

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: Department of Public Safety-Division of EMS

Regulation/Package Title: EMS Curricula, Continuing Education and Scopes of Practice

Rule Number(s): OAC 4765-15-01, OAC 4765-15-03, OAC 4765-15-04, OAC 4765-15-05,

OAC 4765-16-01, OAC 4765-16-02, OAC 4765-16-03, OAC 4765-16-04, OAC 4765-16-05,

OAC 4765-16-06, OAC 4765-17-01, OAC 4765-17-02, OAC 4765-17-03, OAC 4765-17-04

Date: 6-20-2013

**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☐ Rescinded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.

Please include the key provisions of the regulation as well as any proposed amendments.

Chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code (OAC) sets forth the curriculum standards, continuing education requirements and scopes of practice established by the EMS board

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for the emergency medical technician (EMT), advanced emergency medical technician (AEMT) or paramedic certificate to practice.

Chapter 4765-15 of the Administrative Code sets forth the curriculum standards to be met by an EMT training program and an EMT refresher training program that began prior to September 1, 2012 and the training programs that began on or after to September 1, 2012. The chapter also sets forth the conditions under which the EMS board will renew an EMT certificate to practice and the emergency medical services that may be performed by an EMT and the conditions under which they may be performed.

Chapter 4765-16 of the Administrative Code sets forth the curriculum standards to be met by an AEMT training program and an AEMT refresher training program that began prior to September 1, 2012 and the training programs that began on or after to September 1, 2012. The chapter also sets forth the conditions under which the EMS board will renew an AEMT certificate to practice and the emergency medical services that may be performed by an AEMT and the conditions under which they may be performed.

Chapter 4765-17 of the Administrative Code sets forth the curriculum standards to be met by a paramedic training program and a paramedic refresher training program that began prior to September 1, 2012 and the training programs that began on or after to September 1, 2012. The chapter also sets forth the conditions under which the EMS board will renew a paramedic certificate to practice and the emergency medical services that may be performed by a paramedic and the conditions under which they may be performed.

All rules, except rule 4765-16-05, in chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code, have been amended to address the materials incorporated by reference in compliance with section 121.71 through section 121.74 of the Revised Code. No additional adverse impact resulted from the additional changes to the amended rule. Rule 4765-16-05 of the Administrative Code had no materials incorporated by reference.

Rules 4765-15-04, 4765-16-04 and 4765-17-03 of the Administrative Code must be amended to implement statutory changes to sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> 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.

Rule 4765-15-04 of the Administrative Code has also been amended to remove references to EMT assisted administration of epinephrine auto-injectors and replace with language that allows EMT administration of epinephrine auto-injectors with a patient suffering from anaphylaxis. Rule 4765-17-04 of the Administrative Code is being amended to reference rule 4765-17-03 of the Administrative Code and remove the reference to rule 4765-16-04 of the Administrative Code.

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

Sections 4765.11, 4765.35, 4765.37, 4765.38, and 4765.39 of the Revised Code

**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.**

Although not required to implement or enforce federal legislation or law, the regulation complies with a national initiative for EMS education and training. The EMS Education Agenda for the Future is approved by the United States National Highway Traffic Safety Administration (NHTSA), who oversees EMS at the federal level. The regulations align with NHTSA's systems approach for national EMS education standards, scope of practice model, accreditation and standard testing.

The regulation also follows the EMS board's strategic plan to ensure the EMS system has a stable workforce of essential trained and certified EMS providers to perform required tasks. The comprehensive, statewide plan includes consistent training programs with effective local, regional and state support.

**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 section 4765.11 of the Revised Code, the EMS board is directed to adopt rules that establish the standards for the performance of emergency medical services by EMS providers, including administration of epinephrine to patients who suffer life-threatening allergic reactions. The EMS board is directed to adopt rules that establish the EMS curricula, the hours and materials used in adult and pediatric continuing education programs and courses in recognizing symptoms of life-threatening allergic reaction.

Pursuant to section 4765.11 of the Revised Code, the EMS board is directed to adopt procedures for approving additional emergency medical services authorized under sections 4765.35, 4765.37, 4765.38, 4765.39 of the Revised Code to perform. In addition, the EMS board must amend the regulation to implement statutory changes to sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> 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.

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**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 number of qualified EMS providers serving Ohio citizens. Success of the EMS curricula regulation will be measured by comparing the pass rate of Ohio candidates who attempted the EMS national certification examination against the national pass rate. The EMS continuing education regulation will be measured by the number of EMS providers who renew their certificates to practice and the number of successful certification audits conducted in accordance with rule 4765-8-04 of the Administrative Code. The scopes of practice regulation will be measured by utilizing the Emergency Medical Services Reporting System (EMSIRS) established by the EMS board for the collection of regarding the delivery of emergency medical services. The EMSIRS data will be analyzed to determine the performance skills utilized by EMS providers, the frequency at which the services are provided 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 EMS education subcommittee and the medical oversight committee. 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 EMS education subcommittee members were contacted via email to attend their regularly scheduled public meetings held on July 18, 2012 and November 14, 2012. The medical oversight committee members were contacted via email to attend their regularly scheduled public meetings held on August 15, 2012.

