



Common Sense Initiative

Mike DeWine, Governor
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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](#)

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Regulation/Package Title (a general description of the rules' substantive content):
[4765-14 \(Trauma Triage\) Five-year Review](#)

Rule Number(s): [4765-14-01, 4765-14-02, 4765-14-03, 4765-14-04, 4765-14-05, And 4765-14-06](#)

Date of Submission for CSI Review: [April 1, 2022](#)

Public Comment Period End Date: [April 25, 2022](#)

Rule Type/Number of Rules:

New/___ rules

No Change/ 4 rules (FYR? [Yes](#))

Amended/ 2 rules (FYR? [Yes](#))

Rescinded/___ rules (FYR?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.

Chapter 4765-14 of the Ohio Administrative Code (OAC) is authorized by sections 4765.11 and 4765.40 of the Ohio Revised Code (RC) and specify the methods to be used by emergency medical services personnel to determine which injured patients they treat are severely injured and require transportation to a trauma center.

A summary of each of the rules and its proposed amendments is provided below:

4765-14-01	Amend	Definitions.
Rule 4765-14-01 sets forth the EMS definitions for Chapter 4765-14 of the OAC. The rule is amended with the addition of paragraph (C)(7), which is an additional symptom indicating "evidence of respiratory distress or failure."		
4765-14-02	Amend	Determination of a trauma victim.
Rule 4765-14-02 sets forth specific criteria for EMS personnel to use in evaluating whether an injured person qualifies as an adult, geriatric, or pediatric trauma victim. Criteria to consider includes anatomic and physiologic conditions and injuries, in addition to mechanism of injury and special considerations as taught in EMS curricula. The paragraph "On scene fatality in same vehicle" is added to paragraphs (A), (B), and (C). A statement concerning use of use of anticoagulant or anti-platelet medications is added to paragraph (D).		

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4765-14-03	No Change	Enforcement of state or regional trauma triage protocols.
Rule 4765-14-03 specifies that EMS medical directors are responsible for enforcing triage protocols through a performance improvement or peer review process. This rule also requires the EMFTS Board to investigate all complaints regarding violations of triage protocols.		
4765-14-04	No Change	Education of state and regional trauma triage protocols.
Rule 4765-14-04 specifies a variety of entities that the EMFTS Board shall consult with in creating and presenting educational opportunities regarding triage protocols.		
4765-14-05	No Change	Exceptions to mandatory transport.
Rule 4765-14-05 sets forth five exceptions to mandatory transport of a trauma patient to a trauma center. These exceptions include: need for initial assessment and stabilization; adverse weather or ground conditions; shortage of EMS resources; undue delay; and patient request.		
4765-14-06	No Change	Amendments affecting regional protocols.
Rule 4765-14-06 sets forth the manner in which changes to the state triage protocol will affect regional triage protocol variants. This rule also specifies the manner in which changes to regional composition will affect regional triage protocol variants.		

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.**

Authorizing statutes for rules 4765-14-01 through 4765-14-06 of the OAC are sections 4765.11 and 4765.40 of the RC; the amplifying statute for the rules is section 4765.40 of the RC.

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?**

The regulations do not implement a federal requirement.

If yes, please briefly explain the source and substance of the federal requirement. N/A

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

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 the directives of ORC 4765.40, the State Board of EMFTS established these rules to define "trauma," to create protocols for the identification of trauma victims, and to direct trauma victim destination determination to maximize chances of survival and minimize costs associated with subsequent transfers to a trauma center.

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

The Ohio Department of Public Safety operates two state-level data systems created under ORC 4765.06 that collect relevant data:

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- the EMS Incident Reporting System (EMSIRS), which collects data on all emergency runs made by emergency medical services, and
- the Ohio Trauma Registry, which collects data on all injured person admitted to Ohio hospitals.

Analysis of this data allows for determination of over/under triage. This type of analysis and monitoring is ongoing by the EMFTS Board and its Trauma Committee.

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.

None of the proposed rules contained in this rule package are being submitted pursuant to RC 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.

Copies of the proposed five-year review schedule and the rules set forth in OAC Chapter 4765-14 were provided to members of the Trauma Committee prior to their May 12, 2021 meeting and for other 2021 meetings. The information was provided to members of the EMFTS Board prior to their August 18, 2021 meeting and for other 2021 meetings.

