

ACTION: Final

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 (ODPS) - Division of Emergency Medical Services (EMS), State Board of Emergency Medical, Fire, and Transportation Services (EMFTS)

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Regulation/Package Title (a general description of the rules' substantive content): Chapters 4766-3 and 4766-4 - Five-Year Review

Rule Number(s): 4766-3-01, 4766-3-02, 4766-3-03, 4766-3-04, 4766-3-05, 4766-3-06, 4766-3-07, 4766-3-08, 4766-3-09, 4766-3-12, 4766-3-13, 4766-3-14, 4766-3-15, 4766-3-16, 4766-3-17, and 4766-3-18; and 4766-4-01, 4766-4-02, 4766-4-03, 4766-4-04, 4766-4-05, 4766-4-06, 4766-4-07, 4766-4-08, 4766-4-09, 4766-4-11, 4766-4-12, 4766-4-13, 4766-4-14, 4766-4-15, 4766-4-16, 4766-4-17, and 4766-4-18

Date of Submission for CSI Review: December 29, 2021

Public Comment Period End Date: January 24, 2022

Rule Type/Number of Rules:

New/_0_ rules No Change/_15_ rules (FYR? _Yes_)

Amended/<u>18</u> rules (FYR? <u>Yes</u>) Rescinded/<u>0</u> rules (FYR? <u>___</u>)

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. \boxtimes Requires specific expenditures or the report of information as a condition of compliance.
- d. \boxtimes Is likely to directly reduce the revenues 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.

Chapters 4766-3 and 4766-4 of the Ohio Administrative Code (OAC) are being filed for five-year review. Chapter 4766-3 (*Ambulettes*) of the OAC includes sixteen rules; eight are being filed as a no change rules and eight are proposed to be filed as amended rules. Chapter 4766-4 (*Mobile Intensive Care Units*) of the OAC includes seventeen rules; seven are being filed as a no change rules and ten are proposed to be filed as amended rules. The rules in OAC Chapter 4766-3 pertain to MTOs (medical transportation organizations) operating ambulettes. The rules in OAC Chapter 4766-4 pertain to MTOs operating mobile intensive care units (MoICUs).

Amendments are proposed to incorporate information about the Medical Transportation Licensing System or MTLS online system, a Web based system for medical transportation agencies to obtain, renew, and maintain their licenses and vehicle permits. The MTLS online system, in some instances, supersedes the need for forms that were used to obtain, renew, and maintain MTO licenses and permits. Amendments to the rules in OAC chapters 4766-4 and 4765-13 are proposed to add information about operating a mobile stroke unit. The definitions and incorporated by reference chapters are updated.

A summary of each of the rules being filed in this package is provided below:

Chapter 4766-3 Ambulettes

| | Amend | Definitions. |
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| | · · · · · · · · · · · · · · · · · · · | e twenty definitions associated with OAC Chapter 4766-3, entitled |
| | | itions under which the State Board of Emergency Medical, Fire, and |
| The second secon | | approve, renew, or deny an application to operate a medical |
| | | erating ambulettes and sets license and permit fees for ambulettes. |
| | | to standards for ambulette organizations, including record-keeping, |
| • | | vehicle maintenance, inspections, investigations, and disciplinary |
| - | | two definitions, deleting the "service number" definition, and |
| deleting the comme | ent related to the ir | ncorporated by reference rule |
| 4766-3-02 | Amend | Application for initial or renewal licensure. |
| | | processes that an MTO providing ambulette services is required to |
| use to make applica | ation to the EMFTS | Board for an initial or renewal license to operate. The rule also sets |
| forth the requireme | ent for submitting a | fee and supporting documentation with each request and prohibit |
| the submission of fa | alse information; it | defines licenses as "not transferable." The rule states that |
| supporting docume | entation records mu | ist be maintained and that applications not completed in the |
| manner specified sh | hall be deemed inco | omplete. Amendments include adding references to the MTLS |
| online system and o | deleting references | to some application forms replaced by the MTLS online system |
| and deleting the co | mment related to t | he incorporated by reference rule. |
| 4766-3-03 | Amend | Fees. |
| Rule 4766-3-03 set | s forth the fees tha | t ambulette services are required to submit to the EMFTS Board |
| with initial and ren | ewal applications w | then applying for a license to operate providing ambulette service; |
| for a vehicle permit | and inspection or i | reinspection of an ambulette, which is a requirement to obtain a |
| vehicle permit; to a | cquire a temporary | permit; or to acquire a reprinted vehicle decal to replace a lost, |
| | | or a decal created based on incorrect vehicle information provided |
| | | |
| by the service. Am | enaments include d | deleting paragraph (G) and deleting two regulatory restrictions from |
| | | deleting paragraph (G) and deleting two regulatory restrictions from e new paragraph (G). |
| | | |
| the last paragraph, 4766-3-04 | which becomes the Amend | e new paragraph (G). Physical facilities. |
| the last paragraph, 4766-3-04 Rule 4766-3-04 set | which becomes the Amend as forth the criteria is | Physical facilities. used to inspect physical facilities designated as ambulette service |
| the last paragraph, 4766-3-04 Rule 4766-3-04 set headquarters and s | which becomes the Amend as forth the criteria pervice satellite base | Physical facilities. used to inspect physical facilities designated as ambulette service es and ambulettes. Criteria include the licenses that must be posted |
| the last paragraph, 4766-3-04 Rule 4766-3-04 set headquarters and s and adherence to a | which becomes the Amend s forth the criteria cervice satellite base standard of cleanli | Physical facilities. used to inspect physical facilities designated as ambulette service es and ambulettes. Criteria include the licenses that must be posteriness. The rule also sets forth what may be inspected and when |
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ambulette configurations. The rule requires ambulettes to maintain sanitary conditions and bear license plates as set forth in rule 4766-3-07, and it states that permits are not transferable.

