



## Common Sense Initiative

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

**Sean McCullough**, 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):** [4765-4 \(Reporting Delivery of Emergency Medical Services and Trauma Care\)](#)

**Rule Number(s):** [4765-4-01, 4765-4-02, 4765-4-03, 4765-4-04, 4765-4-05, 4765-4-06, 4765-4-07, 4765-4-08, and 4765-4-09](#)

**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/\_\_\_9\_\_\_ rules (FYR? [Yes](#))

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

Rescinded/\_\_\_ rules (FYR?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 4765-4 of the Administrative Code (OAC) is authorized by sections 4765.06 and 4765.11 of the Revised Code (RC) and specifies the methods and standards for maintaining and reporting data collected for the delivery of emergency medical services and trauma care by emergency medical services agencies and hospitals. The rules in OAC 4765-4 set forth the consequences of failure to report.

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

<b>4765-4-01</b>	No Change	Definitions.
Rule 4765-4-01 sets forth the definitions for terms used in Chapter 4765-4 of the Administrative Code.		
<b>4765-4-02</b>	No Change	Purpose.
Rule 4765-4-02 sets forth the reasons for comprehensive reporting of EMS incidents and trauma registry data and the requirement that information remain confidential, as set forth in section 4765.06 of the ORC.		
<b>4765-4-03</b>	No Change	Required reporting.
Rule 4765-4-03 identifies the entities required by section 4765.06 of the Revised Code to report EMS incident data and trauma registry data and sets the minimum categories of information to be collected.		

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<b>4765-4-04</b>	No Change	Risk adjustment.
Rule 4765-4-04 defines the purpose of risk adjustment and specifies certain methodologies, analyses, outcomes, and deliberations for risk adjustment of data. The rule provides guidelines to protect confidential information and sets forth penalties for individuals performing risk adjustment who fail to maintain the confidentiality of information.		
<b>4765-4-05</b>	No Change	Protected information.
Rule 4765-4-05 defines how data collected as required by Chapter 4765-4 of the Administrative Code shall be protected and sets forth what data cannot be made public or provided in response to a public records request.		
<b>4765-4-06</b>	No Change	Submission of data.
Rule 4765-4-06 authorizes the State Board of EMFTS to establish the format and the secure method used to submit information and data. The format authorized by the EMFTS Board is required to maintain confidentiality, including using codes or similar designations to identify specific health care facilities and EMS organizations, and to avoid or minimize duplication of entry.		
<b>4765-4-07</b>	No Change	Reporting deadlines.
Rule 4765-4-07 sets forth the location of the reporting schedules for data that is required to be submitted and allows for the State Board of EMFTS to develop and post policies to grant extensions to those deadlines.		
<b>4765-4-08</b>	No Change	Failure to report.
Rule 4765-4-08 sets forth the consequences for an entity should that entity fail to report data as required by Chapter 4765-4 of the OAC.		
<b>4765-4-09</b>	No Change	Regional reporting.
Rule 4765-4-09 permits entities to submit data to the trauma registry through a regional trauma registry rather than directly to the state trauma registry with proper notification to the EMFTS Board.		

**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 4765-4-01 through 4765-4-09 of the OAC are sections 4765.06 and 4765.11 of the RC; the amplifying statute for the rules is section 4765.06 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?**

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

The regulations do not implement a federal requirement.

**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)?**

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Pursuant to RC section 4765.06, the emergency medical services incidence reporting system (EMSIRS) is established “...for the collection of information regarding the delivery of emergency medical services in this state and the frequency at which the services are provided.” This regulation specifies and standardizes data reporting methods in order to ensure consistent, coherent data is received for study.

Pursuant to RC section 4765.06, the state trauma registry is established “...for the collection of information regarding the care of adult and pediatric trauma victims in this state. The registry shall provide for the reporting of adult and pediatric trauma-related deaths, identification of adult and pediatric trauma patients, monitoring of adult and pediatric trauma patient care data, determination of the total amount of uncompensated adult and pediatric trauma care provided annually by each facility that provides care to trauma victims, and collection of any other information specified by the board.”

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

The rules in OAC 4765-4 provide clear, easily understood standards for reporting of required data. Stakeholders who report data have found these regulations to be helpful. The data collected is used to inform and guide the decisions of the EMFTS Board, its committees and stakeholders. Additionally, the data has been shared at the national level and contributes to the general scientific body of knowledge on these subjects.

**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 4765-4 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. No amendments were proposed for OAC Chapter 765-4. The rules were proposed as no change rules and presented to the Trauma Committee during its November 10, 2021. The rules were

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discussed and the Committee approved filing the rules with CSI during its November 10, 2021 meeting.

The EMFTS Board received information, including filing OAC Chapter 4765-4 as no change rules, 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.

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

No comments or recommendations for amendments were provided concerning the rules in OAC Chapter 4765-4.

**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 EMS and Trauma data elements collected are based on national data standards

**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?**

Entities required to report to the state trauma registry may choose to report required information to the regional trauma registry. In addition the EMFTS Board may grant extensions to the deadlines for submitting information to EMSIRS or to the state trauma registry.

**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.***

EMS considers these performance-based regulations. The rules do not prescribe specifications for how EMS agencies and hospitals collect, process, and report their data to their own independently managed data systems. These rules establish standards for which data is submitted in a consistent and timely manner to the State.

