



Common Sense Initiative

Mike DeWine, Governor
Jon Husted, Lt. Governor

Joseph Baker, Director

Comments on the proposed rules will be accepted until close of business on January 3, 2025. Please send all comments to the following email address:

RuleComments@pharmacy.ohio.gov

In addition, please copy your comments to: CSIPublicComments@governor.ohio.gov

Business Impact Analysis

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

Rule Contact Name and Contact Information: Summer Reyburn
Summer.Reyburn@pharmacy.ohio.gov

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

Home Medical Equipment Services Providers

Rule Number(s): 4729:11-1-01, 4729:11-2-01, 4729:11-2-02, 4729:11-2-03, 4729:11-2-04, 4729:11-2-05, 4729:11-3-01, 4729:11-3-02, 4729:11-3-03, 4729:11-3-04, 4729:11-3-05, 4729:11-3-06, 4729:11-4-01

Date of Submission for CSI Review: 12/11/2024

Public Comment Period End Date: 1/3/2025

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

Rule Type/Number of Rules:

New/ 1 rules

No Change/ 2 rules (FYR? Y)

Amended/ 10 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Rescinded/ rules (FYR?)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.

New

- **4729:11-3-06 | Minimum standards for registered home medical equipment services providers:** Establishes the minimum standards for registration as a HME services provider.

Amended

- **4729:11-1-01 | Definitions – home medical equipment:** Definition section for home medical equipment division. Removes definition for acts of moral turpitude and adds a definition for a client or patient.
- **4729:11-2-01 | Licensure, registration and renewal:** Establishes the requirements for licensing, registering and renewing a home medical equipment license. Removes a reference to an old date.
- **4729:11-2-02 | Designated representative:** Establishes the requirements for the designated representative on a home medical services license or certification of registration. Adds language regarding disqualifying offenses.
- **4729:11-2-03 | Applications:** Provides the requirements for application as a home medical services provider. Made updates to mirror application rules for other Board licensees and other facility application rules.
- **4729:11-2-05 | Change in description of a HME services provider or discontinuation of business:** Defines the requirements for reporting a change in business or discontinuation of business to the Board and outlines when a new license number and application fee is required. Made updates to mirror other Board facility licensure rules, specifically with the change in ownership definition and change of address information.
- **4729:11-3-01 | Minimum standards for licensed home medical equipment services providers:** Establishes the minimum standards for home medical equipment providers. Added a section regarding access to records. Added a section for recordkeeping.
- **4729:11-3-02 | Recordkeeping:** Provides the requirements for recordkeeping for home medical equipment providers. Made small change to clarify the rule applies to licensed or registered HME service providers.

- **4729:11-3-03 | Inspections and corrective actions:** Establishes the Board of Pharmacy’s authority to inspect a home medical equipment provider. Changed instances of “agent” to “employee” to mirror language in other Board of Pharmacy facility rules.
- **4729:11-3-05 | Advertising and solicitation:** Defines the requirements for advertising and solicitation standards. Made small change to clarify the rule applies to licensed or registered HME service providers and fixed a spelling error.
- **4729:11-4-01 | Disciplinary Actions:** Establishes the Board of Pharmacy’s authority to impose disciplinary actions on a home medical equipment provider. Adds language regarding disqualifying offenses and removes mentions of moral turpitude since it is now prohibited as a licensing standard according to Ohio law.

No Change

- **4729:11-2-04 | Recognized accrediting bodies:** Establishes the approved accrediting organizations for registered home medical equipment providers.
- **4729:11-3-04 | Continuing education:** Establishes the continuing education requirements for home medical equipment providers.

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 rules are authorized by section 4752.17 of the Ohio 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)?

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117

CSIPublicComments@governor.ohio.gov

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 rules written in plain language, licensee compliance with the rules, and minimal questions from licensees regarding the provisions of the rules.

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.

N/A.

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 package 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. Changes included adding requirements for registered home medical equipment service providers, enforcement of national standards established by the Centers for Medicare & Medicaid Services, and ensuring that authorized contractors of the HME service provider have access to facilities.

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 package.

- 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 rules to ensure that they do 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 rules will be posted on the Board of Pharmacy's website, information concerning the rules 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 rules. 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 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 rules.

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.

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 these rules 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.

- 4729:11-2-03 – Provides the requirements for application as a home medical services provider. The application fee for registration is \$150 and the licensure fee is \$300. Filling out the licensure form would take approximately 15 minutes to complete.
- 4729:11-2-05 – Defines the requirements for reporting a change in business or discontinuation of business to the Board and outlines when a new license number and application fee is required. Filling out a change of address notification form would take approximately 15 minutes to complete.
- 4729:11-3-01 – Establishes the minimum standards for home medical equipment providers. Requires patient records and HME equipment to be locked up when no employees are on-site to provide supervision. Licensees may have to purchase a barrier with locks or an alarm system to maintain compliance.
- 4729:11-3-06 – Requires employees to submit to a criminal record check with BCI before employment. The cost of a background check per person is \$22 and some agencies may charge a processing fee (e.g. \$5-\$40).

