

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Respiratory Care Board

Regulation/Package Title: 119.032 review for HME rules 8-2013

Rule Number(s): OAC 4761:1-9-01, OAC 4761:1-9-05

Date: August 15, 2013

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Rescinded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.

OAC Chapter 4761:1-9 establish a series of standards that must be met to obtain and retain a license to provide home medical equipment services in the state of Ohio. ORC 4761.07 requires a home medical equipment license holder to do all of the following:

- (1) Maintain a physical facility and a medical equipment inventory;

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- (2) Establish equipment management and personnel policies;
- (3) Provide life-sustaining home medical equipment, as described in division (B)(1) of section 4752.01 of the Revised Code, and related home medical equipment services twenty-four hours per day, seven days per week;
- (4) To successfully complete continuing education programs in home medical equipment services that meet the standards established by rule adopted under section 4752.17 of the Revised Code and maintain records on participation in those programs;
- (5) Maintain records on all individuals to whom it provides home medical equipment and services;
- (6) Maintain liability insurance, including coverage for professional and products liability;
- (7) Comply with all other requirements established by rule adopted under section 4752.17 of the Revised Code that apply to persons licensed under this chapter.

In addition, ORC 4761.17 requires the Ohio Respiratory Care Board to adopt rules establishing:

- (1) Standards an applicant must meet to be eligible to be granted a license under section 4752.05 of the Revised Code;
- (2) Standards for personnel policies, equipment storage, equipment maintenance, and record keeping to be followed by home medical equipment services providers licensed under this chapter;
- (3) Standards for continuing education programs in home medical equipment services for individuals who provide home medical equipment services while employed by or under the control of a home medical equipment services provider licensed under this chapter;
- (4) Standards and procedures for inspection of home medical equipment providers licensed under this chapter and the facilities from which their home medical equipment services are provided and for appeal of inspection results;

In accordance with the aforementioned provisions of law, OAC Rules 4761:1-9-01 and 4761:1-9-05 establish standards of practice. OAC 4761:1-9-01 establishes the criteria the Board will use to evaluate a licensee's compliance with practice standards. OAC 4761:1-9-05 establishes standards for personnel employed by the HME services provider.

Please include the key provisions of the regulation as well as any proposed amendments.

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

ORC 4752.17(A)(11)

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- 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.**

No.

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

In 2004, the Governor signed Chapter 4752 of the Revised Code into law, requiring the licensure or registration of entities seeking to provide home medical equipment services in the state of Ohio. The federal government has no specific licensure or registration requirement in this regard.

- 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)?**

The Ohio General Assembly passed this statute to assure the public that persons engaging in the sale and rental of specific home medical equipment are adequately trained in the demonstration and installation of the equipment, equipment is properly stored, maintained and cleaned prior to sale or rental, records are appropriately completed and stored, and that the providers meet all other regulatory requirements relative to the sale and/or lease of home medical equipment. Rule 4761:1-9-01 establishes criteria the Board will use to evaluate a licensee's compliance with these standards. Rule 4761:1-9-05 establishes specific standards for personnel employed by the HME provider.

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

The Ohio Respiratory Care Board will gauge the success of these regulations by monitoring the inspection results received by the Board and specifically compliance with these requirements. The standards should be easily understood and measured by the license holder and the Ohio Respiratory Care Board inspection staff.

Development of the Regulation

- 7. Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

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If applicable, please include the date and medium by which the stakeholders were initially contacted.

The Ohio Respiratory Care Board mailed this rule to 497 licensed/certificate of registration holding home medical equipment providers representing over 900 licensed or registered home medical equipment facilities providing services to Ohio citizens. In addition, this rule was sent to the Ohio Association of Medical Equipment Service providers (OAMES).

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

Stakeholders were given an active seat at the table during the initial drafting of this rule. During the five-year review process, the Ohio Respiratory Care Board collected comments on the current rule. The Board, as part of the drafting process, reviewed recommendations and comments sent to the Board. Where practical and when not specifically required by the Ohio Revised Code, the Ohio Respiratory Care Board amended the rule to reflect the input of the stakeholders. Stakeholders offered no recommended changes to these rules.

