

# CSI - Ohio

## The Common Sense Initiative

### Business Impact Analysis

**Agency Name:** Ohio Department of Public Safety, Division of Emergency Medical Services

**Regulation/Package Title:** EMS Services

**Rule Number(s):** OAC 4765-06-1, OAC 4765-06-2, OAC 4765-06-3, OAC 4765-06-4, OAC 4765-06-5, OAC 4765-06-6

**Date:** December 12, 2013

**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☒ Rescinded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.**

Chapter 4765-06 of the Administrative Code sets general provisions for evaluating, approving, and delivering emergency medical services that extend the scope of practice for EMS providers, in accordance with section 4765.11 of the Revised Code (R.C.), as well as curriculum and instruction guidelines for EMS accredited programs.

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Rule 4765-6-01 of the Administrative Code sets forth the procedures by which the Board evaluates additional services to extend EMS scopes of practice. Rule 4765-6-01 of the Administrative Code has no changes.

Rule 4765-6-02 of the Administrative Code is being proposed as a new rule while simultaneously proposed for rescission due to the fifty percent rule-formatting guideline. The rule sets forth the conditions under which an EMS training program and EMS continuing education program will be offered. The rule has been reorganized for consistency, updated to reflect statutory changes to EMS provider titles, and revised to address availability of materials incorporated by reference.

Rule 4765-6-03 of the Administrative Code sets forth the services which may be performed by an EMS provider in the event of an emergency declared by the governor. Rule 4765-6-03 of the Administrative Code has no changes.

Rule 4765-6-04 of the Administrative Code sets forth the conditions under which EMS providers may take part in a research study that includes performing services beyond their scopes of practice. The rule has been amended to reflect statutory changes to EMS provider titles.

Rule 4765-6-05 of the Administrative Code sets forth the conditions under which an EMS provider may administer medication in response to suspected or known exposure to a nerve or organophosphate agent. Rule 4765-6-05 of the Administrative Code has no changes.

Rule 4765-6-06 of the Administrative Code sets forth the conditions under which an advanced emergency medical technician or a paramedic may withdraw blood for the purpose of evidence collection. The rule has been amended to reflect statutory changes to EMS provider titles.

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

R. C. 4765.11, R. C. 4765.35, R. C. 4765.37, R. C. 4765.38, and R. C. 4765.39

**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, this regulation 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.**

Not Applicable.

**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)?**

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This regulation sets parameters for the delivery of pre-hospital emergency medical services training and patient care to assure well-trained EMS providers, improved response in emergencies, and increased safety while delivering services.

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

The success of the regulation will be measured by analyzing the data in the Emergency Medical Services Incident Reporting System (EMSIRS) to evaluate response, determine the number of times these procedures are performed, if reported, and the success of delivery. EMSIRS was established by the Board for the collection of information on all urgent and emergent responses regarding the delivery of emergency medical services in Ohio.

**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 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, EMS Providers, EMS instructors and program coordinators representing EMS training organizations and fire service organizations.

The Medical Oversight Committee members were notified via email that the Chapter 6 rules would be reviewed during the regularly scheduled public meeting held on June 18, 2013.

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

The Medical Oversight Committee reviewed the rules on June 18, 2013 and recommended that EMS titles be amended to reflect statutory changes to sections 4765.01 of the Revised Code as set forth by Am. Sub. H.B. 128, 129<sup>th</sup> General Assembly. The Medical Oversight Committee also recommended that incorporated materials be accurately referenced.

**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?**

EMS curricula and scopes of practice are based on research studies and results acquired by the Emergency Medical, Fire, and Transportation Services Board (Board) from national EMS organizations, national publications, and research funded through Division of EMS grants. Provisions in the rules reflect the Board's statutory responsibility to adopt rules that establish standards for the performance of emergency medical services by emergency medical responders (EMR), emergency

medical technicians (EMT), advanced emergency medical technicians (AEMT) and paramedics pursuant to section 4765.11 of the Revised Code.

**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?**

In order to assure safe, effective, and efficient response and delivery of emergency medical services, few regulatory alternatives can be considered for scopes of practice. However, rule 4765-6-02 allows EMS providers to receive credit for previous training when evidence demonstrates such training meets competency in advanced EMT or paramedic training objectives.

**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 standards referenced in proposed rule 4765-6-02 of the Administrative Code are competency-based (performance based) education standards. Pursuant to section 4765.16 of the Revised Code, 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 as long as the course meets the curricula and course objectives set forth in this chapter.

