Ohio | 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:

Joseph Kirk, jakirk@dps.ohio.gov, 614-466-5605

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

Paramedic scope of practice - pediatric non-emergent transport with ventilator

Rule Number(s): 4765-17-03

Date of Submission for CSI Review: November 8, 2019

Public Comment Period End Date: December 4, 2019

Rule Type/Number of Rules:

- ☐ **New/** 0 **rules**
- ☒ **Amended/** 1 **rules (FYR?** No**)**
- ☐ **No Change/** 0 **rules (FYR? ___)**
- ☐ **Rescinded/** 0 **rules (FYR?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.

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.**

X **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.

A summary of the scope of practice rule being amended is:

4765-17-03	Amend	Paramedic scope of practice.
Rule 4765-17-03 sets forth the emergency medical services that may be performed by a paramedic 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 paramedics within the organization. The rule requires paramedics 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. Paragraph (B) is added to permit non-emergent ambulance transport of a stable patient less than sixteen years of age who has a chronic condition requiring a tracheostomy tube and a ventilator, provided the patient's caregiver accompanies the patient during transport.		

- Rules 4765-17-03 is amended to add approved additional services to the paramedic scope of practice as set forth in section 4765.39 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.**

RC 4765.11, 4765.39

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 to adopt procedures for approving additional emergency medical services the paramedics are authorized to perform under section 4765.39 of the Revised Code.

   The rule change related to non-emergent transport of a pediatric patient with a tracheostomy tube was initially identified as a need during discussions among members of the Transportation Committee. Discussions among members of the EMFTS Board were held the following day, where the proposed revisions were referred to the Medical Oversight Committee (MOC) and the EMS for Children (EMSC) Committee.

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

   Usually the success of the scope of practice regulations can be measured using data collected in the Emergency Medical Services Reporting System (EMSIRS), which 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 of emergency medical services performed, and the impact on patient care. EMSIRS reports are reviewed annually to measure the success of scope of practice regulations.

   However, this revision to the paramedic scope of practice permits the non-emergent ambulance transport of patients, which will not be captured as an EMSIRS data entry. To monitor the success of the regulation, members of the committees that proposed and developed the amendment will be asked to report on non-emergent ambulance transports of stable pediatric

patients who have chronic conditions requiring a tracheostomy tube and a ventilator, after the rule becomes effective.

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, none of the proposed rules contained in this rule package are being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931.

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, emergency physicians, EMS training institutions, and ODPS. Members of the EMFTS Board and individuals with similar backgrounds and experiences make of 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 April 2019 and October 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) participate in the revisions to the scope of practice rules.

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

    The need to permit non-emergent ambulance transport of a pediatric patient with a ventilator emerged during a discussion among members of the Medical Transportation Committee during its April 16, 2019 meeting. The issue was referred to the MOC by the EMFTS Board. MOC consulted with members of the EMS for Children (EMSC) Committee. The MOC discussed amending the paramedic scope of practice rule during its June 18, 2019 meeting, and the MOC chair presented the

information to the EMSC members at its June 18, 2019 meeting, immediately following the MOC meeting. The discussion among MOC members addressed the growing need, over the past several years, based on the number of children on ventilators cared for by family members and others at home. Those using wheelchairs can be transported in wheelchair vans, cabs, and other vehicles. Those confined to bed require transportation by stretcher. The current EMS scope of practice does not permit transporting this population by ambulance in a non-emergent situation, such as from home to an appointment or from hospital discharge to home or to a nursing facility.

The EMSC worked toward creating a protocol to address the non-emergent transport of pediatric patients who have a tracheostomy tube and utilize a ventilator. The MOC approved a motion for the protocol recommendation to be presented to the EMFTS Board during its June 19, 2019 meeting. The request for a motion was presented by the state medical director, and the motion approved by the EMFTS Board in June 2019 is:

> …to amend rule 4765-17-03 of the Ohio Administrative Code paramedic scope of practice to include the non-emergent transport of a patient with a tracheostomy tube who utilizes a ventilator to be transported provided the patient's caregiver accompanies the patient during transport.

