

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: [Department of Public Safety \(DPS\) - Division of Emergency Medical Services \(EMS\)](#)

Regulation/Package Title: [Mobile Intensive Care Units](#)

Rule Number(s): [O.A.C. Rules 4766-4-01 to 4766-4-18](#)

Date: [January 3, 2017](#)

Rule Type:

☒ New

☒ 5-Year Review

☒ Amended

☒ Rescinded

☒ No Change

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.

Chapter 4766-4 of the Ohio Administrative Code (O.A.C.) sets forth the conditions under which the State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) may approve, renew, or deny an application to operate a medical transportation organization (MTO) operating Mobile Intensive Care Units (MoICUs) as defined by section 4766.01 of the Revised Code and sets license and permit fees. In addition, this chapter sets forth standards for MTO organizations, including record-keeping and reporting, health and safety requirements, communications, vehicle maintenance, staffing compliance, inspections, investigations, and disciplinary grounds.

O.A.C. rules 4766-4-01 to 4766-4-18 are proposed for filing pursuant to a completed Revised Code (R.C.) 119.032 five-year rule review. Proposed revisions include:

- Replace “Ohio medical transportation board” with “state board of emergency medical, fire, and transportation services” and revise references to “the board” to “the board or its designee” (multiple locations);
- Additions and revisions to the definitions (O.A.C. 4766-4-01);
- Add language requiring submission of a service’s medical director’s contact information and state of Ohio medical license number (O.A.C. 4766-4-02);
- Add language defining an incomplete application and permitting such applications to be returned to the applicant (O.A.C. 4766-4-02);
- Add language initiating a \$5.00 fee to re-print vehicle decals (O.A.C. 4766-4-03) and change a reference from “deficiency” to “violation notification”;
- Revise paragraph regarding inspections and commencing operations to be similar to the language in O.A.C. 4766-3 (4766-4-04);
- Add language requiring MTO facilities be in compliance with state and local building codes and state and local fire codes (O.A.C. 4766-4-04);
- Add language to explain submitting lists of vehicles or use the terms “any auto” or “all autos owned” with certificates of liability insurance;
- Update communications requirements (OAC 4766-4-06);
- Removal of the roadworthiness requirements (O.A.C. 4766-4-08) and equipment list and non-transport vehicle equipment list (O.A.C. 4766-4-10) from the rules and referring to Board-approved lists (inspection forms) available at the Medical Transportation page of the EMS Web site;
- Add requirements for:
 - *periodic mechanical safety inspections conducted by certified mechanics (O.A.C. 4766-4-09) and;
 - *documentation of compliance with inspection requirements to be maintained by licensed services (4766-4-05);
- Addition of the name of a specific emergency vehicle operator’s course (O.A.C. 4766-4-13);
- Add references to sections of the R.C. regarding license plate requirements and a paragraph about license plates for vehicles that may be eligible for gratis plates (4766-4-11);
- Revisions regarding “investigations of alleged offenses” (O.A.C. 4766-4-16) and “suspension, revocation, or denial of license or permit” (O.A.C. 476-4-17); and
- Addition of an *Incorporated by Reference* rule (O.A.C. 4766-4-18).

In reviewing O.A.C. Chapter 4766-4, the Medical Transportation Committee, members of EMFTS Board, and members of the Division of EMS staff and DPS legal staff set out to maintain as much consistency as possible with revisions made to O.A.C 4766-2 *Ambulances*. O.A.C. 4766-2 rules were filed with CSI on June 29, 2016 and have been approved by the EMFTS Board to be filed with JCARR.

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

R.C. 4766.03

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)?**

These regulations assure that medical transportation organizations (MTOs) operate with the required medical equipment, qualified medical staff, and effective delivery of EMS care to patients who must use a MoICU vehicles.

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

MoICUs, their satellite locations, and all permitted vehicles are inspected annually and as needed to determine compliance with applicable statutes and rules. These inspections are conducted by qualified Medical Transportation Field Inspectors contracted by the Department of Public Safety (DPS). The success of these regulations will be measured by fewer violations and an increase in compliance with the requirements set forth in O.A.C. Chapter 4766-4. In addition, the Division of Emergency Medical Services (EMS) will track complaints made by MoICUs and complaints regarding MoICUs that lead to investigations.

