INSPECTION GUIDE

Registered Home Medical Equipment Services Providers

For Registered 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 registered 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.

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.
- 4729:11-2-05 – Change in description of an HME services provider or discontinuation of business.
- 4729:11-3-01 – Minimum standards for licensees. (**NOTE:** Does not apply to registered HME Services Providers)
- 4729:11-3-02 – Record keeping.
- 4729:11-3-03 – Inspections and corrective actions.
- 4729:11-3-04 – Continuing education. (**NOTE:** Does not apply to registered HME Services Providers)
- 4729:11-3-05 – Advertising and solicitation.
- 4729:11-3-06 – Minimum standards for registered home medical equipment 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:

Notification/Submission Requirement	How to Submit
Change in Business Description *OAC 4729:11-2-05* 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 **within thirty days** of any change in the ownership, business or trade name, category, or address. **NOTE:** 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.	A change of business description must be completed online using Ohio's eLicense system. Instructions on submitting this information can be accessed **here**.
Discontinuation of Business *OAC 4729:11-2-05* 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, **within thirty days of discontinuation of business** as a terminal distributor of dangerous drugs.	Requires submission of a **Written Notice of Discontinuing Business Form**.
Change of Designated Representative *OAC 4729:11-2-02* A location licensed or registered as a home medical equipment services provider must have a designated representative at all times.	Requires submission of a **Change of Designated Representative Form**.

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.	
Notification of Off-Site Records Storage *OAC 4729:11-3-02* A HME services provider located **in this state** 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.	Requires submission of an **Off-Site Records Notification Form**.

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 and registrants.

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

Reminder of Compliance with Federal Rules for Registered HME Services Providers

For registered HME Services Providers and approved accrediting bodies, the Ohio Revised Code (ORC 4752.09) requires compliance with the following:

> *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.*

Therefore, registered entities and accrediting bodies are advised that they should comply with all applicable federal rules on supplier and quality standards including, but not limited to, the following:

- The Centers for Medicare and Medicaid Services "Durable Medical Equipment, Prosthetics, Orthotics, And Supplies (DMEPOS) Quality Standards" (NOTE: This specific standard is referenced in OAC 4729:11-3-06)

Failure for registered HME services providers to comply with these standards is considered a violation of ORC 4752.09 (B)(12) and may subject the registrant to administrative sanctions.

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 supervision 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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OAC = Ohio Administrative Code / ORC = Ohio Revised Code

Registration, Ownership, and Designated Representative

Question	Description / Guidance	Law/Rule
Is the applicant accredited by the Joint Commission or another national accrediting body that has been recognized by the Board?	Accreditation is required to obtain and maintain registration as a HME services provider. A list of recognized accrediting bodies can be accessed here. Registrant will be asked to provide documentation demonstrating compliance with this requirement.	ORC 4752.15
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?	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. For more information on what constitutes a change of ownership, see OAC 4729:11-2-05.	OAC 4729:11-2-05
Does the designated representative match what is indicated in eLicense?	A location registered as a HME services 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	OAC 4729:11-2-02

	designated representative form is available on the Board's website: www.pharmacy.ohio.gov/DR	
How many hours per week does the designated representative work at the facility?	Registrant will be asked to provide this information.	
Does the designated representative work at another HME service provider facility?	Registrant will be asked to provide this information.	

Operations

Question	Guidance	Law/Rule
Are employee BCI criminal record checks for employees available for inspection?	For any employee that provides HME services, supervises an employee who provides HME services, or has access to records maintained in accordance with OAC 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. Board staff will ask to review this documentation to determine compliance.	OAC 4729:11-3-06
What types of HME services does this facility provide?	Board staff will document the types of HME services provided by the registrant. **NOTE:** "Home medical equipment services" means the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment.	ORC 4752.01
How many patients does the facility service each month?	Registrant will be asked to provide this information.	
What type of home medical equipment does the facility provide?	Registrant will be asked to provide this information. **NOTE:** "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	OAC 4729:11-1-01

