Common Sense Initiative

Mike DeWine, *Governor*
Jon Husted, *Lt. Governor*
Joseph Baker, *Director*

Comments on the proposed rules will be accepted until close of business on June 24, 2024. Please send all comments to the following email address: RuleComments@pharmacy.ohio.gov

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

Business Impact Analysis

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

Rule Contact Name and Contact Information: Summer Corson
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Regulation/Package Title (a general description of the rules' substantive content):

EMS

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

Date of Submission for CSI Review: 6/6/2024

Public Comment Period End Date: 6/24/2024

Rule Type/Number of Rules:

New/ 2 rules

No Change/____ rules (FYR? ___)

Amended/ 3 rules (FYR? Y)

Rescinded/ 1 rules (FYR? Y)

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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.

Amend

- 4729:5-14-01 – Defines terms related to emergency medical service organizations. Updates definitions to harmonize with Ohio EMS Board regulations.
- 4729:5-14-04 – Establishes record keeping requirements for emergency medical service organizations. Updates paragraphs to harmonize with other record keeping sections for other Board of Pharmacy licensees.
- 4729:5-14-02 – Establishes licensure requirements for emergency medical service organizations. Rule is being amended to specify that the EMS headquarters shall be the location where records and drugs for distribution to satellite locations are maintained.

Rescind Current/New

- 4729:5-14-03 – Establishes requirements for the security and storage of dangerous drugs by emergency medical service organizations. Specifies that drugs maintained on the ambulance must be maintained in a tamper-evident manner or secured physically. Rescinds current rule 4729:5-14-03.

New

- 4729:5-14-05 – Establishes requirements for administering a dangerous drug by an emergency medical service organization. Authorizes the administration of medication for opioid use disorder by EMS personnel.

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 do not implement a federal requirement.

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.**
   N/A

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 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 licensees and registrants of the Board.

   Prior to filing with CSI, the rules were also 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?**
    The Board received 4 comments from stakeholders that were against incorporating pending DEA regulations because the regulations had not been finalized. All references to pending DEA regulations were removed prior to filing with CSI.

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 this rule.

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 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 internal email updates, regular staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, 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 licensure discipline for a licensee. Discipline might include reprimand, 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 $220.00. EMS Satellite license fees are $120.00.
- 4729:5-14-03: Establishes requirements for the security and storage of dangerous drugs by an emergency medical service organization. Requires drugs maintained by the EMS organization to be stored in a tamper-evident manner. Such requirements can be met in several ways including locked cabinets, tamper-evident seals/tape, or a locked closet or medication room. 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. 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.

16. Are there any proposed changes to the rules that will <u>reduce</u> 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).

N/A

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 recordkeeping standards. Such requirements are intended to preserve drug integrity and reduce opportunity for drug diversion.

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. However, any failure of a standard of care in the practice of an emergency medical service organization is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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. (AMEND)

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

~~**(B) "Certificate to practice" means the level to which an individual is trained and licensed as defined in sections 4765.01, 4765.011 and 4765.30 of the Revised Code and rule 4765-1-01 of the Administrative Code.**~~

(B) "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.

(C) "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.

(D) "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.

(E) "Emergency medical service organization," "EMS organization," or “emergency medical services agency” has the same meaning as in section 4765.01 of the Revised Code.

~~**(F) "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.**~~

(F) "Mutual aid" means a formal written agreement between two or more EMS organizations to assist in emergency medical coverage in the other's usual area of coverage, including having access to dangerous drugs during the emergency.

(G)

(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; 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, such as a password, for entry into a secure mechanical or electronic system.

(H) "Program medical director" or "medical director" means a physician who is involved in the practice or supervision of emergency medicine in a hospital or prehospital setting in accordance with Chapter 4765. of the Revised Code and who advises the accredited institution or approved institution regarding the courses taught within an EMS training program or EMS continuing education program as set forth in section 4765.16 of the Revised Code and Chapter 4765-7 of the Administrative Code.

The program medical director shall be registered with the United States drug enforcement administration pursuant to 21 U.S.C. 823 (12/7/2023).

(I) "Posting up" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy for less than twenty-four hours and where the EMS unit is under the direct supervision of the EMS personnel on duty.

(J) "Posting up at a special event" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy for more than twenty-four consecutive hours pursuant to a formal agreement with the sponsors of the event and where the EMS unit is under the direct supervision of the EMS personnel on duty.

(1) Posting up at a special event requires notification to the board. Notification shall be provided prior to the special event in a manner determined by the board.

