9/26/2018

The following information is being provided pursuant to the requirements of Executive Order 2011-01K and Senate Bill 2 of the 129th General Assembly, which require state agencies, including the State of Ohio Board of Pharmacy, to draft rules in collaboration with stakeholders, assess and justify an adverse impact on the business community (as defined by S.B. 2), and provide an opportunity for the affected public to provide input on the following rules.

New

- 4729:11-1-01- Definition section for home medical equipment division. (Rescinds current rules 4761:1-3-01 and 4761:1-3-02).
- 4729:11-2-01- Establishes the requirements for licensure or certificate of operation for a home medical equipment provider, including renewal. (Rescinds current rules 4761:1-5-02, 4761:1-7-01, 4761:1-7-02, 4761:1-7-03).
- 4729:11-2-02- Establishes the requirements for the designated representative on a home medical services license or certification of registration.
- 4729:11-2-03- Provides the requirements for application as a home medical services provider.
- 4729:11-2-04- Establishes the approved accrediting organizations for registered home medical equipment providers. (Rescinds current rules 4761:1-4-01).
- 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.
- 4729:11-3-01- Establishes the minimum standards for home medical equipment providers. (Rescinds current rules 4761:1-9-01, 4761:1-9-02, 4761:1-9-04, 4761:1-9-05).
- 4729:11-3-02- Provides the requirements for record keeping for home medical equipment providers.
- 4729:11-3-03- Establishes the Board of Pharmacy's authority to inspect a home medical equipment provider.
- 4729:11-3-04- Establishes the continuing education requirements for home medical equipment providers. (Rescinds current rule 4761:1-13-01).
- 4729:11-3-05- Defines the requirements for advertising and solicitation standards. (Rescinds current rules 4761:1-15-01 and 4761:1-15-02).
- 4729:11-4-01- Establishes the Board of Pharmacy's authority to impose disciplinary actions on a home medical equipment provider. (Rescinds current rules 4761:1-11-01, 4761:1-11-02, 4761:1-11-03, 4761:1-11-04).

77 SOUTH HIGH STREET | 30TH FLOOR | COLUMBUS, OHIO 43215-6117
CSIOhio@governor.ohio.gov

Comments on the proposed rules will be accepted until close of business on **October 17, 2018**. Please send all comments to the following email address: **Ali.Simon@pharmacy.ohio.gov**

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

CSI - Ohio
The Common Sense Initiative

Business Impact Analysis

Agency Name: State of Ohio Board of Pharmacy

Regulation/Package Title: Home Medical Equipment

Rule Number(s):

New:

- **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**
- **4729:11-4-01**

Rescinded: 4761:1-1 through -16

Date: 9/26/2018

Rule Type:

New	5-Year Review
Amended	**Rescinded**

The Common Sense Initiative was established by Executive Order 2011-01K and placed within the Office of the Lieutenant Governor. Under the CSI Initiative, agencies should

balance the critical objectives of all regulations with the costs of compliance by the regulated parties. Agencies should promote transparency, consistency, predictability, and flexibility in regulatory activities. Agencies should prioritize compliance over punishment, and to that end, should utilize plain language in the development of regulations.

Regulatory Intent

1. Please briefly describe the draft regulation in plain language.

New

- 4729:11-1-01- Definition section for home medical equipment division. (Rescinds current rules 4761:1-3-01 and 4761:1-3-02).
- 4729:11-2-01- Establishes the requirements for licensure or certificate of operation for a home medical equipment provider, including renewal. (Rescinds current rules 4761:1-5-02, 4761:1-7-01, 4761:1-7-02, 4761:1-7-03).
- 4729:11-2-02- Establishes the requirements for the designated representative on a home medical services license or certification of registration.
- 4729:11-2-03- Provides the requirements for application as a home medical services provider.
- 4729:11-2-04- Establishes the approved accrediting organizations for registered home medical equipment providers. (Rescinds current rules 4761:1-4-01).
- 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.
- 4729:11-3-01- Establishes the minimum standards for home medical equipment providers. (Rescinds current rules 4761:1-9-01, 4761:1-9-02, 4761:1-9-04, 4761:1-9-05).
- 4729:11-3-02- Provides the requirements for record keeping for home medical equipment providers.
- 4729:11-3-03- Establishes the Board of Pharmacy's authority to inspect a home medical equipment provider.
- 4729:11-3-04- Establishes the continuing education requirements for home medical equipment providers. (Rescinds current rule 4761:1-13-01).
- 4729:11-3-05- Defines the requirements for advertising and solicitation standards. (Rescinds current rules 4761:1-15-01 and 4761:1-15-02).
- 4729:11-4-01- Establishes the Board of Pharmacy's authority to impose disciplinary actions on a home medical equipment provider. (Rescinds current rules 4761:1-11-01, 4761:1-11-02, 4761:1-11-03, 4761:1-11-04).

