



# Licensed Home Medical Equipment Service Providers

## Inspection Guide

*For Licensed HME Service Providers ONLY*

**Updated 11/15/2019**

**IMPORTANT NOTICE:** On or before June 30, 2022, all licensed home medical equipment service providers located outside of Ohio are required to obtain registration (i.e. obtain [national accreditation](#)) as a HME service provider [OAC [4729:11-2-01](#) (H)].

**The requirements listed in this inspection guide are effective on December 15, 2019.**

***This document is reference material for licensees, registrants, and applicants. The document does not bind the State of Ohio Board of Pharmacy, and does not confer any rights, privileges, benefits, or immunities for or on any person, applicant, licensee or registrant.***

## **Applicability**

This guide applies only to locations licensed as home medical equipment service providers pursuant to section [4752.02 of the Ohio Revised Code](#).

## **Inspection Authority**

Pursuant to section [4752.08](#) of the Revised Code and rule [4729:11-3-03](#) of the Administrative Code, an entity licensed or registered by the State Board of Pharmacy as home medical equipment services provider 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 or registered by the Board.

Upon verification of the Board agent's credentials, the agent shall be permitted to enter the licensed or registered entity.

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.

After the completion of the inspection, the authorized Board agent will provide an inspection report for review and any corrective actions required. If the inspection report requires a written response, responses must be mailed within 30 days of the inspection to [writtenresponse@pharmacy.ohio.gov](mailto:writtenresponse@pharmacy.ohio.gov).

## **Applicable Rules**

The following provides a general list of rules that apply to home medical equipment service providers:

### **4729:11 – Home Medical Equipment Service Providers (Effective 12/15/2019)**

- [4729:11-1-01](#) – Definitions – home medical equipment.
- [4729:11-2-01](#) – Licensure, registration and renewal.
- [4729:11-2-02](#) – Designated representative.
- [4729:11-2-03](#) – Applications.
- [4729:11-2-04](#) – Recognized accrediting bodies. (**NOTE:** Does not apply to licensed HME Service Providers)
- [4729:11-2-05](#) – Change in description of a HME services provider or discontinuation of business.
- [4729:11-3-01](#) – Minimum standards for licensees.
- [4729:11-3-02](#) – Record keeping.
- [4729:11-3-03](#) – Inspections and corrective actions.
- [4729:11-3-04](#) – Continuing education.
- [4729:11-3-05](#) – Advertising and solicitation.
- [4729:11-4-01](#) – Disciplinary actions.

## **Notification of a Designated Representative by December 15, 2019**

Per rule [4729:11-2-02](#), a **designated representative** is responsible for compliance with all applicable state and federal laws, regulations, and rules governing the provision of HME services. 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.

**ALL** licensed HME service providers are required to electronically submit notification to the Board of the licensee's designated representative **no later than December 15, 2019**. The notification form and instructions are available by visiting: [www.pharmacy.ohio.gov/DR](http://www.pharmacy.ohio.gov/DR)

For questions regarding this provision or any other requirements of the new rules, a HME service provider should submit question via the Board's contact page:

<https://www.pharmacy.ohio.gov/Contact.aspx>. Be sure to select "Home Medical Equipment Service Provider Information" as the subject.

## **Required Notifications or Document Submissions**

Board of Pharmacy rules require the following notifications to the Board:

<b>Notification/Submission Requirement</b>	<b>How to Submit</b>	<b>Timeframe for Submission</b>
Change of designated representative. (OAC <a href="#">4729:11-2-02</a> )	Form and instructions are available here: <a href="http://www.pharmacy.ohio.gov/DR">www.pharmacy.ohio.gov/DR</a>	Within ten days of the effective date of the appointment of the new designated representative
Any change in ownership, business or trade name, category, or address requires a new application, required fee, and license or certificate of registration. (OAC <a href="#">4729:11-2-05</a> )	Instructions are available <a href="#">here</a> .	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.
Off-site storage of required records. Only applies to in-state licensee or registrant. (OAC <a href="#">4729:11-3-02</a> )	Form and instructions are available here: <a href="http://www.pharmacy.ohio.gov/HMErecords">www.pharmacy.ohio.gov/HMErecords</a>	Prior to records being moved off-site (for new licensees/registrants).  For existing HME service providers, the form should be submitted no later than 12/15/2019.