**14. What measures did the Agency take to ensure that this regulation does not duplicate an existing Ohio regulation?**

As EMS is the only division statutorily directed to administer the EMSIRS and state trauma data system, a review of RC Chapter 4765. and OAC Chapter 4765 was performed. 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.**

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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 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**

**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 business community includes hospitals, acute care facilities, free standing emergency departments, and any local EMS agency that provides patient transportation to one of these facilities. As technology continues to permeate the industry and electronic patient document becomes common, the reporting burden has become increasingly automated. The primary nature of the adverse impact is time for compliance; however, failure to comply with RC section 4765.06 may result in an EMS agency being ineligible to receive grants awarded by the State Board of EMFTS under RC section 4765.05.

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

The nature of the financial impact of this rule on smaller hospitals, acute care facilities, and free standing emergency departments not otherwise required to have an actual trauma registry as required by their trauma facility status would be measured in time to enter medical record data into the clinical data systems. It is presumed that most of this activity is performed by some form of medical records technician or healthcare information specialist who, according to the Bureau of Labor Statistics ([www.bls.gov](http://www.bls.gov)), earn a median \$21.75/hour. Based on historical data in the Ohio Trauma Registry, one of the clinical data systems governed by this rule, these small facilities will be required to submit data on fewer than ten patients per month. Because these facilities are not trauma centers, the patients they treat are not as complex, creating a data entry time of approximately fifteen minutes per record. This creates a compliance time of approximately 150 minutes per month at a cost of \$54.38 per month (\$652/year). Additionally,

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some of these facilities may incur no adverse impact as they will not treat any trauma victims in a given year and will not be subject to this rule.

Failure to comply with reporting requirements under section 4765.06 of the RC may prevent hospitals from being eligible to receive research grants. In state fiscal year (SFY) 2020-2021, a total of \$198,185 was awarded to two grantees. In state fiscal year (SFY) 2021-2022, two research grants were awarded in the amounts of \$25,000 and \$75,000. [SOURCE: EMS staff and ODPS 2020 Annual Report]

The primary nature of the adverse impact related to EMSIRS data is time for compliance, and applicants for EMS priority 1 grants that fail to submit data to EMSIRS may be deemed ineligible to receive grants.

**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 adverse impact of this rule on the local EMS agencies and private ambulance services in Ohio is extremely small. The information gathered by the EMS Incident Reporting System (EMSIRS), one of the data systems governed by this rule, is already collected by the services as part of their patient billing process. Time for compliance is comprised of creating an export file of the already collected information and submitting it to EMSIRS, which takes approximately fifteen minutes per quarter, or one hour per year. According to the Bureau of Labor Statistics ([www.bls.gov](http://www.bls.gov)), median pay for paramedics who may be performing this task is \$17.62/hour. This creates a cost of compliance of \$17.62 per year. Additionally, as technology continues to permeate the industry and electronic patient documents become common, the reporting burden has become increasingly automated. Most EMS and private ambulance services bill for their services when possible, and some billing companies provide data submission services gratis to their clients.

Failure to comply with reporting requirements under section 4765.06 of the RC may prevent EMS services from being eligible to receive training and equipment grants. In state fiscal year (SFY) 2020-2021, a total of 676 training and equipment grants were awarded. The average grant award was \$3,175. [SOURCE: ODPS 2020 Annual Report]

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

The EMIIRS and state trauma data systems were created in RC section 4765.06 to allow the State Board of EMFTS to oversee the provision of EMS and trauma care to the citizens of Ohio. The collection of patient care data is necessary to assess and determine if all Ohioans are receiving appropriate EMS and trauma care throughout Ohio. Declaring entities ineligible to receive grants created in RC section 4765.05 is considered not only a fair incentive to remain compliant with RC section 4765.06, but also ensures that taxpayer money is not given to entities that are not in compliance with the RC.

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As set forth in paragraph (C) of rule 4765-4-03, "...the board shall take into consideration the financial and other burdens that...[reporting] requirements will place on the entities that are required to report."

### **Regulatory Flexibility**

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

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, but the methods in place are designed with the smallest, rural volunteer EMS agencies in mind; therefore, they are as unobtrusive as possible.

**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 Division of EMS provides all entities required to submit data with adequate warning of non-compliance before moving to sanctions. These include friendly reminders of the need for compliance by e-mail or telephone, offers of assistance in training on the clinical data systems, and implementing escalating warnings. Over the past decades, sanctions have only been levied against entities that have been non-compliant over multiple regular deadlines.

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

Web-based data entry systems are provided to any entity wishing to avoid the expense of purchasing its own database systems. These are available on the Ohio Department of Public Safety's *Data Center* website ( <http://www.ems.ohio.gov/data-center.aspx> ) 24 hours a day, 7 days a week and are free of charge.

Training in use of these systems is provided on request to EMS agencies, hospitals, and inpatient rehabilitation facilities. These training sessions can be held at the EMS station, hospital, or rehab facility, over the phone, by webinar, or at the Ohio Department of Public Safety. These sessions are free of charge.

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.

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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](mailto:emsdata@dps.ohio.gov) ) email address.

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

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