

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: Ohio Respiratory Care Board

Regulation/Package Title: 119.032 review for HME license application requirements

Rule Number(s): OAC 4761:1-5-02

Date: June 20, 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- Rescinded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 4761:1-5-02 establishes the application form requirements for persons (facilities) applying for a license to provide home medical equipment services in the state of Ohio. The current rule lists form requirements. The Board is proposing to amend this rule to list all of the form components need to conform to the current version of the application form.

*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) and 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.**

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. Under ORC 4752, specific standards of practice have been developed or have been recognized to assure the public safety and welfare of persons that require medically prescribed medical equipment.

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

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The Ohio Respiratory Care Board will gauge the success of this regulation by the monitoring the ease of use of the application process for persons seeking licensure in Ohio.

### **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 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. Most comments were not substantive and did not address any specific language.

**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?**

Scientific data was not applicable to the drafting of this rule.

**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 considered rescinding the specific language found in this rule and in lieu of this rule, require the completion of an application form incorporated by reference to the rule. The Ohio Respiratory Care Board saw no advantage or disadvantage in

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the alternative approach, so chose to retain the rule structure and amend it as need to conform to the current specification of the application form used.

**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.***

No, the Ohio Respiratory Care Board did not consider a performance-based regulation, since the regulation is specifically required under ORC 4752.17(A) (4).

**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 to 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.**

Each person seeking licensure in the state of Ohio is required to complete the same application. There is not another entity or process that conflicts. Consistency and predictability is assured.

**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 affects any entity seeking to rent or sell home medical equipment to Ohio citizens. The Ohio Revised Code defines home medical equipment under three classifications found in ORC 4752.01. OAC rule 4761:1-3-02 amplifies Section 4752.01 of the Revised Code by listing specific equipment classifications for each definition type. A business desiring to sell or rent any of these items would be required to obtain a license or certification of registration from the Ohio Respiratory Care Board.

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

This specific rule does not have direct adverse impact, as the rule's intent is to identify the items required on the application form for an HME license. The application; however, reflects the provisions of many other portions of the Ohio Revised Code and/or rules requiring specific compliance that would have direct

impact. For instance, one impact of this rule would certainly be time. To provide the information required a business would need to collect information specific to the requirements of the rule, which is, in many instances, are requirement of the Ohio Revised Code or other rules under ORC 4752.

Cost is also another adverse impact. For example, ORC 4752.07 requires an HME provider holding a license to comply with specific standards and requirements. Among these is liability insurance coverage. By rule, the Board established the minimum coverage needed to meet the requirements of the Ohio Revised Code. Persons associated with the HME industry are often used to these requirement and carry insurance needed to comply; however, if the liability minimum held does not meet Ohio standards or if the provider does not have the minimum coverage, it could cost the applicant a significant (variable) amount to retain coverage. Additionally, meeting the minimum standards of practice in all areas covered under OAC 4761:1-9, as required by 4752.05(A)(1) of the Revised Code may result in costs to the applicant. These costs will vary depending upon the readiness of the applicant to engage in home medical equipment services, but meeting each standard would have degree of time and money associated with compliance.

**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 staff of the Board estimates would take approximately an hour to complete if the applicant had all of the information requested. Other costs, such as, liability insurance coverage is variable depending upon the chosen insurance agent, but coverage meeting Ohio’s standards can range into a few thousand dollars per year based on insurance certificates received in the Board office. Persons employed by the home medical equipment provider must have a criminal background check for Ohio, which can cost approximately 25 -30 dollars per employee. Although not direct related to this rule, applicants must provide affirmative response that standards listed under OAC 4761:1-9 are being met. These standards are diverse and comprehensive. The costs to comply would be variable, but usual in the HME industry.

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

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The standards used by the Ohio Respiratory Care Board were adopted after researching and vetting the standards of practice employed by four major accreditation organizations. These organizations are recognized as industry leaders in the U.S., including the Joint Commission standards recognized by the state of Ohio under ORC 4752.12 (A) for the issuance of certificates of registration to home medical equipment providers (an alternative to licensure). The Ohio Respiratory Care Board sought to apply equally effective standards for persons holding home medical equipment licenses in order to assure the public that each business engaged in the sale or rental of home medical equipment meets industry and state minimal standards in the area of product knowledge, demonstration, installation, cleaning, maintenance and repair.

### **Regulatory Flexibility**

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

The Ohio Revised Code does not differentiate or provide regulatory latitude based on the size of a 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 this rule.

**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 this rule and the Ohio Revised Code and Ohio Administrative Code relating to the regulation of home medical equipment providers in the state of Ohio. The Board staff daily engages business owners to guide them through the licensure process.