9/11/2017

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 State of 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.

New

- 4729:5-14-01: Defines terms related to emergency medical service organizations.
- 4729:5-14-02: Establishes licensure requirements for emergency medical service organizations.
- 4729:5-14-03: Establishes requirements for the security and storage of dangerous drugs by an emergency medical service organization.
- 4729:5-14-04: Establishes record keeping requirements for emergency medical service organizations.

Rescinded

- 4729-33: Regulates the licensure of emergency medical service organizations that hold a terminal distributor of dangerous drugs license.

Comments on the proposed rules will be accepted until close of business on September 25, 2017. Please send all comments to the following email address:
Cameron.mcnamee@pharmacy.ohio.gov

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Emergency Medical Services

Rule Number(s): New: 4729:5-14-01; 4729:5-14-02; 4729:5-14-03; 4729:5-14-04

Rescinded: 4729-33

Date: 9/11/2017

Rule Type:

New	5-Year Review
Amended	**Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

New

- 4729:5-14-01: Defines terms related to emergency medical service organizations.
- 4729:5-14-02: Establishes licensure requirements for emergency medical service organizations.
- 4729:5-14-03: Establishes requirements for the security and storage of dangerous drugs by an emergency medical service organization.

- 4729:5-14-04: Establishes record keeping requirements for emergency medical service organizations.

Rescinded

- 4729-33: Regulates the licensure of emergency medical services that hold a terminal distributor of dangerous drugs license.

2. Please list the Ohio statute authorizing the Agency to adopt this regulation.

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.

3. 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?

These rules do not implement a federal requirement.

4. If the regulation includes provisions not specifically required by the federal government, please explain the rationale for exceeding the federal requirement.

This rule package exceeds federal requirements because the regulation of the distribution of dangerous drugs by EMS organizations is required by ORC 4729.54.

5. 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.

6. 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.

Development of the Regulation

7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.

The rules were reviewed by the Ohio Fire Chiefs' Association (OFCA). Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

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

For the proposed rules, the OFCA recommended the removal of positive identification for drug administration. Such requirements were removed in the proposed rule.

9. 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.

10. 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?

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the licensure of and safe distribution of drugs by emergency medical service organizations, the State of Ohio Board of Pharmacy did not consider any regulatory alternatives.

11. Did the Agency specifically consider a performance-based regulation? Please explain. ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform regulations across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

12. 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 State of Ohio Board of Pharmacy regulation.

13. 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 and quarterly webinars from the Director of Policy and feedback from the Board's legal department for every citation submitted.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Emergency medical service organizations.

b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and

Violation of these rules may result in administrative licensure discipline for a pharmacy intern. Discipline might include reprimand, suspension of a license, monetary fine and/or revocation of a license.

c. Quantify the expected adverse impact from the regulation.

New

- 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 (effective September 29, 2017).
- 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, however, the removal of the positive ID requirement for drug administration will result in significant savings to EMS organizations according to feedback provided by the Ohio Fire Chiefs' Association.

Rescinded

- 4729-33: Regulates the licensure of emergency medical services that hold a terminal distributor of dangerous drugs license. This should have no adverse impact as the rules are in this chapter are being moved to Chapter 4729:5-14.

15. 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

16. 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.

17. 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 State of 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.

18. 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.

RESCIND Chapter 4729-33

4729:5-14-01 - Emergency Medical Services - Definitions. (NEW)

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

(A) "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.

(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.

(C) "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.

(D) "Emergency medical service organization" or "EMS organization" has the same meaning as in section 4765.01 of the Revised Code.

(E) "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. 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, such as a password, for entry into a secure mechanical or electronic system.

(H)

(1) "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 constant supervision of the EMS personnel on duty, including but not limited to, the following:

(a) Local school sports event;

(b) Coverage of a station pursuant to a written mutual aid agreement.

(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.

(I) "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 pursuant to a formal agreement with the sponsors of the special event and where the EMS unit is under constant supervision of the EMS personnel on duty.

(1) Posting up at a special event requires prior notification to, and approval from, the board's executive director or the executive director's designee. Notification shall be provided in a

manner determined by the board and shall be submitted no later than ten business days prior to the special event.

(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.

(J) "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) “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 produced for review by an agent of the board within three business days.

(L) “Responsible person” has the same meaning as defined pursuant to agency 4729. of the Administrative Code who is responsible for the practice of the profession of pharmacy, including, but not limited to, 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.

