

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Respiratory Care Board

Regulation/Package Title: 119.032 review for HME licensure standards requirements

Rule Number(s): OAC 4761:1-9-02, OAC 4761:1-9-03, and OAC 4761:1-9-04

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- Rescinded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 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;
- (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 4761:1-9-02, 4761:1-9-03, and 4761:1-9-04 establish the standards for maintaining a physical facility (OAC 4761:1-9-02), maintaining equipment (OAC 4761:1-9-03), and maintaining client records (OAC 4761:1-9-04).

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.

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ORC 4752.17(A)(4) through (7) and 4752.07

- 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. These rules provide applicants and licensees with the standards required to obtain and retain a license to provide home medical equipment services in the state of Ohio.

- 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. The Ohio Respiratory Care Board received a recommendation on OAC rule 4761:1-9-02 asking to combine paragraphs (E) and (F). This recommendation was adopted in the proposed amended rule 4761:1-9-02.

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 industry standards required of accredited home medical equipment entities. The standards adopted by the Ohio Respiratory Care Board were based on 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.

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. Based upon the requirement contained therein, no alternative was considered.

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 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;

This rule affects any entity holding a license to provide home medical equipment services in the state of Ohio. The rule does not apply to facilities holding a certificate of registration.

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

These rules provide standards for the operation of licensed home medical equipment facilities in the area of facility maintenance, equipment maintenance and record keeping. Each standard has a potential adverse impact on the licensee; however, each impact is justified by the health and safety benefit for persons that receive home medical equipment services. These standards are very similar to the standards imposed by accrediting organizations recognized by the Ohio Respiratory Care Board for the purpose of issuing certificates of registration. Both, licensing standards and certificate of registration accreditation, are designed to assure the customers and recipients of home medical equipment services that the home medical equipment facility (or business) meets quality standards. These standards do have cost implications. For example, if a facility's physical space is too small to safely store, maintain, and service equipment, the facility would need to increase space or reduce inventory. Both would have a cost impact.

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. In some cases, the impact is variable based upon the size of the business and the needs of the community. A growing company, for example, would need to find more space to safely store, maintain, clean, repair equipment, and maintain records. In some cases, the cost is directly affected by the products being sold. For example, manufacture's standards or federal/state law may establish minimum cleaning and disinfecting requirements for specific types of home medical equipment sold or rented. The

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Board does not establish the specific standards for compliance, but through the standards of operations, it establishes an outcome measure that dictates the facility must be in compliance with manufacture's standards or federal/state law. Meeting these requirements can result in costs associated with the products sold or rented.

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

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 Respiratory Care Board believes the standards of operation do take into consideration the size of the business, since the rules are out-come based.

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.