Facility Self-Assessment for Ohio Licensure or Registration as a Home Medical Equipment Services Provider

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The Ohio home medical equipment (HME) licensure act was enacted on September 16, 2004, requiring certain HME service providers to obtain a license or certificate of registration to provide HME services in Ohio. **Ohio law requires only those facilities providing specific HME services to the public to obtain a license or be registered with a designated accrediting body.**

Under Section 4752.01 (C) of the Revised Code, HME Services are defined as, "the sale, delivery, installation, maintenance, replacement, or demonstration of home medical equipment." Section 4752.01 (B) of the Revised Code broadly defines HME as, "equipment that can stand repeated use, is primarily and customarily used to serve a medical purpose, is not useful to a person in 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; or

3) An item specified by the Ohio respiratory care board in rules adopted under division (B) of section 4752.17 of the Revised Code.

Because this law is not applicable to all HME providers, the Ohio Board of Pharmacy encourages the use of this document to help you determine if you may qualify for a license or

certificate of registration. If, after completing this form, you determine you qualify for an HME license or certificate of registration, you may apply using Ohio's eLicense System.

Step 1: Evaluating the exceptions to meeting the licensure requirements under Chapter 4752 of the Revised Code.

Section 4752.02 (B) of the Revised Code excludes specific entities from the licensing and certificate of registration requirements. Please review the following list. If you mark yes to any of the exceptions below, your business might not require a license or certificate of registration to operate in Ohio. The Board urges you to seek legal counsel to verify whether your business requires a license.

- ○ A health care practitioner, as defined in section 4729.01 of the Revised Code, who does not sell or rent home medical equipment;
- ○ A hospital that provides home medical equipment services only as an integral part of patient care and does not provide the services through a separate entity that has its own Medicare or Medicaid provider number;
- ○ A manufacturer or wholesale distributor of home medical equipment that does not sell directly to the public;
- ○ A home health agency that is certified under Title XVIII of the "Social Security Act," 79 Stat. 286 (1965), 42 U.S.C. 1395, as a provider of home health services and does not sell or rent home medical equipment;
- ○ An individual who holds a current, valid license issued under Chapter 4741. of the Revised Code to practice veterinary medicine;
- ○ An individual who holds a current, valid license issued under Chapter 4779. of the Revised Code to practice orthotics, prosthetics, or

pedorthists;

- ○ A hospice care program, as defined by section 3712.01 of the Revised Code, that does not sell or rent home medical equipment;
- ○ A pharmacy licensed under Chapter 4729. of the Revised Code that either does not sell or rent home medical equipment or receives total payments of less than ten thousand dollars per year from selling or renting home medical equipment;
- ○ A home, as defined by section 3721.01 of the Revised Code;
- ○ A home dialysis equipment provider regulated by federal law.

-OR-

- ○ The business does not provide any HME Service as it is defined under Section 4752.02 of the Ohio Revised Code or provides any HME equipment defined under Section 4729.02 of the Ohio Revised Code or rule 4729:11-1-01 of the Ohio Administrative Code.

Step 2: Determining the HME services rendered under Chapter 4752 of the Revised Code.

The next step is to determine if you sell, deliver, install, maintain, replace, or demonstrate HME. Rule 4729:11-1-01 of the Ohio Administrative Code lists equipment determined by the Board to be qualifying HME. Please check all equipment that you sell, deliver, install, maintain, replace, or demonstrate.

THE FOLLOWING ARE LISTED AS HME UNDER RULE 4729:11-1-01 OF THE OHIO ADMINISTRAIVE CODE. PLEASE CHECK ALL THAT APPLY:

1) **"Life sustaining equipment" means equipment prescribed by an authorized health care professional that mechanically sustains, restores, or supplants a vital bodily function, such as breathing, and includes the following:**

- ○ Ventilators;
- ○ Oxygen concentrators;
- ○ Oxygen liquid systems;
- ○ Oxygen compressed gas systems;
- ○ Non-invasive ventilator system (e.g. bi-level, iron lungs, rocking beds, diaphragmatic pacers, etc.).

2) **"Technologically sophisticated medical equipment" means medical equipment prescribed by an authorized health care professional that requires individualized adjustment or regular maintenance by an HME service provider to maintain a patient's health care condition or the effectiveness of the equipment, including but not limited to:**

- ○ Oxygen conservation devices;
- ○ CPAP (continuous positive airway pressure) devices;
- ○ High frequency chest wall oscillators (vests);
- ○ Intrapulmonary percussive ventilation (IPV) devices;
- ○ Intermittent positive pressure breathing (IPPB) devices;
- ○ Cough-assist mechanical inexsuffaltor;
- ○ Suction machines;
- ○ Feeding pumps;
- ○ Infusion pumps;
- ○ Continuous passive motion (CPM) devices;
- ○ Custom seating or positioning systems;
- ○ Custom rehab equipment (e.g. standers & gait trainers);
- ○ Vacuum assisted wound closure devices;

- ○ Apnea monitors;
- ○ Percussors for chest physiotherapy;
- ○ Electric wheelchairs and custom scooters;
- ○ Auto-titrating airway devices.

3) **"Technologically sophisticated medical equipment" means medical equipment prescribed by an authorized health care professional that requires individualized adjustment or regular maintenance by an HME service provider to maintain a patient's health care condition or the effectiveness of the equipment, including but not limited to:**

- ○ Hospital grade pulse oximeters pursuant to a prescription issued by a prescriber;
- ○ Individually sized or customized accessories that are an integral part of either life sustaining equipment or technologically sophisticated medical equipment;
- ○ 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";
- ○ Home photo therapy (bili lights or blankets);
- ○ Drop foot stimulators;
- ○ Bone growth stimulators;
- ○ Vision restoration therapy devices;
- ○ In-home patient lifts.

<u>Step 3: Evaluation</u>

If you do not meet an exception listed in Step 1 of this checklist but render one or more HME services listed under Step 2 above, you may be required to obtain a license or certificate of

registration to render these services to residents in the state of Ohio.

Applications for a license or certificate of registration must be submitted using Ohio's eLicense system.

IMPORTANT: Licensure is only available for in-state HME service providers. Providers located in another state must apply for a certificate of registration.

HME Inspection Guides

The Board has published inspection guides for both Licensed and Registered HME Service Providers. The guide, which mirrors the Board's internal inspection guide, serves as a reference for licensees, registrants, and applicants.

The Licensed HME Service Provider Inspection Guide can be found here.

The Registered HME Service Provider Inspection Guide can be found here.