



## Common Sense Initiative

**Mike DeWine**, Governor  
**Jon Husted**, Lt. Governor

**Carrie Kuruc**, Director

### Business Impact Analysis

**Agency, Board, or Commission Name:** [Ohio Department of Public Safety \(DPS\) - Division of Emergency Medical Services \(EMS\), State Board of Emergency Medical, Fire, and Transportation Services](#)

**Rule Contact Name and Contact Information:**

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**Regulation/Package Title (a general description of the rules' substantive content):**

[EMS - Scope of Practice Update – 9/2019](#)

**Rule Number(s):** [OAC Rules 4765-12-04; 4765-16-04](#)

**Date of Submission for CSI Review:** [September 30, 2019](#)

**Public Comment Period End Date:** [October 23, 2019](#)

**Rule Type/Number of Rules:**

New/\_\_\_ rules

No Change/\_\_\_ rules (FYR? \_\_\_)

Amended/\_\_\_2 rules (FYR? No)

Rescinded/\_\_\_ rules (FYR? \_\_\_)

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

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### **Reason for Submission**

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

**Which adverse impact(s) to businesses has the agency determined the rule(s) create?**

**The rule(s):**

- a. ☐ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**
- b. ☐ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**
- c. ☒ **Requires specific expenditures or the report of information as a condition of compliance.**
- d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

### **Regulatory Intent**

2. **Please briefly describe the draft regulation in plain language.**

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

Rules 4765-12-04 and 4765-16-04 of the Administrative Code (OAC) set forth the scopes of practice established by the EMFTS board for the emergency medical responder (EMR) and advanced emergency medical technician (AEMT) certificates to practice. In ORC 4765.011, the designations of individuals certified to practice emergency medical services are described. A first responder is also known as an EMR. An emergency medical technician-intermediate or EMT-I is also known as an AEMT.

EMS providers can perform the services set forth within their certification level scope of practice rule and the services set forth in the scope of practice rules for lower levels of certification. EMS providers cannot perform services set forth for providers at a higher level of certification. For example, an AEMT can perform services set forth in rule 4765-16-04 (AEMT scope of practice) and the services set forth in rule 4765-15-04 (emergency medical technician [EMT] scope of practice) and rule 4765-12-04 (EMR scope of practice). An AEMT cannot perform services set forth in rule 4765-17-03 (paramedic scope of practice).

A summary of each of the scope of practice rules being amended is provided below:

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<b>4765-12-04</b>	<b>Amend</b>	<b>Emergency medical responder scope of practice.</b>
Rule 4765-12-04 sets forth the emergency medical services that may be performed by an emergency medical responder (EMR) and the conditions under which the services may be performed. The rule states that a medical director for an emergency medical organization may limit the scope of practice for EMRs within the organization. The rule requires EMRs performing emergency medical services within the scope of practice to have received training as part of their initial certification course or through subsequent training approved by the EMFTS board, or in certain emergency medical services, after having received training approved by the local medical director. <b>The rule is amended to add CO-oximetry in paragraph (B)(4).</b>		
<b>4765-16-04</b>	<b>Amend</b>	<b>Advanced emergency medical technician scope of practice.</b>
Rule 4765-16-04 sets forth the emergency medical services that may be performed by an advanced emergency medical technician (AEMT) and the conditions under which the services may be performed. The rule states that a medical director for an emergency medical organization may limit the scope of practice for AEMTs within the organization. The rule requires AEMTs performing emergency medical services within the scope of practice to have received training as part of their initial certification course or through subsequent training approved by the EMFTS board, or in certain emergency medical services, after having received training approved by the local medical director. <b>The rule is amended with the addition of Ketamine in paragraph (B)(1) to the list of medications that can be administered.</b>		

- Rule OAC 4765-12-04 is amended to add approved additional services to the EMR scope of practice as set forth in section 4765.35 of the ORC.
- Rules 4765-16-04 is amended to add approved additional services to the AEMT scope of practice as set forth in section 4765.38 of the ORC.

**3. Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

ORC 4765.11, 4765.35, and 4765.38

**4. 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.*

The regulations do not implement federal requirements, nor are they being adopted to participate in a federal program.

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

Not applicable.

**6. 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 and is

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directed to adopt procedures for approving additional emergency medical services the providers are authorized to perform under sections 4765.35 and 4765.38 of the Revised Code.

The Board also is authorized to list additional approved services in the scope of practice rules.