16. Are there any proposed changes to the rules that will reduce 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).

- 4729:11-2-05 – Defines the requirements for reporting a change in business or discontinuation of business to the Board and outlines when a new license number and application fee is required. Adds section clarifying that a change of address will not require an application and fee if the address change resulted from a change within a local government entity or USPS that does not include any physical relocation of HME operations.

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 rules 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.

These rules do 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 is 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 and host regional meetings to discuss changes to Ohio laws and

rules. Additionally, staff are trained to educate licensees on compliance with all Board of Pharmacy rules and regulations.

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

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) "Act of moral turpitude" means an act or behavior that gravely violates moral sentiment or accepted moral standards of the community and is a morally culpable quality held to be present in some criminal offenses as distinguished from others.~~

(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 an 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) "Expired certificate of registration" means the holder of a certificate of a 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.
- (M) "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 who has failed to request that the board place the certificate on inactive status.
- (N) "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 (T) and (DD) 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 (T) of this rule; and
 - (10) Technologically sophisticated medical equipment as defined in paragraph (DD) of this rule.
- (O) "Home medical equipment services" or "HME services" has the same meaning as defined in section [4752.01](#) of the Revised Code.
- (P) "Home medical equipment services provider" or "HME services provider" has the same meaning as defined in section [4752.01](#) of the Revised Code.
- (Q) "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.
- (R) "In-service education" means that a continuing education program is offered by a HME service provider organization and not an approved peer review organization.

(S) "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.

(T) "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.

(U) "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.

(V) "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.

(W) "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.

(X) "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.

(Y) "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.

(Z) "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.

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

(BB) "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.

(CC) "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.

(DD) "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-exsufflator;
- (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 & gait trainers);
- (15) Vacuum assisted wound closure devices;
- (16) Electric wheelchairs and custom scooters;
- (17) Auto-titrating airway devices; and
- (18) Any other technologically sophisticated medical equipment as determined by the board.

Rule 4729:11-2-01 | Licensure, registration and renewal. (AMEND)

(A) An applicant applying for licensure as a HME services provider shall:

- (1) File an application with the board pursuant to rule [4729:11-2-03](#) of the Administrative Code; and
- (2) Submit the required fee as established in paragraph (F) of this rule.
- (3) To be licensed as a HME services provider, the applicant shall comply with the following:
 - (a) The applicant shall be physically located in Ohio. A HME services provider located outside the boundaries of the state of Ohio may only apply for a certificate of registration pursuant to paragraph (B) of this rule.
 - (b) Meet the minimum standards set forth in rule [4729:11-3-01](#) of the Administrative Code.
 - (c) Comply with all recordkeeping requirements in accordance with rule [4729:11-3-02](#) of the Administrative Code.
 - (d) Submit to an on-site inspection pursuant to rule [4729:11-3-03](#) of the Administrative Code.

(B) An applicant applying for a certificate of registration as a HME services provider shall:

- (1) File an application with the board pursuant to rule [4729:11-2-03](#) of the Administrative Code.
- (2) Submit the required fee as established in paragraph (F) of this rule.
- (3) The applicant shall be accredited by the joint commission on accreditation of healthcare organizations or another national accrediting body recognized by the board in accordance with rule [4729:11-2-04](#) of the Administrative Code. Part of the registration process shall be an inquiry to the accrediting agency with which the entity is accredited. This information will be used as a part of the consideration in granting a registration.

(C) The persons listed in paragraphs (A) and (B) of this rule shall be a natural person that owns and/or operates the business entity applying for licensure or registration. In the event the applicant is not owned by a natural person, each business entity with an ownership interest

in the applicant must be disclosed on the application up to and through the entity that is owned by a natural person.

(D) A license or registration expires at the end of the period for which it is issued and may be renewed. For purposes of issuing and renewing licenses, the board shall use a biennial licensing period that begins on the first day of July of each even-numbered year and ends on the thirtieth day of June of the next succeeding even-numbered year.

(E) A person who seeks to renew a license or registration shall submit an application for renewal, containing information as required by the board, and pay the required fee in accordance with paragraph (F) of this rule on or before the thirtieth day of June each even-numbered year.

(F) The board establishes the following non-refundable fees:

(1) All applications for initial and biennial renewal of a license shall include a fee no greater than one thousand two hundred dollars;

(2) All applications for initial and biennial renewal of a certificate of registration shall include a fee no greater than five hundred dollars.

(3) If an application for renewal of a license or certificate of registration is filed with the board after the renewal date, the applicant will be charged an additional late fee of two hundred dollars.

(4) If a complete application for renewal has not been submitted by the sixty-first day after the renewal date specified in this rule, the license or certificate of registration is considered void and cannot be renewed, but the holder may reinstate the licensure or registration in accordance with procedures specified by the board.

(G) A person that fails to renew a license or certificate or registration in accordance with this rule is prohibited from engaging in the provision of HME services.

(H) **On or before June 30, 2022, a** HME services provider located outside the boundaries of the state of Ohio currently licensed under Chapter 4752. of the Revised Code shall obtain a registration as a HME services provider.

