OHIO STATE BOARD OF PHARMACY

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-Equal Opportunity Employer and Service Provider-

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5/16/14

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 State 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 rule.

Proposed Rule Change

- **4729-33-01:** Updates definitions section to reflect change in EMS terminology and to reference the correct cross references to sections of the OAC and ORC.

- **4729-33-02:** Updates the EMS licensure section to reference to the official name of the state board of emergency medical, fire and transportation services and clarifies that volunteer personnel should also be listed on the terminal distributor of dangerous drugs license application.

- **4729-33-05:** Defines “posting up” as a temporary, short-term location of the EMS unit for less than twenty-four hours where the EMS unit is under constant supervision of the EMS personnel on duty. Exempts emergency situations from this requirement.

No Change Rules

- **4729-33-04:** Outlines the required recordkeeping for EMS agencies that possess and store dangerous drugs.

You can view the proposed rules below.

Comments on the proposed rules will be accepted until close of business on May 30, 2014. Please send all comments to the following email address:

Cameron.mcnamee@bop.ohio.gov

In addition, please copy your comments to:

CSIPublicComments@governor.ohio.gov

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio State Board of Pharmacy

Regulation/Package Title: Emergency Medical Services.

Rule Number(s): Amended: 4729-33-01; 4729-33-02; 4729-33-05

No Change: 4729-33-04

Date: 5/16/2014

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✓ Amended	Rescinded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.

Proposed Rule Changes

- **4729-33-01:** Updates the definitions section to reflect change in EMS terminology and to reference the correct cross references to sections of the OAC and ORC.
- **4729-33-02:** Updates the EMS licensure section to reference the official name of the state board of emergency medical, fire and transportation services and clarifies that volunteer

personnel should also be listed on the terminal distributor of dangerous drugs license application.

- **4729-33-05:** Defines "posting up" as a temporary, short-term location of the EMS unit for less than twenty-four hours where the EMS unit is under constant supervision of the EMS personnel on duty. Exempts emergency situations from this requirement.

No Change Rules

- **4729-33-04:** Outlines the required recordkeeping for EMS agencies that possess and store dangerous drugs.

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. The following sections of the Ohio Revised Code are also considered authorizing statutes for this rule package: 4729.01, 4729.51, 4729.54, and 4729.55.

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?

The rule does 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 pharmacy profession has traditionally been done at the state level by legislatively created state boards of pharmacy, such as the Ohio State Board of Pharmacy. The Ohio State Board of Pharmacy regulates all aspects of pharmacy practice, including admission to practice, standards of practice, dispensing and storage of drugs and the discipline of pharmacists. While the Food and Drug Administration closely regulates the manufacture and distribution of prescription drugs, the day-to-day practice of pharmacy, including the storage and dispensing of dangerous drugs, traditionally has been left to state boards.

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 Codes authorizes the state board of pharmacy to adopt rules governing the practice of pharmacy and the storage and dispensing of dangerous drugs. The rules proposed under this statutory authority are necessary to facilitate compliance with the provisions in Chapter 4729 of the Ohio Revised Code to promote the public's safety to prevent drug diversion. Without these regulations, the Ohio State Board of Pharmacy would not be able to:

- Provide the requirements for licensure of EMS agencies as terminal distributors of dangerous drugs.
- Ensures uniform record keeping requirements for drugs stored by EMS agencies.
- Regulate the practice of posting up to prevent the diversion of dangerous drugs.

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 and prescribers of dangerous drugs 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 and approved by the Ohio State Board of Pharmacy's Rules Review Committee. The committee is comprised of a broad array of stakeholders including:

- OhioHealth
- Trumbull Memorial Hospital
- Kroger
- Hock's Pharmacy
- Northeast Ohio Medical University
- Nationwide Children's Hospital
- Giant Eagle
- Absolute Pharmacy
- St Ann's Hospital

- Akron General
- Cedarville University

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 Ohio State Board of Pharmacy Rules Review Committee reviewed the proposed changes. The rules were also reviewed by the Ohio Department of Public Safety – Division of EMS. Following this input, the Ohio State Board of Pharmacy formally approved the rules.

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. However, input was solicited from registered pharmacists through the Board's Rules Review Committee representing health systems, hospitals and retail practice.

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 regulations for the safe storage of dangerous drugs by EMS agencies, the Ohio State 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 the remainder of the rules in this package. It is the Board's responsibility to ensure that the safe storage of dangerous drugs by EMS agencies is consistent throughout the state. 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 Legal Affairs reviewed the Ohio Administrative Code to ensure that the regulation does not duplicate an existing Ohio 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 rule will be posted on the Pharmacy Board's web site, information concerning the rule will be included in materials e-mailed to licensees, and notices will be sent to associations, individuals and groups. Pharmacy Board staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance agents are trained to educate licensees on current and/or new regulations during on-site inspections.

