

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Respiratory Care Board

Regulation/Package Title: HME Inspection Requirements

Rule Number(s): 4761:1-14-02

Date: 02/23/2012

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- Rescinded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.

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

This rule instructs home medical equipment facilities that are regulated by the Board on the document and records access privileges of a representative of the Board during the course of an inspection. The rule addresses the use of certified copies provided to the representative of the Board and under what circumstances original records shall be provided.

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

The rule is authorized under ORC 4752.17 (A)(7). The rule amplifies ORC 4752.08.

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.

This rule does not implement a federal requirement, administer or enforce a federal law, or participate in a federal program.

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

This rule does not include provisions not specifically required by the federal government.

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)?

ORC 4752.08 permits the Board to inspect the operations of licensed HME facilities, subpoena records, and compel the testimony of witnesses. In addition, ORC 4752.08 permits an inspector to review and audit records. This rule establishes process that will be employed when an inspection or investigation of an HME facility is undertaken and what records must be made available to the inspector or investigation. If the inspector or investigator requires copies or original records, this rule establishes a procedure for securing the records and returning the records to the HME provider.

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

The rule is not a quantitative regulation, nor does it impose a measureable (if any) quantitative burden on the licensee. The success of the regulation will be measured by the licensees understanding or legal objections to processes of inspection or investigation.

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 Board reached out to the Ohio Association of Medical Equipment Services (OAMES). This rule was initially reviewed as a five year no change rule; however, the OAMES provided the Board with comments on the burden of licensees to hand over original documents to the Board. Revisions took into consideration the comments of the OAMES. The revised draft was sent again for comment and the organization issued a notice of support.

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

The OAMES stated that the inspection requirements of the rule contained in paragraphs (A) and (B) seemed appropriate. Paragraph (C); however, concerned the association. The Association argued that the original language allowed the Board to remove original records, which they stated could be problematic for providers if they were audited by Medicare, Medicaid or other agencies. Further, the OAMES argued that the removal of original records increased the chances of destruction or loss.

In response, the amended paragraph (C) of the rule to permit the licensee or registration holder to provide certified copies of records and only when a subpoena is issued would the Board request original records, which would be subject to chain of evidence and custody standards.

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?

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This rule does not incorporate a scientific data basis or develop a measurable outcome approach. The rule is procedural in nature.

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?

This rule was originally scheduled as a no-change rule. The rule had been in existence since 2004 without any issues or problems; however, given the comments provided by the OAMES, the Board felt some modification was necessary to assure the licensees that the Board would only require the production of original records, if needed during the course of an investigation. Otherwise, copies would be sufficient.

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 Board did not consider a performance-based regulation. Again, this regulation is a procedural rule and the regulatory burden for compliance is minimal, if not non-existent.

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

The Board's authority to regulate the practice of home medical equipment facilities is unique to the Ohio Respiratory Care Board. We are aware of no other regulations that regulate this group in the manner stipulated under ORC 4752.

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 regulation would generally have no impact for most home medical equipment providers. The rule, when adopted, will be emailed to the state association and posted on the Board's website. The Board will also instruct inspectors and investigative staff on the procedural updates to insure consistent application of its provisions.

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

This regulation should have no cost of compliance or adverse impact on the regulated community.

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

Again, this regulation should have no cost of compliance or adverse impact on the regulated community.

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 exemptions or alternative means of compliance for small businesses. All home medical equipment facilities offering qualifying home medical equipment under ORC 4752.01 must have a license or certificate of registration to provide services in Ohio. The law does not differentiate on the size of the business. In kind, this rule would apply to all licensed or registered providers.

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?

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This is a non-applicable section.

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

The rule establishes a procedure for compliance with a request for records. The Board believes the rule will have no financial impact or burden on small businesses and therefore, it would need no resources allocated for compliance.