4766-3-09 No Change Maintenance documentation.

Rule 4766-3-09 sets forth the documentation that licensed ambulette services are required to maintain related to the inspection conducted on each ambulette, based on odometer readings, which includes: the "Periodic Mechanical Safety Report" signed by mechanic who completed the inspection; documentation of corrections made to failed items identified during the periodic mechanical safety inspections; "out of service" signs on permitted vehicles that have been removed from service; and documentation about the periodic maintenance, cleaning, and repair of each vehicle and its lifts, ramps, locking mechanisms, fasteners, straps, and other devices. The rule sets a document retention period of twelve months after a vehicle is removed from inventory.

4766-3-12 Amend Temporary and disaster operations.

Rule 4766-3-12 sets forth operational standards for ambulette services located in disaster situations, including the process to obtain a temporary permit for an ambulette. The rule is amended to reference the MTLS online system and to delete a reference to an application form replaced by the MTLS online system. The list of information submitted to obtain a temporary permit is amended to delete two items, and paragraphs (C), (E), and (F), are deleted. The comment related to the incorporated by reference rule is deleted

4766-3-13 Amend Driver training and qualifications.

Rule 4766-3-13 sets forth the documentation to be maintained by ambulette services as evidence that driver/operators meet the requirements for employment. The requirements include a valid driver/operator license; a minimum age requirement; a minimum driving experience requirement; a valid driver/operator's abstract obtained from the BMV; current and valid CPR and first aid training; periodic passenger assistance training; a criminal background check; and copies of results from alcohol and controlled substances tests. Rule 4766-3-13 references staffing requirements in section 4766.15 of the RC and provides instructions for provisional employment of applicants. The rule is amended to include a DOT physical as an acceptable declaration of a driver/operator's medical and physical condition. The term "driver/operator" is amended on paragraph (A) to match the term used throughout the rule.

4766-3-14 No Change Regulations for out of state providers.

Rule 4766-3-14 references division (B) of section 4766.09 of the RC and the exemptions applied to out of state ambulette services receiving clients in Ohio for transport to out-of-state locations or transporting clients received in another state to locations in Ohio.

4766-3-15 Amend Changes to be reported to the board.

Rule 4766-3-15 sets forth changes (such as executive officers, board members, business identification numbers, contact information, facility address, and vehicle status) an ambulette service is required to report to the EMFTS Board and provides the names of the forms that can be used to report the information. Amendments include adding references to the MTLS online system and deleting references to some application forms replaced by the MTLS online system. The comment related to the incorporated by reference rule is deleted.

4766-3-16 No Change Investigations.

Rule 4766-3-16 sets forth the investigations process that will be used be the Ohio State Board of EMFTS to investigate complaints against ambulette services and their employees, and, based on those findings, the initiation of disciplinary proceeding under RC Chapter 119. and OAC Chapter 4766-3. The rule sets forth the role of the Division of EMS to act on behalf of the EMFTS Board, the circumstances under which a case may be closed, the requirement to protect patient confidentiality, and the role of EMFTS Board members in the investigation and adjudication processes.