Rule 4729:11-2-02 | Designated representative. (AMEND)

(A) A location licensed or registered as a HME provider shall have a designated representative at all times.

(B) When there is a change of designated representative, the state board of pharmacy shall be notified by the new designated representative within ten days of the effective date of the appointment of the new designated representative in a manner determined by the board.

(C) The designated representative shall be responsible for compliance with all applicable state and federal laws, regulations, and rules governing the provision of HME services.

(D) The designated representative shall be physically present at the licensed or registered location for a sufficient amount of time to provide supervision of the activities conducted by a HME services provider.

(E) Unless otherwise approved by the board, a HME services provider shall not have a designated representative who:

(1) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(2) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(3) Has committed an act that constitutes a **misdemeanor theft disqualifying** offense, regardless of the jurisdiction in which the act was committed.

~~(4) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~

~~(4)~~ Is addicted to or abusing alcohol or drugs.

~~(6) Has committed an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed.~~

(5) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

(6) Has been excluded from participation in medicare or a state health care program.

(7) Has been the subject of any of the following by an accrediting agency or a licensing or certification agency of any state or jurisdiction:

(a) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license, registration, certification, or accreditation; or

(b) A disciplinary action that was based, in whole or in part, on the person's provision of home medical equipment services.

~~(7) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee's professional practice.~~

~~(11) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.~~

Rule 4729:11-2-03 | Applications. (AMEND)

(A) The following information shall be required on a form supplied by the state board of pharmacy from each person making an application for a HME services provider license or certificate of registration:

(1) The name, full physical business address (not a post office box), and telephone number of the applicant.

(2) All trade, fictitious, or business names used by the applicant (e.g. "doing business as" or "formerly known as").

(3) Addresses, telephone numbers, and the full names of contact persons for all facilities used by the applicant for the storage, handling, and distribution of HME.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, **limited liability company**, corporation, ~~or~~ government agency, **or nonprofit organization**).

(5) The following information for the owner(s) and/or operator(s) of the applicant:

(a) For a partnership:

(i) The full name, business address, social security number, and date of birth of each partner. If the partner is not a natural person, each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(ii) The name of the partnership.

(iii) The partnership's federal employer identification number.

(b) For a sole proprietorship: the full name, business address, social security number, and date of birth of the sole proprietor.

(c) For a limited liability company: the full name, business address, social security number, and date of birth of each member. If the member(s) is not a natural person, each business entity that is a member having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person.

(d) For a corporation:

(i) The full name, business address, social security number, and date of birth of the corporation's president, vice-president, secretary, treasurer, and chief executive officer, or any equivalent position. For a publicly traded corporation that obtains a criminal records check waiver pursuant to paragraph (A)(3) of rule 4729:6-2-03 of the Administrative Code, the full name, business address, social security number, and date of birth of the corporate officers subject to a criminal records check as determined by the board's executive director or director's designee.

(ii) The name or names of the corporation.

(iii) The state of incorporation.

(iv) The corporation's federal employer identification number.

(v) The name of the parent company, if applicable.

(vi) If the corporation is not publicly traded on a major stock exchange, the full name, business address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation.

(e) For a government agency: the full name, business address, social security number, and date of birth of the agency director.

(f) For a nonprofit organization: the full name, business address, social security number, and date of birth of the executive director or any equivalent position.

(5) The following information for the owner(s) and/or operator(s) of the applicant:

(a) For a partnership:

(i) The full name, business address, social security number, and date of birth of each partner; if the partner is not a natural person each business entity that is a partner having an ownership interest must be disclosed on the application up to and through the entity that is owned by a natural person;

(ii) The name of the partnership; and

~~(iii) The partnership's federal employer identification number.~~

~~(b) For a corporation:~~

~~(i) The full name, business address, social security number and date of birth of the corporation's president, vice president, secretary, treasurer and chief executive officer, or any equivalent position;~~

~~(ii) The name or names of the corporation;~~

~~(iii) The state of incorporation;~~

~~(iv) The corporation's federal employer identification number;~~

~~(v) The name of the parent company, if applicable;~~

~~(vi) If the corporation is not publicly traded on a major stock exchange, the full name, business address, and social security number of each shareholder owning ten percent or more of the voting stock of the corporation.~~

~~(c) For a sole proprietorship:~~

~~(i) The full name, business address, social security number, and date of birth of the sole proprietor; and~~

~~(ii) If applicable, the federal employer identification number of the business entity.~~

(6) If the person making application for a certificate of registration, information necessary to verify accreditation authorized pursuant to rule [4729:11-2-04](#) of the Administrative Code.

(7) If applicable, the Ohio medicaid number, federal medicare number, and federal tax identification number for the applicant.

(8) A copy of the applicant's certificate of product and professional liability insurance from an insurer showing a minimum one million dollars per occurrence, three million dollars aggregate of coverage.

(9) A list of the HME to be stored, repaired, leased or sold by the applicant.

(10) A brief description of the HME services provided, including square footage of the facility.

(11) A list of the personnel currently employed by the applicant who are engaged in the delivery of HME services, including job titles.

(12) List of other licenses, registrations, or certifications held by the applicant.

