BOARDS AND COMMISSIONS

KENTUCKY BOARD OF DURABLE MEDICAL EQUIPMENT SUPPLIERS

(Amendment)

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

RELATES TO: KRS[~~17.500, Chapter 209, 224.10-052,~~] 309.404, 309.406, 309.412, 309.414, 309.416, 309.418, 309.420, 324B.030 and 324B.040[~~439.3401~~]

STATUTORY AUTHORITY: KRS 309.404, 309.406, 309.412, 309.414, 309.416, 309.418, 309.420, 324B.030 and 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 [~~a person~~]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, [~~An~~]Application for Licensure[~~Home Medical Equipment License~~] or Renewal; and

(b) [~~A license fee of $350; and~~

~~(c)~~]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, [~~An~~]Application for Licensure[~~Home Medical Equipment License~~] or Renewal; and

(2) The evidence required by Section 2(1)(b[~~c~~]) of this administrative regulation[~~; and~~

~~(3) A license renewal fee of $350~~].

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

(1) Form 1, [~~An~~]Application for Home Medical Equipment License or Renewal;

(2) A certified copy of the applicant's license issued in a contiguous state which grants reciprocity to Kentucky licensees[~~another state~~];

(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[~~c~~]) of this administrative regulation[~~;~~

~~and~~

~~(4) A reciprocal license fee of $350~~].

Section 5. [~~License Fee Refunds. If an applicant's license is denied or remains incomplete for more than sixty (60) days following submission, $150 of the license fee shall be refunded to the applicant.~~

~~Section 6.~~](1) Annual Training Requirement. Licenses 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)[~~OSHA~~] and safety issues to include fire safety, disaster preparedness, and office security;

(c) Health Insurance Portability and Accountability Act of 1996 (HIPAA)[~~HIPAA~~], privacy and security; and

(d) Any new home medical equipment or services the licensee plans to provide.

Section 6[~~7~~]. 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, [~~address,~~]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 set forth a detailed description of how the operation will comply with applicable federal, state, or local laws or administrative regulations.

Section 7[~~8~~]. 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) Maintain 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[~~9~~]. 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[~~6~~] 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 [~~material~~]safety data sheet (SDS)[~~(MSDS)~~] 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 specify the location to which the records shall be delivered and if the board shall require electronic or hard copies of the records.

Section 9.[~~10. Other fees. Pursuant to KRS 309.406(1)(f), the board shall charge the following fees for services~~] Fees. (1) License fees. An applicant for licensure shall pay the following licensing fees:

(a) An initial license fee of three hundred and fifty dollars ($350);

(b) A renewal license fee of three hundred and fifty dollars ($350); and

(c) A reciprocal license fee of three hundred and fifty dollars ($350).

(2) Inspection fees. An applicant for licensure shall pay the following inspection fees:

(a) If an inspection is required within the Commonwealth, the fee for such inspection shall be three hundred and fifty dollars ($350);

(b) If an inspection is required outside of the Commonwealth, the fee for such inspection shall be the cost of the inspection, including inspector's hourly rate, mileage, and travel expenses; and

(c) For any inspection, the sum of three hundred and fifty dollars ($350) is due before the inspection occurs. Any remaining balance is payable before the license is issued.

(3) Other fees:

(a) Duplicate License fee of twenty-five dollars ($25);

(b) License verification fee of ten dollars ($10);

(c) Mailing list fee for a noncommercial purpose of fifteen dollars ($15); and

(d) Mailing list fee for a commercial purpose of seventy-five dollars ($75).

~~Service~~	~~Fee~~
~~Duplicate license~~	~~$15~~
~~Discipline history~~	~~$15~~
~~Paper copies of documents~~	~~$.10 per page if for a noncommercial purpose; or $.25 per page if for a commercial purpose~~
~~Disks~~	~~$2.00 per disk if for a noncommercial purpose; or $10.00 per disk if for a commercial purpose~~
~~Mailing lists~~	~~$15.00 per list if for a noncommercial purpose; or $75.00 per list if for a commercial purpose~~

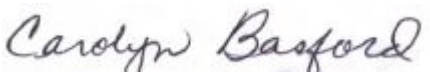
Section 10[~~11~~]. Department of Professional Licensing. Pursuant to KRS 309.404, 324B.030 and 324B.040[~~224.10-052~~], the Department of Professional Licensing may accept payments,

employ inspectors, receive complaints, and receive appeals on behalf of the board.

Section 11[~~12~~]. Incorporation by Reference. (1) Form 1, "Application for Licensure[~~Home Medical Equipment License~~] or Renewal", June 2021[~~December 2016~~], 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/.