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

The EMS education subcommittee reviewed the regulation on July 18, 2012, and as chapters 4765-15, 4765-16 and 4765-17 had all been recently revised (January 2012) to implement changes in the national EMS education standards and scopes of practice, the subcommittee made a recommendation to file this package as “no change” with the exception of rule 4765-17-04 of the Administrative Code. The language in rule 4765-17-04 of the Administrative Code would be corrected to reflect rule 4765-17-03 of the Administrative Code as the paramedic scope of practice.

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On August 14, 2012, the medical oversight committee reviewed the regulation and made a recommendation to amend rule 4765-15-04 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.

At their regular board meeting on August 15, 2012, the EMS board approved a motion to expand the EMT scope of practice pursuant to section 4765.37 of the Revised Code. On November 14, 2012, the EMS education subcommittee made a recommendation to file chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code as “no change” with the exception of rules 4765-15-04 and 4765-17-04 of the Administrative Code.

On January 31, 2013, EMS education subcommittee and medical oversight committee members were contacted by email regarding the statutory changes set forth by Am. Sub. H.B. 284, 129<sup>th</sup> General Assembly which added 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.

On or about February 14, 2013, to reach a wider stakeholder audience, chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code were posted to the division of EMS’ website with the information about the upcoming five-year rule review date and solicited public comment regarding the filing. The notice of the five-year rule review was also distributed through the division of EMS’ list serve, that includes EMS providers, program directors of EMS training organizations, trauma physicians, medical directors, registered nurses, and EMS instructors in order to solicit input on the rules.

At their regular board meeting on February 21, 2013, the EMS board approved a motion to file chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code as “no change” with the exception of rules 4765-15-04, 4765-16-04, 4765-17-03 and 4765-17-04 of the Administrative Code.

On April 16, 2013, the medical oversight committee reviewed the regulation and made a recommendation to amend rule 4765-15-04 of the Administrative Code to remove the references to assisted administration of epinephrine auto-injectors and replace with language to allow EMT administration of epinephrine auto-injectors with a patient suffering from anaphylactic shock.

At their regular board meeting on April 17, 2013, the EMS board approved a motion to rescind an earlier motion to file chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code until language amending rule 4765-15-04 of the Administrative Code could be written and reviewed. At their special board meeting on May 15, 2013, the EMS board approved a motion to file chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code. The EMS education committee reviewed the regulation on May 22, 2013 and had no concerns with the new language.

At their regular board meeting on June 19 2013, the EMS board approved a motion to allow EMT administration of epinephrine auto-injectors with a patient suffering from anaphylaxis. The EMS board also approved a motion to file with the Joint Committee on Agency Rule Review.

**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?**

Pursuant to section 4765.11 of the Revised Code, the EMS board is directed to adopt rules that establish the EMS curricula, continuing education programs, standards for the performance of emergency medical services and the procedures for approving the additional emergency medical services authorized by sections 4765.35, 4765.37, 4765.38, 4765.39 of the Revised Code, the regulations align with NHTSA's systems approach for national EMS education standards, scope of practice model, accreditation and standard testing and the EMS board's strategic plan to ensure the EMS system has stable workforce of essential trained and certified EMS providers.

The EMS board has no alternative but to amend rules 4765-15-04, 4765-16-05 and 4765-17-03 of the Administrative Code to add the statutory language changes sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> 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 curricula set forth in chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code are competency-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. The continuing education requirements set forth in chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code offer four options to complete the certificate of accreditation renewal requirements. The statutory language changes to sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> General Assembly provide no option for performance-based regulation

Pursuant to section 4765.11 of the Revised Code the EMS board must determine the emergency medical services that may be performed by an EMS provider and the conditions under which they

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may be performed. In accordance with rule 4765-10-06 of the Administrative Code, nothing in chapter 4765 of the Administrative Code 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 services, or to withdraw blood for evidence collection, under the auspices of the medical directors 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 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.

**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 chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code. The division will also distribute notices, regarding the addition of 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, to hospitals and physicians through the ten Regional Physicians Advisory Boards. Notices to EMS organizations will be distributed through THE SIREN, the division newsletter, and presentations for EMS conferences statewide. Division staff will receive email communication of the rule changes. The Ohio EMS curriculum web page can be found using the following link:  
<http://ems.ohio.gov>

**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 estimated costs of compliance for chapters 15, 16, and 17 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. The scope of the impacted business community includes 41,983 EMS providers, 630 EMS training institutions, and 1,819 EMS instructors.