(13) Any additional information required on the application as determined by the board.

(14) Any follow-up information as deemed necessary upon the receipt of the application materials.

Rule 4729:11-2-04 | Recognized accrediting bodies. (NO CHANGE)

(A) The board recognizes the joint commission as a national body that accredits HME services providers.

(B) The board, at its discretion, may recognize other national accrediting bodies if an agency submits a written request to the board for recognition. The board shall consider the following criteria in determining whether to recognize an agency:

- (1) The agency is recognized by CMS or other nationally recognized independent quality review organization;
- (2) The agency operates under the control of a multi-disciplinary governing body or board;
- (3) The agency operates within the continental United States;
- (4) The agency currently accredits and maintains accreditation of at least fifty HME, respiratory, or rehab organizations;
- (5) The agency has a measurable process with outcome standards for determining whether to accredit a HME services provider;
- (6) The agency performs on site evaluations of organizations using quantitative performance criteria;
- (7) The agency awards accreditation for a finite period of time;
- (8) The agency develops and publishes surveyor/site visitor qualifications and competencies;
- (9) The agency provides written reports of survey visits, observations, violations, citations, and requirements for improvement; and
- (10) The agency signs a cooperative agreement with the board, for mutual reporting of legal or accrediting violations.

(C) National accrediting bodies recognized by the board shall be posted to the board's website (www.pharmacy.ohio.gov).

(D) National accrediting bodies recognized by the former respiratory care board prior to January 21, 2018 shall be deemed recognized by the state board of pharmacy.

(E) If the board determines that the agency applying to be recognized does not meet the requirements of paragraph (B) of this rule, the board may deny recognition of the agency. An agency denied by the board may not resubmit a request for recognition for twenty-four months from the date of denial.

Rule 4729:11-2-05 | Change in description of a HME services provider or discontinuation of business. (AMEND)

(A) Any change in the ownership, business or trade name, category, or address of a HME services provider requires a new application, and required fee, ~~and license or certificate of registration~~. The ~~new~~ application and required fee shall be submitted within thirty days of any change in the ownership, business or trade name, category, or address.

~~(B) A change of ownership includes any of the following:~~

~~(1) A change of controlling interest of ten percent or more of a licensed or registered corporation's outstanding shares of voting stock.~~

~~(2) Any business entity change from its original form, as licensed or registered, to a sole proprietor ownership, partnership, limited liability company, corporation or any other business entity.~~

~~(3) An existing corporation ceases and a new corporation or other business entity is formed.~~

~~(4) An existing corporation continues and there is a one hundred percent stock purchase by another corporation or other business entity.~~

~~(5) Two wholly owned subsidiaries of a parent company are merged.~~

~~(6) A currently licensed or registered HME services provider is purchased or operated by a different business entity than what is listed on the original application, even if the location maintains the original "doing business as" (DBA) and/or designated representative.~~

~~(7) Any partnership change other than that which was originally licensed.~~

~~(a) A partnership change is deemed to have occurred when:~~

~~(i) There is an addition or removal of one or more partners in a partnership to which a license is issued.~~

~~(ii) The entity is sold and the sale becomes final.~~

~~(b) For partnerships, a transfer of a proportion of ownership among existing partners is not a change of ownership, if there is no addition or removal of a partner.~~

~~(8) Any other business model change as determined by the board to be a change of ownership.~~

~~(C) For publicly traded corporations, a routine sale of stock is not a change of ownership.~~

~~A publicly traded corporation is a corporation owned by stockholders who are members of the general public and who trade shares publicly, often through a listing on a stock exchange.~~

(B) A change of ownership includes any of the following:

(1) For all HME services providers:

(a) Any business entity change from its original form, as licensed, to a sole proprietorship, partnership, limited liability company, corporation, or any other business entity.

(b) Two wholly owned subsidiaries of a parent company are merged.

(c) A HME services provider is purchased or operated by a different business entity than what is listed on the original application, even if the location maintains the original "doing business as" (DBA) and/or responsible person.

(2) For corporations:

(a) Except as provided in paragraph (B)(2)(d) of this rule, a change of controlling interest of ten per cent or more of a licensed corporation's outstanding shares of voting stock.

(b) An existing corporation ceases, and a new corporation or other business entity is formed.

(c) An existing corporation continues and there is a one hundred per cent stock purchase by another corporation or other business entity.

(d) For publicly traded corporations, a routine sale of stock is not a change of ownership.

A publicly traded corporation is a company that has listed itself on at least one public stock exchange or has issued securities and is subject to public reporting requirements.

(3) For partnerships, any partnership change, other than that which was originally licensed.

(a) A partnership change is deemed to have occurred when:

(i) There is an addition of one or more partners in a partnership to which a license is issued.

(ii) The entity is sold, and the sale becomes final.

(b) Transfer of a portion of ownership among existing partners is not a change of ownership, if there is no addition of a partner.

(4) For a limited liability company, any membership change of a limited liability company, other than that which was originally licensed.

(a) A membership change is deemed to have occurred when:

(i) There is an addition of one or more members in a company to which a license is issued.

