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FACILITY SELF EVALUATION FOR OHIO HME REGULATION

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;
- (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 Respiratory Care Board has developed this self evaluation form 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 completion, you may obtain an application on the Board's website www.hme.ohio.gov. If you believe you do not provide any qualifying home medical equipment services or meet a specific exception from Ohio's home medical equipment regulations, please complete an Affidavit of Services found on our website.

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.

Please check any that apply:

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| <input type="checkbox"/> A health care practitioner, as defined in section 4769.01 of the Revised Code, who does not sell or rent home medical equipment; | <input type="checkbox"/> 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; |
| <input type="checkbox"/> 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; | <input type="checkbox"/> An individual who holds a current, valid license issued under Chapter 4741. of the Revised Code to practice veterinary medicine; |
| <input type="checkbox"/> A manufacturer or wholesale distributor of home medical equipment that does not sell directly to the public; | <input type="checkbox"/> An individual who holds a current, valid license issued under Chapter 4779. of the Revised Code to practice orthotics, prosthetics, or pedorthics; |
| <input type="checkbox"/> A hospice care program, as defined by section 3712.01 of the Revised Code, that does not sell or rent home medical equipment; | <input type="checkbox"/> 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 |
| <input type="checkbox"/> A home, as defined by section 3721.01 of the Revised Code; ¹ | |

thousand dollars per year from selling or renting home medical equipment;

A home dialysis equipment provider regulated by federal law.

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 4761:1-3-02 lists equipment determined by the Board to be qualifying HME. Please check all equipment that you sell, deliver, install, maintain, replace, or demonstrate.

Please check any that apply:

THE FOLLOWING ARE LISTED AS HME UNDER RULE 4761:1-3-2 OAC. PLEASE CHECK ALL THAT APPLY TO YOUR FACILITY.

"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, including but not limited to:

- | | |
|--|---|
| <input type="checkbox"/> Ventilators | <input type="checkbox"/> Oxygen Compressed Gas Systems |
| <input type="checkbox"/> Oxygen Concentrators | <input type="checkbox"/> Non Invasive Ventilator System (i.e. Bi-Level, Iron Lungs, Rocking Beds, Diaphragmatic pacers, etc.) |
| <input type="checkbox"/> Oxygen Liquid Systems | |

"Technologically-sophisticated" 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:

- | | |
|--|---|
| <input type="checkbox"/> Oxygen conservation devices | <input type="checkbox"/> Infusion pumps |
| <input type="checkbox"/> Continuous positive airway pressure devices (CPAP) | <input type="checkbox"/> Continuous passive motion devices (CPM) |
| <input type="checkbox"/> Bi-level positive airway pressure devices (BiPAP) | <input type="checkbox"/> Custom seating or positioning systems |
| <input type="checkbox"/> Intrapulmonary percussive ventilation devices (IPV) | <input type="checkbox"/> Custom rehab equipment (i.e. standers & gait trainers) |
| <input type="checkbox"/> Intermittent positive pressure breathing devices (IPPB) | <input type="checkbox"/> Vacuum Assisted Wound Closure Devices |
| <input type="checkbox"/> Cough-assist mechanical in-ExSufflator | <input type="checkbox"/> Drop foot stimulators |
| <input type="checkbox"/> Apnea monitors | <input type="checkbox"/> Bone growth stimulators |
| <input type="checkbox"/> Percussors for chest physiotherapy | <input type="checkbox"/> Vision Restoration Therapy Devices |
| <input type="checkbox"/> Suction machines | <input type="checkbox"/> Electric wheelchairs and custom scooters |
| <input type="checkbox"/> Feeding pumps | <input type="checkbox"/> Auto-titrating airway devices |
| | <input type="checkbox"/> In-home patient lifts |

"Other items" means equipment specified by the board under division (B) (3) of section 4752.01 of the Revised Code and division (B) of section 4752.17 of the Revised Code. Other items include, but are not limited to:

- Pulse oximeters
- Home phototherapy (Bili lights or blankets)
- Individually sized or customized accessories that are an integral part of equipment defined in paragraphs (A), (B), or (C) of OAC rule 4761:1-3-02.
- 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".

