Common Sense Initiative

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Business Impact Analysis

Agency, Board, or Commission Name: Ohio Board of Pharmacy

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Regulation/Package Title (a general description of the rules' substantive content):

FYR – Home Medical Equipment

Rule Number(s): 4729:11-1-01

Date of Submission for CSI Review: 1/12/2026

Public Comment Period End Date: 2/10/2026

Rule Type/Number of Rules:

New/___ rules **No Change/____ rules (FYR? ___)**

Amended/__1__ rules (FYR? _Y_) **Rescinded/____ rules (FYR? ___)**

The Common Sense Initiative is established in R.C. 107.61 to eliminate excessive and duplicative rules and regulations that stand in the way of job creation. Under the

Common Sense Initiative, agencies must balance the critical objectives of regulations that have an adverse impact on business with the costs of compliance by the regulated parties. Agencies should promote transparency, responsiveness, predictability, and flexibility while developing regulations that are fair and easy to follow. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Reason for Submission

1. **R.C. 106.03 and 106.031 require agencies, when reviewing a rule, to determine whether the rule has an adverse impact on businesses as defined by R.C. 107.52. If the agency determines that it does, it must complete a business impact analysis and submit the rule for CSI review.**

   Which adverse impact(s) to businesses has the agency determined the rule(s) create?

   The rule(s):

   a. ☒ **Requires a license, permit, or any other prior authorization to engage in or operate a line of business.**

   b. ☒ **Imposes a criminal penalty, a civil penalty, or another sanction, or creates a cause of action for failure to comply with its terms.**

   c. ☐ **Requires specific expenditures or the report of information as a condition of compliance.**

   d. ☐ **Is likely to directly reduce the revenue or increase the expenses of the lines of business to which it will apply or applies.**

Regulatory Intent

2. **Please briefly describe the draft regulation in plain language.**

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

4729:11-1-01: Definition section for home medical equipment division. Adds wearable cardioverter defibrillators to the definition of "technologically sophisticated medical equipment."

3. **Please list the Ohio statute(s) that authorize the agency, board or commission to adopt the rule(s) and the statute(s) that amplify that authority.**

The proposed rule is authorized by section 4752.17 of the Revised Code.

4. **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.

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

This rule package includes provisions not specifically required by the federal government because the regulation of home medical equipment providers in Ohio has been authorized by the Ohio General Assembly.

6. **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)?**

Section 4752.17 of the Ohio Revised Code authorizes the Board of Pharmacy to adopt rules governing home medical equipment services.

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

The success of the regulation will be measured by having it written in plain language, licensee compliance with the rule, and minimal questions from licensees regarding the provisions of the rule.

8. **Are any of the proposed rules contained in this rule package being submitted pursuant to R.C. 101.352, 101.353, 106.032, 121.93, or 121.931?**
If yes, please specify the rule number(s), the specific R.C. section requiring this submission, and a detailed explanation.

No.

Development of the Regulation

9. **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.

This rule was reviewed by the Home Medical Equipment Advisory Council, which is established under ORC 4752.24 for the purpose of advising the Board on issues relating to providing home medical equipment services. Prior to filing with CSI, the rules were also reviewed and approved by the Board of Pharmacy.

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

For the proposed rules, the Home Medical Equipment Advisory Council reviewed the proposed changes. The Council recommended and the Board approved the addition of wearable cardioverter defibrillators to the definition of "technologically sophisticated medical equipment."

11. 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 used to develop or review this rule.

12. 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? ***Alternative regulations may include performance-based regulations, which define the required outcome, but do not dictate the process the regulated stakeholders must use to comply.***

As the regulations are essential to protecting the public's safety by ensuring uniform standards for the provision of home medical equipment services, the Ohio Board of Pharmacy did not consider any regulatory alternatives.

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

The Board of Pharmacy's Director of Policy and Communications reviewed the proposed rule to ensure that it does not duplicate another Ohio Board of Pharmacy regulation.