(ii) The entity is sold, and the sale becomes final.

(b) For limited liability companies, a transfer of a portion of ownership among existing members is not a change of ownership, if there is no addition of a member.

(5) Any other business model change, as determined by the board to be a change of ownership.

(C) If any change of ownership in accordance with paragraph (B) of this rule results in a new or different DBA, or a new or different employer identification number (EIN), ~~an~~ a new application fee is required.

(D) A change of ownership set forth in this rule or as otherwise determined by the board's executive director or the director's designee, may require the board to issue a new license or registration number.

(E) A change of ownership, as described in paragraph (B) of this rule, of a licensee's parent or holding company shall not require a new application, required fee, or license/registration.

(F) A change of address includes the physical relocation of a HME services provider's operations and location of home medical equipment. This shall include a change of suites within an existing building or campus.

(G) A change of address that results from a change within a local government entity or United States postal service (U.S.P.S.) that does not include any physical relocation of a HME service provider's operations shall not require an application and fee. The HME services provider shall submit written notification to the board, in a manner determined by the board, indicating the change of address.

(H) A HME services provider who plans to discontinue business activities shall file a notice with the **state** board **of pharmacy**. The notice shall be submitted, in a manner determined by the board, **at least within** thirty days in advance of the proposed date of discontinuing business, ~~unless waived by the board's executive director or the director's designee due to extraordinary circumstances beyond the provider's control~~. This notice shall include the following information:

- (1) The name, address, and license or registration number of the HME services provider discontinuing business.
- (2) The name and address of the location where the records will be maintained in accordance with rule [4729:11-3-02](#) of the Administrative Code.
- (3) The proposed date of discontinuing business.

Rule 4729:11-3-01 | Minimum standards for licensed home medical equipment services providers licensees. (AMEND)

(A) This rule sets forth the minimum acceptable standards for licensure as a HME services provider under Chapter 4752. of the Revised Code.

(B) A licensee shall maintain knowledge of the duties and responsibilities of a HME services provider and shall practice in accordance with the following:

- (1) Chapter 4752. of the Revised Code;
- (2) Division 4729:11 of the Administrative Code;
- (3) Any other applicable federal and state laws, rules and regulations; and
- (4) Position statements, standards of care or guidelines for providing HME services from nationally recognized organizations, ~~including medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier standards, joint commission, or other accrediting bodies recognized by the board pursuant to rule 4729:11-2-04 of the Administrative Code.~~

(C) A licensee and the licensee's staff shall demonstrate competence and accountability in all areas of HME services in which they are engaged, including, but not limited to, the following:

- (1) HME storage, leasing, sales, delivery, billing services, maintenance, cleaning, infection control, and repair;
- (2) Appropriate recognition, referral, or consultation and intervention when a complication arises in conjunction with the function of HME or when a change in patient or client compliance occurs; and
- (3) Referral to another HME services provider if the client's needs are beyond the scope of the license holder.

(D) A licensee is responsible for maintaining a facility that meets all the following requirements:

- (1) The facility must have appropriate physical space to safely store, maintain and service on site equipment;
- (2) The facility must have separation of business office, patient records, equipment cleaning, maintenance, and storage functions, as applicable;
- (3) The facility must be able to demonstrate appropriate equipment flows through various stages to ensure that the equipment is properly disinfected, repaired, stored, and maintained;
- (4) The facility must maintain inventory on site or by arrangement with a supplier to meet the needs of the licensee's current client base; **and**
- (5) The facility must meet all federal, state and local laws, rules, and regulations, including those pertaining to the storage, maintenance, **rental**, and sale of upholstery or bedding, if applicable.

(E) Only employees and authorized contractors of a HME services provider shall be permitted to have unsupervised access to client records and HME maintained by the provider. When no HME employees are on-site to provide supervision, all patient records and HME equipment shall be secured by either:

(i) A physical barrier with suitable locks to prevent unauthorized access; or

(ii) An alarm system that is monitored by a central station for control and can detect unauthorized access. The alarm system shall be tested on a biannual basis. The HME services provider or the entity that manages security for the provider shall maintain testing records for three years from the date of testing and shall make such records readily retrievable.

(F) In maintaining equipment, a licensee shall:

- (1) Maintain and document equipment in accordance with the manufacturer's guidelines;
- (2) Clean, disinfect, repair, store, segregate and identify all equipment in a manner that ensures the equipment is safe for use by the public;

(3) Ensure that all equipment is used within the manufacturer's recommended guidelines and expirations dates, if applicable.

(G) A licensed HME services provider shall:

(1) Maintain appropriate staffing to handle the scope of equipment sold, rented and maintained and to appropriately meet the demands of the business.

(2) Ensure that all staff members are trained and supervised by qualified persons.

(3) Maintain personnel records for each employee, which shall include all of the following:

(a) Job description for the position held by the employee.

(b) Application qualifications.

(c) For any employee that provides HME services, supervises an employee who provides HME services, or has access to records maintained in accordance with rule [4729:11-3-02](#) of the Administrative Code who is working within the state of Ohio, a criminal background check shall be performed only upon initial hire by the Ohio bureau of criminal ~~identification and~~ investigation (BCI&I) and shall consist of ~~both~~ a BCI&I ~~and FBI~~ criminal records check.