Based on continuing discussions among Medical Transportation Committee and Critical Care Subcommittee members during their meetings, a revision was proposed and approved by members of the MOC and EMSC Committee. After rescinding the motion of June 19, 2019, The EMFTS approved the following amendment as an addition to rule 4765-17-03 during its October 16, 2019 meeting:

> *(B) A paramedic may perform non-emergent ambulance transport of a stable patient less than sixteen years of age who has a chronic condition requiring a tracheostomy tube and a ventilator provided the patient's caregiver accompanies the patient during transport.*
>
> *(1) The caregiver must have received appropriate training in use of the patient's ventilator.*
>
> *(2) A caregiver is not required to accompany the patient if the patient is accompanied by an Ohio licensed registered nurse or respiratory therapist, or other appropriately trained and licensed Ohio healthcare provider.*

In addition to the scope of practice revisions, committee members and the board discussed broader issues about the EMS scope of practice, including how it impacts paramedics working in mobile integrated health care and emergency room environments and the employers who hire them. The EMFTS Board organized a Scope of Practice Ad Hoc Committee to address the broader issues; it met for the first time on July 25, 2019 and has scheduled meetings for the fourth Thursday of each month thereafter.

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?

An article in the May 2018 *Respiratory Care* (Vol. 63 No 5, "Analysis of a Pediatric Home Mechanical Ventilator Population") states, "The population of children requiring home mechanical ventilation

has grown in number and complexity since the advent of the home mechanical ventilator nearly 40 years ago." Members of the Transportation Committee, and later, members of the EMFTS Board, discussed receiving an increased number of calls to transport pediatric patients in non-emergent situations. Examples include calls to transport a pediatric patient using a ventilator from home to a doctor's office or from a nursing facility to home.

Paragraph (A)(9) of OAC rule 4765-17-03 includes ventilator management of patients sixteen years of age or older in the paramedic scope of practice during emergency transports. This rule will remain in effect, and requires a paramedic for this type of transport. Currently, non-emergent transport of pediatric patients utilizing ventilators requires a mobile intensive care unit (MoICU). MoICUs are a limited resource and often are not available in rural areas.

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 standards for the performance of emergency medical services, and the procedures for approving the additional emergency medical services authorized by section 4765.39 of the RC.

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 Chapter 4765-17 of the OAC provide a competency-based education standard. Pursuant to section 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.

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.

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 and the gov.delivery.com user groups, the division provides stakeholders with final rules, rule summaries, and changes to amended rules in OAC chapters. 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 (https://www.ems.ohio.gov/portal.aspx). Division of EMS staff will receive email notification of the rule change 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 rule, when it becomes effective, will be available through that link. The Division of EMS will use the EMS gov.delivery.com system, which includes EMS instructors, EMS agencies, and "EMS for Children" lists, to distribute the final rule to stakeholders when it becomes effective. Division of EMS staff will receive email notification of the rule change 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 change 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;
- 41,225 EMS providers;
- 90 EMS accredited institutions, which include 38 paramedic training programs; and
- 553 approved EMS continuing education institutions.

SOURCE: Division of Emergency Medical Services

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

Adverse impacts for accredited institutions (stakeholders) vary depending on the levels of training 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. 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. In general, accredited institution provide paramedic training for a tuition fee of $4,000 to $10,000.

The expansion to the scope of practice proposed in this amendment to 4765-17-03 will create a minimal need for additions to paramedic training. EMS staff will be responsible for transporting pediatric patients—already included in paramedic training. An appropriately trained caregiver, Ohio licensed registered nurse or respiratory therapist, or other appropriately trained and licensed Ohio healthcare provider will accompany the patient and will be responsible for ventilator management.

SOURCE: The tuition information was updated in 2017 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 Division of EMS staff determined that the change to chapter 4765-17 will enhance patient care with minimal costs of compliance to the provider.

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 chapter 4765-17 would be the expense of providing or obtaining training that meets the medical standard of care established by the EMFTS Board. In general, 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. Based on this amendment to OAC rule 4765-17-03, the ventilator management provided by the patient's caregiver, who accompanies the patient during transport. Minimal additional training will be required, resulting in minimal adverse impact.

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

Revisions to the paramedic scope of practice rule are made pursuant to sections 4765.11 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. 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.

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 scope of practice rules in OAC Chapter 4765 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 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.