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 the Medical Transportation Committee and members of EMFTS Board and its Critical Care Subcommittee; members of the Division of EMS staff and DPS legal staff; the Medical Transportation Field Inspectors contracted by DPS; the 127 licensed MoICUs and their owners and employees; and two industry associations. Because of the similarities in the operation of ambulance and MoICU services, the 126 licensed ambulance services and their owners and employees were also contacted as stakeholders during the rule review process.

Using the proposed revision made to O.A.C. Chapter 4766-2 *Ambulances* as a model, DEMS staff prepared the first draft of proposed revisions to O.A.C. 4766-4 in early May 2016. On July 15, 2016, O.A.C. Chapter 4766-4 rules were posted at the EMS *Small Business Regulatory Website* page as "Rules Scheduled for Review."

EMS staff initially worked with members of the Medical Transportation Committee, who reviewed and revised O.A.C. Chapter 4766-4 during their regularly scheduled meetings on:

- June 14, 2016
- October 18, 2016

- August 16, 2016
- December 13, 2016

R.C. 4765.04 requires the State Board of Emergency Medical, Fire, and Transportation Services (EMFTS) to create the Medical Transportation Committee and appoint committee members to advise and assist the EMFTS board in matters related to the licensing of emergency and nonemergency medical service organizations. The Medical Transportation Committee and Critical Care Subcommittee members have experience transporting patients and are appointed as representatives of the emergency medical transportation community, including ambulance, MoICU, ambulette, and air medical providers. The committee has members representing EMS providers, owners and administrators for medical transportation agencies, and full-time and volunteer fire departments.

The Medical Transportation Committee's strategic goals include creating effective and enforceable rules written to meet standards that do not "put undue financial burden on all providers" and developed by groups including "providers within the public and private sector."

The draft rules provided by the Medical Transportation Committee after its August 2016 meeting were reviewed and revised by EMS and DPS legal staff in September and during two meetings in October 2016. A revised draft was returned to the Medical Transportation Committee for discussion and review at its October 2016 meeting, requesting comments before November 2, 2016, when the rules were emailed to stakeholders.

On November 2, 2016, the proposed revisions to O.A.C. Chapter 4766-4 were emailed with a request for stakeholder comments to be submitted by November 14, 2016 to the 137 addresses available on the "Licensed MoICU Providers Email List" and the "Licensed Ambulance Providers Email List." Deleting the undeliverable emails from that count, a total of 121 requests for stakeholder comment were delivered. Also on November 2, 2016, the proposed revisions to O.A.C. 4766-4 and a request for stakeholder comments to be submitted by November 14, 2016 were emailed to the Ohio Ambulance and Medical Transportation Association (OAMTA) and the Ohio Association of Critical Care Transport (OACCT) and to members of the Medical Transportation Committee and the Critical Care Subcommittee of the EMFTS Board, along with a request to forward the information to their members.

On November 2, 2016, the proposed revisions to O.A.C. Chapter 4766-4 were emailed with a request for stakeholder comments to be submitted by November 14, 2016 to the EMS-General email list via govdelivery.com—a total of 1,808 addresses—with a reported 1,716 deliveries.

EMS and DPS legal staff held discussions after November 14, 2016 and made additional revisions to O.A.C. Chapter 4766-4 based on stakeholder comments that had been submitted regarding the ambulette rules but that could be applied to the MoICU rules. The November 30, 2016 draft of proposed revisions to O.A.C. Chapter 4766-4 was emailed to the Medical Transportation Field Inspectors prior to discussion during their regularly scheduled meeting on December 6, 2016. The November 30, 2016 draft of proposed revisions to O.A.C. Chapter 4766-4 was emailed to members of the Medical Transportation Committee and Critical Care

Subcommittee in early December 2016 in preparation for their December 13, 2016 meeting. A proposed change to the language in paragraph (C)(3) of rule 4766-4-11 was provided to members of the Medical Transportation Committee and the Critical Care Subcommittee and discussed by them during their December 13, 2016 meetings.