4766-3-17 No Change Disciplinary grounds.

Rule 4766-3-17 sets forth the sanctions that may be imposed by the EMFTS Board on licensed ambulette services and their employees for violations of RC Chapter 4766. and any rules adopted thereunder. The EMFTS Board is authorized, pursuant to an adjudicatory hearing under RC Chapter 119. and section

4766.08 of the RC, and by a vote of the majority of all members, to suspend, revoke, or refuse to renew any license or permit or issue a fine not to exceed fifteen hundred dollars. The sanctions and fine described in the rule are set forth in section 4766.08 of the RC and are not a change for ambulette services.

4766-3-18 Amend Incorporated by reference.

Rule 4766-3-18 is the incorporated by reference rule for Chapter 4766-3 (*Ambulettes*) and includes three documents incorporated throughout the chapter, their publication dates, and the Web addresses where the documents can be accessed. Amendments include inserting paragraph (B), which sets forth information about the MTLS online system, including its location. Five forms that are no longer in use have been deleted, and dates and locations of forms still in use have been updated, when applicable.

Chapter 4766-4 Mobile Intensive Care Units

| 4766-4-01 | Amend | Definitions. |
|-----------|-------|--------------|
|-----------|-------|--------------|

Rule 4766-4-01 is amended to provide twenty-four definitions associated with OAC Chapter 4766-4, entitled *Mobile Intensive Care Units*, which 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) and sets license and permit fees for Mobile Intensive Care Units, or MolCUs. The definitions for this chapter relate to standards for MTO organizations, including record-keeping, health and safety requirements, communications, vehicle maintenance, inspections, investigations, and disciplinary grounds. Amendments include adding seven definitions, deleting three definitions, and deleting the comment related to the incorporated by reference rule.

4766-4-02 Amend Application for initial or renewal licensure.

Rule 4766-4-02 sets forth the forms or processes that a medical transportation organization is required to use to make application to the EMFTS Board for an initial or renewal license to operate as an MTO providing MolCU service. The rule also sets forth the requirement for submitting a fee and supporting documentation with each request, the levels of service for which a license may be issued, and prohibits the submission of false information; it defines licenses as "not transferable." The rule states that supporting documentation records must be maintained and that applications not completed in the manner specified shall be deemed incomplete. Amendments include adding references to the MTLS online system and deleting references to some application forms replaced by the MTLS online system and deleting the comment related to the incorporated by reference rule. Paragraph (H) concerning levels of service is amended to reference advanced life support (ALS) and basic life support (BLS) levels of service that are set forth in OAC Chapter 4766-2.

4766-4-03 Amend Fees.

Rule 4766-4-03 sets forth the fees that medical transportation organizations are required to submit to the EMFTS Board with initial and renewal applications when applying for a license to operate as an MTO providing MolCU service; for inspection or reinspection of MolCUs and non-transport vehicles, which is a requirement to obtain a vehicle permit; to acquire a temporary permit; or to acquire a reprinted vehicle decal to replace a lost, damaged, or incorrectly applied decal or a decal created based on incorrect vehicle information provided by the service. Amendments include a grammatical correction in paragraph (B), the deletion of paragraph (G), and deleting a regulatory restriction in the last paragraph.

4766-4-04 Amend Physical facilities.

Rule 4766-4-04 sets forth the criteria used to inspect physical facilities designated by medical transportation organization as service headquarters and service satellite bases and vehicles. Criteria include the licenses that must be posted, the need for a required sanitation plan and adherence to a standard of cleanliness and state and local building and fire codes. The rule also sets forth what may be inspected and when inspections may occur and references the location of the "MoICU Inspection" form, which identifies the single use supplies and equipment which must be maintained at each physical facility. Amendments include revising "a" to "an" in two paragraphs.

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| 4766-4-05 | No Change | Record keeping requirements. |
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Rule 4766-4-05 sets forth the record keeping requirements for licensed MoICU services, including: (1) the documents that must be maintained or readily available at headquarters facilities; (2) the documents which must be maintained or readily available at each satellite base; (3) the original certifications of licensure which must be displayed at each headquarters and satellite base facility; and (4) a description of the requirements for maintaining patient records.

