

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

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

Regulation/Package Title: [Trauma Triage](#)

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

Date: [August 22, 2017](#)

Rule Type:

New

☒ Amended

☒ No Change

☒ 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Rescinded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.

Pursuant to Ohio Revised Code (RC) sections 4765.11 and 4765.40, Chapter 4765-14 of the Ohio Administrative Code (OAC) amplifies RC section 4765.40 and specifies 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. The key provisions in OAC Chapter 4765-14 are:

4765-14-01	AM	Definitions.	This rule sets forth the EMS definitions for Chapter 4765-14 of the Administrative Code to be used to determine if an injured person will be considered a trauma patient.
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4765-14-02	AM	Determination of a trauma victim.	This rule 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 in addition to mechanism of injury and special considerations as taught in EMS curricula.
4765-14-03	NC	Enforcement of state or regional trauma triage protocols.	This rule 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	NC	Education of state and regional trauma triage protocols.	This rule specifies a variety of entities that the EMFTS Board shall consult with in creating and presenting educational opportunities regarding triage protocols.
4765-14-05	AM	Exceptions to mandatory transport.	This rule sets forth five exceptions to mandatory transport of a trauma patient to a trauma center. These exceptions include: need for initial assessment; adverse weather; shortage of EMS resources; undue delay; and patient request.
4765-14-06	NC	Amendments affecting regional protocols.	This rule 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.

Three of the rules are proposed as “no change” (NC) rules. Amendments (AM) are proposed for rule 4765-14-01, rule 4765-14-02, and rule OAC 4765-14-05. Paragraph (I)(1) of rule 4765-14-01 lists, as an example of evidence of traumatic brain injury, “Decrease in level of consciousness from the victim’s baseline;” the word “decrease” is changed to “alteration.” In addition, the missing opening quotation mark is added at the beginning of paragraph (I) of rule 4765-14-01.

Rule 4765-14-02 is revised to end the intro paragraph and paragraphs (A), (B), (C), and (D) with a period and standardize the punctuation within each paragraph. Revisions made in 2014 to rule 4765-14-2 added a cause of injury triage indicator at the end of paragraphs (A), (B), and (C) based on advancements in vehicle telematics. A reference to the 2014 addition has been made in the beginning of paragraphs (A), (B), and (C), to provide a parallel structure. The cause of injury headings have been revised to include the word “indicator(s)” in paragraphs (A), (B), and (C), and the sentence structure in (A)(3) and (B)(3) have been improved by adding “provided by.”

The formatting of rule 4765-14-05 is revised to change paragraph (A) to in introductory paragraph and change paragraphs (1) to (5) to (A) to (E). This eliminates an (A) that is not followed by a (B).

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

R.C. 4765.11 and R.C. 4765.40

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.

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

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

N/A

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 the directives of ORC 4765.40, the State Board of Emergency Medical, Fire, and Transportation Services (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.

6. 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: 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 overtriage and undertriage. This type of analysis has been ongoing for more than a decade.

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.

Stakeholders include members of EMFTS Board and members of the Division of EMS staff and DPS legal staff. In addition, members of the Trauma Committee advised EMS during the rule review process. The Trauma Committee of the State Board of EMFTS is established in section 4765.04 of the RC to advise and assist the EMFTS Board in all matters regarding trauma care and the Ohio Trauma System. The State Board of EMFTS is established pursuant to section 4765.02 of the RC. EMFTS board members are nominated by organizations including:

- the Ohio Ambulance and Medical Transportation Association,
- the Ohio Association of Critical Care Transport,
- the Ohio Association of Emergency Medical Services,
- the Ohio Association of Professional Firefighters,
- the Ohio Chapter of the American Academy of Pediatrics,
- the Ohio Chapter of the American College of Emergency Physicians.
- the Ohio Department of Public Safety,
- the Ohio EMS Instructor Coordinator Society,

- the Ohio Fire Chiefs' Association,
- the Ohio Hospital Association
- the Ohio Osteopathic Association, and
- the Ohio State Firefighters Association.

Additional organizations, represented by members of the Trauma Committee, include: the Alliance of Ohio Trauma Registrars, the Ohio Committee on Trauma (American College of Surgeons), and the Ohio Society of Trauma Nurse Leaders.

In January 2017, the OAC 4765-14 rule numbers and tag lines were posted at the EMS Small Business Regulatory Impact Web site (http://www.publicsafety.ohio.gov/ems_rules.stm) under the heading "Rules Scheduled for Review."

EMS administration and trauma and research staff members were provided with copies of the OAC 4765-14 rules and a proposed filing schedule in November 2016, January 2017, and March 2017.

Members of the Trauma Committee of the State Board of EMFTS received copies of the OAC 4765-14 rules and proposed filing schedules on April 17, 2017 and discussed the rules during their May 10, 2017 and July 12, 2017 meetings. Members of the State Board of EMFTS received copies of the OAC 4765-14 rules and proposed filing schedules as part of the board packets in advance of the April 19, May 24, June 21, and August 16, 2017 board meetings. The EMFTS Board received a Trauma Committee report at the April 19, June 21, and August 16, 2017 board meetings.

