

# CSI - Ohio

The Common Sense Initiative

## Business Impact Analysis

Agency Name: Ohio Respiratory Care Board

Regulation/Package Title: 119.032 review for HME and RC Rules 8-2013

Rule Number(s): OAC 4761:1-3-02 (amended)

Date: March 3, 2014

**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Rescinded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 4761:1-3-02 is the rule that defines home medical equipment types under the definitions found in ORC 4752.01(B)(1) through (B)(3). The draft rule reorganizes some of the noted equipment types by moving them from the classification “other” to the classification of “technologically sophisticated medical equipment.” In addition, the

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proposed rule would exclude transcutaneous electronic nerve stimulation devices that are labeled as “over the counter” by the Federal Food and Drug Administration.

The proposed changes will redefine equipment listed in OAC 4761:1-3-02. Some of the changes will move equipment from the “Other” classification to the “Technologically sophisticated” classification. This change is primarily based upon the board’s research. Equipment listed as “Life-sustaining equipment” or “Technologically sophisticated” must be prescribed by an authorized health care professional. The Board notes that equipment moved to the “Technologically sophisticated” classification require a prescription.

*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.**

4752.17(A)(1) , 4752.17(B)

**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.

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

The federal government has no specific requirements 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)?**

This rule provides clarity on the types of equipment defined by the Board as Home Medical Equipment. Persons selling or renting these equipment types to Ohio citizens would be required to obtain a license or certificate of registration. ORC 4752.17(A)(1) specifically requires the adoption of this rule and ORC 4752.17(B) requires the adoption of this rule if equipment other than those defined under ORC 4752.02 (B)(1) and (2).

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

The Board believes these rules will provide better definition of equipment determined to meet the definition of home medical equipment under ORC 4752.02 (B). In addition, this rule re-defines transcutaneous electrical nerve stimulation devices as only those requiring prescription from an authorized professional and not over the counter (OTC) devices. The Board believes this change aligns the regulation with its intent, by removing an item labeled as OTC TENS devices by the Food and Drug Administration. This definition may affect some HME providers that only sell and rent TENS devices, labeled as OTC TENS. Redefining this item does not remove it from the regulation, but does more narrowly define the classification to include those devices deemed to require a physician's prescription.

**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 consulted the Ohio Association for Medical Services and the Ohio Chiropractic Association.

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

The Ohio Chiropractic Association has engaged the Board to consider removing TENS devices from OAC 4761:1-3-02. The association and some of its members argued that TENS devices were not complex devices and did not require regulatory oversight. Based on the Board's research of this item, the Board found that the item was properly identified as HME equipment and should remain in the regulatory realm. The Board also found that some TENS items were non-prescription and classified as OTC items by the FDA. The rule amendment reflects this determination. The rule change has been brought to the attention of the Ohio Chiropractic Association and the organization voice support for the change.

**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?**

The Board considered classification filings approved by the Federal Food and Drug Administration for determining OTC labeling for transcutaneous electrical nerve stimulation devices.

**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 Board considered other definitions of HME items, particularly TENs units, but settled on items that are prescription based.

**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.***

This rule is developed under ORC 4752.17(A)(1) and ORC 4752.17(B). In this sense, the rule is not considered to be a performance based rule, but a rule required of the Board under the Ohio Revised Code.

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

These rules are written specifically for entities regulated by the Ohio Respiratory Care Board. The Board is aware of no other Ohio regulation that duplicates these requirements.

**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 rules are posted on the Board's website and are available by request for any person or entity requesting them. In addition, the Board will send all amended rules, by email, to licensed providers upon adoption. The Board will also list rules in its newsletter and discuss rule impact.

**Adverse Impact to Business**

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**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 defines transcutaneous electrical nerve stimulation devices as only those requiring prescription from an authorized professional and not OTC labeled devices. This change may have an impact on persons currently renting or selling over the counter transcutaneous electrical nerve stimulation devices. If licensing was not required to sell these devices it would significantly reduce costs and regulatory oversight for persons choosing to rent or sell OTC labeled transcutaneous electrical nerve stimulation devices.

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

There would be no adverse impact associated with this rule.

**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.*

There would be no adverse impact associated with this rule.

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

The Board evaluated ORC 4752.02 (B) when initialing defining classifications of home medical equipment. ORC 4752.02 (B) defines home medical equipment and establishes the underlying intent of the legislation, which requires regulation of businesses that sell or rent life sustaining, technologically sophisticated medical equipment, other equipment defined by the Board in rule. The changes be proposed in this rule amendment are within the intent of the legislation. The Board believes the proposed change protects the health safety and welfare of Ohio citizens while reducing unnecessary regulation.

**Regulatory Flexibility**

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

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Yes, the proposed rule does not provide for alternative means of compliance. Any HME provider that chooses to sell or rent qualifying HME must be expected to meet the same standard of practice, regardless of the size of the 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 Board does not fine for paperwork violations in this instance, because the rule does not address paperwork issues or create paperwork issues.

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

The rules are posted on the Board's website and are available by request for any person or entity requesting them. The rules will be sent, by email, to all active licensees and the Board will list them in their newsletter.