It was determined that changes to rules 4765-15-04, 4765-16-04, 4765-17-03 and 4765-17-04 will enhance patient care at no cost of compliance with the rules. The addition of physician assistants to the list of health care professionals who may be designated by a medical director to provide authorization to EMS personnel through a direct communication device decreases the delay in patient treatment.

The nature of the adverse impact which may result from chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code would be the expense of providing or obtaining training that meets the medical standard of care established by the EMS board. The cost 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.

	EMT Training Program	AEMT Training Program	Paramedic Training Program
EMS Instructor Salaries/Benefits	\$73,746	\$90,785	\$163,786
Equipment	\$0	\$0	\$0
Operations	\$6514	\$8346	\$18,404
Indirect Services	\$5000.00	\$5000.00	\$5000.00
<b>Average General Business Expense</b>	<b>\$85,260</b>	<b>\$104,130</b>	<b>\$187,190</b>

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.

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

Pursuant to sections 4765.11, 4765.16, 4765.37, 4765.38, and 4765.39 of the Revised Code, the EMS Board is statutorily required to promulgate rules in regard to establishing the curricula, procedures and standards for the performance of EMS providers, training institutions, and instructors. This requirement, in addition to EMS board's intent to ensure high standards in a 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.**

The rules do not mandate an EMS organization to operate a training program, adopt any procedure or purchase any equipment. An EMS organization issued a certificate of accreditation or approval is not required to operate all levels of EMS training. Organizations holding certificates of accreditation may form a consortium to operate paramedic training programs under a single national certificate. Each EMS organization, with the approval of its medical director, determines the extent to which the EMS scopes of practice are 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?**

The EMS Board will look at each situation on a case-by-case basis to ensure compliance with section 119.04 of the Revised Code.

**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. 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](http://www.ems.ohio.org).

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## Business Impact Analysis

**Agency Name:** Department of Public Safety-Division of EMS

**Regulation/Package Title:** EMS Curricula, Continuing Education and Scopes of Practice

**Rule Number(s):** OAC 4765-15-01, OAC 4765-15-03, OAC 4765-15-04, OAC 4765-15-05,

OAC 4765-16-01, OAC 4765-16-02, OAC 4765-16-03, OAC 4765-16-04, OAC 4765-16-05,

OAC 4765-16-06, OAC 4765-17-01, OAC 4765-17-02, OAC 4765-17-03, OAC 4765-17-04

**Date:** 1-14-2013 As filed with CSIO on 3/4/13

**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.**

Chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code (OAC) sets forth the curriculum standards, continuing education requirements and scopes of practice established by the EMS board for the emergency medical technician (EMT), advanced emergency medical technician (AEMT) or paramedic certificate to practice.

Chapter 4765-15 of the Administrative Code sets forth the curriculum standards to be met by an EMT training program and an EMT refresher training program that began prior to September 1, 2012 and the training programs that began on or after to September 1, 2012. The chapter also sets forth the conditions under which the EMS board will renew an EMT certificate to practice and the emergency medical services that may be performed by an EMT and the conditions under which they may be performed.

Chapter 4765-16 of the Administrative Code sets forth the curriculum standards to be met by an AEMT training program and an AEMT refresher training program that began prior to September 1, 2012 and the training programs that began on or after to September 1, 2012. The chapter also sets forth the conditions under which the EMS board will renew an AEMT certificate to practice and the emergency medical services that may be performed by an AEMT and the conditions under which they may be performed.

Chapter 4765-17 of the Administrative Code sets forth the curriculum standards to be met by a paramedic training program and a paramedic refresher training program that began prior to September 1, 2012 and the training programs that began on or after to September 1, 2012. The chapter also sets forth the conditions under which the EMS board will renew a paramedic certificate to practice and the emergency medical services that may be performed by a paramedic and the conditions under which they may be performed.

Rules 4765-15-04, 4765-16-04 and 4765-17-03 of the Administrative Code must be amended to implement statutory changes to sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> 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.

Rule 4765-15-04 of the Administrative Code is being amended to add the utilization of EMS-provided adult epinephrine auto-injectors and pediatric epinephrine auto-injectors with written protocol to the EMT scope of practice. Rule 4765-17-04 of the Administrative Code is being amended to reference rule 4765-17-03 of the Administrative Code and remove the reference to rule 4765-16-04 of the Administrative Code.

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

Sections 4765.11, 4765.35, 4765.37, 4765.38, and 4765.39 of the Revised Code

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- 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.**

Although not required to implement or enforce federal legislation or law, the regulation complies with a national initiative for EMS education and training. The EMS Education Agenda for the Future is approved by the United States National Highway Traffic Safety Administration (NHTSA), who oversees EMS at the federal level. The regulations align with NHTSA's systems approach for national EMS education standards, scope of practice model, accreditation and standard testing.