4766-4-06 Amend Communication requirements.

Rule 4766-4-06 sets forth the required communications devices and standards of operation, including required radio/communications log documentation, for licensed medical transportation organizations and the permitted MoICUs and non-transport vehicles they operate. The rule requires a written certification of compliance for an MTO contracting with a communications center. An amendment is made to revise "a" to "an" in paragraph (D).

4766-4-07 No Change Health and safety requirements.

Rule 4766-4-07 sets forth the health and safety requirements for licensed medical transportation organizations, including: a reference to 29 C.F.R. 1910.1030, the Occupational Safety and Health Administration (OSHA) bloodborne pathogens regulations; requirements regarding the creation and distribution of the required written sanitation plan; and requirements regarding the required written policy for warning devices.

Rule 4766-4-08 sets forth the requirement the EMFTS Board to inspect MolCUs and non-transport vehicles for roadworthiness and the equipment the vehicles are required to carry. The rule references division (C)(2) of section 4766.07 of the RC, which includes information related to federal ambulance construction specifications. The rules sets forth the process used to issue and correct violations and the signage standards, and the rules permits the Board to conduct unannounced inspections at any time. The rule refers to sections of the RC that provide licensing and registration requirements. Amendments include adding references to the "Mobile Stroke Unit Inspection" form and revising "a" to "an" in paragraph (G). An amendment is made to paragraph (H) concerning signage for a mobile stroke unit.

4766-4-09 No Change Maintenance documentation.

Rule 4766-4-09 sets forth the documentation that licensed MTOs are required to maintain related to the inspection conducted at least annually on each of their MoICU and non-transport vehicles, which includes: the "Periodic Mechanical Safety Report" completed by a qualified mechanic; documentation of corrections made to failed items identified during the periodic mechanical safety inspections; "out of service" signs on permitted vehicles that have been removed from service; and documentation about the periodic maintenance and repair of biomedical and patient care equipment. The rule sets a document retention period of twelve months after a vehicle is removed from inventory.

Rule 4766-4-11 sets forth the qualifications for permitted MolCUs and non-transport vehicles to be considered public safety vehicles and use lights and warning devices and the licensing and registration requirements for the vehicles.

4766-4-12 Amend Temporary and disaster operations.

Rule 4766-4-12 sets forth the process for obtaining a temporary vehicle permit, valid for a period not to exceed sixty days, for an MolCU or non-transport vehicle that may be used to replace a permitted ambulance or non-transport vehicle removed from service and defines the emergency circumstances under which a licensed medical transportation organization may utilize "whatever means necessary to transport and treat patients." Amendments include adding a reference to the MTLS online system and deleting a reference to an application form replaced by the MTLS online system and deleting the comment related to the incorporated by reference rule. Paragraphs (C), (D), and (E) ae deleted. The list of information submitted to obtain a temporary permit is revised, and a new paragraph (C) is added requiring temporarily permitted MolCU or non-transport vehicle to meet specified roadworthiness and insurance requirements.

| 4766-4-13 | Amend | Staffing compliance. |
|----------------------|--|--|
| | | ements, including the number of staff and the required |
| | | ovide MoICU transport services. Paragraph (A) of the rule sets |
| • | · · | el who serves as a driver/operator of an MolCU vehicle for a |
| | | requirements for healthcare personnel serving on an MoICU |
| | | paragraph (C) is added to set forth staffing requirements for a |
| | | ver/operator" is amended in the first two paragraphs to match |
| the term used throu | | |
| 4766-4-14 | No Change | Regulations for out of state providers. |
| | | ction 4766.09 of the RC and the exemptions applied to out of |
| | * * | transport to out-of-state locations or transporting patients |
| | | o. NOTE: The LSC Website displays the incorrect tagline "Use |
| | varning devices." for rule | |
| 4766-4-15 | Amend | Changes to be reported to the board. |
| | | executive officers, board members, medical director contact |
| | | nd business identification numbers and contact information) an |
| | | rd and provides the names of the forms that can be used to |
| | - | de adding references to the MTLS online system and deleting |
| • | | ITLS online system and deleting the comment related to the |
| incorporated by ref | | , |
| 4766-4-16 | No Change | Investigations. |
| Rule 4766-4-16 sets | forth the investigations | process that will be used be the Ohio State Board of EMFTS to |
| | | sportation organizations and their employees and, based on |
| | | roceeding under RC Chapter 119. and OAC Chapter 4766-4. |
| | | f EMS to act on behalf of the EMFTS Board, the circumstances |
| | | irement to protect patient confidentiality, and the role of |
| | | and adjudication processes. |
| 4766-4-17 | No Change | Disciplinary grounds. |
| | • | may be imposed by the EMFTS Board on licensed medical |
| | | RC Chapter 4766. and any rules adopted thereunder. The |
| - | | adjudicatory hearing under RC Chapter 119. and section |
| | | prity of all members, to suspend, revoke, or refuse to renew |
| | - | xceed fifteen hundred dollars. The sanctions and fine |
| | | 4766.08 of the RC and are not a change for MTOs. |
| 4766-4-18 | Amend | Incorporated by reference. |
| | | ence rule for Chapter 4766-4 (<i>Mobile Intensive Care Units</i>) and, |
| | the state of the s | rughout the chapter, their publication dates, and the Web |
| | | essed. Paragraph (D) has been added to provide information |
| | | on" form. Other amendments include inserting paragraph (F), |
| | | S online system, including its location. Six forms that are no |
| | | and locations of forms still in use have been updated, when |
| ionger in use nave t | been deleted, and dates of | and locations of forms still ill use have been updated, when |