Pharmacy Board staff receive regular updates on rules via a quarterly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, monthly email updates from the legislative affairs liaison and feedback from the Board's legal director 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:

- EMS agencies.

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

Violation of the rules may result in administrative licensure discipline for the EMS agency licensed as a terminal distributor of dangerous drugs license (TDDD). Discipline might include reprimand, suspension or revocation.

c. Quantify the expected adverse impact from the regulation.

4729-33-01: Updates the definitions section to reflect changes in EMS terminology and to reference the correct section of the OAC and ORC. This is a definitional section and is not expected to have an adverse impact.

4729-33-02: Updates the EMS licensure section to reference the official name of the state board of emergency medical, fire and transportation services and clarifies that volunteer personnel should also be listed on the terminal distributor of dangerous drugs license application. This rule requires EMS agencies to obtain licensure as a terminal distributor of dangerous drugs. The license fee, depending on the type of drugs stored by each EMS agency, ranges from $112.50 to $150 per year. The initial application for a terminal distributor license takes about one hour to complete. Online renewal of the license takes about 10 minutes.

4729-33-05: Defines "posting up" as a temporary, short-term location of the EMS unit for less than twenty-four hours where the EMS unit is under constant supervision of the EMS personnel on duty. The rule also exempts emergency situations from this requirement. This rule requires notification and approval of the Board to allow for posting up at a special event. This notification process takes about 10 minutes and will result in a negligible increase in administrative costs.

4729-33-04: Outlines the required recordkeeping for EMS agencies that possess and store dangerous drugs. This regulation will result in increased administrative costs to comply with the record keeping requirements.

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

The Ohio State Board of Pharmacy is committed to ensuring emergency medical services safely store dangerous drugs in order to protect the health and safety of all Ohioans.

Regulatory Flexibility

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

This rule does 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 Ohio State 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 pharmacy 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 an update on current regulations. Additionally, field staff (i.e. compliance officers) is trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

4729-33-01 DEFINITIONS (5-YEAR RULE REVIEW & PROPOSED CHANGE)

As used in Chapter 4729-33 of the Administrative Code:

(A) "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) "Controlled substance" has the same meaning as in section 4729.01 of the Revised Code.

(C) "Dangerous Drug" has the same meaning as in section 4729.01 of the Revised Code and in rule 4729-9-01 of the Administrative Code.

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

(E) "Medical director" has the same meaning as in rule 4765-10-06 of the Administrative Code.

(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 situation.

(G) "Posting up" means locating an EMS unit containing dangerous drugs at a location other than a location licensed by the board of pharmacy.

(H) "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.

(I) "Readily retrievable" means all records which are required to be maintained must be provided upon request to the inspector or agent of the board of pharmacy within three working days.

(J) "Responsible person" has the same meaning as in rule 4729-13-01 of the Administrative Code.

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

(L) "Scope of practice" shall be defined as in section 4765.35 of the Revised Code and rule 4765-12-034 of the Administrative Code for a ~~first~~ emergency medical responder, section 4765.37 of the Revised Code and rule 4765-15-04 of the Administrative Code for an 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 ~~intermediate~~, section 4765.39 of the Revised Code and rule 4765-17-03 of the Administrative Code for a~~n~~ ~~emergency medical technician~~ paramedic, and sections 4765-6-01, 4765-6-03, 4765-6-04 and 4765-6-05 of the Administrative Code.

(M) "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.

(N) "Standing order" and "protocol" have the same meanings as in rule 4729-5-01 of the Administrative Code.

(O) "Tamper-evident" means the package is sealed 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) "Terminal distributor of dangerous drugs" has the same meaning as in section 4729.01of the Revised Code.

4729-33-02 LICENSURE (5-YEAR RULE REVIEW/PROPOSED CHANGE)

(A) Any emergency medical service (EMS) organization that desires to stock dangerous drugs shall apply for and maintain a license as a terminal distributor of dangerous drugs. The one location that serves as the main station will be deemed the headquarters location. Any other locations associated with this headquarters where dangerous drugs will be stored will be licensed as "satellites". Only the headquarters location will be charged a license fee or renewal license fee.

(B) Each location, headquarters and satellites, must be licensed as a limited terminal distributor of dangerous drugs and must maintain a current terminal distributor of dangerous drugs license and drug addendum.