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;
- the Ohio chapter of the American college of surgeons;
- the Ohio chapter of the American academy of pediatrics;
- OHA: the association for hospitals and health systems;
- the Ohio osteopathic association; and
- the association of Ohio children's hospitals.

When the rules are filed with CSI, govdelivery.com will be used to notify approximately 480 trauma system and 150 Ohio trauma registry subscribers about the OAC Chapter 4765-14 filing and stakeholder comment period.

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

Members of the Division of EMS trauma and research section and members of the Trauma Committee reviewed the rules during the committee's May 10, 2017 meeting and proposed one change, in paragraph (I)(1) of rule 4765-14-01. Paragraph (I)(1) lists, as an example of evidence of traumatic brain injury, "Decrease in level of consciousness from the victim's baseline." Trauma Committee members agreed to change the word "decrease" to "alteration."

EMS staff proposed the formatting revisions to OAC rules 4765-14-02 and 4765-14-05 and adding the opening quotation mark in OAC rule 4765-14-01.

Members of the Trauma Committee of the State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) reviewed the rules and proposed amendments and the draft Business Impact Analysis (BIA) prior to the Committee's July 12, 2017 meeting. At the July 12 meeting, the Committee voted to recommend the draft rules and BIA to the EMFTS Board for approval and submission to the Common Sense Initiative Office and the Joint Committee on Agency Rule Review. The chair of the Trauma Committee and EMFTS Board members were notified of the formatting and punctuation revisions made to rule 4765-14-02 prior to the August 2017 EMFTS meeting. The EMFTS Board approved filing the OAC 4765-14 rules and BIA with the Common Sense Initiative (CSI) office at its August 16, 2017 meeting.

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?

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.

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?

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 rules represent the most appropriate methods and are based on the best available science.

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.*

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.

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 and legal staff members reviewed R.C. Chapter 4765. and O.A.C. 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.

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.

The revision proposed to OAC rule 4765-14-05 is to improve formatting; the content of the rule is not changed. Revisions to rule 4765-14-02 are made to improve punctuation and formatting and do not alter the content of the rule. In OAC rule 4765-14-01, the Trauma Committee proposes changing the word “decrease” to “alteration” to be more precise. No substantive or procedural changes are proposed to the rules. Four of the rules have been in effect with no significant amendments since December 2008 or earlier. Rules 4765-14-02 and 4765-14-06 have been in effect since December 2014, and no revisions have been proposed for either rule as part of this filing. The minor modifications made to the rules in OAC Chapter 4765-14 rule will be distributed to stakeholders via the EMS.gov.delivery.com system using the *Trauma System* subscribers list of approximately 480 addresses and the *Ohio Trauma Registry* subscribers list of approximately 150 addresses.

In addition, 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 *Small Business Regulatory Impact* Web site (http://www.publicsafety.ohio.gov/ems_rules.stm). The laws and rules associated with trauma triage are provided as links at the *EMS Trauma System* Web site (<http://www.ems.ohio.gov/trauma-system.aspx>), and the amended rules, when they become effective, will be available through that link. 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.

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.

- a. The scope of the business community is limited to private ambulance companies that are involved in emergency response (102).
- b. The nature of the financial impact is additional costs for transporting a small fraction of their patients a slightly longer distance to get the trauma victim to a trauma center instead of the closest hospital.

- c. 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 there will be a minimal cost to primary EMS providers due to the need to transport a slightly larger number of their injured patients a longer distance to a trauma center. These costs will be more than offset by an anticipated decrease in the costs to the trauma victim associated with subsequent transfers of these same patients from local hospital emergency departments to a trauma center, which will necessitate 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.

15. 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 15+ years without any harm, real or perceived. The primary concern is preventing the avoidable death or disabling of citizens from life-threatening injuries.

Regulatory Flexibility

16. 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.

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?

As specified by Revised Code 119.14(C)(5), 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.

18. 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 EMT-Basic, EMT-Intermediate, and the EMT-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 available at the Ohio Department of Public Safety (ODPS) *Public Safety Training Campus* using the link <https://trainingcampus.dps.ohio.gov/cm/cm710/home.html>. The Web-based, on-line training

course is free, available 24-hours a day, and provides EMS personnel with continuing education credits, also 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 2017. A PowerPoint version of the Ohio Trauma Triage Training course is provided to EMS CE instructors upon request.

The Division of EMS's Web site contains a "Small Business Regulatory Impact" section (<http://www.ems.ohio.gov/laws.aspx>) with links to R.C. 4766. and R.C. 4765., O.A.C. 4766, and O.A.C. 4765, CSIO, and JCARR. Rules scheduled for review, open for public comment, proposed, and recently adopted are posted at the Web site, 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 *Trauma System* Web page (<http://www.ems.ohio.gov/trauma-system.aspx>), includes links to the laws and rules associated with that topic, along with an overview section. The *Agency Directory* at the EMS Web site (<http://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, including the Trauma & Research staff. The Trauma & Research 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 Trauma System Section (DPS Trauma or trauma@dps.ohio.gov) email address.