- The use of CO-oximetry by EMS providers has proven to be critical in the detection of potentially lethal levels of carbon monoxide in non-flammable scenarios such as malfunctioning fuel-powered devices such as furnaces, cars, space heaters, or poorly ventilated spaces. This is vital information for the emergency physician; these levels may become normal or the patient may become asymptomatic upon removal from the toxic environment and arrival in the emergency department erroneously leading the physician to discharge the patient home to a persistently dangerous environment.
- The regional chairs of Ohio Regional Physician Advisory Board (RPAB), during review of the NASEMSO (National Association of State EMS Officials) and the Ohio clinical guidelines documents, reported to the state medical director that they support the addition of Ketamine for administration at the AEMT level and asked her to present it to the MOC for its approval.

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

Success of the regulation will be measured utilizing data collected in the Emergency Medical Services Reporting System (EMSIRS).

**8. Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**

*If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.*

No.

**Development of the Regulation**

**9. 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.*

The Ohio State Board of Emergency Medical, Fire, and Transportation Services is a twenty-one member board. The director of the Department of Public Safety designates a member of the Department of Public Safety as a member of the Board. Twenty members who each have “background or experience in emergency medical services or trauma care” are appointed by the Governor with the advice and consent of the Ohio Senate. The Governor attempts “to include members representing urban and rural areas, various geographical regions of the state, and various schools of training” in making appointments to the Ohio State Board of EMFTS. The appointees to the board represent Ohio’s fire and emergency medical services, private medical transportation services, mobile intensive care providers, air medical providers, trauma programs, hospitals,

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emergency physicians, EMS training institutions, and ODPS. Members of the EMFTS Board and individuals with similar backgrounds and experiences make up the committees, subcommittees, and workgroups of the EMFTS Board.

Scope of practice rules are an agenda item at the bi-monthly meetings of the Medical Oversight Committee (MOC) and frequently appear on the bi-monthly meeting agendas of the Education Committee. Other committees, including the Medical Transportation Committee and EMS for Children Committee were involved in the development of these amendments. Discussions and recommendations that resulted in these amendments to the scope of practice rules occurred between August 2017 and August 2019. In addition, the state medical director, EMS education coordinators and other staff of the Ohio Division of EMS (DEMS), and legal staff of the Ohio Department of Public Safety (ODPS) participated in the revisions to the scope of practice rules.

Members of the MOC discussed adding CO-oximetry to the EMR scope of practice and Ketamine to the AEMT scope of practice at its August and October 2017 meetings. The State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) approved adding CO-oximetry to the EMR scope of practice matrix and ketamine to the AEMT scope of practice matrix at its October 2017 meeting. The State Board of EMFTS approved revising rule OAC 4765-12-04 to include CO-oximetry and rule 4765-16-04 to include Ketamine at its June 2019 meeting, and with slight revisions to the motions, again in August 2019.

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

The scopes of practice are relevant to current state and national standards and the proposed revisions will align the rules with the EMS scope of practice matrix published at the EMS Website at [http://www.publicsafety.ohio.gov/links/ems\\_scope\\_practice.pdf](http://www.publicsafety.ohio.gov/links/ems_scope_practice.pdf). The recommendations for changes to the scope of practice rules were brought to the EMFTS Board from the Medical Oversight Committee and discussed at the Board meetings and, at times, Education Committee meetings to consider how the additional services will impact curriculum and equipment requirements at accredited EMS training organizations.

Following EMFTS Board approval of the CO-oximetry and Ketamine rule revisions, the Education Committee requested that the Medical Oversight Committee consult with the Education Committee during the rule drafting process to identify potential adverse impacts to the education programs.

**11. 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?**

The state medical director provided several articles related to the CO-oximetry revision:

EMR Scope, 4765-12-04, Add CO-oximetry	
<a href="https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6303a6.htm">https://www.cdc.gov/mmwr/preview/mmwrhtml/mm6303a6.htm</a>	CDC, QuickStats: Average Annual Number of Deaths and Death Rates from Unintentional, Non-Fire-Related Carbon Monoxide

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	Poisoning, *† by Sex and Age Group — United States, 1999–2010
<a href="https://www.emsworld.com/article/1222360/hidden-dangers-carbon-monoxide">https://www.emsworld.com/article/1222360/hidden-dangers-carbon-monoxide</a>	The Hidden Dangers of Carbon Monoxide
<a href="https://www.bramptonguardian.com/news-story/5200563-tragedy-in-making-avoided-by-portable-detector/">https://www.bramptonguardian.com/news-story/5200563-tragedy-in-making-avoided-by-portable-detector/</a>	Tragedy-in-making avoided by portable detector

**12. 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 were considered. Pursuant to section 4765.11 of the Revised Code, the EMS board is directed to adopt rules that establish the EMS standards for the performance of emergency medical services and the procedures for approving the additional emergency medical services authorized by sections 4765.35 and 4765.38 of the RC. The regulations align with the National Highway Traffic Safety Administration's (NHTSA's) systems approach for national EMS education standards, scope of practice models, accreditation, and standard testing, and the EMFTS board's strategic plan to ensure the EMS system has stable workforce of essential trained and certified EMS providers.