(2) The requirements of this paragraph do not apply in the event of an emergency management assistance compact or an emergency declared by the governor.

~~**(K) "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, in accordance with the individual's scope of practice, when providing limited medical services to individuals in an emergency.**~~

(K) "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.

(L) "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.

(M) "Responsible person" has the same meaning as defined in rule 4729:5-2-01 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.

(N) "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.

(O) "Scope of practice" has the same meaning as defined in section 4765.35 of the Revised Code and rule 4765-12-04 of the Administrative Code for an emergency medical responder or first responder, section 4765.37 of the Revised Code, and rule 4765-15-04 of the Administrative Code for an emergency medical technician or emergency medical technician-basic; section 4765.38 of the Revised Code and rule 4765-16-04 of the Administrative Code for an advanced emergency medical technician or emergency medical technician-intermediate; and section 4765.39 of the Revised Code and rule 4765-17-03 of the Administrative Code for a paramedic or emergency medical technician-paramedic.

~~(P) "Tamper-evident" means a package, storage container or other physical barrier 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.~~

(P) "Tamper-evident" means a storage container or other physical barrier 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.

(Q) “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. (AMEND)

(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 program 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 program 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 **program** 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 specified 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 to 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 signed protocols, personnel list, and drug list at each licensed location.

Rule 4729:5-14-03 | Security and control of dangerous drugs. (RESCIND CURRENT / NEW)

(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 theft and diversion of dangerous drugs.

(C) All dangerous drugs maintained in an ambulance or other vehicle operated by the EMS organization shall be secured in a tamper-evident manner, if not physically secured within the ambulance or other vehicle, to deter and detect unauthorized access, except for the following:

(1) Solutions labeled for irrigation use;

(2) Dextrose solutions;

(3) Saline solutions;

(4) Lactated ringers;

(5) Sterile water; and

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

(D) All dangerous drugs maintained at the location licensed as a terminal distributor of dangerous drugs outside of an ambulance or other vehicle operated by the EMS organization shall be physically secured with access limited to EMS organization personnel.

Except as provided in paragraph (E) of this rule, only the following may have access to any controlled substances maintained by the EMS organization:

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

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

(3) Licensed prescribers, nurses, or pharmacists who are employed or affiliated with the EMS organization.

(E) Other EMS organization personnel may have access to controlled substances only under the direct supervision of the individuals listed in paragraph (D) of this rule.

(F) All areas where dangerous drugs and devices are stored shall be dry, well-lighted, 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.

(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.

(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 hospital acting as the EMS organization's responsible DEA registrant.

(J) Except as provided in paragraph (K) of this rule, disposal of controlled substances shall be conducted in accordance with rule 4729:5-3-01 of the Administrative Code by individuals listed in paragraph (D) 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/certified healthcare personnel, one of whom shall meet the qualifications listed in paragraph (D) 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. (AMEND)

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

~~**(B) Records of receipt shall contain a description of all dangerous drugs received, the kind and quantity of dangerous drugs received, the name and address of the persons from whom received, and the date of receipt.**~~

(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.

(C) All records of receipt, ~~**delivery,**~~ 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, in a manner determined by the board, is obtained by the EMS organization.

(D) Records of administration 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 ~~**dose**~~ **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.

~~**(E) 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, if disposal is performed on-site, the positive identification of the EMS personnel who disposed of the drugs.**~~

(E) 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 identification of the EMS personnel that performed the disposal.

(F) Records for the disposal of controlled substance drugs shall 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**.

Records for the disposal or destruction of the unused portion of a controlled substance resulting from administration to a patient from a ~~**licensees**~~ **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.

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

(H) An EMS organization that holds a registration with the drug enforcement administration shall conduct an annual inventory of all controlled substances in accordance with ~~**agency 4729**~~ **rule 4729:5-3-07** of the Administrative Code.

Notwithstanding any other provision of the Administrative Code, this paragraph does not apply to an EMS utilizing a 1:1 exchange system with a hospital acting as its responsible DEA registrant.

(I) 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) Complies with the requirements of this rule;

(2) All paper records maintained electronically shall be scanned in full color via technology designed to capture all information in the paper record in one form and reproduce it in an electronic medium presentable and usable to an end user;

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

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

(J) 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 (NEW)

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:

(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 agency; 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.

(C) An emergency medical service organization may administer an initial dose of buprenorphine, or another medication for opioid use disorder approved by the board, to a patient in accordance with a protocol approved by the organization's medical director. Such a protocol shall ensure that the EMS agency is able to provide a direct linkage to a program or prescriber who will continue the patient's therapy.

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