## **Health Insurance Portability and Accountability Act (HIPAA)**

*Upon inspection, Board staff may ask to review patient records to determine compliance with Ohio laws and rules. To address concerns regarding compliance with HIPAA, the Board has developed the following FAQ to assist licensees.*

### **What is HIPAA?**

- HIPAA is a federal [privacy rule](#) created to protect individuals' medical records and other personal health information and applies to health plans, health care clearinghouses, and those health care providers that conduct certain health care transactions electronically.

### **Why does the HIPAA privacy rule not apply to the State of Ohio Board of Pharmacy?**

- HIPAA applies to health plans, health clearinghouses, and to any health care provider who transmits health information in electronic form in connection with a transaction for which the Secretary of HHS has adopted standards under HIPAA, known as "covered entities" and to their business associates.
  - The Board of Pharmacy does not fit the definition of a covered entity because:
    - 1) The Board does not provide or pay for the cost of medical care;
    - 2) The Board is not a health care provider; and
    - 3) The Board does not process health information on behalf of other organizations (billing, community health management information systems, etc.).
- In addition, the Board is not considered a "business associate" because it does not perform activities on behalf of or provide services to a covered entity (as described in 1-3 above) that involves the use or disclosure of identifiable health information.
- Examples of a business associate include, but are not limited to, the following: third-party administrators that assist with claims processing or a consultant that performs utilization review for a hospital.

### **How can a licensee or registrant be assured the Board will protect patient information?**

- The Board's confidentiality statute, ORC [4729.23](#), provides that any information provided to the Board in the course of an investigation is confidential and is not a public record.
- In addition, there are exemptions in Ohio's Public Records law, that exempt medical records/patient information from being released in response to a public record request (ORC Section 149.43(A)(1)(a)).

For more information about the HIPAA Privacy Rule, visit: <https://www.hhs.gov/hipaa/for-professionals/privacy/index.html>

## **Important Terms**

- **"Readily retrievable"** means that records maintained by a licensee or registrant in 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.
- **"Designated representative"** is responsible for compliance with all applicable state and federal laws, regulations, and rules governing the provision of HME services. The designated representative shall be physically present at the licensed or registered location for a sufficient amount of time to provide supervisions of the activities conducted by a HME services provider.
- **"Home medical equipment"** means equipment that can stand repeated use, is primarily and customarily used to serve a medical purpose, is not useful to a person in the absence of illness or injury, is appropriate for use in the home, and is one or more of the following:
  - (1) Life-sustaining equipment prescribed by an authorized health care professional that mechanically sustains, restores, or supplants a vital bodily function, such as breathing;
  - (2) Technologically sophisticated medical equipment prescribed by an authorized health care professional that requires individualized adjustment or regular maintenance by a home medical equipment services provider to maintain a patient's health care condition or the effectiveness of the equipment;
  - (3) An item specified by the state board of pharmacy in rules adopted under division (B) of section 4752.17 of the Revised Code.

See OAC [4729:11-1-01](#) for references to specific types of home medical equipment.

- **"Home medical equipment services"** means the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.
- **"Home medical equipment services provider"** means a person engaged in offering home medical equipment services to the public.

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## Home Medical Equipment - Inspection Guide

OAC = Ohio Administrative Code / ORC = Ohio Revised Code

### Licensing, Ownership, and Designated Representative

Question	Description / Guidance	Law/Rule
<p><b>Have there been any changes in the facility's ownership, business name or trade name, category, or address without submitting a new application to the Board?</b></p>	<p>Any change in ownership, business or trade name, category, or address 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.</p> <p>For more information on what constitutes a change of ownership, see OAC <a href="#">4729:11-2-05</a>.</p>	<p>OAC <a href="#">4729:11-2-05</a></p>
<p><b>Does the designated representative match what is indicated in eLicense?</b></p>	<p>A location licensed as a HME service provider must have a designated representative at all times. When there is a change of designated representative, the Board must be notified within ten days of the effective date of the appointment of the new designated representative. A change of designated representative form is available on the Board's website: <a href="http://www.pharmacy.ohio.gov/DR">www.pharmacy.ohio.gov/DR</a></p>	<p>OAC <a href="#">4729:11-2-02</a></p>
<p><b>How many hours per week does the designated representative work at the facility?</b></p>	<p>Licensee will be asked to provide this information.</p>	
<p><b>Does the facility have the required liability insurance?</b></p>	<p>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. Licensee will be asked to produce a certificate of insurance.</p>	<p>OAC <a href="#">4729:11-3-01</a></p>

