

201 KAR 47:010. Home medical equipment and supplier licenses, requirements, and fees.

RELATES TO: KRS 309.404, 309.406, 309.412, 309.414, 309.416, 309.418, 309.420, 324B.030, 324B.040, Pub. L. 104-191

STATUTORY AUTHORITY: KRS 309.404, 309.406, 309.412, 309.414, 309.416, 309.418, 309.420, 324B.030, 324B.040

NECESSITY, FUNCTION, AND CONFORMITY: KRS 309.404(4) and 309.406(1)(a) authorize the board to promulgate administrative regulations governing home medical equipment and service providers. This administrative regulation establishes the minimum requirements for the licensing of a home medical equipment and services provider.

Section 1. License Required. Unless exempted by KRS 309.412(2), an entity engaged in providing home medical equipment and services in the commonwealth shall hold a license.

Section 2. Initial License.

(1) An applicant for licensure that does not currently hold or that has not previously held a license in the commonwealth shall submit:

(a) Form 1, Application for Licensure or Renewal; and

(b) Evidence of the ability to comply with KRS 309.400 through KRS 309.422 and 201 KAR Chapter 47. To demonstrate the ability to comply with those provisions, the applicant shall:

1. At the time of application, submit proof of accreditation or exemption by a national accreditation organization approved by the Centers for Medicare and Medicaid Services that accredits suppliers of durable medical equipment; or

2. Within sixty (60) days of application, submit to an inspection by the board to ensure the applicant's ability to comply with the provisions of KRS 309.400 through KRS 309.422 and 201 KAR Chapter 47. The board shall not consider a license application, a license shall not be issued, and the applicant shall not engage in the business of providing home medical equipment or services until the board is provided a final report from the inspector demonstrating the applicant's ability to comply with the provisions of KRS 309.400 through KRS 309.422 and 201 KAR Chapter 47.

(2)

(a) An applicant issued a license based on proof of accreditation by a national accreditation organization approved by the Centers for Medicare and Medicaid Services shall maintain accreditation during the license period.

1. Each licensee shall advise the board in writing of any change in accreditation, including if the accreditation is revoked, suspended, not renewed, or expires.

2. If the accreditation is revoked, suspended, not renewed, or expires, the licensee shall request and submit to an inspection by the board to ensure the applicant's ability to comply with the provisions of KRS 309.400 through KRS 309.422 and 201 KAR Chapter 47.

(b) An applicant that does not maintain an accreditation by a national accreditation organization approved by the Centers for Medicare and Medicaid Services and is issued a license based upon an inspection by the board to ensure the applicant's ability to comply with the provisions of KRS 309.400 through KRS 309.422 and 201 KAR Chapter 47 shall submit to an annual inspection by the board.

Section 3. License Renewals. A licensee seeking to renew a license shall submit:

(1) Form 1, Application for Licensure or Renewal; and

(2) The evidence required by Section 2(1)(b) of this administrative regulation.

Section 4. Reciprocal Licenses. An applicant seeking licensure pursuant to KRS 309.420 on the basis of reciprocity shall submit:

- (1) Form 1, Application for Licensure or Renewal;
- (2) A certified copy of the applicant's license issued in a contiguous state that grants reciprocity to Kentucky licensees;
- (3) A copy of the applicant's discipline history certified by the licensing authority that issued the license referenced in subsection (2) of this section; and
- (4) The evidence required by Section 2(1)(b) of this administrative regulation.

Section 5.

- (1) Annual Training Requirement. Licensees shall provide to employees and persons engaged in the provision of home medical equipment and services operating under its license at least six (6) hours of annual training related to providing home medical equipment and services, which may be provided in-house by the licensee.
- (2) The training shall include programs in:
 - (a) Infection control and blood borne pathogens;
 - (b) Occupation Safety and Health Administration (OSHA) and safety issues to include fire safety, disaster preparedness, and office security;
 - (c) Health Insurance Portability and Accountability Act of 1996, Pub. L. 104-191 (HIPAA), privacy and security; and
 - (d) Any new home medical equipment or services the licensee plans to provide.

Section 6. Safety Requirements. Each licensee shall:

- (1) Refrain from modifying home medical equipment in a way that might reasonably cause harm to its user;
- (2) Maintain electrical components on licensed premises in a manner to prevent fire or shock hazard;
- (3) Provide adequate lighting for the licensed premises;
- (4) Provide adequate ventilation for the licensed premises;
- (5) If essential to maintain life or if the lack of service might reasonably cause harm to the user, provide services twenty-four (24) hours daily if contracted for by supplier and user;
- (6) Ensure that all home medical equipment is free of defects and operates within the manufacturer's specifications;
- (7) Document the chain of custody and possession of home medical equipment;
- (8) Establish, maintain, and adhere to a protocol for retrieving home medical equipment if a recall is initiated;
- (9) Ensure that home medical equipment bears the appropriate labels, including:
 - (a) Warning labels and tags; and
 - (b) A label that contains the licensee's name, and telephone number;
- (10) Maintain in a secure location all home medical equipment stored on the licensed premises;
- (11) Establish, maintain, and adhere to procedures for accurately and precisely tracking records of all home medical equipment shipped or received that includes the home medical equipment purchased or the services rendered in each transaction, the date of the transaction, the quantity of the transaction, and an itemized description of the home medical equipment and services rendered; and
- (12) Establish, maintain, and adhere to procedures that establish a detailed description of how the operation shall comply with applicable federal, state, or local laws or administrative regulations.