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

The proposed rules are authorized by sections 4752.17 of the Ohio Revised Code.

3. **Does the regulation implement a federal requirement? Is the proposed regulation being adopted or amended to enable the state to obtain or maintain approval to administer and enforce a federal law or to participate in a federal program?**

These rules do not implement a federal requirement.

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

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.

5. **What is the public purpose for this regulation (i.e., why does the Agency feel that there needs to be any regulation in this area at all)?**

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

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

The success of the regulations will be measured by having rules written in plain language, licensee compliance with the rules, and minimal questions from licensees/registrants regarding the provisions of the rules.

Development of the Regulation

7. **Please list the stakeholders included by the Agency in the development or initial review of the draft regulation.**

This rule package was reviewed by the Home Medical Services Advisory Council and other stakeholders.

Prior to filing with CSI, the rules were reviewed and approved by the Board of Pharmacy.

8. **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 Board of Pharmacy Home Medical Services Advisory Council reviewed the proposed changes. Changes included having the board approve accrediting organizations and continuing education providers. Clarifying who is required to complete continuing education.

9. **What scientific data was used to develop the rule or the measurable outcomes of the rule? How does this data support the regulation being proposed?**

Scientific data was not used to develop or review this rule package.

10. **What alternative regulations (or specific provisions within the regulation) did the Agency consider, and why did it determine that these alternatives were not appropriate? If none, why didn't the Agency consider regulatory alternatives?**

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

11. **Did the Agency specifically consider a performance-based regulation? Please explain.** ***Performance-based regulations define the required outcome, but don't dictate the process the regulated stakeholders must use to achieve compliance.***

The agency did not consider a performance-based regulation for this rule package. It is the Board's responsibility to ensure uniform standards across Ohio. At this juncture, it was the determination of the Board that the rule package did not lend itself to performance-based regulations.

12. **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 the regulations do not duplicate another State of Ohio Board of Pharmacy regulation.

13. **Please describe the Agency's plan for implementation of the regulation, including any measures to ensure that the regulation is applied consistently and predictably for the**

regulated community.

The rules will be posted on the Board of Pharmacy's web site, 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 agents 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.

Adverse Impact to Business

14. Provide a summary of the estimated cost of compliance with the rule. Specifically, please do the following:

a. Identify the scope of the impacted business community;

The rule package impacts the following:

- Those providing or selling home medical equipment services

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

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.

c. Quantify the expected adverse impact from the regulation.

15. New

- 4729:11-1-01- Definition section for home medical equipment division. This should not have an adverse impact as it is definitional.
- 4729:11-2-01- Establishes the requirements for licensure or certificate of operation for a home medical equipment provider, including renewal. Registration renewal costs $300 biennially, licensure costs $400 biennially. The Board is removing the costs of an inspection fees that were charged under the Ohio Respiratory Care Board. The Board is requiring that all out of state providers be registered. There are costs associated with accreditation, but the proposed rules would allow for those that are impacted, by the new rule, their first licensure fees to be waived by the Board.

- 4729:11-2-02- Establishes the requirements for the designated representative on a home medical services license or certification of registration.
- 4729:11-2-03- Provides the requirements for application as a home medical services provider. The application fee for registration is $150, licensure fee is $300.
- 4729:11-2-04- Establishes the approved accrediting organizations for registered home medical equipment providers. (Rescinds current rules 4761:1-4-01).
- 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. The Board offers both licensure and registration to home medical equipment providers. Registration renewal costs $300 biennially, licensure costs $400 biennially.
- 4729:11-3-01- Establishes the minimum standards for home medical equipment providers. Requires employees to submit to a criminal record check with BCI&I before employment. The cost of a background check per person is BCI&I is $22, with some agencies that may change a processing fee (e.g. $5-$40).
- 4729:11-3-02- Provides the requirements for record keeping for home medical equipment providers. There may be an overall increase in administrative costs associated with complying with the rule.
- 4729:11-3-03- Establishes the Board of Pharmacy's authority to inspect a home medical equipment provider. There may be overall increase in administrative costs if the provider is required to submit a corrective action plan.
- 4729:11-3-04- Establishes the continuing education requirements for home medical equipment providers. HME providers can include in-service education by the facility to fulfill continuing education requirements. Other continuing education providers will be approved by the Board. (Rescinds current rule 4761:1-13-01).
- 4729:11-3-05- Defines the requirements for advertising and solicitation standards. There may be administrative costs associated with compliance, but the rules have not changed from current requirements. (Rescinds current rules 4761:1-15-01 and 4761:1-15-02).
- 4729:11-4-01- Establishes the Board of Pharmacy's authority to impose disciplinary actions on a home medical equipment provider. (Rescinds current rules 4761:1-11-01, 4761:1-11-02, 4761:1-11-03, 4761:1-11-04).