## Personnel

Question	Guidance	Law/Rule
<p><b>Are employee FBI/BCI criminal record checks for employees available for inspection?</b></p>	<p>For any employee that provides HME services, supervises an employee who provides HME services, or has access to records a criminal background check shall be performed only upon initial hire by the Ohio Bureau of Criminal Identification and Investigation (BCI&amp;I) and shall consist of both a BCI&amp;I and FBI criminal records check.</p> <p>Board staff will ask to review this documentation to determine compliance.</p> <p><b>NOTE:</b> The requirement is for employees to obtain FBI criminal record checks shall not be applied retroactively to current employees of facility.</p> <p>An FBI criminal records check will only apply to new employees at the time of hire.</p>	<p>OAC <a href="#">4729:11-3-01</a></p>
<p><b>Does the facility keep the required personnel files for all employees?</b></p>	<p>Facilities are required to keep personnel files that include job description, application qualifications, orientation and training records, verification of competence, and annual performance plan to be completed by the licensee.</p> <p>Board staff will ask to review this documentation to determine compliance.</p>	<p>OAC <a href="#">4729:11-3-01</a></p>
<p><b>Does the licensee maintain documentation demonstrating compliance with employee continuing education requirements?</b></p>	<p>Licensed HME services providers shall provide ten contact hours of continuing education per renewal cycle for staff rendering home medical equipment services. 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.</p> <p>The following are acceptable sources of continuing education:</p> <p>(1) In-service education developed and taught by the licensed HME services provider.</p>	<p>OAC <a href="#">4729:11-3-04</a></p>



	<p>(2) In-service education developed and taught by a HME manufacturer.</p> <p>(3) Continuing education approved by any organization recognized by the board that offers continuing education relevant to HME services rendered. Board approved CE providers can be found <a href="#">here</a>.</p> <p>The documentation must be maintained in the employee's personnel file for three years from the date of completion.</p> <p>NOTE: Documentation of in-service education may include any of the following:</p> <ul style="list-style-type: none"><li>(1) Sign in logs;</li><li>(2) Agendas and training manuals;</li><li>(3) Certificates of completion; or</li><li>(4) Online completion logs/rosters.</li></ul> <p>Board staff will ask to review this documentation to determine compliance.</p>	
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## **Minimum Standards**

<b>Question</b>	<b>Guidance</b>	<b>Law/Rule</b>
<b>Does the facility have appropriate physical space to safely store, maintain and service on site equipment?</b>	<p>The facility must have appropriate physical space to safely store, maintain and service on site equipment.</p> <p>A licensee shall maintain separate areas/spaces for the following: the business office, patient records, equipment cleaning, maintenance, and storage.</p>	OAC <a href="#">4729:11-3-01</a>
<b>Is the facility able to demonstrate appropriate equipment flows through various stages to ensure that the equipment is properly disinfected, repaired, stored, and maintained?</b>	<p>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.</p> <p>Licensee will be asked to demonstrate compliance.</p>	OAC <a href="#">4729:11-3-01</a>
<b>Does the facility maintain inventory to meet the needs of the licensee's client base?</b>	<p>The facility must maintain inventory on site or by arrangement with a supplier to meet the needs of the licensee's current client base.</p> <p>Licensees will be asked for documentation demonstrating agreements with HME suppliers or processes in place for referrals to another HME services provider if the client's needs are beyond the scope of the facility.</p>	OAC <a href="#">4729:11-3-01</a>
<b>Does the facility maintain and document equipment in accordance with the manufacturer's guidelines?</b>	<p>In maintaining equipment, a licensee shall maintain and document equipment in accordance with the manufacturer's guidelines.</p> <p>Equipment will be reviewed by Board staff to determine compliance.</p>	OAC <a href="#">4729:11-3-01</a>