**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 section 4765 of the Revised Code and chapter 4765 of the Administrative Code was completed. The Division of Emergency Medical Services staff reviewed section 4729 of the Revised Code and chapter 4729 of the Administrative Code to avoid duplication and/or conflict with Board of Pharmacy authority. In addition, the Division of Emergency Medical Services staff reviewed section 4731 of the Revised Code and chapter 4731 of the Administrative Code 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>

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

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### **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 scope of the impacted business community includes the 1329 EMS organizations, 41,662 EMS providers and/or their medical directors. OAC chapter 4765-6 in and of itself, does not require specific expenditures. However, the rules which amplify Revised Code that specify the EMS authorized services and EMS curriculum standards. The nature of the adverse impact may result from obtaining or providing training when additional services are approved by the Board. The cost of compliance will be determined by the EMS organization and the Medical Director, who determines the extent to which the emergency medical services approved by the Board are adopted into local protocol.

OAC rule 4765-6-01 sets forth the procedures the Board shall take when approving additional services. Stakeholders indicated that there would be no cost to comply with these rules.

OAC rule 4765-6-02 sets forth the general provisions to be met by a training program operating EMS initial training programs approved by the Board. This rule, in and of itself, does not require specific expenditures. However, it requires compliance with the education standards set forth in rules 4765-12, 4765-15, 4765-16 and 4765-17. Stakeholders indicated the estimated costs of compliance to the EMS training institutions will vary depending on the EMS level of training and number of training hours. The average cost of doing business for an EMS institution that provides a 150-hour EMT course is \$73,746. The average cost of doing business for an EMS institution that provides a 200-hour AEMT course is \$90,785 and \$163,786 for a 900-hour Paramedic course. The cost of compliance to the EMS student will also vary depending on the EMS level of training and number of training hours. Tuition costs range from \$500-\$1200 for EMT training, \$1000-\$2000 for AEMT training and \$4000-\$10,000 for Paramedic training.

OAC rule 4765-6-04 sets forth the process by which the Board shall approve research studies impacting scope of practice. This rule does not require an EMS organization to conduct a research study. However, if an organization desires to conduct a Board-approved research study, which

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would allow EMS providers to perform a particular emergency medical services outside their usual scopes of practice, it must agree to submit a research proposal, report findings, submit a final report, and appear before the Board, if requested.

OAC rules 4765-6-03 and 4765-6-05 set forth the conditions under which an EMS provider may administer immunizations, necessary medications when exposure to a nerve agent and withdrawing of blood for evidence collection. Stakeholders indicated that there would be no cost to comply with these rules. The fire departments, EMS agencies and private ambulance services currently possess the training kits and the Division of EMS has provided EMS training modules on the administration of immunizations and dangerous medications and the exposure to a nerve of organophosphate agent. Both modules are approved by the State Medical Director, at no cost to the organization and available on the EMS website at the following link: [www.ems.ohio.gov](http://www.ems.ohio.gov).

The estimated costs of compliance for were determined by averaging the expenditures anticipated by representatives of the emergency medical profession. Data was submitted by EMS initial and continuing education training organizations, EMS instructors, EMS providers, private ambulance agencies and fire service organizations representing full-time and volunteer fire departments.

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

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

Pursuant to section 4765.11 of the Revised Code, the Board is statutorily required to promulgate rules in regard to establishing the procedures for approving additional EMS to be performed EMS providers beyond those specified in law. Allowing additional services pursuant to a research study will ultimately determine whether such services are necessary for patient health and safety to be included in the normal sop..

**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, few alternatives can be considered for scopes of practice. The rules do not mandate an EMS organization to offer EMS training, EMS continuing education, adopt any procedure or purchase any equipment. However, the Board However, rule 4765-6-02 allows EMS providers to receive credit for previous training when evidence demonstrates such training meets competency in advanced EMT or paramedic training objectives. Advanced emergency medical technicians and paramedics may provide evidence of previous training that establishes his or her competency in training objectives.

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**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 4765-6, in and of itself, does not impose a penalty or sanction. However, pursuant to RC 4765.33 and OAC chapter 4765-10-03 sets forth 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 the provisions set forth in this chapter. 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.

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

Pursuant to section 4765.07 of the Revised Code, the EMS board administers grant awards as defined in section 4513.263 of the Revised Code. Grants are awarded to EMS organizations for EMS training, and to conduct research that may 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](http://www.ems.ohio.org).