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.

applicable.

| Rule Number | Authorized by | Rule amplifies |
|-------------|---------------|----------------|
| 4766-3-01 | 4766.03 | 4766.01 |

| 4766-3-02 | 4766.03 | 4766.03, 4766.04, 4766.07 |
|-----------|---------|--|
| 4766-3-03 | 4766.03 | 4766.05 |
| 4766-3-04 | 4766.03 | 4766.03, 4766.04 |
| 4766-3-05 | 4766.03 | 4766.04, 4766.06 |
| 4766-3-06 | 4766.03 | 4766.04, 4766.07 |
| 4766-3-07 | 4766.03 | 4766.07, 4503.49, 4503.111 |
| 4766-3-08 | 4766.03 | 4766.03, 4766.04, 4766.07 |
| 4766-3-09 | 4766.03 | 4766.04, 4766.07 |
| 4766-3-12 | 4766.03 | 4766.07, 4766.09 |
| 4766-3-13 | 4766.03 | 4766.04, 4766.15 |
| 4766-3-14 | 4766.03 | 4766.13 |
| 4766-3-15 | 4766.03 | 4766.04, 4766.07 |
| 4766-3-16 | 4766.03 | 4766.08, 4766.11, 4765.102 |
| 4766-3-17 | 4766.03 | 4766.04, 4766.08 |
| 4766-3-18 | 4766.03 | 4766.03 |
| 4766-4-01 | 4766.03 | 4766.01 |
| 4766-4-02 | 4766.03 | 4766.03, 4766.04, 4766.07 |
| 4766-4-03 | 4766.03 | 4766.05 |
| 4766-4-04 | 4766.03 | 4766.04 |
| 4766-4-05 | 4766.03 | 4766.04, 4766.06 |
| 4766-4-06 | 4766.03 | 4766.04, 4766.07 |
| 4766-4-07 | 4766.03 | 4766.04, 4766.07 |
| 4766-4-08 | 4766.03 | 4766.03, 4766.04, 4766.07 |
| 4766-4-09 | 4766.03 | 4766.04, 4766.07 |
| 4766-4-11 | 4766.03 | 4503.111, 4503.49, 4511.01, 4511.24, 4766.07 |
| 4766-4-12 | 4766.03 | 4766.09 |
| 4766-4-13 | 4766.03 | 4766.03, 4766.04 |
| 4766-4-14 | 4766.03 | 4766.06, 4511.24 |
| 4766-4-15 | 4766.03 | 4766.04, 4766.07 |
| 4766-4-16 | 4766.03 | 4766.08, 4766.11, 4765.102 |
| 4766-4-17 | 4766.03 | 4766.04, 4766.08 |
| 4766-4-18 | 4766.03 | 4766.03 |
| | | |

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.

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

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)?

These regulations assure ambulettes, MoICUs, and medical transportation organizations operate with the required medical equipment, qualified medical staff and drivers, and effective delivery of EMS care to clients and patients who must use an MTO and its vehicles.