## Operations

Question	Guidance	Law/Rule
<b>What types of HME services does this facility provide?</b>	<p>Board staff will document the types of HME services provided by the licensee.</p> <p><b>NOTE:</b> "Home medical equipment services" means the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.</p>	ORC <a href="#">4752.01</a>
<b>How many patients does the facility service each month?</b>	Licensee will be asked to provide this information.	
<b>What type of home medical equipment does the facility provide?</b>	<p>Licensee will be asked to provide this information.</p> <p><b>NOTE:</b> "Home medical equipment" or "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 pursuant to a prescription issued by a prescriber; (2) Home photo therapy (bili lights or blankets); (3) 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"; (4) Drop foot stimulators; (5) Bone growth stimulators; (6) Vision restoration therapy devices; and (7) In-home patient lifts.</p>	OAC <a href="#">4729:11-1-01</a>
<b>What types of technologically sophisticated equipment does the facility provide?</b>	<p>Licensee will be asked to provide this information.</p> <p><b>NOTE:</b> "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-exsufflator; (7) Apnea monitors; (8) Percussors for chest physiotherapy; (9) Suction machines; (10) Feeding pumps; (11) Infusion pumps; (12) Continuous passive motion (CPM)</p>	OAC <a href="#">4729:11-1-01</a>

	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; (18) Any other technologically sophisticated medical equipment as determined by the Board.	
<b>What types of life sustaining equipment are provided by the facility?</b>	<p>Licensee will be asked to provide this information.</p> <p><b>NOTE:</b> "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.</p>	OAC <a href="#">4729:11-1-01</a>
<b>Does the facility have a telephone number that is operational twenty-four hours a day, seven days a week that clients can call to seek assistance?</b>	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 a voicemail system or 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.	OAC <a href="#">4729:11-1-01</a>

## **Record Keeping**

<b>Question</b>	<b>Guidance</b>	<b>Law/Rule</b>
<b>Are all records uniformly maintained and readily retrievable for inspection?</b>	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.	OAC <a href="#">4729:11-3-02</a>
<b>Does the facility maintain all client records for the required time period?</b>	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.  Board staff will review records to determine compliance.	OAC <a href="#">4729:11-3-02</a>
<b>Do all client records contain a physician order if required?</b>	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.	OAC <a href="#">4729:11-3-02</a>
<b>Does the HME services provider maintain required records off-site?</b>	A HME services provider located in this state intending to maintain records at a location other than the location licensed 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.  An off-site records storage notification form is available by visiting: <a href="http://www.pharmacy.ohio.gov/HMErecords">www.pharmacy.ohio.gov/HMErecords</a>  A HME services provider maintaining records at location other than the location licensed by the State Board of Pharmacy 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.  If yes, Board staff will ask to review an executed agreement.	OAC <a href="#">4729:11-3-02</a>
<b>Are records electronically created and maintained?</b>	A HME service provider maintaining records via a computerized record keeping system shall maintain an executed agreement with the company possessing or storing the records authorizing an agent	OAC <a href="#">4729:11-3-02</a>

	<p>of the Board access to the records maintained in accordance with this rule within three business days.</p> <p>If yes, Board staff will ask to review an executed agreement.</p>	
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## **Advertising**

<b>Question</b>	<b>Guidance</b>	<b>Law/Rule</b>
<p><b>Does the licensee advertise or solicit for patronage?</b></p>	<p>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.</p> <p>The disclaimer must clearly state:</p> <p>(1) Any exclusions, prohibitions, restrictions, limitations, conditions, or eligibility requirements which apply to the offer; and</p> <p>(2) Any additional services, which are associated with the offer, that are rendered on the same day but are not provided free of charge.</p> <p>All advertisements and solicitations must include the name of the licensee.</p> <p>Board staff will review advertisements to determine compliance.</p>	<p>OAC <a href="#">4729:11-3-05</a></p>
<p><b>Does the licensee use testimonials to advertise HME services?</b></p>	<p>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.</p> <p>If yes, Board staff will ask the licensee to document patient consent.</p>	<p>OAC <a href="#">4729:11-3-05</a></p>