14. 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 rule will be posted on the Board of Pharmacy's website; information concerning the rule will be included in materials e-mailed to licensees; and notices will be sent to associations, individuals, and groups. Board of Pharmacy staff are also available via phone or email to answer questions regarding implementation of the rule. In addition, the Board's compliance staff are trained to educate licensees on current and/or new regulations during on-site inspections.

Board of Pharmacy staff receive regular updates on rules via a monthly internal newsletter, biannual staff meetings featuring a regulatory update, mandatory all-day law reviews for new employees, email updates and quarterly webinars from the Director of Policy and Communications, and feedback from the Board's legal department for every citation submitted.

The Board will also update its external inspection guides to reflect the changes to the rule.

Adverse Impact to Business

15. Provide a summary of the estimated cost of compliance with the rule(s). Specifically, please do the following:

a. Identify the scope of the impacted business community, and

- Those providing or selling home medical equipment services, including wearable cardioverter defibrillators.

b. Quantify and identify the nature of all adverse impact (e.g., fees, fines, employer time for compliance, etc.).

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.

In general, violation of this rule may result in administrative licensure discipline for a home medical provider. Discipline might include reprimand, suspension of a license, monetary fine, and/or revocation of a license.

4729:11-1-01: The addition of wearable cardioverter defibrillators under the definition of home medical equipment will trigger a licensure or registration requirement for those who are engaged in the sale of these products in Ohio. The cost of an initial application for a HME Service Provider license is $150 and the cost of a HME Service Provider registration is $300.00.

16. **Are there any proposed changes to the rules that will <u>reduce</u> a regulatory burden imposed on the business community? Please identify. *(Reductions in regulatory burden may include streamlining reporting processes, simplifying rules to improve readability, eliminating requirements, reducing compliance time or fees, or other related factors).***

Not applicable.

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

The Board believes that the regulatory intent of the proposed rule is necessary to protect the health and safety of all Ohioans by providing uniform regulations for home medical equipment service providers.

Regulatory Flexibility

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

This rule does not provide any exemptions or alternative means of compliance for small businesses. The law does not differentiate on the size of the business and therefore the regulation is uniform across Ohio.

19. **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 Board of Pharmacy does not fine licensees or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the sale of home medical equipment is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

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

Board of Pharmacy staff are available by telephone and e-mail to answer questions. Board staff members also provide presentations to groups and associations who seek updates on current regulations. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

Additionally, to assist our licensees, including those representing small businesses, the Board developed inspection guides. These guides align with internal guidance used by Board inspectors and allow licensees to conduct self-inspections to maintain compliance. The guides also include links to the rules, important definitions, and reminders of when a licensee is required to submit notification or additional information to the Board. The guides may be accessed by visiting: www.pharmacy.ohio.gov/inspection. The Board also has a number of resources on its licensing and continuing education websites to educate our licensees.

Rule 4729:11-1-01 | Definitions - home medical equipment.

As used in this division:

(A) "24/7 coverage" means that facilities that provide HME services must have a telephone number that is operational twenty-four hours a day, seven days a week that clients can call to seek assistance. The telephone line may be an answering service that is monitored on a regular basis by the HME provider and should also alert clients to contact 911 in an emergency.

(B) "Abandoned application" means an application submitted for licensure or registration where an applicant fails to complete all application requirements within thirty days after being notified of the incomplete application by the board. An applicant forfeits all fees associated with an abandoned application. The board shall not be required to act on any abandoned application and the application may be destroyed by board staff. If an application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the licensure or registration requirements in effect at the time of reapplication.

An application shall not be deemed abandoned if the application is subject to any of the following:

(1) An administrative proceeding; or

(2) If there is discipline pending against the applicant.

(C) "Accrediting body" means an agency recognized by the board under rule 4729:11-2-04 of the Administrative Code.

(D) "Addicted to or abusing alcohol or drugs" means the chronic and habitual use of alcohol or the use of a drug of abuse as defined in section 3719.011 of the Revised Code by an individual to the extent that the individual no longer can control the individual's use of alcohol or drugs, the individual is physically or psychologically dependent on alcohol or drugs, or the individual's use or abuse of alcohol or drugs endangers the health, safety, or welfare of the individual or others.

