

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Respiratory Care Board

Regulation/Package Title: 119.032 review for HME Certificate of Registration application requirements

Rule Number(s): OAC 4761:1-6-01, OAC 4761:1-6-02

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- Rescinded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.

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OAC 4761:1-6-01 4761:1-6-02 establish the qualifications for obtaining a certificate of registration and the application form requirements for persons (facilities) applying for a certificate of registration to provide home medical equipment services in the state of Ohio. The Board is proposing no changes to OAC rule 4761:1-6-01. The Board is proposing to amend rule 4761:1-6-02 to list the form components needed 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) (2) 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, a certificate of registration can be issued to home medical equipment facilities that are accredited by the Joint Commission or other organizations recognized by the Ohio Respiratory Care Board pursuant to rule OAC 4761:1-4-01. These private organizations are nationally recognized for their expertise in quality

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assurance monitoring for the home medical equipment industry. Each organization's standards have been stringently reviewed by the Ohio Respiratory Care Board to validate these standards. Home medical equipment facilities that are accredited by any of the organization recognized must continue to meet these standards to remain eligible for continued issuance of a certificate of registration.

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 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. The Ohio Respiratory Care Board received a recommendation on OAC rule 4761:1-6-01 asking that the Joint Commission be removed from the rule. This recommendation was not adopted, since the Ohio Revised Code specifically noted recognition of the Joint Commission. It was also suggested to amend OAC 4761:1-6-02 (G) by limiting the personnel roster to only those providing direct patient care to Ohio residents. In response, the Ohio Respiratory Care Board proposed to rescind paragraph (G) of this rule.

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 rule 4761:1-6-02 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 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 regulations are designed to inform persons of the qualifications for a certificate of registration and then collect information needed to evaluate a person's qualifications.

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 a certificate of registration in the state of Ohio are informed through the Ohio Respiratory Care Board's website of the organizations recognized by the state of Ohio for the purpose of qualifying for a certificate of registration. Each applicant 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;

These rules affect 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

These rules provide applicants with the qualifications for a certificate of registration and the application form requirements to obtain a certificate of registration. The requirement to be accredited by the Joint Commission or another recognized organization is established in law and not rule. The adverse impact is related to the costs of achieving accreditation through one of the eight organizations recognized pursuant to rule. A review of the websites of each organization reveals inconsistent information relative to costs. Most organizations do not reveal costs, but state the costs are based upon the scope of home medical equipment services rendered and annual revenues generated. Two of the eight organizations list costs, which vary between \$4,300 and \$7,566 every three years. The application requires specific information to allow the Ohio Respiratory Care Board to determine the applicant's qualifications for the certificate of registration. One impact of rule 4761:1-6-02 would certainly be time. To provide the information required a business would need to collect information required on the application.

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 one half hour to complete if the applicant had all of the information requested. The costs to comply with voluntary accreditation would be variable, but usual in the HME industry. Most

home medical equipment providers, for example, participate in Medicare. The Center for Medicare/Medicaid Services require home medical equipment companies to be accredited by one of ten deemed organizations. The Ohio Respiratory Care Board recognizes eight of the ten. This level of recognition results in a large number of applicants already possessing the accreditation needed to obtain a certificate of registration.

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

The qualifications for a certificate of registration are not established by rule, but through statute. The Ohio Respiratory Care Board's rules reflect the requirements established in law.

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 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. The Board staff daily engages business owners to guide them through the registration process.