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?

These rules were developed based upon the requirements of the Ohio Revised Code and the Board's authority to effectively regulate HME services. The Board did not consider scientific data or measurable outcomes in the development of this rule. The rules were developed to inform licensees of the minimum standards required for employed personnel and also the methodology the Board would employ to evaluate compliance with all standards contained in OAC 4761:1-9.

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 Ohio Respiratory Care Board based these rules on requirements for the operations of a licensed home medical equipment provider contained in Section 4752.07 of the Ohio Revised Code. Also, the Board considered its duty to develop rules under ORC 4752.17(A)(11) that are necessary for the effective regulation of HME services. Regulatory alternatives were for this purpose were not considered.

11. Did the Agency specifically consider a performance-based regulation? Please explain.

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Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.

The standards of operation for licensed home medical equipment facilities do include performance-based standards. The standards, in most circumstances, define the expected outcome, but not the specific steps to achieve the outcome. Licensed home medical equipment facilities are inspected on a regular basis to verify compliance with the outcome expectations listed in these rules. Inspectors, for many of the standards, consider the licensee's demonstration of compliance, via their policies and processes, when rating compliance.

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

The Ohio Respiratory Care Board is the only regulatory entity in the state of Ohio that is authorized to license home medical equipment providers. Accordingly, the Board deemed it very unlikely that other duplicate requirements exist in the state of Ohio.

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 operational standards for home medical equipment facilities are provided to each licensee. In addition, the Ohio Respiratory Care Board prepares self-evaluation materials to assist licensees with compliance. Inspectors are trained on all aspects of the Board's rules and provided inspection reporting material designed to flow with the requirement of each operational standard, including reference to each rule or regulation upon which the standard is based.

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;

Rule 4761:1-9-01 does not have an adverse impact on the business community since the rule establishes evaluation criteria for the Board.

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Rule 4761:1-9-05 establishes personnel standards for persons employed by the HME provider. Many of the components listed in the standard are documentation the employer must have on record for the employees. Much of the documentation (maintaining personnel records, job descriptions, application qualifications, and orientation documentation) are standard for business. Others documents are items the employer must collect and maintain. One item, criminal background checks, will cost approximately \$30 - \$40 to complete per employee working in the state of Ohio.

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

The nature of the impact, particularly OAC 4761:1-9-05, is time required to collect and verify that each employee record has the required components. The cost of the criminal background check.

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 expected impact of the regulations is difficult to quantify. Time and some paper expense to maintain a proper employee record in compliance with the rule is a true cost. The total cost will depend upon the size of the business and the number of employees engaged in HME services. One item, criminal background checks, will cost approximately \$30 - \$40 to complete per employee working in the state of Ohio.

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

Rule 4761:1-9-01 is intended to provide the Board with a methodology to evaluate compliance with practice standards, as well as informing the licensee how the Board will evaluate compliance. Rule 4761:1-9-05 establishes personnel standards for persons engaged in HME services. This rule requires documentation to verify that the employee is trained, qualified (having the skills and competence to perform the job and/or possessing the credentials to work/drive, etc.

Regulatory Flexibility

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

The Ohio Respiratory Care Board believes the standards personnel are both prescriptive and outcome based. The outcome based component, such as employing enough staffing to handle the scope of equipment sold and the demands of the business are not prescriptive, but demonstrable upon inspection. Accordingly, the Board believes the rule does take into consideration the size of the business.

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?

Deficiencies determined through an inspection process are communicated to the authorized representative of the licensed entity. The entity is given 90 days to develop and demonstrate compliance with the standard.

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

The Ohio Respiratory Care Board and its staff are well versed in the provisions of these rules and the Ohio Revised Code and Ohio Administrative Code relating to the regulation of home medical equipment providers in the state of Ohio. A simplified checkoff manual has been prepared for home medical equipment providers. The manual is mailed to each license holder and it is available on our website. The manual allows the licensee to evaluate their own compliance with the standards, address and correct the areas of deficiency.