Section 7. Sanitation Requirements. A home medical equipment supplier shall:

- (1) Instruct users of the home medical equipment on proper cleaning techniques as specified by the manufacturer;
- (2) Repair and clean all components of home medical equipment in a confined and properly ventilated area;
- (3) Maintain and store home medical equipment to ensure proper lighting, ventilation, temperature, humidity control, sanitation, space, and security; and
- (4) Establish, maintain, and adhere to a protocol for cleaning and disinfecting home medical equipment that addresses both aerobic and anaerobic pathogens. The protocol shall include:
 - (a) Maintaining segregated areas on the licensed premises and in delivery vehicles for clean, dirty, and contaminated home medical equipment; and
 - (b) Cleaning and disinfecting home medical equipment according to manufacturer specifications.

Section 8. Record Retention and Inspection.

- (1) Licensees shall maintain the following records for a period of at least three (3) years:
 - (a) Invoices and receipts for all home medical equipment and services provided;
 - (b) A complete and accurate list that includes the following information for the licensee's employees:
 1. Names;
 2. Addresses;
 3. Telephone numbers;
 4. Criminal history, if any; and
 5. Dates of employment;
 - (c) Records of training required by Section 5 of this administrative regulation, which shall include:
 1. The names of the persons attending the training;
 2. The date of attendance;
 3. The title of the course;
 4. The entity offering the course; and
 5. A certificate of completion or similar document;
 - (d) Documentation of home medical equipment and services that includes:
 1. The types of home medical equipment;
 2. The manufacturer;
 3. The model number;
 4. The serial number;
 5. Date of repair;
 6. Specific repair made; and
 7. The name of the person performing the repair;
 - (e) Documentation of any complaints received and how the complaint was resolved;
 - (f) Documentation of a function and safety check of home medical equipment that was performed prior to delivery of the home medical equipment and that the user of the home medical equipment is provided instruction on its proper use, safety, and maintenance; and
 - (g) A safety data sheet (SDS) documenting the solutions, products, and procedures used in cleaning and disinfecting home medical equipment.
- (2) A licensee shall provide the records required by subsection (1) of this section to the board for inspection within three (3) business days of a request by the board. The board shall state the location to which the records shall be delivered and if the board shall require electronic or hard copies of the records.

Section 9. Fees.

- (1) License fees. An applicant for licensure shall pay:

- (a) An initial license fee of \$350;
 - (b) A renewal license fee of \$350; or
 - (c) A reciprocal license fee of \$350.
- (2) Inspection fees. An applicant for licensure shall pay the inspection fees established in paragraphs (a) through (c) of this subsection.
- (a) If an inspection is required within the Commonwealth, the fee for the inspection shall be \$350.
 - (b) If an inspection is required outside of the Commonwealth, the fee for the inspection shall be the cost of the inspection, including inspector's hourly rate, mileage, and travel expenses.
 - (c) For any inspection, the sum of \$350 shall be due before the inspection occurs. Any remaining balance shall be payable before the license is issued.
- (3) Other fees.
- (a) Duplicate License fee shall be twenty-five (25) dollars.
 - (b) License verification fee shall be ten (10) dollars.
 - (c) Mailing list fee for a noncommercial purpose shall be fifteen (15) dollars.
 - (d) Mailing list fee for a commercial purpose shall be seventy-five (75) dollars.

Section 10. Department of Professional Licensing. Pursuant to KRS 309.404, 324B.030, and 324B.040, the Department of Professional Licensing may accept payments, employ inspectors, receive complaints, and receive appeals on behalf of the board.

Section 11. Incorporation by Reference.

- (1) Form 1, "Application for Licensure or Renewal", June 2021, is incorporated by reference.
 - (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Department of Professional Licensing, 500 Mero Street, 23SC32, Frankfort, Kentucky 40601, Monday through Friday, 8:00 a.m. to 4:30 p.m., and is available at <http://kbdmes.ky.gov/>.
- (43 Ky.R. 641, 1170; eff. 2-3-2017; TAm eff. 10-16-2020; 48 Ky.R. 543, 1527; eff. 11-23-2021.)