(d) Orientation and training records.

(e) Verification of competence.

(f) Performance plan to be completed annually by the licensee.

(H) A licensed HME services provider shall possess product and professional liability insurance coverage in the amount of one million dollars per occurrence, three million dollars aggregate. The certificate of insurance must show that the product and professional liability insurance coverage is contained in the total aggregate amount.

Rule 4729:11-3-02 | Record keeping. (AMEND)

(A) A licensed or registered HME services provider shall maintain records for each client that has been sold or leased equipment.

(1) All records maintained in accordance with this rule shall be uniformly maintained and readily retrievable for inspection and copying by properly identified agents, inspectors or employees of the state board of pharmacy.

(2) All client records must contain a prescriber order, if required, and documentation of settings and other data relevant to the equipment that has been sold or leased, and other documentation regarding service checks of the equipment sold or rented to the client.

(3) All client records must be maintained for three years from the date of sale or in the case of a minor client, records must be maintained for seven years after the client turns eighteen years of age.

(B) A HME services provider located in this state intending to maintain records at a location other than the location licensed or registered by the state board of pharmacy shall notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the licensee or registrant.

(C) A HME services provider maintaining records at location other than the location licensed or registered by the state board of pharmacy or via a computerized record keeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent of the board access to the records maintained in accordance with this rule within three business days.

Rule 4729:11-3-03 | Inspections and corrective actions. (AMEND)

(A) An entity licensed or registered by the state board of pharmacy pursuant to Chapter 4752. of the Revised Code is subject to an on-site inspection by the board. An authorized board **agent employee** may, without notice, carry out an on-site inspection or investigation of an entity licensed or registered by the board. Upon verification of the board **agent's employee's** credentials, the **agent employee** shall be permitted to enter the licensed or registered entity.

(B) Submission of an application for a license or registration as a HME services provider with the state board of pharmacy constitutes permission for entry and on-site inspection by an authorized board agent.

(C) If an agent of the state board of pharmacy identifies a violation specified in paragraph (D) of this rule, the agent may provide written notice, in a manner determined by the board, of the nature of the observed violations to the designated representative on the license, registration or application. The licensee, registrant or applicant may also be subject to disciplinary actions pursuant to Chapter 4752. of the Revised Code and this division of the Administrative Code.

(D) Violations may include any of the following:

- (1) Violating any rule of the board;
- (2) Violating any provision of Chapter 4752. of the Revised Code;
- (3) Violating any federal, state and local law, rule, or regulation regarding the provision of HME services.

(E) The licensee, registrant or applicant shall submit to the board within thirty days of a written notice provided in accordance with paragraph (C) of this rule, in a manner determined by the board, either of the following:

- (1) The action(s) the licensee, registrant or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
- (2) An explanation disputing the observed violations.

(F) The designated representative of a HME services provider shall comply with investigations and inspections conducted by the board or accrediting body recognized in accordance with rule [4729:11-2-04](#) of the Administrative Code and shall instruct their staff members to comply with all requests made by the board or accrediting body.

Rule 4729:11-3-04 | Continuing education. (NO CHANGE)

(A) Licensed HME services providers shall provide ten contact hours of continuing education per renewal cycle for staff rendering home medical equipment services.

(B) Of the number of continuing education contact hours required, one contact hour shall include subject content on infection control, equipment cleaning standards and cleaning agents, rotation of inventory, or equipment separation requirements. The remaining contact hours must be relevant to the HME services rendered. The following are acceptable sources of continuing education:

- (1) In-service education developed and taught by the licensed HME services provider.
- (2) In-service education developed and taught by a HME manufacturer.
- (3) Continuing education approved by any organization recognized by the board that offers continuing education relevant to HME services rendered.

(C) Any organization that provides HME continuing education may apply to the board to be recognized as an authorized continuing education provider. Request for recognition must be made in writing to the board and must include an overview of the organization and an outline of the continuing education courses provided by the organization, including course content.

(D) Documentation of all completed continuing education courses taken by each staff member must be maintained in the employee's personnel file for three years from the date of completion and shall be made readily retrievable.

In-service continuing education credits shall be documented for employed staff involved in HME service delivery to the public. Records of attendance and completion shall include any of the following:

- (1) Sign in logs;
- (2) Agendas and training manuals;
- (3) Certificates of completion; or
- (4) Online completion logs/rosters.

Rule 4729:11-3-05 | Advertising and solicitation. (AMEND)

(A) No **licensed or registered** HME services provider shall advertise or solicit for patronage in connection with the licensee or registrant's business if any communication contained therein is false, fraudulent, deceptive, or misleading.

(B) Excluding a free consultation, any advertisement or solicitation which offers HME services on a gratuitous basis shall include a disclaimer. If the advertisement is visual, the disclaimer shall be contained therein. If the advertisement is audio-based, the disclaimer shall be read. A written copy of the disclaimer shall be provided to every patient who responds to an offer, prior to the rendering of patient care.