Members of the EMFTS Board received a copy of the proposed changes to O.A.C. Chapter 4766-4 as part of the Board's October 19, 2016 meeting packet and were advised that a motion to approve filing the rules and required documents with the CSI office would be requested at the December 14, 2016 meeting. Before the December 14, 2016 EMFTS meeting, Board members received the December 5, 2016 draft of O.A.C. 4766-4, the proposed change to paragraph (C)(3) of rule 4766-4-11, and a draft of the Business Impact Analysis (BIA) form to be filed with CSI and, at that EMFTS meeting, the board passed a motion to approve the CSI filing.

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

On November 7, 2016, a representative of a medical transportation company submitted two comments related to the proposed revisions to O.A.C. 4766-4. Regarding O.A.C. rule 4766-4-05, she asked if the use of encrypted electronic charts for patient records and the use of electronic dispatch logs are acceptable. In an answer dated later the same day, she was told that the use of electronic records is acceptable in both cases. Her comment also asked for clarification about communications devices described in O.A.C. rule 4766-4-06. Her concern was for the cost required to use radios instead of telephones. The November 7, 2016 response stated that the requirement for a "radio" has been removed in the proposed changes to O.A.C. 4766-4-06, which have been made less restrictive in terms of the devices used and is intended to assure that services "maintain voice communications, within their service area, between dispatch, the vehicles and hospital/medical control."

Several comments were received regarding O.A.C. Chapter 4766-3 *Ambulettes*, which are on the same five-year rule review schedule and were sent out for stakeholder comments during the same time period. One of these comments was used to further revise O.A.C. Chapter 4766-4.

On November 3, 2016, a staff member with the Red Cross commented that his organization is issued gratis license plates from the Bureau of Motor Vehicles. He asked if gratis ambulette plates could be used in place of the required ambulette license plate. Following discussions with BMV personnel and DPS legal staff, the ambulette rules and also O.A.C. 4766-4-11 were revised. Based on this stakeholder comment, the proposed addition to O.A.C. 4766-4 includes:

Permitted MoICU(s) and non-transport vehicle(s) owned and operated by a federal, state, county, city, or township or a service that qualifies for gratis license plates from the bureau of motor vehicles are not required to bear ambulance license plates or non-transport vehicle license plates.

On December 9, 2016, a member of Medical Transportation Committee and the program manager for a hospital critical care transport team, sent an email comment regarding the

proposed revisions to O.A.C. 4766-4-09 (A)(2)(b). She reported that she would be unable to attend the December 13, 2016 committee meeting. She said that in conversations with Ford and International repair facilities, she learned that they allow mechanics to drop their ASE certification upon achieving a higher general certification or higher chassis-specific certification. Her concern was that the proposed revision would eliminate master or senior dealership-certified mechanics as inspectors of all types of vehicles, which would require services to use multiple shops.

The comment was discussed among members of the EMS and Medical Transportation staffs and the DPS legal staff. On December 13, 2016, members of the Critical Care Subcommittee and Medical Transportation Committee considered and discussed the comment and the stakeholder's concern. They felt the stakeholder's emailed comment did not provide adequate information to revise the language. It was decided to forward the rule as revised to the EMFTS Board at its December 14, 2016 meeting, where a motion to file the rules with CSI would be requested. However, the Medical Transportation Committee also directed the medical transportation section chief to continue discussions with the stakeholder and advise her that revisions to O.A.C. 4766-4-09 (A)(2)(b) or other rules could be submitted during the CSI comment period.

On December 15 and 16, 2016, the medical transportation section chief left voicemail messages with the stakeholder. On December 19, 2016, he emailed the stakeholder and held a phone conversation with her, followed by calls and email exchanges on December 20 and 21 2016. The section chief explained that the intent of the rule is to have a trained certified mechanic inspect the vehicle using the Periodic Mechanical Safety Inspection form at least once per year, with the mechanic certified in one of three areas: (1) factory training and certification from the original (motor vehicle) equipment manufacturer; (2) equivalent certification for "Emergency Vehicle Technicians" (EVT); or (3) "National Institute for Automotive Service Excellence" (ASE). He added, "A mechanic that is certified at a Master or Senior level from a vehicle manufacturer would be qualified to do the inspection."

The stakeholder, following a conversation with one of her mechanics, expressed concern about a reference to "the original manufacturer," and the following revised version of O.A.C. 4766-4-09 (A)(2)(b) was proposed:

Each mechanical safety inspection shall be conducted by a mechanic with factory training and certification from ~~the~~ an original (motor vehicle) equipment manufacturer or equivalent certification for "Emergency Vehicle Technicians" (EVT) or from the "National Institute for Automotive Service Excellence" (ASE).

