2	KENTUCKY BOARD OF DURABLE MEDICAL EQUIPMENT SUPPLIERS
3	(New Administrative Regulation)
4	201 KAR 47:030. Complaint and Disciplinary Process.
5	RELATES TO: KRS 309.406, 309.412, 309.414, 309.416, 309.418, 309.420
6	STATUTORY AUTHORITY: <u>KRS[309.404,]</u> 309.406[309.412, 309.414, 309.416], 309.418[,
7	309.420]
8	NECESSITY, FUNCTION, AND CONFORMITY: KRS[309.404(4) and] 309.406(1)(<u>d[</u> a])
9	authorize the board to promulgate administrative regulations governing home medical equipment
10	and service providers. KRS 309.406(1)(d) authorizes the board to investigate complaints or
11	violations of the home medical equipment laws and the administrative regulations. This
12	administrative regulation details the process by which the board investigates complaints and
13	violations.
14	Section 1. Definitions. (1) "Board" is defined by KRS 309.402.
15	(2) "Charge" means a specific allegation contained in a document issued by the board or
16	hearing panel alleging a violation of a specified provision of KRS 309.400 through 309.422 or
17	201 KAR Chapter 47.
18	(3) "Complaint" means a written complaint alleging a violation of KRS 309.400 through
19	309.422 and 201 KAR Chapter 47.

BOARDS AND COMMISSIONS

(4) "Complainant" means a person who files a complaint pursuant to this administrative
 regulation.

3 (5) "Complaint Committee" means the committee appointed pursuant to Section 2 of this
4 administrative regulation.

(6) "Formal complaint" means a formal administrative pleading or notice of
administrative hearing authorized by the board that sets forth charges against a licensee or
applicant and commences a formal disciplinary proceeding in accordance with KRS Chapter
13B.

9 (7) "Initiating complaint" means an allegation alleging misconduct by a licensee or
10 applicant or alleging that an unlicensed person is engaging in unlicensed practice or using a title
11 without holding a license.

12 (8) "Order" means the whole or a part of a final disposition of a hearing.

(9) "Respondent" means the individual or entity against whom an initiating or a formal
complaint has been made.

Section 2. Initiating Complaint. (1) An initiating complaint may be initiated by the board,
 an individual, an organization, an entity, or a governmental agency. A certified copy of a court

17 record for a misdemeanor or felony conviction shall be considered a valid initiating complaint.

18 (2) Initiating complaints shall:

19 (a) Be in writing;

20 (b) Clearly identify the individual or entity against whom the initiating complaint is being
21 made;

22 (c) Contain the date;

23 (d) Identify the individual or entity making the initiating complaint; and

(e) Contain a clear and concise statement of the facts giving rise to the initiating
 complaint.

(3) An initiating complaint may be submitted to the Board in any manner.

4 (4) Upon receipt of an initiating complaint, a copy of the initiating complaint shall be
5 mailed to the respondent along with a request for a response to the complaint within twenty (20)
6 days of the date on which the initiating complaint was received, unless an extension is granted by
7 the board.

8 (5) Upon receipt of the written response of the respondent, a copy of the response shall be 9 sent to the complainant. The complainant shall have seven (7) days from receipt to submit a 10 written reply to the response to the board unless an extension is granted by the board.

11 (6) Complaint Committee.

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12 (a) The complaint committee shall consist of two (2) board members appointed by the13 chair of the board to:

14 1. Review initiating complaints, responses, replies, investigative reports, and any other
relevant material;

16 2. Participate in informal proceedings to resolve formal complaints; and

3. Make recommendations for disposition of initiating complaints and formal complaintsto the full board.

(b) The complaint committee may be assisted by the board staff and counsel to the board.
Section 3. Initial Review. (1) At the next regularly scheduled meeting of the board or as

soon thereafter as practicable, the board, upon recommendation of the complaint committee,

shall determine the proper disposition of the complaint.