Beginning in May 2021, the chair of the Trauma Committee discussed the five-year rule process during the Committee's meetings and invited members to submit proposed amendments to her. Proposed amendments were compiled and presented to the Trauma Committee during its November 10, 2021. The proposed amendments were discussed and the Committee approved filing the proposed amendments with CSI during its November 10, 2021 meeting.

The EMFTS Board received information, including proposed amendments, as part of its meeting packets from August 2021 through February 2022 and approved filing the rules with CSI during its February 16, 2022 meeting.

Stakeholders copied on the rules and Business Impact Analysis (BIA) filed with the Common Sense Initiative (CSI) office include:

- the Ohio Chapter of the American College of Emergency Physicians (Ohio ACEP);
- the Ohio Chapter of the American College of Surgeons (OCACS);
- the Ohio Chapter of the American Academy of Pediatrics (Ohio AAP);
- the Ohio Hospital Association (OHA);
- the Ohio Osteopathic Association (OOA); and
- the Ohio Children's Hospital Association (OCHA).

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In addition, the Commission on Minority Health will receive a copy of the trauma rules and BIAs filed with CSI.

When the rules in OAC Chapter 4765-14, along with the rules in OAC Chapter 4765-4 (*Reporting Delivery of Emergency Medical Services and Trauma Care*), are filed with CSI, a general notice to subscribers of the Trauma System, EMSIRS Incident Reporting, Ohio Trauma Registry, EMS for Children, and EMS General Bulletins user groups will be notified of the filing and the public comment period using the govDelivery.com system.

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

Rule 4765-14-01 (*Definitions.*) is amended with the addition of paragraph (C)(7), which is an additional symptom indicating "evidence of respiratory distress or failure."

The paragraph "On scene fatality in same vehicle" is added to paragraphs (A), (B), and (C) of rule 4765-14-02 (*Determination of a trauma victim.*). In addition, the rule is amended to include a statement concerning use of anticoagulant or anti-platelet medications in paragraph (D).

Rule 4765-14-05 (*Exceptions to mandatory transport.*) includes paragraph (C), which states, as an exception, "Transporting the victim to an adult or pediatric trauma center would cause a shortage of local emergency medical service resources." A member of the Trauma Committee submitted a comment that paragraph (C) is the weakest of the exceptions and the most vulnerable to be used inappropriately. However, no amendments are proposed for rule 4765-14-05.

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 "Guidelines for Field Triage of Injured Patients; Recommendations of the National Expert Panel on Field Triage, 2011" published by the Centers for Disease Control and Prevention is an expert consensus document that provides the national "gold standard" from triage and is based on the best available science. The 2011 guidelines were used during the 2014 rule review process. The guidelines have not been updated since 2011.

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. These rules have been in place and under review by the emergency services agencies that are bound to their use and by the trauma centers that receive those patients. Members of the Trauma Committee, as subject matter experts, believe that these rule represent the most appropriate methods and are based on the best available science.

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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.

No performance-based regulations were contemplated for these rules, which set medical care standards for severely injured people in Ohio. The rules create protocols for the identification of trauma victims, to direct trauma victim destination determination to maximize chances of survival and to minimize costs associated with subsequent transfers to a trauma center.

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 and legal staff members reviewed RC Chapter 4765. and OAC Chapter 4765 to assure there was no duplication or conflict among Ohio EMS and trauma regulations. No reports or complaints of duplication of effort have been reported. Additionally, a search was completed in RegExplorer to ensure that there was no duplication of existing regulation.

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.

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, is posted at the Division of EMS *Laws & Rules Overview* Web site (<https://www.ems.ohio.gov/laws.aspx#gsc.tab=0>) and 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 trauma care and EMSIRS are provided as links at the *EMS Trauma System Overview* Web site (<https://www.ems.ohio.gov/trauma-system.aspx#gsc.tab=0>) and Data Center Web site (<https://www.ems.ohio.gov/data-center.aspx#gsc.tab=0>). The state triage protocols are set forth in OAC Chapter 4765-14, and the rules and proposed amendments are available at the *EMS Laws & Rules Overview* Web site and the Department of Public Safety *Administrative Rules* Web site.

The Division of EMS will use the EMS govDelivery.com notification system, which includes a *Trauma System* subscribers list of approximately 480 addresses, an *Ohio Trauma Registry* subscribers list of approximately 150 addresses, and an *EMS Incident Reporting System* subscribers list of approximately 1,150 addresses, 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. Phone and email contacts for members of the EMS Research and Analysis staff are available in the *EMS Agency Directory* (<https://www.ems.ohio.gov/about-directory.aspx#gsc.tab=0>).

