergency medical services. The following information shall be included in each record:

(1) Name of the drug.

(2) Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter).

(3) Date administered.

(4) Identification of the patient (consumer), which may include a medical record number or run number.

(5) Amount administered.

(6) Except as provided in paragraph (D)(7) of this rule, last name or initials of the person who administered the non-controlled dangerous drug, which shall be documented using either:

(a) An electronic signature in a computerized record keeping system; or

(b) Any form of positive identification.

(7) In the event that a non-controlled dangerous drug is administered by certified EMS personnel during an emergency response that are not directly employed or do not otherwise have access to the record keeping system operated by the EMS organization who own the drug, the personnel of the EMS organization who own the drug being administered shall document the administration as follows:

(a) Last name or initials of the EMS organization personnel who witnessed the administration, which shall be documented using either:

(i) An electronic signature in a computerized record keeping system; or

(ii) Any form of positive identification.

(b) The last name or initials of the certified EMS personnel administering the drug and the name of the EMS organization for which they are employed or under contract.

(F) For each delivery of controlled substances between an EMS organization's headquarters and a satellite locations:

(1) Name of the drug.

(2) Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter).

(3) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial).

(4) Number of units or volume of finished form in each commercial container and number of commercial containers delivered (e.g., 100-tablet bottle or 3-milliliter vial).

(5) Date of the delivery.

(6) Name and address of the designated location to which the drug is delivered.

(7) Name and title of the person in receipt of the controlled substances.

(G) 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**~~ **manner** of disposal, and the positive identification of the EMS personnel that performed the disposal.

(H) Records for the disposal of controlled substance drugs **from inventory** shall **be documented using a form approved by the United States drug enforcement administration that contains the following information:** ~~**be maintained in accordance with rule 4729:5-3-01 of the Administrative Code and, if disposal is performed on-site, the positive identification of the two EMS personnel who disposed of the drugs in accordance with rule 4729:5-14-03 of the Administrative Code.**~~

(1) Name of the drug;

(2) Finished form of the drug (e.g., 10-milligram tablet or 10-milligram concentration per fluid ounce or milliliter);

(3) Number of units or volume of finished form in each commercial container (e.g., 100-tablet bottle or 3-milliliter vial);

(4) Number of units or volume of finished form in each commercial container and number of commercial containers destroyed (e.g., 100-tablet bottle or 3-milliliter vial);

(5) Date of the destruction;

(6) Manner of disposal of the drug, if applicable;

(7) Name, address, and DEA registration number of the person to whom the drug was distributed, if applicable; and

(8) Name, title, and positive identification of the two EMS personnel who disposed of the drugs in accordance with rule 4729:5-14-03 of the Administrative Code.

~~**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.**~~

(I) All records maintained in accordance with this rule shall be uniformly maintained and readily retrievable.

(J) An EMS organization shall conduct an annual inventory of all controlled substances in accordance with rule 4729:5-3-07 of the Administrative Code.

(K) Records of transfer or sale conducted in accordance with rule 4729:5-3-09 of the Administrative Code 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.

(L) All records maintained pursuant to this rule may be electronically created and maintained, provided that the system that creates and maintains the electronic record does so in accordance with the following:

(1) 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;

(2) A record or image once created shall be unalterable but may be annotated as necessary so long as the original record or image is still available for review and the individual that made the annotation is noted;

(3) Contains security features to prevent unauthorized access to the records; and

(4) Contains daily back-up functionality to protect against record loss.

(M) Records of oxygen transfilling shall include the manufacturer's lot number of the oxygen used for transfilling the portable oxygen tanks.

Rule 4729:5-14-05 | Protocols and verbal orders for drug administration.

(A) 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, including controlled substances, outside the physical presence of a medical director or authorizing prescriber in accordance with the following:

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

(2) A verbal order that is:

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

(b) 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:

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

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

(B) An EMS organization shall maintain a record of all verbal orders issued in accordance with paragraph (A)(2) of this rule. The order shall contain all of the following:

(1) Identification of the patient (consumer), which may include a medical record number or run number.

(2) Name, strength, and dosage form of drug.

(3) Route of administration.

(4) Date ordered.

(5) The last name or initials of the ordering medical director.

(~~B~~ **C**) 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. Such a protocol shall ensure that the EMS organization is able to provide a direct linkage to a program or prescriber who will continue the patient's therapy.

(~~C~~ **D**) A controlled substance administered in accordance with paragraph (B) of this rule is exempted from reporting to the drug database established in section 4729.75 of the Revised Code.