16. 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 in order to protect the health and safety of all Ohioans by providing uniform regulations for home medical equipment providers.

Regulatory Flexibility

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

This rule package 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.

18. 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 State of Ohio Board of Pharmacy does not fine licensees/registrants or impose penalties for first-time paperwork violations. However, any failure of a standard of care in the distribution of dangerous drugs is not considered a paperwork error but a quality assurance issue by the licensee that is necessary for the protection of the public.

19. 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.

Division 4729:11 – Home Medical Equipment

Chapter 4729:11-1 Definitions

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 that 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 the application is abandoned, the applicant shall be required to reapply for licensure or registration, submit the required fee and comply with the requirements in effect at the time of reapplication.

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

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

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

(F) "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.

(G) "Expired certificate of registration" means the status of a certificate of a registration has failed to fulfill all requirements of certificate renewal and has failed to request that the board place the certificate into inactive status.

(H) "Expired license" mean the status of the certificate of a licensee who has failed to fulfill all requirements of certificate renewal, and who has failed to request that the board place the certificate on inactive status.

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

(1) Hospital grade pulse oximeters as prescribed by physician order;

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

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

(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".

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

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

(L) "Inactive status" means the status of a license or registration of a facility that has made a request in writing 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.

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

(N) "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.

(O) "Life sustaining equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes, but is not limited to, 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.).

(P) “Person” has the same meaning as in division (S) of section 4729.01 of the Revised Code and includes any individual member, regardless of the percentage of ownership, of any partnership, association, limited liability company, or corporation.

(Q) “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.

(R) "Refuse to grant or renew" means to deny original or continued licensure or registration for a period of at least twelve months. After twelve months, or such period of time as the individual board order may require, a person licensed or registered by the board or an individual or facility 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. An individual or facility 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 any requirements established by the board.

(S) "Registered" and "licensed" mean that a person has met the initial qualifications for registration or licensure 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.

(T) "Revoke" means to take action against a license or registration rendering such license or registration void and such license or registration may not be reissued. Revoke is an action that is permanent against the license/registration and licensee/registration holder.

(U) "Staff" means employees or their representatives of the licensee or registrant.

(V) "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.

(W) "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.

(X) "Technologically sophisticated medical equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes, but is not limited to, the following:

(1) Oxygen conservation devices;

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

(3) Bi-level airway pressure (BiPAP) devices;

(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 & gait trainers);

(15) Vacuum assisted wound closure devices;

(16) Drop foot stimulators;

(17) Bone growth stimulators;

(18) Vision restoration therapy devices;

(19) Electric wheelchairs and custom scooters;

(20) Auto-titrating airway devices; and

(21) In-home patient lifts.

Chapter 4729:11-2 Licensure or Certificate of Registration

4729:11-2-01 Licensure, registration and renewal

(A) An applicant applying for licensure as an HME service provider shall:

(1) File an application with the board, on forms provided by the board pursuant to 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 an HME service 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.

(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.

(d) Submit to an on-site inspection pursuant to rule 4729:11-3-03 of the Administrative Code.

(B) An applicant applying for registration as an HME service provider shall:

(1) File an application with the board, on forms provided by the board pursuant to 4729:11-2-03 of the Administrative Code; and

(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 4729:11-2-05 of the Administrative Code. Part of the registration process shall be an inquiry to the accrediting authority with which the entity is accredited. This information will be used as a part of the consideration in registering the entity by the board.

(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 licensing 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 (H) 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.

(H) 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.

(I) Upon the effective date of this rule:

An HME services provider located outside the boundaries of the state of Ohio currently licensed under Chapter 4752. of the Revised Code shall apply for a registration as a HME services provider on or before the expiration date of the provider’s license. The licensee shall submit an application for registration in accordance with this rule and shall not be assessed a fee for this application.

4729:11-2-02 – Designated representative.

(A) A location licensed or registered as a home medical services providers 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 location for a sufficient amount of time to provide supervision of the activities conducted by an HME service provider.

(E) Unless otherwise approved by the board, a HME service 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 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.

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

(6) Has committed an act the 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.

(7) 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.

(8) Has been excluded from participation in Medicare or a state health care program.

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

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

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

(10) 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.

4729:11-2-03 – Applications.

(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.

(2) All trade, fictitious, or business names used by the licensee (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 licensee for the storage, handling, and distribution of HME.

(4) The type of ownership or operation (i.e., sole proprietorship, partnership, corporation, or government agency).

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

(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 HME registration, information necessary to verify appropriate accreditation.

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

(8) A copy of the HME services provider'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 from the HME services provider.

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

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

(12) List of other licenses held by the HME services provider.

(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.

4729:11-2-04 Approved accrediting organizations.