**13. 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 OAC chapters 4765-12 and 4765-16 of the OAC are competency-based education standards. Pursuant to sections 4765.11 and 4765.16 of the RC, accredited EMS training organizations and approved continuing education institutions may develop their own training courses under the direction of a physician who specializes in emergency medicine.

Pursuant to section 4765.11 of the Revised Code the EMFTS board must determine the emergency medical services that may be performed by an EMS provider and the conditions under which they may be performed by an EMS provider. In accordance with OAC rules 4765-12-04 and 4765-16-04, the medical director for any EMS organization may limit, but not exceed, the scope of practice for those EMS providers providing emergency medical services under the auspice of the medical director. The medical director is responsible for ensuring that the EMS providers meet the performance standards established by the medical director.

**14. 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 Chapter 4765. of the RC and agency 4765 of the OAC was completed.

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**15. 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 [EMS.ohio.gov](http://ems.ohio.gov) and the [gov.delivery.com](http://gov.delivery.com) user groups, the division will provide stakeholders with final rules, rule summaries, and changes to amended rules in OAC chapters 4765-12 and 4765-16 of the OAC. The approved Ohio EMS scope of practice will be published at the EMS web site using the following link: <http://ems.ohio.gov>. The Division of EMS staff will notify the EMS accredited training center and continuing education program directors about the approved Ohio EMS rule revisions via email and through program director directives published on the [EMS.ohio.gov/program director portal](http://ems.ohio.gov/program-director-portal) (<https://www.ems.ohio.gov/portal.aspx>). Division of EMS staff will receive email notification of the rule changes and attend section briefings regarding implementation policy and procedures.

The Division of EMS posts information about the rule review process, including those rules scheduled for review, drafts open for public comment, proposed rules and public hearing notices, and recently adopted rules, at its *Laws & Rules Overview* Web site ( <https://www.ems.ohio.gov/laws.aspx> ) and at the Department of Public Safety *Administrative Rules* Web site ( <https://publicsafety.ohio.gov/wps/portal/gov/odps/what-we-do/administrative-rules-reviews/> ).

The laws and rules associated with emergency medical services are provided as links at the "*Laws and Rules Overview*" site ( <https://www.ems.ohio.gov/laws.aspx> ), and the amended rules, when they become effective, will be available through that link. The Division of EMS will use the [EMS gov.delivery.com](http://gov.delivery.com) system, which includes EMS instructors, EMS agencies, and "EMS for Children" lists, to distribute the final rules to stakeholders when they become effective. Division of EMS staff will receive email notification of the rule changes and attend section briefings regarding the implementation policy and procedures. During its meetings, the EMFTS Board receives regular updates about EMS rules. In addition, notification of the rule changes to Division staff will be delivered internally through staff meetings, and cross-training of staff on co-workers' job responsibilities that will increase the overall knowledge and efficiency of the Division.

**Adverse Impact to Business**

**16. 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; and**

The scope of the impacted business community fluctuates but includes approximately:

- 1,235 EMS organizations;
- 41,500 EMS providers;
- 93 EMS accredited institutions; and
- 560 approved EMS continuing education institutions.

SOURCE: Division of Emergency Medical Services

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

The Division of EMS staff determined that the changes to chapters 4765-12 and 4765-16, will enhance patient care with minimal costs of compliance to the provider, EMS organizations, and accredited and CE institutions. The changes to the scope of practice rules proposed at this time will have minimal adverse impacts.

**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 nature of the adverse impact which may result from changes to OAC chapters 4765-12 and 4765-16 would be the expense of providing or obtaining training that meets the medical standard of care established by the EMFTS Board. The costs of compliance for the EMS training institutions will vary depending on the level of EMS training and the number of training hours required for each level of certification provided, typical class size, instructor salaries, supplies, equipment, and affiliations as the institution deems appropriate. The institutions have the sole ability to dictate the tuition costs of their programs based on budgetary needs. The costs of compliance to the EMS student will also vary depending on the level of EMS certification and number of training hours required.

Tuition costs range from:

- \$300 - \$700 for EMR training,
- \$500-\$1200 for EMT training,
- \$1000-\$2000 for AEMT training, and
- \$4000-\$10,000 for paramedic training.

These regulations do not require an institution to provide specific levels of EMS training programs, only those that the institution has voluntarily applied to provide.

