

# CSI - Ohio

## The Common Sense Initiative

### Business Impact Analysis

**Agency Name:** Ohio Department of Public Safety, Division of Emergency Medical Services

**Regulation/Package Title:** Reporting Delivery of Emergency Medical Services and Trauma Care

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

**Date:** December 27, 2012

**Rule Type:**

- ☐ New  
☐ Amended

- ☒ 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☐ Rescinded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.**

Chapter 4765-4 of the Administrative Code (OAC) amplifies section 4765.06 of the Revised Code (RC) and specifies the methods and standards for maintaining and reporting data collected on the delivery of emergency medical services and trauma care by emergency medical services agencies and hospitals. Pursuant to a scheduled RC 119.032 five-year rule review, EMS proposes to file Chapter 4765-4 as "no change."

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OAC 4765-4-01 provides definitions of terminology used throughout OAC Chapter 4765-4. OAC 4765-4-02 states the purpose of EMS and trauma data reporting and how the received data is to be used by the Ohio State Board of Emergency Medical Services. OAC 4765-4-03 identifies the entities, pursuant to RC section 4765.06, required to report data, as well as the general nature of the data to be reported. OAC 4765-4-04 defines risk adjustment procedures needed to be implemented prior to releasing data that identifies a provider of care, as directed by RC section 4765.06. OAC 4765-4-05 identifies the methods to be used to maintain the confidentiality of received data and what data cannot be made public to maintain confidentiality. OAC 4765-4-06 describes the format and method of transmission of required data reporting. OAC 4765-4-07 specifies the deadlines for identified entities to report required data. OAC 4765-4-08 specifies the consequences for failure of an entity to report as required by RC section 4765.06. OAC 4765-4-09 allows hospitals to transmit their required data through a regional repository, rather than directly to the state trauma registry.

2. **Please list the Ohio statute authorizing the Agency to adopt this regulation.** Section 4765.11 of the Revised Code.
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?**  
The regulation does not implement a federal requirement.
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 RC section 4765.06, both the EMS and trauma data systems exist to study and improve the delivery of care to ill and injured people in Ohio. This regulation specifies and standardizes data reporting methods in order to ensure consistent, coherent data is received for study.
6. **How will the Agency measure the success of this regulation in terms of outputs and/or outcomes?** OAC Chapter 4765-4 has served well to provide clear, easily understood standards for reporting of required data. Stakeholders who report data have found these regulations to be helpful. Additionally, multiple scientific studies using the data in the data systems covered by these rules have been published; therefore, continued contributions to the body of scientific knowledge will also be used as a measure of success.

### **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 who participated in the review of OAC Chapter 4765-4 included representatives from the Alliance of Ohio Trauma Registrars, Ohio

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Association of Critical Care Transport, Ohio Fire Chiefs Association, Ohio Ambulance and Medical Transportation Association, Ohio Association of Professional Firefighters, Ohio Committee on Trauma (American College of Surgeons), Ohio Hospital Association, Ohio State Firefighters Association, Ohio Society of Trauma Nurse Leaders. All stakeholders were contacted on October 29, 2012 via e-mail, provided with copies of the rule, and invited to submit comments and recommendations.

8. **What input was provided by the stakeholders, and how did that input affect the draft regulation being proposed by the Agency?** No input was received, which EMS accepted as support for the "no change" filing. The Trauma Committee of the Ohio State Board of Emergency Medical Services, established in RC section 4765.04, also reviewed these rules at its November 14, 2012 meeting. The Committee agreed with the proposed "no change" filing.
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?** There is no scientific data to be considered.
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 alternatives were considered as the Ohio State Board of Emergency Medical Services is required by RC section 4765.06 to create the data systems these rules cover. These rules simply set the standards for the reporting of data to those statutorily prescribed systems.
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.** 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 the data systems. These rules establish standards for which data is needed to consistently monitor the EMS and trauma systems, as well as deadlines for timely submission of that data.
12. **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 these systems, only a review of RC Chapter 4765 and OAC 4765 was performed. Additionally, EMS has not received any stakeholder complaints of duplication in the ten-plus years of these systems' existence.
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.** *As this is a "no change" filing of rules that have been in existence for over a decade, there is no implementation needed at this time, only carrying forward with*

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existing programs. EMS policies are in place to ensure that all parties are treated equally and fairly.

### **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.**

The scope of the business community includes smaller hospitals and in-patient rehabilitation facilities (n= 104) and private ambulance companies (n= 119). The primary nature of the adverse impact is time for compliance; however, failure to comply with RC section 4765.06 will result in ineligibility to receive grants awarded by the Ohio State Board of Emergency Medical Services under RC section 4765.05.

The adverse impact of this rule on small hospitals and in-patient rehab facilities 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 medical records technicians who, according to the Bureau of Labor Statistics ([www.bls.gov](http://www.bls.gov)), earn a median \$15.55/hour. Based on 13 years of 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 10 patients per month. Because these facilities are not trauma centers, the patients they treat are not complex, creating a data entry time of approximately 15 minutes per record. This creates a compliance time of approximately 150 minutes per month at a cost of \$38.87 per month (\$466/year).

Additionally, 10-15 of these facilities will incur no adverse impact as they do not treat any trauma victims and will not be subject to this rule.

Failure to comply with RC section 4765.06 will prevent hospitals from being eligible to receive research grants. Fewer than 10 of these grants are awarded each year, with an average award of approximately \$115,000.

The adverse impact of this rule on the private ambulance services in Ohio is extremely small. The information gathered by the EMS Incident Reporting System (EMSIRS), one of the clinical 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

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submitting it to EMSIRS, which takes approximately 15 minutes per quarter, or 1 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 \$14.60/hour. This creates a cost of compliance of \$14.60 per year.

Additionally, all private ambulance services bill for their services and some billing companies provide data submission services gratis to their client EMS agencies. EMS cannot provide cost estimates for such arrangements.

Failure to comply with RC section 4765.06 will prevent ambulance services from being eligible to receive training and equipment grants. The average award is for \$4,500.

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

The clinical data systems were created in RC section 4765.06 to allow the Ohio State Board of Emergency Medical Services to oversee the provision of EMS and trauma care to the citizens of Ohio. The collection of patient care data is the only method to determine if all citizens 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.

**Regulatory Flexibility**

**16. 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 simple and as unobtrusive as possible.

**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?** Policies have long existed to provide 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 a policy of escalating warnings. Over the past decade, sanctions have only been levied against entities that have been non-compliant over multiple regular deadlines.

**18. 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

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expense of purchasing its own database systems. These are available on the Ohio *Department of Public safety's website* 24 hours a day, 7 days a week and are free of charge. Additionally, training in use of these systems is provided 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. *The location is the trainee's choice and the sessions are free of charge.*