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

MTOs, including ambulette and mobile intensive care unit (MoICU) services, and their satellite locations and all permitted vehicles, are inspected periodically 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 OAC chapters 4766-3 and 47664. In addition, the Division of Emergency Medical Services (EMS) will track complaints made by MTOs and complaints regarding MTOs that lead to investigations.

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.

No, none of the proposed rules in this 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.

Stakeholders include members of the Medical Transportation Committee and the Critical Care Subcommittee, members of EMFTS Board and its other committees and subcommittees; members of the Division of EMS staff and DPS legal staff; and the Medical Transportation Field Inspectors contracted by DPS. Additional stakeholders include:

the 27 licensed MoICU services and their owners, employees, and customers;

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- the 335 licensed ambulette services, and their owners, employees, and customers;
- the Ohio Ambulance Association (OAA) and its members;
- medical transportation organizations that use Medicare/Medicaid funding;
- Ohio-based representatives of the Centers for Medicare & Medicaid Services (CMS); and
- members of the Ohio Legislature.

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

Input to date has been provided by members of the Medical Transportation Committee and the Critical Care Subcommittee, who developed the proposed revisions over the past nine months. When the rules are filed with the Common Sense Initiative office, a request for public comments will be emailed to licensed ambulette providers and licensed MoICU providers and to the Ohio Ambulance Association for redistribution to its members.

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?

There is no scientific data available for the proposed regulations.

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?

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

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.

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 ambulette service.

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 4766., OAC Chapter 4766, RC Chapter 4765., and OAC Chapter 4765 to assure there was no duplication or conflict among Ohio EMS and Medical Transportation regulations.

^{*}Information provided by the Medical Transportation Section, Ohio Division of EMS

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.

The Division of EMS posts information about the rule review process, including those rules scheduled for review, drafts open for public comment, and proposed rules and public hearing notices at its Laws & Rules Overview page (https://www.ems.ohio.gov/laws.aspx#gsc.tab=0) and the Department of Public Safety Administrative Rules page (https://publicsafety.ohio.gov/wps/portal/gov/odps/what-we-do/administrative-rules-reviews/). The Division of EMS provides a link to the Register of Ohio, where the text of proposed rules, public hearing notices, Rule Summary and Fiscal Analysis (RSFA) forms, copies of each Business Impact Analysis (BIA), and other information is published.

The laws and rules associated with Medical Transportation are provided as links at the *Medical Transportation* Web site (https://www.ems.ohio.gov/medical-transportation-laws.aspx#gsc.tab=0), and the amended rules, when they become effective, will be available at that link. The Division of EMS will use the gov.delivery.com and the email addresses provided by licensed ambulette providers and licensed MoICU providers 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, Medical Transportation Committee, and Critical Care Subcommittee members receive regular updates about EMS rules.

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 impact fluctuates but in general affects the following portion of the business community *:

| Ambulettes (2021) | 327 licensed MTOs that operate a total of 1,373 ambulettes |
|-------------------|--|
| MoICU (2021) | 30 licensed MTOs that operate a total of 144 MolCUs |

^{*}Information provided by the Medical Transportation Section, Ohio Division of EMS

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

OAC rule 4766-3-02 sets forth the application process required to obtain or renew a license to operate as an ambulette service. OAC rule 4766-4-02 sets forth the application process required to obtain or renew a license to operate as a mobile intensive care unit service.

The estimated costs of compliance for stakeholders obtaining and maintaining either license may include:

- the cost of employee time spent to submit the applications and required documentation using the MTLS online system;
- the cost of employee time and fees to obtain required vehicle plates (rule 4766-3-07 of the OAC and section 4503.49 of the RC); and);
- the initial application fee and annual renewal application fees, set forth in rules 4766-3-03 and 4766-4-03, of \$100 annually; and
- the cost to provide color photographs showing the distinguishing characteristics of an applicant's vehicles.

Applicants are required to provide and maintain the following information as part of their application or supporting documentation in order to be in compliance with the rule and have their applications accepted as complete and processed:

- the name of the service and identification of the organizational structure;
- tax identification or employer identification number, the name(s) under which the applicant plans to operate and copies of all trade name registrations and fictitious name registrations on file with the Ohio secretary of state;
- the address of the physical location of the applicant's headquarters, and the mailing address of the applicant;
- all Medicare and Medicaid provider numbers (MoICUs only);
- the highest level of service to be provided (MoICUs only);
- the service areas (county and state);
- a list of the names of all officers, directors, and/or owners of the medical transportation organization;
- the name, contact information, and proof of compliance with rule OAC 4765-3-05 for the medical director (MoICUs only);
- the physical address, city, county, state, and zip code of each of the service's satellite bases:
- the name, office telephone number, email address, and, if applicable, fax number of the primary contact;
- the year of manufacture, make, model, VIN, and license plate number of each ambulance or non-transport vehicle permitted;
- the license plate number of permitted vehicles, if submitting a renewal application for a license; and
- a current certificate of liability insurance that includes the actual name on the license application and the VIN of each permitted vehicle.