(E) "Board" means the state board of pharmacy.

(F) "Business day" means any day other than Saturday, Sunday or a holiday recognized by the state of Ohio on which the offices of the board of pharmacy are not open for business.

(G) "Certificate of registration" or "registration" means a person holding a valid certificate of registration issued under Chapter 4752. of the Revised Code.

(H) "Client" or "patient" means a person who receives HME services from a HME services provider.

(I) "CMS" means the centers for medicare and medicaid services.

(J) "Contact hour" means a period of sixty minutes with a minimum of fifty minutes of instruction. For credit hours earned on an academic quarter system, one credit hour is equivalent to ten contact hours. For credit hours earned on an academic trimester system, one credit hour is equivalent to twelve contact hours. For credit hours earned on an academic semester system, one credit hour is equivalent to fifteen contact hours.

(K) "Disciplinary action" means any of the following by a federal agency or licensing agency of any state or jurisdiction, regardless of whether the action occurred by formal proceeding, consent, settlement, or other agreement:

(1) An action to revoke, suspend, restrict, limit, or refuse to grant or renew a license, registration or certification;

(2) A summary or emergency suspension of a license, registration or certification, of any length, and any subsequent revision to the action;

(3) An administrative fine or monetary penalty, taken as a result of a formal proceeding, to include any fine or money penalty connected to the delivery of health care services or taken in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, censure, reprimand, or probation;

(4) An action to reprimand or place the license, registration, or certification holder on probation;

(5) The issuance of a corrective action plan only if such issuance is in conjunction with other adverse licensure, registration or certification actions, such as revocation, suspension, reprimand, probation, or surrender;

(6) The withdrawal of a renewal application for licensure, registration or certification while under investigation;

(7) The non-renewal of a license, registration or certification while under investigation or to avoid an investigation;

(8) The surrender of a license or other relinquishment, registration or certification in lieu of a formal sanction against a person's license, registration or certificate, whether permanent or temporary;

(9) In lieu of an adverse licensure, registration or certification action, a licensing agency issues a consent order in which a person agrees not to re-apply for a license in the future.

(10) An enforceable agreement not to practice or to be placed into inactive or other equivalent status while under investigation or in exchange for not conducting an investigation.

(L) "Disqualifying offense" has the same meaning as defined in rule 4729-3-01 of the Administrative Code.

(M) "Expired certificate of registration" means the holder of a certificate of registration under Chapter 4752. of the Revised Code has failed to fulfill all requirements of certificate renewal and has failed to request that the board place the certificate into inactive status.

(N) "Expired license" means the holder of a license under Chapter 4752. of the Revised Code has failed to fulfill all requirements of licensure renewal and has failed to request that the board place the license into inactive status.

(O) "Home medical equipment" or "HME" has the same meaning as defined in section 4752.01 of the Revised Code. Pursuant to division (B)(3) of that section, HME shall also include the following equipment:

(1) Hospital grade pulse oximeters pursuant to a prescription issued by a prescriber;

(2) Home photo therapy (bili lights or blankets);

(3) Individually sized or customized accessories that are an integral part of equipment defined in this paragraph and paragraphs (U) and (EE) of this rule;

(4) Transcutaneous electronic nerve stimulators (TENS), excluding devices labeled by the federal food and drug administration for over-the-counter use and are identified with the federal food and drug administration product code "NUH.OTC TENS";

(5) Drop foot stimulators;

(6) Bone growth stimulators;

(7) Vision restoration therapy devices;

(8) In-home patient lifts;

(9) Life-sustaining equipment as defined in paragraph (U) of this rule; and

(10) Technologically sophisticated medical equipment as defined in paragraph (EE) of this rule.

(P) "Home medical equipment services" or "HME services" has the same meaning as defined in section 4752.01 of the Revised Code.

(Q) "Home medical equipment services provider" or "HME services provider" has the same meaning as defined in section 4752.01 of the Revised Code.