(C) An application for licensure must include all of the following:

(1) A completed application;

(2) A compilation of all protocols involving dangerous drugs that have been signed by the medical director and notarized;

(3) A list of drugs referenced in the protocols to be stocked by the EMS organization, signed by the medical director and notarized;

(4) A list of personnel employed, including volunteers, by the EMS organization who may access and administer dangerous drugs, which includes the name of the individual, level of certification, their certification number, and expiration date;

(5) A list of any and all formal written mutual aid agreements with other EMS organizations;

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

(D) Each location, headquarters and satellite, may only possess those dangerous drugs that are listed on the drug addendum and only at locations licensed by the board of pharmacy.

(1) A medical director may add dangerous drugs to the drug list by submitting revised, signed and notarized protocols and list of medications, and the addendum update fee.

(2) A medical director may delete dangerous drugs from the drug list by submitting a letter listing the drugs to be deleted.

(E) A new application and fee is required prior to any change of location, addition of a satellite location, change of category, name change, or change of ownership. These changes may be made during the annual renewal period with no additional fee other than the renewal fee.

(F) The responsible person shall provide supervision and control of all locations where dangerous drugs are stored. The responsible person must be a physician licensed pursuant to Chapter 4731. of the Revised Code or a pharmacist licensed pursuant to Chapter 4729. of the Revised Code.

(1) To change the responsible person, the new responsible person must complete and return a notification of change of responsible person form within thirty days by regular mail or verified facsimile transmission.

(2) To change the medical director, the new medical director must submit a signed and notarized letter stating that he/she is accepting responsibility for the EMS organization.

(a) If the new medical director approves of the current protocol and drug list, a signed and notarized letter must be submitted stating the current protocols and drug list on file have been reviewed and are approved by the medical director for use by this EMS organization, or

(b) If the new medical director desires to change the protocols or drug list, the medical director must submit the revised, signed, and notarized protocols and drug list, and the addendum update fee.

(G) Any changes in protocols that involve dangerous drugs must be submitted to the state board of pharmacy prior to the implementation of the protocols involved. The state board of pharmacy may discuss such protocols with the ~~state board of emergency medical services~~ state board of emergency medical, fire and transportation services, state medical board, or other governmental agencies as needed to assure their validity.

(H) Any change of personnel requires a letter from the organization within thirty days of the change listing the type of change (addition, update, or deletion), names of the personnel involved, level of certification, their certification number, and expiration date.

4729-33-05 POSTING UP (5-YEAR RULE REVIEW)

(A) Except when "posting up at a special event", "posting up" must be a temporary, short-term location of the EMS unit for less than twenty-four hours where the EMS unit is under constant supervision of the EMS personnel on duty, including but not limited to:

(1) Local school sports event;

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

(B) "Posting up at a special event" requires prior written notification to, and approval from, the state board of pharmacy office. This notification must include the name and location of the event, dates of the event, and name and telephone number of the contact person of the EMS unit.

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

4729-33-04 RECORD KEEPING (5-YEAR RULE REVIEW)

(A) All emergency medical service (EMS) organizations are required to keep complete and accurate records for at least three years of receipt, use, administration, destruction, and waste of dangerous drugs. These records must be readily available for inspection by state board of pharmacy agents or inspectors as per section 3719.27 of the Revised Code and rule 4729-5-29 of the Administrative Code.

(B) Records from satellites may be stored at the headquarters if prior notice is sent to the board office. A letter requesting storage of records at the headquarters must be sent to the state board of pharmacy office by verifiable delivery. The board will notify the organization of the board's approval or denial of the request within sixty days.

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

(D) If there is a recall of oxygen by the manufacturer, all portable oxygen tanks that may have any of that lot number shall be dealt with according to the manufacturer's recommendations; but, in all such cases, such portable oxygen tanks must be purged and then refilled.

(E) A readily retrievable record of controlled substances shall be kept containing documentation of administration, use, or waste of the controlled substances. Such records shall contain at least the following information:

(1) The name, strength, and quantity of the controlled substance administered, used, or wasted;

(2) The date of administration, use, or waste;

(3) The name or other means of identifying the patient, such as medical record number or run number;

(4) The signature and identification number of the individual administering the controlled substance;

(5) In the case of waste, the signatures and identification numbers of both individuals involved in wasting the controlled substance.

(F) If a computerized record keeping system is being utilized to document any drug transactions, including but not limited to the receipt, use, administration, destruction, and wastage, then the system must have "positive identification",

pursuant to paragraph (N) of rule 4729-5-01 of the Administrative Code, of the individual responsible for the drug transaction and be approved by the state board of pharmacy.