CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: Department of Public Safety-Division of EMS

Regulation/Package Title: EMR Curriculum, Continuing Education and Scope of Practice

Rule Number(s): OAC 4765-12-01, OAC 4765-12-02, OAC 4765-12-03, OAC 4765-12-04, OAC 4765-12-05

Date: 2-26-2014

Rule Type:

- ☐ New
- ▪ Amended
- ▪ 5-Year Review
- ☐ Rescinded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.**
   Please include the key provisions of the regulation as well as any proposed amendments.

   Chapter 4765-12 of the Administrative Code (O.A.C.) sets forth the curriculum standards to be met by an emergency medical responder (EMR) training program and an EMR refresher training program, in accordance with section 4765.11 of the Revised Code (R.C.), as well as the continuing education requirements necessary to renew an EMR certificate to practice.

1.29.14

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Rule 4765-12-01 sets forth the criteria that must be demonstrated by an applicant requesting the Board to waive the requirement that emergency medical responder must be a volunteer for a non-profit emergency medical services (EMS) organization or non-profit fire department. This rule was amended to reflect statutory changes to EMS provider titles in accordance with Sub. H.B. 128, 129th General Assembly.

O.A.C. 4765-12-02 sets forth the curriculum standards to be met by an emergency medical responder training program that began prior to September 1, 2012. This rule has been amended to address availability of materials incorporated by reference.

O.A.C. 4765-12-03 sets forth the continuing education requirements necessary to renew a certificate to practice as an emergency medical responder. This rule has been amended to address availability of materials incorporated by reference.

O.A.C. 4765-12-04 sets forth the emergency medical services that may be performed by an emergency medical responder and the conditions under which they may be performed. This rule was amended to allow EMR administration of epinephrine auto-injectors with a patient suffering from anaphylaxis and to permit EMR administration of intranasal naloxone with a patient suspected of opiate overdose.

Additionally, this rule was amended to implement statutory changes to R.C. 4765.35 as set forth by Am. Sub. H.B. 284, 129th General Assembly. The regulation adds a physician assistant, designated by a physician, to the list of health care professionals from which EMS personnel may obtain authorization through a direct communication device to perform certain emergency medical services.

O.A.C. 4765-12-05 sets forth the curriculum standards to be met by an emergency medical responder training program. This rule has been amended to address availability of materials incorporated by reference.

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

R.C. 4765.11 and R.C. 4765.35

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?
If yes, please briefly explain the source and substance of the federal requirement.

No.

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

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N/A.

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)?**

   Pursuant to R.C. 4765.11, the Board is directed to adopt rules that establish the standards for the performance of EMS providers, approval of additional emergency medical services, and conditions under which an EMR training program will be conducted. Consistent, statewide, EMR training will help ensure well-trained EMRs, efficient and effective delivery of prehospital patient care, improved response in emergencies, and increased safety while delivering services.

   Additionally, the Board must amend the regulation to implement statutory changes to R.C. 4765.35 as set forth by Am. Sub. H.B. 284, 129th General Assembly. The regulation, which adds a physician assistant to the list of health care professionals from which EMS personnel may obtain authorization, should improve response in emergencies.

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

   Success of the regulation will be measured by the increase in pass rate of Ohio candidates who attempted the EMR national certification examination. In addition, success of the regulation will be measured utilizing data collected in the Emergency Medical Services Reporting System (EMSIRS). EMSIRS data can be analyzed can be analyzed to determine the duration of EMS responses and transports, the emergency medical services performed by EMS providers, the frequency in which EMS providers perform the services, the success emergency medical services performed and the impact on patient care.

Development of the Regulation

7. **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.

   These rules were reviewed by the Education Committee and the Medical Oversight Committee of the Board. Committee members represent various roles of the emergency medical profession including the State medical director, emergency medicine physicians, trauma surgeons, registered nurses, EMS providers, EMS instructors and program coordinators representing EMS training organizations and fire service organizations.

