



# Board of Pharmacy

## **INSPECTION GUIDE**

### **Licensed Home Medical Equipment Services Providers**

*For Licensed HME Services Providers ONLY*

**Updated 5/30/2025**

***This document is reference material for licensees, registrants, and applicants. The document does not bind the 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 Ohio Board of Pharmacy as home medical equipment services provider is subject to an on-site inspection by the Board. An authorized Board 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 employee's credentials, the employee shall be permitted to enter the licensed or registered entity.

Submission of an application for a license or registration as an HME services provider with the Ohio 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).

## **Need Additional Information?**

For questions, an HME services provider should submit question via the Board's contact page: <https://www.pharmacy.ohio.gov/Contact.aspx>. Be sure to select "Home Medical Equipment Services Provider Information" as the subject.

## **Applicable Rules**

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

### **4729:11 – Home Medical Equipment Services Providers**

- [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 Services Providers)
- [4729:11-2-05](#) – Change in description of an HME services provider or discontinuation of business.
- [4729:11-3-01](#) – Minimum standards for licensed home medical equipment services providers.
- [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.
- [4729:11-3-06](#) – Minimum standards for registered home medical equipment services providers. (**NOTE:** Does not apply to licensed HME Services Providers)
- [4729:11-4-01](#) – Disciplinary Actions.

**Required Notifications or Document Submissions**

Links to instructions and forms can be found in the table below and can also be accessed on the Board’s HME Services Provider licensing page: <https://www.pharmacy.ohio.gov/HME>

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

<b>Notification/Submission Requirement</b>	<b>How to Submit</b>
<p><b><u>Change in Business Description</u></b>  <a href="#">OAC 4729:11-2-05</a></p> <p>Any change in the ownership, business or trade name, category, or address of a terminal distributor of dangerous drugs requires a new application and required fee. The new application and required fee shall be submitted <b>within thirty days</b> of any change in the ownership, business or trade name, category, or address.</p> <p><b>NOTE:</b> 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.</p>	<p>A change of business description must be completed online using Ohio’s <a href="#">eLicense</a> system.</p> <p>Instructions on submitting this information can be accessed <a href="#">here</a>.</p>
<p><b><u>Discontinuation of Business</u></b>  <a href="#">OAC 4729:11-2-05</a></p> <p>A HME services provider who plans to discontinue business activities shall file a notice with the Board of Pharmacy. The notice shall be submitted, in a manner determined by the Board, <b>within thirty days of discontinuation of business</b> as a terminal distributor of dangerous drugs.</p>	<p>Requires submission of a <a href="#">Written Notice of Discontinuing Business Form</a>.</p>
<p><b><u>Change of Designated Representative</u></b>  <a href="#">OAC 4729:11-2-02</a></p> <p>A location licensed or registered as a home medical equipment services provider must have a designated representative at all times.</p>	<p>Requires submission of a <a href="#">Change of Designated Representative Form</a>.</p>

<p>When there is a change of designated representative, the Board must be notified <b>within ten days</b> of the effective date of the appointment of the new designated representative.</p>	
<p><b><u>Notification of Off-Site Records Storage</u></b>  OAC <a href="#">4729:11-3-02</a></p> <p>A HME services provider located <b>in this state</b> intending to maintain records at a location other than the location licensed or registered by the Board of Pharmacy shall notify the Board. Any alternate location shall be secured and accessible only to authorized representatives or contractors of the licensee or registrant.</p>	<p>Requires submission of an <b><a href="#">Off-Site Records Notification Form</a></b>.</p>

## **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 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 an 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 of a HME services provider requires a new application and required fee. The 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 shall have a designated representative at all times. When there is a change of designated representative, the Board shall be notified by the new designated representative 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>	

<b>Does the facility have the required liability insurance?</b>	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.	OAC <a href="#">4729:11-3-01</a>
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**Personnel**

<b>Question</b>	<b>Guidance</b>	<b>Law/Rule</b>
<p><b>Are 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 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 Investigation (BCI) and shall consist of a BCI criminal records check.</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 facility keep the required personnel files for all employees?</b></p>	<p>Facilities are required to keep personnel files for each employee that include all of the following: job description for the position held by the employee application qualifications, orientation and training records, verification of competence, and an 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</p>	<p>OAC <a href="#">4729:11-3-04</a></p>

cleaning agents, rotation of inventory, or equipment separation requirements.

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. Board approved CE providers can be found [here](#).

The documentation must be maintained in the employee's personnel file for three years from the date of completion.

NOTE: Documentation of in-service education may include any of the following:

(1) Sign in logs;

(2) Agendas and training manuals;

(3) Certificates of completion; or

(4) Online completion logs/rosters.

	Board staff will ask to review this documentation to determine compliance.	
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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 functions, as applicable.</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</b>	<p>In maintaining equipment, a licensee shall maintain and document equipment in accordance with the manufacturer's guidelines.</p>	OAC <a href="#">4729:11-3-01</a>

<p><b>accordance with the manufacturer’s guidelines?</b></p>	<p>Equipment will be reviewed by Board staff to determine compliance.</p>	
<p><b>Does the facility restrict access to client records and home medical equipment to employees and authorized contractors?</b></p>	<p>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:</p> <p>(1) A physical barrier with suitable locks to prevent unauthorized access; or</p> <p>(2) 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.</p>	<p>OAC <a href="#">4729:11-3-01</a></p>

**Operations**

Question	Guidance	Law/Rule
<p><b>What types of HME services does this facility provide?</b></p>	<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>	<p>ORC <a href="#">4752.01</a></p>
<p><b>How many patients does the facility service each month?</b></p>	<p>Licensee will be asked to provide this information.</p>	
<p><b>What type of home medical equipment does the facility provide?</b></p>	<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) Individually sized or customized accessories that are an integral part of equipment defined in this paragraph and paragraphs (U) and (EE) of this rule; (4) Transcutaneous electronic nerve stimulators (TENS), excluding devices labeled by the federal food and drug administration for over-the-counter use and are identified with the federal food and drug administration product code "NUH.OTC TENS"; (5) Drop foot stimulators; (6) Bone growth stimulators; (7) Vision restoration therapy devices; (8) In-home patient lifts; (9) Life-sustaining equipment as defined in paragraph (U)</p>	<p>OAC <a href="#">4729:11-1-01</a></p>

	of this rule; and (10) Technologically sophisticated medical equipment as defined in paragraph (EE) of this rule.	
<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 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 &amp; 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.</p>	OAC <a href="#">4729:11-1-01</a>
<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 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>
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## Record Keeping

Question	Guidance	Law/Rule
<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>	<p>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.</p> <p>Board staff will review records to determine compliance.</p>	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>	<p>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.</p> <p>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></p>	OAC <a href="#">4729:11-3-02</a>

	<p>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.</p> <p>If yes, Board staff will ask to review an executed agreement.</p>	
<p><b>Are records electronically created and maintained?</b></p>	<p>A HME services 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 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>	<p>OAC <a href="#">4729:11-3-02</a></p>

## Advertising

Question	Guidance	Law/Rule
<p><b>Does the licensee advertise or solicit for patronage?</b></p>	<p>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.</p> <p>The disclaimer must clearly and conspicuously state the following:</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. Testimonials shall be true and shall not be false, fraudulent, deceptive, or misleading.</p>	<p>OAC <a href="#">4729:11-3-05</a></p>

	If yes, Board staff will ask the licensee to document patient consent.	
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