Some of the information entered into the MTLS online system will remain the same or require only occasional updates, which is more time- and cost-efficient than the previous application process that used paper forms, when reporting information to the EMFTS Board, as required by rules 4766-3-15 and d4766-4-15.

In addition, a color photo, preferably digital, of the side of the applicant's vehicle(s) is required with an initial application and within thirty days of the date a change is made to the vehicle's color scheme, insignia, monogram, or other distinguishing characteristic.

Rules4766-3-04 and 4766-4-04 require MTOs to comply with inspection requirements for physical facilities in order to obtain a license and before commencing operations and to maintain compliance in order to renew a license. Rules 4766-3-06 and 4766-4-06 of the OAC set forth communications requirements. Rule 4766-4-07 of the OAC set forth health and safety requirements for licensed MoICU services. Rules 4766-3-08 and 4766-4-08 of the OAC set forth vehicle and equipment inspection requirements, which include compliance with vehicle signage requirements. Subsequently, MTOs incur the costs of applying permanent lettering that displays the name of the service on both sides as well as the back of each vehicle.

Rules 4766-3-05 and 4766-4-05 of the OAC set forth record keeping requirements. Rules 4766-3-09 and 4766-4-09 set forth maintenance documentation requirements and the use of periodic mechanical safety inspections and reports.

Rule 4766-3-13 of the OAC sets forth driver training and qualification requirements for ambulettes. Rule 4766-4-13 of the OAC sets forth staffing requirements for MolCUs, including mobile stroke units.

OAC rules 4766-3-17 and 4766-4-17 permit the imposition of penalties including suspension, revocation, or refusal to renew any license or permit or issuance of a fine not to exceed more than fifteen hundred dollars for specific violations and based on investigations completed in accordance with section 4766.11 and Chapter 119. Of the RC, as set forth in rules 4766-3-16 and 4766-4-16 of the OAC.

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.

OAC rules 4766-3-02 and 4766-4-02 require specific expenditures and the report of information as a condition of compliance.

Rules 4766-3-03 and 4766-4-03 sets forth existing license and permit fees associated with ambulette and MoICU rules and include the following fees for MTOs:

| Initial or Renewal License Fee (MoICU or Ambulette) | \$100.00 annually |
|--|-------------------|
| Ambulette Permit Fee per vehicle | \$ 50.00 annually |
| Ambulette Inspection or Reinspection Fee per vehicle | \$ 50.00 annually |
| Ambulette Temporary Vehicle Permit Fee per vehicle | \$ 50.00 annually |
| MoICU Permit Fee per vehicle | \$100.00 annually |

| Non-transport Vehicle Fee per vehicle | \$100.00 annually |
|--|-------------------|
| MoICU Vehicle Inspection or Reinspection Fee per vehicle | \$100.00 annually |
| Ambulette Temporary Vehicle Permit Fee per vehicle | \$100.00 annually |

A \$5.00 fee may be imposed 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 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.

The vehicle inspection fees were set by the Ohio Medical Transportation Board prior to its merger with the EMFTS Board in June 2013, pursuant to section 4766.03 and section 4766.05 of the RC and based on actual costs. The proposed rule revisions do not change the vehicle inspection fee.

Efficiency has improved as a result of implementing the MTLS online system, which retains the information entered and allows it to be updated as needed; the amount of time required to obtain, renew, and maintain licenses and vehicle permits has been reduced. Use of the MTLS system has also eliminated the costs of postage previously associated with obtaining, renewing, and maintaining MTO licenses and vehicle permits.

The cost of periodic mechanical safety inspections 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. 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.