(1) The disclaimer shall clearly and conspicuously state the following:

(a) Any exclusions, prohibitions, restrictions, limitations, conditions, or eligibility requirements which apply to the offer; and

(b) Any additional services, which are associated with the offer, that are rendered on the same day but are not provided free of charge.

(C) All advertisements and solicitations shall include therein the name of the licensee or registration holder pursuant to Chapter 4752. of the Revised Code who has reviewed and approved the content of the advertisement or solicitation.

(D) Any trade or fictitious names utilized in connection with HME services or sales shall be duly registered with the Ohio secretary of state.

(E) Each of the following shall constitute an abusive telemarketing act and shall be considered a violation of this rule:

(1) Use of threats, intimidation, or profane or obscene language.

(2) Calling a person repeatedly or continuously with intent to annoy, abuse or harass any person at the number called.

(3) Calling a person when that person has previously stated that they do not wish to receive an outbound telephone call made by or on behalf of the seller whose goods or services are

being offered or a person who is listed on federal government's national do not call registry. Every seller of goods or services shall maintain a "do not call" list.

(4) Calling a person's residence at any time other than between eight a.m. and eight p.m. local time at the person's location.

(5) Requiring an immediate response from the prospect to any offer made during the solicitation.

(6) Failure to disclose within the first sixty seconds of the telephone call the solicitors identity and the practice on whose behalf the solicitation is being made; the purpose of the telephone call; a statement of the goods or services being sold; and that no purchase or payment is necessary to participate in a promotion if a promotion is offered.

(7) The solicitors are prohibited from misrepresenting their affiliation with, or endorsement by, any government or third-party organization.

(8) Communicating with prospective patients in a way that invades privacy of the prospective **patient**, or interferes with an existing prescriber/patient relationship.

(F) A licensee or registrant may utilize testimonials in advertising if the patient giving the testimonial has given written consent as to the exact wording and proposed use of the testimonial. A copy of such consent and testimonial shall be retained by the HME service provider for two years from the last date of publication. Testimonials shall be true and shall not be false, fraudulent, deceptive or misleading.

(G) A HME services provider may not utilize signs which include any false, fraudulent, deceptive or misleading information.

Rule 4729:11-3-06 | Minimum standards for registered home medical equipment services providers (NEW)

(A) This rule sets forth the minimum acceptable standards for registration as a HME services provider under Chapter 4752. of the Revised Code.

(B) For any employee that provides HME services, supervises an employee who provides HME services, or has access to records maintained in accordance with rule 4729:11-3-02 of the Administrative Code who is working within the state of Ohio, a criminal background check shall be performed only upon initial hire by the Ohio bureau of criminal **identification and investigation (BCI&I)** and shall consist ~~of both~~ a BCI&I criminal records check.

(C) All registered HME services providers shall comply with:

- (1) All applicable federal and state laws, rules, and regulations;
- (2) The Centers for Medicare and Medicaid Services “Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS) Quality Standards” (8/12/2024);
- (3) Position statements, standards of care or guidelines for providing HME services from nationally recognized organizations;
- (4) Pursuant to section 4752.09, federal rules issued pursuant to the medicare program established under Title XVIII of the "Social Security Act," 49 Stat. 620(1935), 42 U.S.C. 1395, as amended, relating to operations, financial transactions, and general business practices of home medical services providers.

(D) In maintaining equipment, a registrant shall:

- (1) Maintain and document equipment in accordance with the manufacturer's guidelines;
- (2) Clean, disinfect, repair, store, segregate and identify all equipment in a manner that ensures the equipment is safe for use by the public;
- (3) Ensure that all equipment is used within the manufacturer's recommended guidelines and expirations dates, if applicable.

Rule 4729:11-4-01 | Disciplinary Actions. (AMEND)

(A) The state board of pharmacy may, in accordance with Chapter 119. of the Revised Code, impose any one or more of the following sanctions on an applicant for a license or certificate of registration issued under Chapter 4752. of the Revised Code or a license or certificate of registration holder for any of the causes set forth in paragraph (B) of this rule:

- (1) Suspend, revoke, restrict, limit, or refuse to grant or renew a license or certificate of registration;
- (2) Reprimand or place the license or certificate holder on probation;
- (3) Impose a monetary penalty or forfeiture not to exceed in severity any fine designated under the Revised Code for a similar offense or not more than five thousand dollars if the acts committed are not classified as an offense by the Revised Code.

(B) The board may impose the sanctions listed in paragraph (A) of this rule for any of the following:

- (1) Violation of any provision of this chapter or an order or rule of the board, as those provisions, orders, or rules are applicable to persons licensed or registered under this chapter.

~~**(2) A plea of guilty to or a judicial finding of guilt of a felony or a misdemeanor that involves dishonesty or is directly related to the provision of home medical equipment services.**~~

(2) Has a conviction for, judicial finding of guilt of, or plea of guilty to a disqualifying offense.

- (3) Making a material misstatement in furnishing information to the board.
- (4) Professional incompetence.
- (5) Being guilty of negligence or gross misconduct in providing home medical equipment services.