(R) "Inactive status" means the status of a license or registration issued under Chapter 4752. of the Revised Code of a facility that has made a request, in a manner determined by the board, that the board place the license or registration into inactive status. A facility with an inactive license does not hold a current, valid license or certificate of registration under Chapter 4752. of the Revised Code.

(S) "In-service education" means that a continuing education program is offered by a HME service provider organization and not an approved peer review organization.

(T) "Joint commission on accreditation of healthcare organizations," as used in section 4752.12 of the Revised Code, means "the joint commission" or its predecessor organization.

(U) "Life sustaining equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

(1) Ventilators;

(2) Oxygen concentrators;

(3) Oxygen liquid systems;

(4) Oxygen compressed gas systems;

(5) Non-invasive ventilator system (e.g. bi-level, iron lungs, rocking beds, diaphragmatic pacers, etc.);

(6) Any other life sustaining equipment as determined by the board.

(V) "Person" includes any individual, partnership, association, limited liability company, or corporation, the state, any political subdivision of the state, and any district, department, or agency of the state or its political subdivisions. It also includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

(W) "Place on probation" means to take action against a license or registration for a period of time determined by the board which imposes conditions or other requirements, or suspends or otherwise restricts some or all of the activities in which the licensee or registrant may engage.

(X) "Readily retrievable" means that records maintained in accordance with this chapter shall be kept in such a manner that, upon request, they can be produced for review no later than three business days to an agent, officer or inspector of the board.

(Y) "Refuse to grant or renew" means to deny original or continued licensure or registration for a period of at least twenty-four months. After twenty-four months, or such period of time as the individual board order may require, a person licensed or registered by the board or a person seeking to attain such status by licensure or registration, and whose license or registration the state board of pharmacy has refused to grant or renew, may make application to the board for issuance of a new license. A person that seeks to attain such status by licensure or registration, whose license the state board of pharmacy has refused to grant or renew must meet all requirements established by the board in rule and as may be set forth in the person's board order.

(Z) "Registered" and "licensed" mean that a person has met the initial qualifications for a certificate of registration (registered) or license (licensed) with the state board of pharmacy under Chapter 4752. of the Revised Code and rules adopted thereunder and have complied with renewal procedures, including payment of applicable fees.

(AA) "Revoke" means to take action against a license or registration rendering such license or registration void and such license or registration shall not be reissued. Revoke is an action that is permanent against the licensee or registrant.

(BB) "Staff" means employees or their representatives of a licensee or registrant.

(CC) "Suspend" means to take action against a license or certificate of registration rendering such license or registration without force and effect for a period of time as determined by the state board of pharmacy.

(DD) "Summary suspension" means to take immediate action against a license or registration without a prior hearing rendering such license or registration without force and effect for a period of time as indicated in section 4752.09 of the Revised Code. The board may suspend a license or registration issued pursuant to Chapter 4752. of the Revised Code by utilizing a telephone conference call to review the allegations and take a vote.

(EE) "Technologically sophisticated medical equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following:

(1) Oxygen conservation devices;

(2) CPAP (continuous positive airway pressure) devices;

(3) High frequency chest wall oscillators (vests);

(4) Intrapulmonary percussive ventilation (IPV) devices;

(5) Intermittent positive pressure breathing (IPPB) devices;

(6) Cough-assist mechanical in-exsuffaltor;

(7) Apnea monitors;

(8) Percussors for chest physiotherapy;

(9) Suction machines;

(10) Feeding pumps;

(11) Infusion pumps;

(12) Continuous passive motion (CPM) devices;

(13) Custom seating or positioning systems;

(14) Custom rehab equipment (e.g. standers and gait trainers);

(15) Vacuum assisted wound closure devices;

(16) Electric wheelchairs and custom scooters;

(17) Auto-titrating airway devices; ~~**and**~~

(18) Wearable cardioverter defibrillators; and

(~~**18**~~ **19**) Any other technologically sophisticated medical equipment as determined by the board.