Step 3: Evaluation

If you do not meet an exception listed in Step 1 under Section 4752.02 (B) of the Ohio Revised Code, 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. An application for a license or certificate of registration may be obtained on the Board's website at www.hme.ohio.gov or by telephoning the Board office at 614-752-9218. Please read the application carefully to determine if you need to apply for a license or certificate of registration. A full copy of the laws and rules regulating the provision of HME services in Ohio can be obtained on the Board's website at www.hme.ohio.gov.

If you believe you meet an exception to Ohio's HME license or certificate of registration requirement or do not render any HME service involving equipment types listed under rule 4761:1-3-02 in Step 2 above, please complete and mail an "Affidavit of Exception" for HME Services to the Ohio Respiratory Care Board office, which can found under "FORMS" on the Board's website www.hme.ohio.gov. The Board encourages you to review all laws and rules regulating the provision of HME services prior to completing this form.

¹ Pursuant to ORC 3721.01:

(A) As used in [sections 3721.01](#) to [3721.09](#) and [3721.99](#) of the Revised Code:

(1) (a) "Home" means an institution, residence, or facility that provides, for a period of more than twenty-four hours, whether for a consideration or not, accommodations to three or more unrelated individuals who are dependent upon the services of others, including a nursing home, residential care facility, home for the aging, and a veterans' home operated under [Chapter 5907](#), of the Revised Code.

(b) "Home" also means both of the following:

(i) Any facility that a person, as defined in [section 3702.51](#) of the Revised Code, proposes for certification as a skilled nursing facility or nursing facility under Title XVIII or XIX of the "Social Security Act," 49 Stat. 620 (1935), 42 U.S.C.A. 301, as amended, and for which a certificate of need, other than a certificate to recategorize hospital beds as described in [section 3702.522](#) [3702.52.2] of the Revised Code or division (R)(7)(d) of the version of [section 3702.51](#) of the Revised Code in effect immediately prior to April 20, 1995, has been granted to the person under [sections 3702.51](#) to [3702.62](#) of the Revised Code after August 5, 1989;

(ii) A county home or district home that is or has been licensed as a residential care facility.

(c) "Home" does not mean any of the following:

(i) Except as provided in division (A)(1)(b) of this section, a public hospital or hospital as defined in [section 3701.01](#) or [5122.01](#) of the Revised Code;

(ii) A residential facility for mentally ill persons as defined under [section 5119.22](#) of the Revised Code;

(iii) A residential facility as defined in [section 5123.19](#) of the Revised Code;

(iv) A community alternative home as defined in [section 3724.01](#) of the Revised Code;

(v) An adult care facility as defined in [section 3722.01](#) of the Revised Code;

(vi) An alcohol or drug addiction program as defined in [section 3793.01](#) of the Revised Code;

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- (vii) A facility licensed to provide methadone treatment under [section 3793.11](#) of the Revised Code;
- (viii) A facility providing services under contract with the department of mental retardation and developmental disabilities under [section 5123.18](#) of the Revised Code;
- (ix) A facility operated by a hospice care program licensed under [section 3712.04](#) of the Revised Code that is used exclusively for care of hospice patients;
- (x) A facility, infirmary, or other entity that is operated by a religious order, provides care exclusively to members of religious orders who take vows of celibacy and live by virtue of their vows within the orders as if related, and does not participate in the medicare program established under Title XVIII of the "Social Security Act" or the medical assistance program established under [Chapter 5111](#), of the Revised Code and Title XIX of the "Social Security Act," if on January 1, 1994, the facility, infirmary, or entity was providing care exclusively to members of the religious order;
- (xi) A county home or district home that has never been licensed as a residential care facility.