	following equipment: (1) Hospital grade pulse oximeters pursuant to a prescription issued by a prescriber; (2) Home photo therapy (bili lights or blankets); (3) Individually sized or customized accessories that are an integral part of equipment defined in this paragraph and paragraphs (U) and (EE) of this rule; (4) Transcutaneous electronic nerve stimulators (TENS), excluding devices labeled by the federal food and drug administration for over-the-counter use and are identified with the federal food and drug administration product code "NUH.OTC TENS"; (5) Drop foot stimulators; (6) Bone growth stimulators; (7) Vision restoration therapy devices; (8) In-home patient lifts; (9) Life-sustaining equipment as defined in paragraph (U) of OAC 4729:11-1-01; and (10) Technologically sophisticated medical equipment as defined in paragraph OAC 4729:11-1-01.	
What types of technologically sophisticated equipment does the facility provide?	Registrant will be asked to provide this information. **NOTE:** "Technologically sophisticated medical equipment" has the same meaning as defined in section 4752.01 of the Revised Code and includes the following: (1) Oxygen conservation devices; (2) CPAP (continuous positive airway pressure) devices; (3) High-frequency chest wall oscillators (vests); (4) Intrapulmonary percussive ventilation (IPV) devices; (5) Intermittent positive pressure breathing (IPPB) devices; (6) Cough-assist mechanical in-exsuffaltor; (7) Apnea monitors; (8) Percussors for chest physiotherapy; (9) Suction machines; (10) Feeding pumps; (11) Infusion pumps; (12) Continuous passive motion (CPM) devices; (13) Custom seating or positioning systems; (14) Custom rehab equipment (e.g. standers & gait trainers); (15) Vacuum assisted wound closure devices; (16) Electric wheelchairs and custom scooters; (17) Auto-titrating airway devices; and (18) Any	OAC 4729:11-1-01

	other technologically sophisticated medical equipment as determined by the Board.	
What types of life sustaining equipment are provided by the facility?	Registrant will be asked to provide this information. **NOTE:** "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.	OAC 4729:11-1-01
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?	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 4729:11-1-01

Minimum Standards

Question	Guidance	Law/Rule
Is the facility able to demonstrate appropriate equipment flows through various stages to ensure that the equipment is properly disinfected, repaired, stored, and maintained?	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. Registrant will be asked to demonstrate compliance.	OAC 4729:11-3-06
Does the facility maintain and document equipment in accordance with the manufacturer's guidelines?	In maintaining equipment, a registrant shall maintain and document equipment in accordance with the manufacturer's guidelines. Equipment will be reviewed by Board staff to determine compliance.	OAC 4729:11-3-06

Record Keeping

Question	Guidance	Law/Rule
Are all records uniformly maintained and readily retrievable for inspection?	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 4729:11-3-02
Does the facility maintain all client records for the required time period?	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 4729:11-3-02
Do all client records contain a physician order if required?	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 4729:11-3-02
Does the HME services provider maintain required records off-site?	A HME services provider located in this state intending to maintain records at a location other than the location registered by the state board of pharmacy shall notify the board in a manner determined by the board. Any such alternate location shall be secured and accessible only to authorized representatives or contractors of the registrant. An off-site records storage notification form is available on the HME licensing webpage: https://www.pharmacy.ohio.gov/Licensing/HME.aspx	OAC 4729:11-3-02

	A HME services provider maintaining records at location other than the location registered 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.	
Are records electronically created and maintained?	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. If yes, Board staff will ask to review an executed agreement.	OAC 4729:11-3-02

Advertising

Question	Guidance	Law/Rule
Does the registrant advertise or solicit for patronage?	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. The disclaimer must clearly and conspicuously state the following: (1) Any exclusions, prohibitions, restrictions, limitations, conditions, or eligibility requirements which apply to the offer; and (2) Any additional services, which are associated with the offer, that are rendered on the same day but are not provided free of charge. All advertisements and solicitations must include the name of the registrant. Board staff will review advertisements to determine compliance.	OAC 4729:11-3-05
Does the registrant use testimonials to advertise HME services?	A registrant may utilize testimonials in advertising if the patient giving the testimonial has given written consent as to the exact wording and proposed use of the testimonial. A copy of such consent and testimonial shall be retained by the registered 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.	OAC 4729:11-3-05

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