The stakeholder replied, "Thank you Dave. This minor adjustment addresses the concern that was brought to me. It would allow our current mechanic to work on any of our MICU's and that was the concern that was brought forward. Thank you for your assistance with this, I truly appreciate it."

Following a discussion with the EMS legal counsel, the revision from “the” to “an” in the rules pertaining to inspecting mechanic’s certification and training has been proposed in O.A.C. Chapter 4766-4, as well as O.A.C. chapters 4766-2 (*Ambulances*) and 4766-3 (*Ambulettes*).

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 available for the proposed regulations.

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?

It was determined that alternative regulations would not meet the purpose of the rules to assure safe and roadworthy MoICUs and effective delivery of EMS care to patients who must use an MTO and its vehicles.

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.*

The Board has proposed performance-based regulations, as the proposed rules have limited flexibility under which the Board may deny, suspend, or revoke a license or permit to operate an MTO.

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 4766., O.A.C. Chapter 4766, R.C. Chapter 4765., and O.A.C. Chapter 4765 to assure there was no duplication or conflict among Ohio EMS and Medical Transportation regulations.

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 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 Medical Transportation are provided as links at the *Medical Transportation* Web site (<http://www.ems.ohio.gov/medical-transportation.aspx>), and the amended rules, when they become effective, will be available at that link. The Division of EMS will use govdelivery.com, which has replaced the EMS ListServ, and the email addresses on the “Licensed MoICU Providers Email List” and other lists to notify stakeholders when the revised rules become effective. Division of EMS staff and the Medical Transportation Field Inspectors will receive email notification of the rule changes and attend briefings regarding the implementation policy and procedures. During their meetings, usually held once every two months, the EMFTS Board and Medical Transportation Committee receive 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 impacted business community includes 127 licensed MTOs that operate a combined total of 1,646 MoICUs.
 - b. The existing license and permit fees associated with O.A.C. Chapter 4766-4 rules include the following fees for MTOs:

Initial or Renewal License Fee	\$100.00
Mobile Intensive Care Unit (MOICU) Fee per vehicle	\$100.00
Non-transport Vehicle Fee per vehicle	\$100.00
Vehicle Inspection Fee	\$100.00

The license and permit fees are set pursuant to section 4766.05 of the R.C. Vehicle inspection fees of \$100 per inspection were set by the Ohio Medical Transportation Board prior to its merger with the EMFTS Board in June 2013, pursuant to section 4766.03 of the R.C., and based on actual costs. The proposed rule revisions do not change the license and permit fees or the vehicle inspection fee.

One additional fee is proposed as part of this rule review—a \$5.00 fee to cover the actual costs associated with re-printing and mailing each vehicle decal. This fee would only be charged to the services that provide incorrect information to the Division of EMS or lose or destroy the decals they receive from the Division of EMS, requiring that the decal be re-printed. The \$5.00 fee represents actual costs to the agency to re-print and mail a decal. Expenses include \$1.88 per decal, \$0.47 for postage, and no more than \$2.65 for the salary costs of the Medical Transportation and information technology (IT) staff members whose time is required to re-print and mail a decal.

Rule O.A.C. 4766-4-17 *Disciplinary Grounds* is a new proposed rule that permits the EMFTS Board, pursuant to Chapter 119. of the R.C., to conduct an adjudicatory hearing and, by a majority vote of all Board members, to suspend, revoke, or refuse to renew any MTO license or permit or to issue a fine not to exceed more than fifteen hundred dollars. The rule, and the new rule O.A.C. 4766-4-16 *Investigations*, which replaces the rescinded O.A.C. 4766-4-16 *Investigations of Alleged Offenses*, are proposed as part of

the continuing transition required due to the merger of the Ohio Medical Transportation Board with the State Board of EMFTS and its compliance and enforcement section. The sanctions and fine described in the new rule are set forth in section 4766.08 of the revised code and are not a change for MTOs.