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

(B) The board, at its discretion, may approve other national accrediting bodies if the accrediting agency submits a written request to the board for recognition. In determining whether an accrediting organization will be recognized by the board, the board will determine if the agency applying to be an approved accrediting agency meets the following criteria:

(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 they accredit an HME service 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 competency;

(9) The agency provides written reports of survey visits, observations, violations, citation 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 approved by the board shall be posted to the board's website (www.pharmacy.ohio.gov).

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

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

4729:11-2-05 - Change in description of an HME service provider or discontinuation of business.

(A) Any change in the ownership, business or trade name, category, or address of a HME service provider requires a new application, 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 corporation's outstanding shares of voting stock.

(2) Any business entity change from its original form, as licensed, 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 home medical equipment 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 person.

(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.

(D) 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), a new application fee and new license or registration number are required.

(E) A change of ownership set forth in paragraphs (B)(2) and (B)(3) of this rule or as otherwise determined by the board's executive director or the director's designee, shall require the board to issue a new license or registration number.

(F) 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.

(G) A HME services provider who plans to discontinue business activities shall file a notice with the board. The notice shall be submitted, in a manner determined by the board, at least fourteen 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.

Chapter 4729:11-3 General Provisions

4729:11-3-01 Minimum Standards for Licensees

(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 an 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 and rules; 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 organizations 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 service, maintenance, cleaning, infection control and/or 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 service provider if the client's needs are beyond the scope of the licensee 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/or 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 and rules, including all federal, state and local laws and rules regarding the storage, maintenance, and sale of upholstery or bedding, if applicable.

(E) In maintaining equipment, a licensee shall:

(1) Maintain and document equipment in accordance with manufacturers guidelines;

(2) Clean, 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 manufacturers recommended guidelines and expirations dates, if applicable.

(F) The designated representative of a licensed HME services provider shall:

(1) Employ 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:

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

(b) Application qualifications;

(c) For any employee upon hire working within the state of Ohio, a criminal background check performed by the Ohio bureau of criminal identification and investigation (BCI&I) consisting of both a BCI&I criminal records check;

(d) Orientation and training records;

(e) Verification of competence; and

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

(G) 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.

4729:11-3-02 Recordkeeping

(A) The designated representative of an 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 made readily retrievable for inspection and copying by properly identified and authorized state board of pharmacy agents

(2) All client records must contain a physician order, if required, documentation of settings and other data relevant to the equipment that has been sold or leased to them 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, the record must be maintained for seven years after the client turns eighteen years of age.

(B) An HME service provider intending to maintain records at a location other than the place licensed by the state board of pharmacy must notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to representatives or contractors of the licensee.

(C) An HME service provider maintaining records at location other than the location licensed by the state board of pharmacy or via a computerized recordkeeping 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.

4729:11-3-03 Inspections and corrective actions.

(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 may, without notice, carry out an on-site inspection or investigation of an entity licensed by the board. Upon verification of the board agent's credentials, the agent shall be permitted to enter the licensed 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 or rule 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 organization recognized in accordance with rule 4729:11-2-04 and shall instruct their staff members to comply with all requests made by the board or accrediting organization.

4729:11-3-04 Continuing education.

(A) Licensed HME facilities shall provide ten contact hours of continuing education per renewal cycle for staff rendering home medical equipment services as defined in section 4752.01 of the Revised Code.

(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 an 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 the organization must provide the board with an overview of their organization and an outline of the continuing education courses provided by that 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 made readily retrievable.

(1) 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:

(a) Sign in logs;

(b) Agendas and training manuals; or

(c) Certificates of completion.

4729:11-3-05 Advertising and solicitation.

(A) No 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 designated licensee or registration holder who holds a valid Ohio license and 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 called number.

(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. 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 prospect, or interferes with an existing doctor/patient relationship.

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

Chapter 4729:11-4 Disciplinary Procedures

4729:11-4-01 – Disciplinary Actions

(A) The state board of pharmacy, in accordance with Chapter 119. of the Revised Code, may impose any one or more of the following sanctions on a person licensed or registered as a HME services provider 4752 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;

(2) Reprimand or place the license holder on probation;

(3) Impose a monetary penalty as set forth in section 4752.09 of the Revised Code.

(B) The board may impose the sanctions set forth 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 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.

(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 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 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 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.

(16) Commission of a crime of moral turpitude as defined in section 4776.10 of the Revised Code.

(17) 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.

(18) If applicable, 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.

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

(22) Retaliating against or disciplining an employee for filing a complaint with a 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 section, 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.

(23) 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.

(24) 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.

(25) 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.

(26) 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 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.

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

(f) Has committed an act the 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.

(g) 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.

(h) Has been excluded from participation in Medicare or a state health care program.

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

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

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

(j) 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.