   The Education Committee members were contacted via email to attend their regularly scheduled public meetings held on July 17, 2013, September 18, 2013 and November 20, 2013. The Medical

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Oversight Committee members were contacted via email to attend their regularly scheduled public meetings held on May 15, 2013, August 13, 2013 and October 15, 2013.

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

The Education Committee reviewed the regulations on July 17, 2013 and on September 18, 2013 the committee recommended that the Board accept O.A.C. Chapter 12 as amended. As part of the Education Committee meeting on November 20, 2013, members discussed and agreed, with the Medical Oversight Committee recommendation, that the Board permit EMR administration of intranasal naloxone when appropriately trained and under medical direction.

On May 15, 2013, the Medical Oversight Committee reviewed the regulations and made a recommendation to amend rule 4765-12-04 of the Administrative Code to include the utilization of EMS-provided adult epinephrine auto-injectors and pediatric epinephrine auto-injectors with written protocol to the EMT scope of practice. On August 13, 2013, the Medical Oversight Committee reviewed and discussed S.B. 105, 130th General Assembly, regarding the administration of naloxone by all EMS providers. On October 15, 2013, the Medical Oversight Committee recommended that the Board permit EMR administration of intranasal naloxone when appropriately trained and under medical direction.

At their regular board meeting on October 17, 2013, a motion, to add the administration of epinephrine via auto-injectors and naloxone via intranasal route to the EMR scope of practice, was presented by the Medical Oversight Committee Chair and unanimously approved by the Board. At their regular board meeting on February 20, 2014, a motion, to file O.A.C. Chapter 12 with JCARR, was approved by the Board.

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?

Changes to EMS curricula and scopes of practice are based on evidence based research. Research studies and results are acquired from national EMS organizations, national publications and research funded through Division of EMS grants.

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?

No alternative regulations could be considered. These regulations align with the NHTSA's national EMS education standards, scope of practice model, accreditation and standard testing and the Board's strategic plan to ensure the EMS system has stable workforce of essential trained and

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certified EMS providers. In addition, the Board must amend O.A.C. rule 12-04 with language changes to R.C. section 4765.35, as set forth by Am. Sub. H.B. 128, 129th General Assembly.

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 curriculum set forth in O.A.C. chapter 4765-12 is a set of competency-based knowledge and performance standards. Pursuant to R.C. 4765.16, accredited EMS training organizations and approved continuing education programs may develop their own training courses under the direction of a physician who specializes in emergency medicine. The continuing education requirements set forth in O.A.C. chapter 4765-12 offer four options to complete the certificate of accreditation renewal requirements. The statutory language changes to R.C. 4765.35 as set forth by Am. Sub. H.B. 284, 129th General Assembly provides no option for performance–based regulation.

Pursuant to R.C. 4765.11, the EMS board must determine the emergency medical services that may be performed by an EMS provider and the conditions under which they may be performed. In accordance with O.A.C. 4765-10-06, nothing in O.A.C. chapter 4765 restricts or otherwise limits the right of the physician who serves as the medical director to determine those EMS providers whom the medical director will allow to provide emergency medical under the auspices of the medical director's license to practice medicine.

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

The Division of Emergency Medical Services is the only authority for EMS training, instruction and certification; therefore, a review of R.C. 4765 and O.A.C. chapter 4765 was completed. The Division of Emergency Medical Services staff reviewed R.C. 4729 and O.A.C. chapter 4729 to avoid duplication and/or conflict with Board of Pharmacy authority. In addition, the Division of Emergency Medical Services staff reviewed R.C. 4731 and O.A.C. chapter 4731 to avoid duplication and/or conflict with Medical Board authority.

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.

Using the division's web site and EMS listservs, the division will provide stakeholders with final rules, rule summaries and changes to chapter 4765-6 of the Administrative Code. Notices to EMS organizations will be distributed through the division newsletter, THE SIREN. The approved Ohio EMS curriculum will be published to the EMS web site using the following link: http://ems.ohio.gov

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Division of EMS staff will receive email notification of the rule changes and attend section briefings regarding implementation policy and procedures.