1	(2) If the Board determines before formal investigation that the facts alleged in the
2	initiating complaint do not constitute a prima facie violation of KRS 309.400 through 309.422 or
3	201 KAR Chapter 47, the board shall dismiss the complaint and notify the complainant and
4	respondent that no further action shall be taken.
5	(3) If the Board determines that more investigation is warranted, the board shall appoint
6	an agent or representative of the board to investigate the initiating complaint.
7	(4) If the Board determines that there is a prima facie violation of KRS 309.400 through
8	309.422 or 201 KAR Chapter 47, the board shall issue a formal complaint against the
9	respondent.
10	(5) In the case of a prima facie violation of KRS 309.422 and the respondent is not a
11	licensee, the board may take the following actions:
12	(i) Issue a cease and desist;
13	(ii) File an injunction; and
13 14	(ii) File an injunction; and(iii) Seek criminal prosecution pursuant to KRS 309.422.
14	(iii) Seek criminal prosecution pursuant to KRS 309.422.
14 15	(iii) Seek criminal prosecution pursuant to KRS 309.422.Section 4. Final Review. (1) Upon the completion of the investigation, the person or
14 15 16	(iii) Seek criminal prosecution pursuant to KRS 309.422.Section 4. Final Review. (1) Upon the completion of the investigation, the person or persons making that investigation shall submit a written report to the board containing a succinct
14 15 16 17	(iii) Seek criminal prosecution pursuant to KRS 309.422.Section 4. Final Review. (1) Upon the completion of the investigation, the person or persons making that investigation shall submit a written report to the board containing a succinct statement of the facts disclosed by the investigation.
14 15 16 17 18	 (iii) Seek criminal prosecution pursuant to KRS 309.422. Section 4. Final Review. (1) Upon the completion of the investigation, the person or persons making that investigation shall submit a written report to the board containing a succinct statement of the facts disclosed by the investigation. (2) Based on consideration of the complaint, response, reply, the investigative report, if
14 15 16 17 18 19	 (iii) Seek criminal prosecution pursuant to KRS 309.422. Section 4. Final Review. (1) Upon the completion of the investigation, the person or persons making that investigation shall submit a written report to the board containing a succinct statement of the facts disclosed by the investigation. (2) Based on consideration of the complaint, response, reply, the investigative report, if any, and any other relevant evidence, the board shall determine if there has been a prima facie

dismiss the complaint and notify the complainant and the respondent that no further action shall
 be taken.

3 (4) If the Board determines that there is a violation of KRS 309.400 through 309.422 or 4 201 KAR Chapter 47, the board shall issue a formal complaint against the respondent. 5 (5) In the case of a violation of KRS 309.422 and the respondent is not a licensee, the 6 board may take the following actions: 7 (i) Issue a cease and desist; 8 (ii) File an injunction; and 9 (iii) Seek criminal prosecution pursuant to KRS 309.422. 10 Section 5. Settlement by Informal Proceedings. (1) The board, at any time during this 11 process, may enter into informal proceedings with the respondent for the purpose of 12 appropriately dispensing with the matter. 13 (2) An agreed order or settlement reached through this process shall be approved by the 14 board and signed by the chair and the respondent. 15 (3) The board may employ mediation as a method of resolving the matter informally. 16 (4) The board may, at any time during this process, issue a letter of admonishment to the 17 respondent as a means of resolving the complaint. Within thirty (30) day of the date of the letter, 18 the respondent shall have the right to file a written response to the letter and have it attached to 19 the letter of admonishment and placed in the file. The respondent shall also, within thirty (30) 20 days of the date of the letter, have the right to appeal the letter of admonishment and be granted a 21 full hearing on the complaint. If this appeal is requested, the board shall immediately file a 22 formal complaint in regard to this matter and set a date for hearing.