The addition of required periodic mechanical safety inspections included in the proposed rule O.A.C. 4766-4-09 will result in employer time and/or expense. The costs will vary depending the structure and size of each business. Some MTOs employ mechanics who will be qualified to complete the periodic mechanical safety inspections, or MTOs may choose to have vehicles inspected by mechanics at auto service facilities, chain repair stores, dealerships, or independent garages.

An August 15, 2015 article posted by Edmunds.com (<http://www.edmunds.com/car-buying/inspect-that-used-car-before-buying.html>) states that the cost of a pre-purchase inspection for a personal vehicle “is about \$100, roughly the costs of an hour’s labor for a mechanic.” A February 2012 J.D. Powers’ article (<http://www.jdpower.com/cars/articles/tips-advice/used-car-pre-purchase-inspection>) reports that a basic pre-purchase inspection, including a test drive, will cost \$100-to-\$200. The president of an ambulance company--a stakeholder who submitted a comment about the O.A.C. Chapter 4766-2 rules during its stakeholder comment period--estimated an average cost of \$75-to-\$100 per hour for a vehicle inspection at his local garage. During the stakeholder comment period for O.A.C. Chapter 4766-4, no comments regarding a requirement for periodic mechanical safety inspections of MoICU or the cost of inspections were received. It is likely that MTOs can negotiate the fees for periodic mechanical safety inspections with the auto service facilities, chain repair stores, dealerships, or independent garages that service their vehicles.

Members of the Medical Transportation Committee, who are owners and administrators for medical transportation agencies as well as representatives of the industry, report that they routinely conduct periodic mechanical safety inspections and believe it to be essential for maintaining and operating a medical transportation service.

- c. The Division of EMS estimates that these rules will not result in any undue cost of compliance or adverse impact. Additional costs resulting from these rules include \$5.00 per each decal that is reprinted and mailed. This fee is minimal and can be avoided if MTOs provide the correct information to the Division of EMS and do not lose or destroy the decals they receive.

The Medical Transportation Committee proposed rules requiring periodic mechanical safety inspections for MTO vehicles with consideration of its goal to avoid putting “undue financial burden on all providers.” MTOs that are already performing periodic inspections to assure the mechanical safety and roadworthiness of their vehicles will not see a significant change in the cost. MTOs that begin performing mechanical safety

inspections will have an added expense, but one that is essential to medical transportation organizations and the public who rely on their services.

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

Pursuant to R.C. 4766, the Board is statutorily required to adopt rules that establish the standards and procedure under which the Board may approve, renew, or deny an application to operate an MTO and standards for MTO organizations including health and safety, vehicle maintenance, and inspection requirements. Assuring the safety and effective delivery of EMS care to patients who must use a MTO and its vehicles justifies the minimal adverse impact to the business community.

Regulatory Flexibility

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

The regulation does not provide any exemptions or alternative means for compliance.

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?

If disciplinary action is considered, the MoICU will be afforded seventy-two hours to correct violation(s) cited or provide the Board sufficient documentation that the MoICU is correcting the violation(s). Should the Board need to proceed with a sanction, each case is submitted first to the Board's Assistant Attorney General to ensure compliance with R.C. section 119.14. The Board reviews each situation on a case-by-case basis and may consider all information relevant to the requirements of O.A.C. Chapter 4766, and R.C. Chapter 4766 and O.A.C. Chapter 4765, and R.C. Chapter 4765. Depending on the nature and severity of the violation the board may issue a lesser penalty.

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

The Division of EMS 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 *Medical Transportation* Web page (<http://www.ems.ohio.gov/medical-transportation.aspx>), includes links to the laws and rules associated with that topic, along with an overview section, and a *Frequently Asked Questions* 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 Medical Transportation staff. The Medical Transportation 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.

The Division of EMS, through DPS, contracts with Medical Transportation Field Inspectors who conduct annual compliance inspections of each MTO, their satellite locations, and all permitted vehicles. Approximately twenty inspectors work in specified regions covering all of Ohio and its bordering states. Inspectors are available by phone and by email to all MTOs licensed in Ohio and the five states contiguous to Ohio.

Medical Transportation staff members attend and present information at conferences including those conducted by the Ohio Ambulance and Medical Transportation Association (OAMTA) and the Ohio Association of Critical Care Transport (OACCT).

All forms required of MTOs by the Division of EMS are available via the Division of EMS Web site located at <http://www.ems.ohio.gov/forms.aspx>.