- (6) Aiding, assisting, or willfully permitting another person to violate any provision of this chapter or an order or rule of the board, as those provisions, orders, or rules are applicable to persons licensed or registered under this chapter.
- (7) Failing to provide information in response to a written request by the board.
- (8) Engaging in conduct likely to deceive, defraud, or harm the public.
- (9) Denial, revocation, suspension, or restriction of a license or certificate of registration to provide home medical equipment services, for any reason other than failure to renew, in another state or jurisdiction.
- (10) Directly or indirectly giving to or receiving from any person a fee, commission, rebate, or other form of compensation for services not rendered.
- (11) Knowingly making or filing false records, reports, or billings in the course of providing home medical equipment services, including false records, reports, or billings prepared for or submitted to state and federal agencies or departments.
- (12) Failing to comply with federal rules issued pursuant to the medicare program established under Title XVIII of the "Social Security Act," 49 Stat. 620(1935), 42 U.S.C. 1395, as amended, relating to operations, financial transactions, and general business practices of home medical services providers if applicable.
- (13) Failing to satisfy the qualifications for licensure or registration under Chapter 4752. of the Revised Code or the rules of the board or ceasing to satisfy the qualifications after the license or registration is granted or renewed.
- (14) Commission of an act that constitutes a **felony disqualifying offense** in this state, regardless of the jurisdiction in which the act was committed.
- ~~(15) Commission of an act of moral turpitude that constitutes a felony or misdemeanor, regardless of the jurisdiction in which the act was committed.~~
- (15) Commission of a crime of moral turpitude as defined in section [4776.10](#) of the Revised Code.

(16) Violation of any restrictions placed by the state board of pharmacy on a license or registration or violating any terms of a board order issued against the licensee or registrant.

(17) Exclusion from participation in medicare or a state health care program.

~~(19) Commission of an act that constitutes a misdemeanor theft offense, regardless of the jurisdiction in which the act was committed.~~

~~(20) Commission of an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed.~~

(18) Employs a designated representative that does not meet the requirements set forth in rule [4729:11-2-02](#) of the Administrative Code.

(19) Retaliating against or disciplining an employee for filing a complaint with a state board of pharmacy or other licensing body or reporting a violation of state or federal statute or any ordinance or regulation of a political subdivision that the employee's employer has authority to correct. As used in this paragraph, retaliation or discipline of an employee includes, but is not limited to, the following:

- (a) Removing or suspending the employee from employment;
- (b) Withholding from the employee salary increases or employee benefits to which the employee is otherwise entitled;
- (c) Transferring or reassigning the employee;
- (d) Denying the employee a promotion that otherwise would have been received;
- (e) Reducing the employee in pay or position.

(20) The ownership of such entity has been transferred from a person whose license or registration issued in accordance with Chapter 4752. of the Revised Code has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to the spouse or other family member.

(21) The ownership of such facility has been transferred from a licensee or registrant whose license or registration has been revoked or disciplined by the state board of pharmacy or any other state or federal professional licensing or regulatory agency to another who employs the former owner or who allows the former owner to be present within the physical confines of the location to be licensed or registered.

(22) If applicable, failing to comply with the accreditation standards of a national accrediting body recognized pursuant to rule [4729:11-2-04](#) of the Administrative Code upon which a registration by the board has been granted.

(23) Unless otherwise approved by the board, a HME services provider knowingly employs a person who provides HME services to the public who:

(a) Has been denied the right to work in any facility by the state board of pharmacy as part of an official order of the board.

(b) Has been denied the right to work in such a facility by another professional licensing agency as part of an official order of that agency.

(c) Has committed an act that constitutes a ~~misdemeanor theft~~ **disqualifying** offense, regardless of the jurisdiction in which the act was committed.

~~(d) Has committed an act that constitutes a felony, regardless of the jurisdiction in which the act was committed.~~

(d) Is addicted to or abusing alcohol or drugs.

~~(f) Has committed an act that constitutes a misdemeanor involving dishonesty, fraud, or directly related to the provision of HME services, regardless of the jurisdiction in which the act was committed~~

(e) Has been disciplined by the state board of pharmacy pursuant to Chapter 4729. of the Revised Code, except for a disciplinary action related to the failure to timely obtain continuing education required pursuant to agency 4729 of the Administrative Code.

(f) Has been excluded from participation in medicare or a state health care program.

(g) Has been the subject of any of the following by an accrediting agency or a licensing or certification agency of any state or jurisdiction:

(i) A disciplinary action that resulted in the suspension, probation, surrender or revocation of the person's license, registration, certification, or accreditation; or

(ii) A disciplinary action that was based, in whole or in part, on the person's provision of home medical equipment services.

~~(h) Has committed an act that constitutes a misdemeanor that is related to, or committed in, the employee's professional practice.~~

~~(k) Has committed an act of moral turpitude that constitutes a felony or misdemeanor in this state, regardless of the jurisdiction in which the act was committed.~~

(C) On receiving notification, the board shall suspend or revoke any registration found to have the accreditation upon which the certificate of registration was issued revoked, suspended, or otherwise no longer valid.