1	Section 6. Formal Complaint. (1) If the board votes to file a formal complaint, a notice of
2	administrative hearing shall be filed as required by KRS 13B.050.
3	(2) Within twenty (20) days of service of the notice of administrative hearing, the
4	respondent shall file with the board a written response to the specific allegations set forth in the
5	notice of administrative hearing.
6	(3) Allegations not properly responded to shall be deemed admitted.
7	(4) The board may, if there is good cause, permit the late filing of a response.
8	Section 7. Composition of the Hearing Panel. Disciplinary actions shall be heard by:
9	(1) The full board or a quorum of the board;
10	(2) A hearing panel consisting of at least one (1) board member appointed by the board;
11	or
12	(3) The hearing officer alone in accordance with KRS 13B.030(1).
13	Section 8. Notification. Upon final resolution of a complaint submitted pursuant to this
14	process, the board shall notify the complainant and the respondent of the outcome of the action
15	in writing.

READ AND APPROVED:

Carolyn Basford

Carolyn R. Basford, President and Chairperson Kentucky 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: <u>https://governor.ky.gov/covid-19</u>. 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=713 3530212&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 21:035 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: KRS 309.406(1)(a) authorizes the Kentucky Board of Durable Medical Equipment Suppliers (the Board) to promulgate administrative regulations consistent with KRS Chapter 309, relating to manufacturers and wholesale distributors of home medical equipment and home medical equipment and services providers in this state. KRS 309.406(1)(d) authorizes the Board to investigate complaints and violations of the home medical equipment laws and the administrative regulations promulgated by the board. KRS 309.406(2) authorizes the Board to seek recoupment of the cost of its investigations and prosecutions. KRS 309.418(2) authorizes the Board to refuse to issue or renew a license, suspend, temporarily suspend, revoke, fine, place on probation, reprimand, reasonably restrict, or take any combination of these actions against any licensees for reasons set forth by the statute. KRS 309.422 establishes the penalty for unlicensed practice. This administrative regulation establishes the process by which the Board investigates complaints and violations, including the opportunity for the investigated party to respond to allegations, and the opportunity for a complainant to reply to the investigated party's response. The regulation also sets forth the appeal process to appeal a Board action taken following the Board's investigation.

(b) The necessity of this administrative regulation: This administrative regulation is permitted by KRS 309.406(1)(a), (1)(d), and (2), and by KRS 309.418. It is necessary to establish a complaint process to ensure effective Board oversight and clarify the Board's obligations and a licensee's rights and responsibilities in accordance with KRS Chapter 13B.

(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 and control matters set forth in KRS 309.400 to 309.422. KRS 309.406(1)(a), (1)(d), and (2), KRS 309.418, and KRS 309.422 authorize the Board to take administrative action regarding complaints and investigations and sets forth the range of penalties the Board may impose. This administrative regulation establishes the process by which the Board investigates complaints and violations as authorized by statute.

(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 309.400 through 309.422 by establishing a complaint and investigation process so that licensees and the public understand and may avail themselves of the Board process, and ensures that the Board has a clear process to address complaints as they arise.

(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: This is a new regulation and is not an amendment.

(b) The necessity of the amendment to this administrative regulation: This is a new regulation and is not an amendment.

(c) How the amendment conforms to the content of the authorizing statutes: This is a new regulation and is not an amendment.

(d) How the amendment will assist in the effective administration of the statutes: This is a new regulation and is not an amendment.

(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 members of the public and public businesses and organizations that may seek to file complaints. In calendar year 2020, the Board received 0 complaints. 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. In the event a regulated entity seeks to respond to a complaint or appeal a Board action, the regulation will guide the entity to the applicable timeframe and process.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: There is no cost to the regulated entities other than the *de minimis* cost of an entity's correspondence with the Board.

(c) As a result of compliance, what benefits will accrue to the entities: This regulation establishes an informal and formal complaint process, as well as appeal process, so that entities may avail themselves of their rights and fulfill their responsibilities regarding Board investigations.

(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 did not establish any fees.

(9) TIERING: Is tiering applied? This regulation does not distinguish between similarly situated individuals on the basis of any factor.

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 state or local government.

(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? This regulation will not generate revenue for state or local government.

(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