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

The Division of EMS and the State Board of EMFTS estimate that these rules will not result in any undue cost of compliance or adverse impact. Pursuant to Chapter 4766. Of the RC, the Board is statutorily required to adopt rules that establish the standards and procedures under which the Board may approve, renew, or deny an application to operate an MTO, ambulette, or MoICU service and standards for MTOs and ambulette and MoICU service organizations including record keeping, safety and sanitation, vehicle maintenance, and inspection requirements. Assuring the safety and effective delivery of care to clients and patients who

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must use an MTO's ambulette or MoICU service and its vehicles justifies the minimal adverse impact to the business community.

Regulatory Flexibility

18. 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.

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?

If disciplinary action is considered, the MTO or ambulette or MoICU services will be afforded seventy-two hours to correct violation(s) cited or provide the Board sufficient documentation that the MTO or service 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 RC section 119.14. The Board reviews each situation on a case-by-case basis and may consider all information relevant to the requirements of agency 4766 of the OAC and RC Chapter 4766. and agency 4765 of the OAC and RC Chapter 4765. Depending on the nature and severity of the violation the board may issue a lesser penalty.

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

The Division of EMS Web site contains a "Laws & Rules Overview" Web site (https://www.ems.ohio.gov/laws.aspx#gsc.tab=0) with links to RC 4766. and RC 4765. and OAC 4766 and OAC 4765. Rules scheduled for review are posted at the Web site. The Web site includes a link to "Draft and Proposed Rules" posted at the DPS "Administrative Rules" Web site (https://publicsafety.ohio.gov/wps/portal/gov/odps/what-we-do/administrative-rules-reviews/), where public comment and public hearing information and the email link for the ODPS Rules Coordinator are posted. The DPS administrative rules Web site also includes links to the Joint Committee on Agency Rule Review (JCARR), the Legislative Services Commission (LSC), and the Register of Ohio. Proposed rules filed with the Common Sense Initiative (CSI) office and open for public comment are posted at the DPS administrative rules Web site.

Each section of the EMS Web page, including the Medical Transportation section, includes a Web page with links to the laws and rules associated with that topic, along with an overview section, and a Frequently Asked Questions section (https://www.ems.ohio.gov/medical-transportation-faq.aspx#gsc.tab=0). 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 (1-800-233-0875), 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 (<u>ASKEMS@dps.ohio.gov</u>) 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 MTOs and ambulette, ambulance, and MoICU services, their satellite locations, and all permitted vehicles. Approximately fourteen inspectors work in specified regions covering all of Ohio and its bordering states. Inspectors are available by phone and by email to all MTOs and ambulette, ambulance, and MoICU services licensed in Ohio and the five states contiguous to Ohio.

Medical transportation forms and applications are available through the MTLS system or on-line at the EMS Website. Instructions for using the MTLS online system are available at the "Medical Transportation Overview" Web site (https://www.ems.ohio.gov/medical-transportation.aspx#gsc.tab=0) and EMS staff are available by phone and email to assist MTLS online system users. Additional forms required of MTOs and ambulette, ambulance, MoICU, and air services by the Division of EMS are available via the Division of EMS Web sites located at https://www.ems.ohio.gov/medical-transportation-forms.aspx#gsc.tab=0 or https://www.ems.ohio.gov/forms.aspx#gsc.tab=0. Inspection forms are posted at the Web sites so services are aware of inspection guidelines and expectations in advance of inspections.

Medical Transportation staff members maintain contact with and work closely with organizations including the Ohio Ambulance Association (OAA); the Ohio Association of Critical Care Transport (OACCT); the Ohio Hospital Association (OHA); the Ohio Chapter, American College of Emergency Physicians (Ohio ACEP); and other organizations representing emergency room physicians, pediatricians, nurses, and EMS personnel and instructors. As set forth in section 4765.02, the State Board of EMFTS consists of members nominated by these organizations. The Board's committees, subcommittees, and working groups consist of EMFTS board members and other professionals working in emergency medical services and transportation. DEMS medical transportation staff attend and present information at meetings and conferences held by these organizations.

As set forth in Chapter 4765. of the RC, the State Board of EMFTS organizes and consults with eight Regional Physician Advisory Boards (RPABs) and appoints a medical director, who attends EMFTS meetings to "...direct the executive director and advise the board with regard to adult and pediatric trauma and emergency medical services issues." The Division of EMS, including the Medical Transportation section, collaborates with the Ohio Department of Health, the Ohio Department of Aging, and other divisions of the Ohio Department of Public Safety (ODPS) to provide programs and information to the public about emergency medical services, medical transportation services, and regulations in Ohio.