Adverse Impact to Business

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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 impact to the business community is limited to only those private ambulance companies that are involved in emergency response (102).

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

The nature of the financial impact is additional costs incurred when transporting a small fraction of their patients a potentially longer distance in order to deliver a trauma victim to the necessary level of care provided by a trauma center instead of simply delivering them to the closest hospital.

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.

It is impossible to make a legitimate estimate of the cost of compliance as valid cost data are not available. An assumption can be made that by delivering the trauma patient to the appropriate facility initially, the waste generated by secondary transfers of these same patients from local hospital emergency departments to the necessary trauma facility is eliminated. These costs will be more than offset by an anticipated decrease in the costs to the trauma victim associated with subsequent transfers, the use of another ambulance or a costly helicopter air medical transport. These assumptions are made on patient care data collected by the Department of Public Safety from EMS in the EMS Incident Reporting System and from acute care hospitals in the Ohio Trauma Registry.

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

The costs associated with this rule have already been incurred over the past *twenty-two years without any harm, real or perceived. The primary concern is preventing the avoidable death or disabling of citizens from life-threatening injuries.

*“Ohio established a state trauma system in the year 2000.” (2017 Ohio Trauma Registry Annual Report)

Regulatory Flexibility

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

In order to ensure that all citizens are receiving appropriate EMS and trauma care, no provider of such services can be exempted from this regulation. No alternative means of compliance exist.

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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?

As set forth in paragraph(C)(5) of Revised Code section [119.14](#), first-time offenders of this regulation will not have any sanctions automatically waived as these violations would endanger a trauma victim's health and safety.

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

Completion of the Ohio Trauma Triage course is required during each 3-year certification cycle for the Ohio emergency medical technician (EMT), advanced emergency medical technician (AEMT), and the paramedic to meet re-certification requirements. The course can be taken at any Ohio EMS Board Accredited (initial) or Approved (CE) Training Programs, or by using the Web-based, on-line Ohio Trauma Triage Course (WBT912) available at the Ohio Department of Public Safety (ODPS) *Public Safety Training Campus* using the link <https://learning.dps.ohio.gov/PSTC/>. The Web-based, on-line training course is free, available 24-hours a day, and provides EMS personnel with continuing education credits at no charge.

The Ohio Trauma Triage Training course was reviewed and updated by State Medical Director Dr. Carol Cunningham, as approved by the EMFTS Board, in 2022. A PowerPoint version of the Ohio Trauma Triage Training course is provided to Ohio EMS Board Accredited or Approved Training Programs upon request.

The Department of Public Safety and Division of EMS Web sites contain a *Laws & Rules Overview* Web site (<https://www.ems.ohio.gov/laws.aspx#gsc.tab=0>) and the *Administrative Rules* Web site (<https://publicsafety.ohio.gov/wps/portal/gov/odps/what-we-do/administrative-rules-reviews/>) with links to RC 4766. and RC 4765., OAC 4766, and OAC 4765, CSIO, and JCARR. Rules scheduled for review, open for public comment, proposed, and recently adopted are posted at the Web sites, along with public comment and public hearing information and email links for the ODPS Rules Administrator and Division of EMS rules personnel.

Each unit of the EMS Web page, including the *EMS Trauma System Overview* Web site (<https://www.ems.ohio.gov/trauma-system.aspx#gsc.tab=0>) and Data Center Web site (<https://www.ems.ohio.gov/data-center.aspx#gsc.tab=0>), includes links to the laws and rules associated with that topic, along with an overview section. The *Agency Directory* at the EMS Web site (<https://www.ems.ohio.gov/about-directory.aspx#gsc.tab=0>) includes the email addresses, telephone numbers, including a toll free number (1-800-233-0785), and the names of EMS staff, including the Trauma System and Research & Analysis staff. Trauma System and Research & Analysis staff members are available by phone and by email and can be reached via the *Ask EMS* (ASKEMS@dps.ohio.gov) email address available at the EMS Web site and via the Research & Analysis Section (emsdata@dps.ohio.gov) email address.

Trauma System and Research & Analysis staff members attend and present information about data reporting at various conferences and stakeholder meetings whenever possible.

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