

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

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

Regulation/Package Title: Medical Transportation/Air Medical

Rule Number(s): 4766-5-01 to 4766-5-13, 4766-5-15, 4766-5-16 and 4766-5-18 to 4766-5-22

Date: April 3, 2014

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Rescinded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 4766-5 of the Administrative Code (O.A.C.) sets forth the conditions under which the State Board of Emergency Medical, Fire, and Transportation Services (Board) may approve, renew, or deny an application to operate an air medical service organization (AMSO). In addition, this chapter sets forth the air worthiness standards for AMSO aircraft

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and the required state and federal licenses and/or permits, as well as the communication and medical equipment required for each aircraft. Additionally, these rules set forth the transportation and maintenance records retention requirements to be followed by an AMSO.

O.A.C. Chapter 4766-5 is proposed for filing pursuant to a completed R.C. 119.032 five-year rule review. After a thorough review, the Medical Transportation Committee of the Board decided to reorganize the chapter for clarity and consistency and rescind a majority of the rules to relocate their content to other rule numbers. EMS proposes to rescind rules 4766-5-05, 4766-5-09, 4766-5-10, 4766-5-11, 4766-5-12, 4766-5-16, 4766-5-18, 4766-5-19, 4766-5-21, and 4766-5-22 and relocate the content in rules 4766-5-08, 4766-5-05, 4766-5-06, 4766-5-07, 4766-5-09, 4766-5-12, 4766-5-15, 4766-5-16 and 4766-5-10 respectively.

In addition, EMS proposes to file amended O.A.C. rules 4766-5-01, 4766-5-03, 4766-5-04, and 4766-5-20 to address materials incorporated by reference in compliance with R.C. sections 121.71 to 121.74. EMS also proposes to amend rules 4766-5-01 and 4766-5-05 to reflect a statutory change which reorganized two agencies into the State Board of Emergency Medical, Fire, and Transportation Services set forth by Sub. H.B. 51, 130th General Assembly.

Finally, EMS proposes to file O.A.C. 4766-5-02 and 4766-5-13 as rescind/new rules due to LSC's fifty percent rule formatting- guideline and rescind rule 4766-5-21 as the rule solely duplicates the law.

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

R.C. 4766.03, R.C. 4766.04, R.C. 4766.05, R.C. 4766.06, R.C. 4766.07, R.C. 4766.08, R.C. 4766.11, R.C. 4766.17

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. However, the regulations mirror federal requirements for the operation of air medical aircraft in compliance with the Code of Federal Regulations (CFR).

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

N/A

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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 airworthy medical aircraft, with the required medical equipment, qualified medical staff, and effective delivery of EMS care to patients who must utilize an air medical service organization (AMSO) and its aircraft.

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

AMSOs, their satellite locations and all permitted aircraft are inspected annually. 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 4766-5. In addition, the Division of EMS will track complaints by AMSOs and complaints regarding AMSOs 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.

On July 1, 2013, Am. Sub. H.B. 51, 130th General Assembly, directed that the Medical Transportation Board and the State Board of Emergency Medical Services become one entity under the Department of Public Safety. Prior to the merger, copies of Chapter 4766-5 of the Administrative Code were sent to the Ohio Association of Critical Care Transport (OACCT) and Ohio Ambulance and Medical Transportation Association (OAMTA) for input. Following the board merger, the Medical Transportation Committee and the Critical Care Sub-Committee members were contacted via email to attend regularly scheduled public meetings held on November 13, 2013, and December 17, 2013. The committees were asked to review and make changes, as necessary, to Chapter 4766-5 of the Administrative Code. These two committees have various members representing EMS providers, owners and administrators for medical transportation agencies, and full-time and volunteer fire departments.

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

The Critical Care Sub-Committee (CCSC) met on November 13, 2013, to review and draft rules focused on regulations pertaining to medical equipment and staffing. The CCSC forwarded its initial draft rules to the Medical Transportation Committee (MTC) for review. The MTC, which met on the same date, focused on the need to reorganize the rule numbers to align with O.A.C. rules pertaining to ambulances and ambulettes. This reorganization

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would require many rules to be rescinded and their content relocated under different rule numbers.

The CCSC met on December 17, 2013, to finalize the draft rules and forward its recommendations to the MTC. The MTC met on December 17, 2013, approved the draft rules and recommended they be sent to the Board for review and approval. The rules were approved by the Board at a special meeting held March 20, 2014.

9. What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?

The rules mirror the CFR requirements established by the Federal Aviation Administration (FAA), Federal Communications Commission (FCC), and Occupational Safety and Health Administration (OSHA) for air medical aircraft. The FAA, FCC and OSHA conduct national research on airworthiness, air communications, occupational safety, and air medical transportation issue which might impact the safety of occupants and/or the medical care to patients who must utilize an air medical service organization (AMSO) and its aircraft.