READ AND APPROVED:



Carolyn R. Basford, President and Chairperson
Board of Durable Medical Equipment Suppliers

Date: July 14, 2021

PUBLIC HEARING AND PUBLIC COMMENT PERIOD

A public hearing on this administrative regulation shall be held at 1:00 PM EST on September 28, 2021, at 500 Mero Street, 127CW, Frankfort, Kentucky 40601. All attendees shall comply with all Executive Orders relating to the State of Emergency as may be in effect on the date of the public hearing, which may be found at: https://governor.ky.gov/covid-19. Members of the public may utilize the following link to attend the meeting by video conference:

Topic: DME REGULATIONS PUBLIC HEARING
Time: Sep 28, 2021 01:00 PM Eastern Time (US and Canada)

Join from PC, Mac, Linux, iOS or Android:
https://us02web.zoom.us/j/82542024981?pwd=Z2cwZVpxYkhSREVKeC9qR1F1NWw4QT09
Password: 420731

Or Telephone:
Dial:
USA 713 353 0212
USA 8888227517 (US Toll Free)
Conference code: 497796

Find local AT&T Numbers:
https://www.teleconference.att.com/servlet/glbAccess?process=1&accessNumber=7133530212&accessCode=497796

Or an H.323/SIP room system:
H.323:
162.255.37.11 (US West)
162.255.36.11 (US East)
115.114.131.7 (India Mumbai)
115.114.115.7 (India Hyderabad)
213.19.144.110 (Amsterdam Netherlands)
213.244.140.110 (Germany)
103.122.166.55 (Australia Sydney)
103.122.167.55 (Australia Melbourne)
149.137.40.110 (Singapore)
64.211.144.160 (Brazil)
149.137.68.253 (Mexico)
69.174.57.160 (Canada Toronto)
65.39.152.160 (Canada Vancouver)
207.226.132.110 (Japan Tokyo)
149.137.24.110 (Japan Osaka)
Meeting ID: 825 4202 4981
Password: 420731

SIP: 82542024981@zoomcrc.com
Password: 420731

Individuals interested in being heard at this hearing shall notify this agency in writing by five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date (September 21), the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM EST on September 30, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

Contact Person: August L. Pozgay
Title: Attorney for the Board of Durable Medical Equipment Suppliers
Address: 500 Mero Street, 2 SC 32, Frankfort, Kentucky 40601
Phone: +1 (502) 782-0714
Fax: +1 (502) 564-4818
Email: august.pozgay@ky.gov

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Regulation: 201 KAR 47:010
Contact Person: August L. Pozgay
Phone: +1 (502) 782-0714
Email: august.pozgay@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administration clarifies the requirements for a reciprocal license and the fees charged for each type of license. It also adds an inspection fee.

(b) The necessity of this administrative regulation: This administrative regulation is necessary to clarify the requirements for a reciprocal license and the fees charged and to add an inspection fee.

(c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 309.406(1)(a) authorizes the Board to promulgate regulations to regulate matters set forth in KRS 309.400 to 309.422. KRS 309.406(1)(a), KRS 309.406(1)(f), KRS 309.414(1), and KRS 309.416(4) permit the Board to set a reasonable fee schedule. This administrative regulation clarifies the requirements for a reciprocal license and the fees charged and adds an inspection fee.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This regulation assists in the effective administration of KRS Chapter 309 by clarifying the requirements for a reciprocal license and the fees charged and adding an inspection fee.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: The amendment makes minor changes to the fee schedule: it increases the cost of duplicate licenses from $15 to $25; it removes fees charged for a discipline history and discs and for paper copies of documents; and it establishes a license verification fee of $10. It establishes inspection fees to cover the Board's costs in sending inspectors, a flat fee of $350 within the Commonwealth, and the cost of the inspection, including inspector's hourly rate, mileage, and travel expenses, outside of the Commonwealth. The amendment does not change the current licensing and renewal fees, although it does recodify those fees into one section, at Section 9.