The regulation also follows the EMS board's strategic plan to ensure the EMS system has a stable workforce of essential trained and certified EMS providers to perform required tasks. The comprehensive, statewide plan includes consistent training programs with effective local, regional and state support.

- 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 section 4765.11 of the Revised Code, the EMS board is directed to adopt rules that establish the standards for the performance of emergency medical services by EMS providers. The EMS board is directed to adopt rules that establish the EMS curricula, the hours and materials used in adult and pediatric continuing education programs, and the procedures for approving the additional emergency medical services EMS providers are authorized by sections 4765.35, 4765.37, 4765.38, 4765.39 of the Revised Code to perform.

Pursuant to section 4765.11 of the Revised Code, the EMS board must amend the regulation to implement statutory changes to sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> 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.

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

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### **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 EMS education subcommittee and the medical oversight committee. 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 EMS education subcommittee members were contacted via email to attend their regularly scheduled public meetings held on July 18, 2012 and November 14, 2012. The medical oversight committee members were contacted via email to attend their regularly scheduled public meetings held on August 15, 2012.

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

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On August 14, 2012, the medical oversight committee reviewed the regulation and made a recommendation to amend rule 4765-15-04 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.

At their regular board meeting on February 21, 2013, the EMS board approved a motion to file chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code as “no change” with the exception of rules 4765-15-04, 4765-16-04, 4765-17-03 and 4765-17-04 of the Administrative Code.

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**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?**

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The EMS board has no alternative but to amend rules 4765-15-04, 4765-16-05 and 4765-17-03 of the Administrative Code to add the statutory language changes sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> 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 curricula set forth in chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code are competency-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. The continuing education requirements set forth in chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code offer four options to complete the certificate of accreditation renewal requirements. The statutory language changes to sections 4765.37, 4765.38 and 4765.39 of the Revised Code as set forth by Am. Sub. H.B. 284, 129<sup>th</sup> General Assembly provide no option for performance-based regulation

Pursuant to section 4765.11 of the Revised Code 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 rule 4765-10-06 of the Administrative Code, nothing in chapter 4765 of the Administrative Code 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 services, or to withdraw blood for evidence collection, under the auspices of the medical directors 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 section 4765 of the Revised Code and chapter 4765 of the Administrative Code was completed.

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**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 chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code. The division will also distribute notices, regarding the addition of 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, to hospitals and physicians through the ten Regional Physicians Advisory Boards. Notices to EMS organizations will be distributed through THE SIREN, the division newsletter, and presentations for EMS conferences statewide. Division staff will receive email communication of the rule changes. The Ohio EMS curriculum web page can be found using the following link:  
<http://ems.ohio.gov>

**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 estimated costs of compliance for chapters 15, 16, and 17 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. The scope of the impacted business community includes 41,983 EMS providers, 630 EMS training institutions, and 1,819 EMS instructors.

It was determined that changes to rules 4765-15-04, 4765-16-04, 4765-17-03 and 4765-17-04 will enhance patient care at no cost of compliance with the rules. The addition of physician assistants to the list of health care professionals who may be designated by a medical director to provide authorization to EMS personnel through a direct communication device decreases the delay in patient treatment.

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There is no additional cost of compliance as a result of the rule changes. The nature of the adverse impact that results from chapters 4765-15, 4765-16 and 4765-17 of the Administrative Code is the general business expense of providing training that meets the current medical standard of care.

	EMT Training Program	AEMT Training Program	Paramedic Training Program
Average General Business Expense	\$85,260	\$104,130	\$187,190
EMS Instructor Salaries/Benefits	\$73,746	\$90,785	\$163,786
Equipment	\$0	\$0	\$0
Operations	\$6514	\$8346	\$18,404
Indirect Services	\$5000.00	\$5000.00	\$5000.00
Tuition Cost	\$500-\$1200	\$1000-\$2000	\$4000-\$10,000

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

Pursuant to sections 4765.11, 4765.16, 4765.37, 4765.38, and 4765.39 of the Revised Code, the EMS Board is statutorily required to promulgate rules in regard to establishing the curricula, procedures and standards for the performance of EMS providers, training institutions, and instructors. This requirement, in addition to EMS' intent to ensure high standards in a 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.**

The rules do not mandate an EMS organization to operate a training program, adopt any procedure or purchase any equipment. An EMS organization issued a certificate of accreditation or approval is not required to operate all levels of EMS training. Organizations holding certificates of accreditation may form a consortium to operate paramedic training programs under a single national certificate. Each EMS organization, with the approval of its medical director, determines the extent to which the EMS scopes of practice are 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?**

The EMS Board will look at each situation on a case-by-case basis to ensure compliance with section 119.04 of the Revised Code.

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

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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. 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: <http://ems.ohio.gov>

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