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?

The MTO determined that alternative regulations would not meet the purpose of the rules to assure airworthy medical aircraft and effective delivery of EMS care to patients who must utilize an AMSO and its aircraft. These regulations mirror the CFR requirements established by the Federal Aviation Administration (FAA), Federal Communications Commission (FCC), and Occupational Safety and Health Administration (OSHA) for air medical aircraft.

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 criterion-based regulations to assure airworthy medical aircraft and effective delivery of EMS patient care. There is limited flexibility for the AMSO as the regulations mirror the FAA, FCC, and OSHA standards to operate air medical aircraft.

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

The Board is the only authority for air medical services organizations; therefore, a review of R.C. section 4766 and O.A.C. Chapter 4766 was completed. The Division of Emergency Medical Services also staff reviewed section R.C. 4729 and O.A.C. Chapter 4729 to avoid duplication and/or conflict with Board of Pharmacy authority. In addition, the Division of

Emergency Medical Services staff reviewed R.C. section 4731 and O.A.C. Chapter 4731 to avoid duplication and/or conflict with Medical Board authority. Finally, the Division of Emergency Medical Services staff reviewed R.C. section 4723 and O.A.C. Chapter 4723 to avoid duplication and/or conflict with Nursing Board authority.

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 will use the EMS web site and EMS listservs, to distribute the O.A.C. Chapter 4766-5 final rules and rule summaries to stakeholders. Notices to EMS, air medical and medical transportation organizations will be distributed through the Division newsletter, THE SIREN which is located at <http://ems.ohio.gov>. Division of EMS staff will receive email notification of the rule changes and attend section briefings regarding implementation policy and procedures.

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 impacted business community includes 17 licensed AMSOs that operate 46 satellite facilities and a combined total of 76 aircraft. Adverse impact may result from the cost of seeking and maintaining a license to operate an AMSO and permitted aircraft, both required in accordance with section 4766.04 of the Revised Code. In addition, the regulations require AMSOs to develop protocol and procedures that conform to FAA, FCC and OSHA regulations.

O.A.C. rule 4766-5-03 requires each AMSO to submit an annual licensing fee of \$100 to operate an air medical service. In addition, there is a \$100 annual permit fee required for each aircraft and an annual inspection fee of \$100 per aircraft. Stakeholders estimate the cost of compliance ranges \$300 to \$1500 per year for AMSO licensing and aircraft permits

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and inspections. The variance in costs is dependent on the number of permitted aircraft by the AMSO. The established fees do not exceed those authorized in R.C. section 4766.05.

Additionally, the estimated cost to stock the required medical equipment and supplies on each permitted medical aircraft, as listed in O.A.C. rule 4766-5-03, could be up to \$14,000 per year. Required equipment includes, but is not limited to isolation attire, oxygen equipment, ventilators, obstetrical kits, pediatric supplies, IV equipment, defibrillators, ECG monitors, and associated adjunct equipment. The variance in costs is dependent on equipment items and quantity needed.

O.A.C. rules 4766-5-05, 4766-5-06, and 4766-5-09 require an AMSO to written plans, procedures and documentation of procedures be created and maintained. The estimated cost of compliance to an AMSO could be up to \$200 to create and distribute a written sanitation plan, in addition to training costs of up to \$30 per hour per employee. In addition, minimal adverse impact may be expected for an AMSO to provide the written plans and to retain records that meet the requirements, and in the specified format, set forth in these rules. Cost of compliance will vary depending on the AMSO pay rates.

The rules mirror the CFR requirements established by the Federal Aviation Administration (FAA), Federal Communications Commission (FCC), and Occupational Safety and Health Administration (OSHA) for air medical aircraft. The FAA, FCC and OSHA conduct national research on airworthiness, air communications, occupational safety, and air medical transportation issue which might impact the safety of occupants and/or the medical care to patients who must utilize an air medical service organization (AMSO) and its aircraft.

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 air medical services organization (AMSO). Assuring the safety and effective delivery of EMS care to patients who must utilize an AMSO and its aircraft 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.

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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, each case is submitted first to Board's Assistant Attorney General to ensure compliance with R.C. section 119.04. The Board reviews each situation on a case-by-case and may consider all information relevant to the requirements of O.A.C. Chapter 4766. and R.C. Chapter 4766. 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?

A toll-free number (1-800-233-0785) may be utilized to contact the Division of EMS, Medical Transportation Section from 8:00 AM to 5:00 PM, Monday through Friday, excluding state holidays. In addition, all forms required of AMSOs, by the Division of EMS, are available via the Division of EMS web-site located at www.ems.ohio.gov.