(M) "Satellite" means a location licensed by the board as a terminal distributor of dangerous drugs that is separate from the licensed headquarters of the EMS organization.

(N) "Scope of practice” has the same meaning as defined as 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.

(O) "Special event" means an event requiring EMS coverage for more than twenty-four hours including, but not limited to, the following:

(1) A county fair.

(2) A weekend festival.

(P) "Tamper-evident" means a device or process that makes unauthorized access to dangerous drugs easily detected.

4729:5-14-02 - Licensure. (NEW)

(A) An EMS organization that possesses dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs.

(1) The location that serves as the main station of the EMS organization will be deemed the headquarters.

(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 an EMS organization, 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 in accordance with section 4729.54 of the Revised Code.

(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 board of pharmacy.

(1) A medical director may modify the drugs that may be possessed and administered by an EMS organization by submitting a new drug list 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 changes to the list of dangerous drugs referenced in an EMS organization's protocol shall be submitted to the state board of pharmacy prior to the implementation of the protocols authorizing the use of such drugs.

(F) 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.

(G) 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.

(1) An EMS organization's protocols, personnel list and drug list shall be readily retrievable upon inspection by agent of the board.

(H) A satellite location shall not be required to pay a fee for license renewal if there is no change in the ownership, business or trade name, category, or address of the satellite location.

4729:5-14-03 - Security and storage of dangerous drugs. (NEW)

(A) The supervision 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 to access the dangerous drugs for which the personnel are responsible.

(1) A responsible person shall comply with the requirements set forth in agency 4729. 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 must be secured in a tamper-evident manner with access limited to EMS personnel based on certification status, except for the following if stored in a sealed, tamper-evident manner:

(1) Solutions labeled for irrigation use;

(2) Dextrose solutions;

(3) Saline solutions;

(4) Lactated ringers;

(5) Sterile water; and

(6) Naloxone hydrochloride.

(D) 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 4765.30 of the Revised Code;

(2) An advanced emergency medical technician or emergency medical technician-intermediate certified in accordance with 4765.30 of the Revised Code; and

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

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

(F) Administration of dangerous drugs by EMS personnel is limited to the individual's scope of practice based upon certification level and either:

(1) The protocols established by the organization's medical director;

(2) A verbal order by a prescriber received in-person or over an electronic communications device.

(G) 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.

(H) A dangerous drug that reaches its expiration date is considered adulterated and must 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.

(I) 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 the manner that renders the drug unavailable and unusable.

(J) Unless the EMS organization is registered with the United States drug enforcement agency, any controlled substance that is expired shall be returned to the hospital acting as the EMS organization's responsible DEA registrant.

(K) Except as provided in paragraph (L) 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.

(L) 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 but must render the drug unavailable and unusable.

(1) Destruction of partially used controlled substances shall be conducted by two licensed healthcare personnel, one of whom shall meet the qualifications listed in paragraph (D) of this rule.

(M) Any dangerous drug showing evidence of damage or tampering shall be removed from active stock and replaced immediately. The drug shall be stored no longer than one year from the date of discovery of tampering or damage by the EMS organization and shall be stored in a manner that prohibits access by unauthorized persons.

(N) 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.

4729:5-14-04 – Record Keeping. (NEW)

(A) All emergency medical service (EMS) organizations shall keep a record of all dangerous drugs received, administered, sold, transferred, destroyed, 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.

(C) Records from satellites may be stored at the headquarters if prior notice, in a manner determined by the board, is submitted 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 dose 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;

(2) Any form of positive identification.

(E) Records for 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 disposed, the method of disposal, and, if disposal is performed on-site and the positive identification of the EMS personnel who disposed of the drugs.

(F) Except as provided in paragraph (E)(1) of this rule, records for the disposal of controlled substance drugs shall be maintained in accordance with rule 4729:5-3-01 and, if disposal is performed on-site, the positive identification of the EMS personnel who disposed of the drugs.

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

(G) All records of receipt, distribution, administration, selling, disposing, or using dangerous drugs shall be maintained for a period of three years at the place where the dangerous drugs are located and shall be made readily retrievable upon request by an agent of the board of pharmacy.

(H) Except as provided in paragraph (G)(1) of this rule, an EMS organization shall conduct an annual inventory of all controlled substances in accordance with agency 4729. of the Administrative Code.

(1) 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 in accordance with the following:

(1) All electronic records shall be provided to the board within seventy-two hours upon request;

(2) 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.

(3) 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.

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

(5) 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.