

CSI - Ohio

The Common Sense Initiative

Business Impact Analysis

Agency Name: Ohio Respiratory Care Board

Regulation/Package Title: Licenses and certificate holders must comply with investigations conducted by the Board.

Rule Number(s): 4761:1-10-03

Date: 04/19/2012

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Rescinded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.

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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 is directive for home medical equipment (HME) facilities licensed or registered under ORC 4752. The rule informs licensed or registered HME providers that they must comply with investigations conducted by the Board. During the course of an investigation the rule requires licensees and/or registration holders to make records available and if needed, provide copies of records to board investigation staff.

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

The rule is authorized under ORC 4752.17 (A)(11). 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 investigate complaints involving HME facilities licensed or registered by the Board. In addition, ORC 4752.08 permits an investigator to review and

audit records. This rule establishes a directive for HME facilities, requiring copies of records, if needed.

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 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). comments of the OAMES were considered.

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

No recommendations were provided.

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?

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 draft is a modification of the original rule. The Board felt some modification was necessary to delineate differences in the investigative process between registered HME (registered under a cooperative agreement with a recognized organization) and licensed HME (non-accredited) facilities. The Board does not believe a regulatory alternative exists given the authority contained in the Ohio Revised Code.

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 could have a cost of compliance for the regulated community. The rule only addresses HME providers under investigation. This is a very small percent of the regulated community. If copies of records are requested, a cost is incurred. The total cost to copy records is variable and dependent upon the scope of the investigation.

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 to the regulated community at large. This would only impact investigated facilities, which represent an extremely small percentage of licensed and registered HME facilities.

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.

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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?

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 only impacts HME facilities under investigation. Based on this, the rule would have very little impact or burden on small businesses and therefore, there would be no need for allocating resources for compliance.