

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 4761:1-5-01

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Rescinded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 4761:1-5-01 lists the qualifications needed to apply for a license to provide home medical equipment (HME) service in the state of Ohio. The rule also addresses the issuance of provisional licenses under ORC 4752.05 (B).

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

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) (4)

ORC 4752.17(A) (5)

ORC 4752.17(A) (11)

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.

The federal government has no specific requirements 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)?

This rule lists the qualifications needed to apply for a license to provide home medical equipment (HME) service in the state of Ohio. ORC 4752.11(A)(4) requires the Board to establish standards an applicant must meet to be eligible for a license.

The qualifications include compliance with standards adopted under ORC 4752.17(A)(5).

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

This rule has been in place since 2005, shortly after the effective date of the HME Act. The success of this regulation has been measured by the applicants ability to meet the standards.

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIOhio@governor.ohio.gov

The Board is not aware of any person that could not meet all of the standards required by the rule for initial issuance of the license.

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.

The Ohio Association of Medical Equipment Service providers worked closely with the Board on the initial drafting of this rule. In addition, the Board established a focus group in 2005 on the develop of the regulatory rules. This group consistent mainly of licensed HME facilities.

For five-year review, the Ohio Respiratory Care Board mailed these rules 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, these rules were 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 these rules. During the five-year review process, the Ohio Respiratory Care Board collected comments on all rules scheduled for five-year review. The Board received no comment specific to these rules.

Having noted no comment on the rule, the Board notes that ORC 4752.05 (B) is applicable to the period ending one year after September 16, 2004. Since this time period has ended, paragraph (E) is no longer required.

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?

Facilities licensed by the Board are required to undergo periodic inspections to verify compliance with licensing standards under OAC 4761:1-9. The qualifications for initial licensure are repeated in the operational standards contained in OAC 4761:1-9, but with more detail. These inspections serve to verify measurable compliance with the initial qualifications reported and ongoing compliance with these standards..

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?

ORC 4752.17(A) (4) requires the Board to adopt this rule.

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.*

In some measure, this rule does provide for performance-based regulation. The rule requires a facility to have a specific amount of liability insurance coverage, but the rule does not specify whom the coverage should be obtained through, thereby preserving an open-market approach to achieving this requirement. Additionally, this rule requires the facility to have trained staff, but it does not dictate how training should be achieved. In addition, the rule requires licensees to maintain a facility to adequately store, maintain, lease or sell HME. The Board does not define the word "adequate." Adequacy is an observed measure that normally occurs during the first inspection. Board inspectors physically observe how and where HME is stored, is the equipment stored in accordance with law or manufacturer standards and other municipal code requirements.

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

This rule is unique to the Ohio Respiratory Care Board as the only entity that licenses home medical equipment facilities 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.

This rule is iterated on the initial application form for licensure and in the standards for maintaining an HME facility providing HME services. Each person that receives a license is issued an inspection guidance booklet to assist the business with preparation for his or her inspection. The requirements listed in this rule are repeated in detail in the inspection booklet, which provides consistency with information given and hopefully, consistency with the requirements of this rule.

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;

This rule requires licensed HME businesses to possess product and professional liability insurance at 1 million per occurrence/3 million aggregate. Additionally, this rule requires the licensee to have trained staff and maintain a facility to adequately store, maintain, lease or sell HME. This is a required rule under ORC 4752.11(A)(5). The cost of insurance and the costs to maintain a facility in accordance with this rule are variable based upon the size of the business, scope of services rendered, type of equipment sold or leased, and volume of sales.

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

Meeting these requirements will cost money and take time to validate.

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 cost of insurance and the costs to maintain a facility in accordance with this rule are variable based upon the size of the business and the product mix sold or leased by the organization. It is difficult to quantify the cost of insurance, since the private market drives products and coverage costs are competitive. Observed costs appear to run between \$2,000 and \$3,000 annually. The liability requirement is based on industry standards for HME providers.

Costs and time to maintain a facility to adequately store, maintain, lease or sell in manner that is safe to the public. Quantification of this requirement is difficult since it

is dependent on the scope of services rendered, type of equipment sold or leased, and volume of sales.

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

The rule establishes base requirements for the issuance of a license to provide HME services. Included in the rule are standards (eg. Minimum liability insurance coverage, maintenance of facility to adequately stores, maintains leases or sells HME in a safe manner and having trained staffing). These standards are designed to protect the public welfare by requiring HME companies to maintain equipment in accordance with manufacturer requirements, clean and disinfect equipment that is leased or sold, store the equipment in a manner that is safe, keep documentation of the sale or lease of equipment, and training staff. These standards benefit and protect the public. The rule amplifies existing law, which was designed for the same purpose. The costs and adverse impact of this rule is justified to assure the public that persons engaged in HME services are qualified and the equipment provided is properly maintained.

Regulatory Flexibility

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

The rule does not provide any alternative means for compliance for small 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?

The Ohio Respiratory Care Board does not impose paperwork violations as it relates to these rules.

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

Staff is immediately available to explain the application process and assist persons as required. The rules are posted on the Board's website and are available by request for any person or entity requesting them.