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;**
- **b. Identify the nature of the adverse impact (e.g., license fees, fines, employer time for compliance); and**
- **c. Quantify the expected adverse impact from the regulation.**
  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.

The proposed regulations set forth the hours and topics of instruction required of emergency medical responder (EMR) training programs, refresher programs, and continuing education. The proposed rules create adverse impact for individual responders in terms of training costs and minimal time required to make written requests for waivers (as applicable) and to document compliance with continuing education requirements.

Stakeholders estimate that initial training costs range from $0 to $500, while costs for continuing education range from $0-$300. The variance in costs for EMR training is dependent on the selected courses, instructors' pay rate, whether or not an affiliation agreement is utilized, the institution's choice of instructional materials, the number of students enrolled in the course. The variance in costs for EMR continuing education may also be dependent upon whether or not an individual's department provides in-service training and the extent to which the scope of practice is adopted into local protocol by the responder's EMS organization and medical director. EMS organizations and their medical directors determine the level of emergency medical services that responders perform.

The expansion to the scope of practice proposed in rule 4765-04 may require additional training if the responder's EMS organization and medical director add the new skills to the responder's scope of practice. It is estimated that the additional training may cost $0 to $100 dependent upon where the training is obtained.

These regulations require EMR training to be conducted in accordance with the curriculum and instructional hours, therefore, training providers may incur costs of instructional materials, instructor time, and equipment as the program providers deem necessary.

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The estimated cost of compliance was determined by the Education Committee of the Board and replies to a statewide survey sent to all accredited institutions to ascertain adverse impact. The committee members include EMS and continuing education training program directors, EMS instructors, EMS providers, and employers for private ambulance agencies and full-time and volunteer fire departments.

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

Ensuring professional standards in an EMS provider's professional conduct, delivery of emergency medical services and patient care justifies the minimal adverse impact to the business community.

Regulatory Flexibility

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

In order to assure safe, effective, and efficient response and delivery of emergency medical services, no alternatives can be considered for curriculum and training standards. However, O.A.C. Chapter 7 allows alternative formats of delivery using a variety of distance learning technologies. In addition, an EMS organization issued a certificate of accreditation is not required to operate all levels of EMS training.

The regulation does not mandate an EMS organization to operate a training program, adopt any procedure or purchase any equipment. Each EMS organization, with the approval of its medical director, determines the extent to which the EMR scope of practice is adopted into local protocol.

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?

OAC chapter 4765-12, in and of itself, does not impose a penalty or sanction. However, provisions in R.C. 4765.33 and R.C. 4765.50 the Board may impose administrative sanctions up to and including revocation of a certificate of accreditation, certificate of approval, certificate of practice or certificate to teach for violations of R.C. 4765 or any rule adopted under it.

If disciplinary action is considered, each case is submitted first to Board's Assistant Attorney General to ensure compliance with R.C. 119.04. The Board reviews each situation on a case-by-case and may consider all information relevant to the requirements of OAC chapter 4765 and R.C. 4765. Depending on the nature and severity of the violation the board may issue a lesser penalty or decide the case.

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

The Board administers grant awards set forth in R.C. 4765.07, and as defined in R.C. 4513.263. First priority is given to EMS organizations for the training of personnel, the purchase of equipment and to improve accessibility and quality of emergency medical services in this state. Grant funds are distributed through a reimbursement process as costs are incurred by the grantee. The Division of EMS website includes a grants web page that summarizes distribution details and provides grant applications. The EMS web page can be found using the following link: www.ems.ohio.org .

In addition, the Medical Oversight Committee of the Board have developed training courses, approved by the State Medical Director, which cover EMR administration of epinephrine via auto-injector and naloxone via intranasal route. These are not Board-required courses; however they are available, at no charge, to the EMS provider at http://ems.ohio.gov/ems_education.stm.

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