(b) The necessity of the amendment to this administrative regulation: The amendment is necessary to cover the cost of sending inspectors to inspect licensees and prospective licensees and to ensure fiscally responsible use of the Board's revolving fund in accordance with KRS 309.404(9) and 309.408. The regulation is being amended to address the situation where the Board conducts an investigation as requested by an entity in accordance with Section 2(1)(b)2., Section 2(2)(a)2., and Section 2(2)(b), and the inspection identifies such deficiencies that the entity does not qualify for licensure. Under the current regulation, in such an instance, the costs

of the investigation are born by the Board, rather than the entity. With this amendment, the Board will be able to recoup the cost of investigation. Additionally, the cost for charging minor fees for discs and copy paper was administratively cumbersome and there is now the option of secure digital transfer by email. Finally, the amendment is necessary to set a fee for license verification.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 309.406(1)(a) authorizes the Board to promulgate regulations to regulate matters set forth in KRS 309.400 to 309.422. KRS 309.406(1)(a), KRS 309.406(1)(f), KRS 309.414(1), and KRS 309.416(4) permit the Board to set a reasonable fee schedule. This administrative regulation establishes a reasonable fee schedule and clarifies the requirements for a reciprocal license.

(d) How the amendment will assist in the effective administration of the statutes: This amendment assists in the effective administration of KRS Chapter 309 by carrying out the legislative mandate for the Board to set reasonable fees.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: This regulation will affect the Board, 814 licensees of the Board, as well as an unknown number of businesses that may request inspections for licensure in accordance with Section 2(1)(b)2., Section 2(2)(a)2., and Section 2(2)(b). The Board is an independent state agency and state and local governments are unlikely to be affected by this regulation.

(4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: No action is required of the regulated entities to comply with this regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: There is no regular cost to the regulated entities. For entities that do not maintain an accreditation by a national accreditation organization approved by the Centers for Medicare and Medicaid Services that accredits suppliers of durable medical equipment, and therefore require an inspection by the Board in order to obtain licensure in accordance with Section 2(1)(b)2., Section 2(2)(a)2., and Section 2(2)(b), the entity shall now pay a fee for the cost of inspection as set forth in Section 9(2).

(c) As a result of compliance, what benefits will accrue to the entities: This regulation will ensure that inspections that do not result in licensure will not deplete Board funds necessary to fulfill its other duties to licensed entities in ensuring effective oversight of manufacturers and wholesale distributors of home medical equipment and home medical equipment and services providers.

(5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially: This administrative regulation does not create a cost for the administrative body.

(b) On a continuing basis: This administrative regulation does not create a cost for the administrative body.

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Board is self-funded through the fees paid by licensees. No additional funding is necessary for the implementation and enforcement of this administrative regulation.

(7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increases in fees or funding is necessary to implement the amendment to this administrative regulation.

(8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: This regulation indirectly increases the cost of licensure where applicants require an inspection, by requiring the applicant to pay for the Board's inspection. This applies to those licensees that do not maintain an accreditation by a national accreditation organization approved by the Centers for Medicare and Medicaid Services that accredits suppliers of durable medical equipment.

(9) TIERING: Is tiering applied? Tiering is not applied because it only affects the Board of Durable Medical Equipment Suppliers and its licensees.

FISCAL NOTE ON STATE OR LOCAL GOVERNMENT

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Kentucky Board of Durable Medical Equipment Suppliers (the "Board").

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation: KRS Chapter 309.400 to 309.422.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? This regulation will not generate revenue for the Board of Durable Medical Equipment Suppliers, but be used to pay the inspector.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? All revenue generated will be used to pay the inspector.

(c) How much will it cost to administer this program for the first year? There will be no additional cost to the agency.

(d) How much will it cost to administer this program for subsequent years? There will be no additional cost to the agency.

Revenues (+/-): Neutral
Expenditures (+/-): Neutral
Other Explanation: None

SUMMARY OF CHANGES TO MATERIAL INCORPORATED BY REFERENCE

Contact Person: August L. Pozgay
Title: Attorney for the Board of Durable Medical Equipment Suppliers
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Fax: +1 (502) 564-4818
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"Form 1, Application for Licensure or Renewal," June 2021, is a two (2) page form used by new applicants seeking licensure by the Kentucky Board of Durable Medical Equipment Suppliers (the Board) and licensees seeking renewal of their licenses. It amends the "Application for Home Medical Equipment License or Renewal," December 2016.

The proposed amendment to this form makes the following changes: (1) simplifies the title of the form; (2) clarifies that the applicant must provide a home office physical location as well as business premises and contact information; (3) requests the applicant provide personal telephone and email addresses; (4) renumbers the questions on the form; (5) inserts the term, "contiguous," to the term, "states" in the question at section C.; (6) adds a question asking for the statutory basis for the reciprocity claimed by the applicant; (7) adds a statement above the signature block that the applicant's certification is under penalty of perjury; and (8) removes the revision designation, "December 2016," and replaces it with the revision as reviewed by the Board, "June 2021."