Source: The information was updated in 2019 by DEMS staff following review of a sample of initial and renewal applications submitted by accredited institutions during the period of 01/01/2017 to 08/01/2017.

The proposed revisions to the scope of practice rules are not anticipated to increase tuition costs for students or require training institutions to purchase additional supplies or equipment or hire additional staff.

The costs to add CO-oximetry to the EMR scope and curriculum and Ketamine to the AEMT scope and curriculum will be minimal as will the added time required to the curriculum. The EMR curriculum currently includes training in the use of a pulse oximeter, which is similar to the CO-oximeter. The addition of Ketamine to the AEMT curriculum requires its addition to fourteen items currently in the pharmacology list.

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

Revisions to the scope of practice being filed are made pursuant to sections 4765.11, 4765.35, and 4765.38 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. EMS providers respond to medical and traumatic emergencies in the pre-hospital setting and function without direct oversight. It is critical that the EMS workforce maintain an acceptable knowledge and skill level to provide quality care before and during transport to a medical facility. EMS agencies utilizing EMS providers depend upon the EMFTS Board and the Division of EMS to ensure individuals issued a certificate to practice have met a recognized standard. The Division of 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.

Additionally, EMS agencies can apply to the EMFTS Board each year for grant money to offset the cost of continuing education renewal and training requirements for their personnel. EMS agencies can also apply for a certificate of approval to offer continuing education in-house, at no cost, to ensure their providers obtain sufficient training and CE to meet the requirements to renew and practice.

**Regulatory Flexibility**

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

In order to assure safe, effective, and efficient delivery of emergency medical services, no alternatives can be considered for curriculum and training standards. The rules do not mandate an EMS organization to operate a training program, adopt any procedure, or purchase any equipment. In addition, an EMS organization issued a certificate of accreditation is not required to operate all levels of EMS training. Each EMS organization, with the approval of its medical director, determines the extent to which the provider scope of practice is adopted into local protocol and, therefore, the equipment and training required.

**19. 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 rules in OAC chapters 4765-12 and 4765-16 in and of themselves do not impose any penalties or sanctions. However, as set forth in provisions in RC sections 4765.33 and 4765.50, the EMFTS 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 Chapter 4765. of the RC or any rule adopted under it.

If disciplinary action is considered, each case is submitted first to the EMFTS Board's Assistant Attorney General to ensure compliance with RC section 119. The EMFTS Board reviews each

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situation on a case-by-case basis and may consider all information relevant to the requirements of OAC agency 4765 and RC Chapter 4765.

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

The EMFTS Board administers grant awards set forth in RC section 4765.07, and as defined in RC section 4513.263. First priority awards are available 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. The Division of EMS website includes a grants Web page that summarizes distribution details and provides grant applications. The EMS “Grant Program” Web page can be found using the following link: <https://www.ems.ohio.gov/grants.aspx>.

In addition, the Medical Oversight Committee of the EMFTS Board have developed training courses, approved by the State Medical Director, available at no charge. These courses, as well as several others, can be found at the EMS “Training & Education Resources” Website at <https://www.ems.ohio.gov/education-resources.aspx>. Training at no cost is available at the “Public Safety Training Campus” at <https://trainingcampus.dps.ohio.gov/cm/cm710/pstc/pstc.html> or a similar publicly accessible Website.

The EMS Web page includes links to the laws and rules associated with emergency medical services, along with an overview section about accredited and approved continuing education institutions, certifications, medical direction, scope to practice, and training and education. The *Agency Directory* at the EMS Web site ( <https://www.ems.ohio.gov/about-directory.aspx> ) includes the email addresses, telephone numbers, including a toll free number (1-800-233-0875), and the names of EMS staff.

Division of EMS staff members attend and present information at various conferences, seminars, and symposiums throughout the State of Ohio, such as the annual International Trauma Life Support (ITLS) Emergency Care Conference, the Ohio Association of Emergency Medical Services (OAEMS) Summer Conference, Ohio Fire and EMS Expo, Ohio EMS Grant Hospital/Ohio Health Conference, Ohio Ambulance Association Conference, Ohio State Fire Instructors Society, and the Ohio State Fair. The Division of EMS presents stakeholder conferences and Webinars for stakeholders, including EMS program directors and medical directors.

When the rules are filed with CSI, govdelivery.com will be used to notify approximately 545 EMS instructors, 705 EMS agencies, and 163 “EMS for Children” subscribers about the revised rules in OAC chapters 4765-12 and 4765-16, the filing with CSI, and the stakeholder comment period. Notification about the filing and comment period for the rules in OAC chapters 4765-12 and 4765-16 will also be placed on the EMS.Ohio.gov website.

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