KENTUCKY BOARD OF MEDICAL LICENSURE (New Administrative Regulation)

201 KAR 9:067. Professional standards and procedures for medicinal cannabis practitioners.

RELATES TO: KRS 218B.015, 218B.050. 218B.202, 311.592, 311.595, 311.599 STATUTORY AUTHORITY: KRS 218B.050(10), 311.565(1)(a)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 311.565(1)(a) authorizes the board to promulgate administrative regulations to regulate the conduct of its licensees. KRS 218B.050(10) requires that the board promulgate administrative regulations to establish procedures for applying for authorization to provide written certifications; the conditions that must be met to be eligible for authorization to provide written certifications; the process and procedures for renewing authorization to provide written certifications; continuing education requirements for medicinal cannabis practitioners; reasons for which authorization to provide written certifications may be suspended or revoked; and the minimal standards of care, including record maintenance and follow up care requirements.

Section 1. Definitions.

- (1) "Board" means the Kentucky Board of Medical Licensure.
- (2) "Bona fide practitioner-patient relationship" is defined by KRS 218B.010(1).
- (3) "Cabinet" is defined by KRS 218B.010(2).
- (4) "Good standing" means a license that is at the time of initial application or renewal:(a) Active;
 - (b) Not the subject of a pending board investigation;

(c) Not probated, limited, restricted, suspended, revoked, or subject to peer assistance; and

(d) Not held by a person who has ever been subject to disciplinary action by a licensing entity of any jurisdiction, including the board or the U.S. Drug Enforcement Administration (DEA), that was based, in whole or in part, on the person's inappropriate prescribing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.

(5) "Immediate family member" means husband or wife; natural or adoptive parent; child or sibling; stepparent, stepchild, stepbrother or stepsister; father-in-law, mother-in-law, son-in-law, daughter-in-law, brother-in-law or sister-in-law; grandparent or grandchild; spouse of a grandparent or grandchild; or any person residing in the same residence as the medicinal cannabis practitioner.

(6) "Licensee" means a person licensed by the board to practice medicine or osteopathy in the Commonwealth of Kentucky.

(7) "Medicinal cannabis" is defined by KRS 218B.010(15).

(8) "Medicinal cannabis practitioner" means a medical or osteopathic physician who is authorized to prescribe controlled substances and who is authorized to by the board to provide written certifications pursuant to KRS 218B.050 and this administrative regulation.

(9) "Minor" is defined by KRS 218B.010(19).

(10) "PDMP" means the electronic prescription drug monitoring program system for monitoring scheduled controlled substances and medicinal cannabis currently in use in Kentucky pursuant to KRS 218A.202, including the Kentucky All Schedule Prescription Electronic Reporting (KASPER) System.

(11) "Qualified patient" is defined by KRS 218B.010(25).

(12) "Qualifying medical condition" is defined by KRS 218B.010(26).

(13) "Telehealth" is defined by KRS 211.332(5).

(14) "Use of medicinal cannabis" is defined by KRS 218B.010(37).

(15) "Written certification" is defined by KRS 218B.010(39).

Section 2. Applicability. The procedures and standards established in this administrative regulation shall not apply to a licensee who recommends treatment with cannabis or a drug derived from cannabis in accordance with KRS 218B.050(11).

Section 3. Eligibility for Authorization to Provide Written Certifications. A licensee shall be eligible to provide written certifications for the use of medicinal cannabis, pursuant to KRS 218B.050 within the Commonwealth of Kentucky, if the licensee:

(1) Holds a license issued by the board to practice medicine or osteopathy in the Commonwealth of Kentucky in good standing;

(2) Holds a valid DEA permit;

(3) Is registered to use any and all PDMP currently in use in the Commonwealth of Kentucky pursuant to KRS 218A.202;

(4) Holds no ownership or investment interest in or compensation agreement with a cannabis business licensed under KRS Chapter 218B;

(5) Pursuant to Section 6 of this administrative regulation, has completed the required number of hours of education in a course or courses approved by the board specific to the following:

(a) Diagnosing qualifying medical conditions;

(b) Treating qualifying medical conditions with medicinal cannabis; and

(c) The characteristics of medicinal cannabis and possible drug interactions; and

(6) Has submitted an initial or renewal application for authorization to provide written certifications for the use of medicinal cannabis and received confirmation of its process pursuant to Sections 4 and 5 of this administrative regulation.

Section 4. Procedures for Submitting an Initial Application for Authorization to Provide Written Certifications.

(1) To become a medicinal cannabis practitioner an initial applicant shall:

(a) Submit to the board a completed Initial Application for Authorization to Provide Written Certifications for the Use of Medicinal Cannabis;

(b) Submit proof of completion of six (6) hours of education established in Section 6 of this administrative regulation; and

(c) Submit payment of a non-refundable fee of \$100.

(2) Upon receipt of an initial application, the board shall review all application materials submitted and determine whether the licensee meets qualifications to become a medicinal cannabis practitioner.

(a) The board may contact individuals, agencies, or organizations for information about the licensee.

(b) If deemed appropriate by the board or its staff, the board may require a licensee to appear before the board to answer questions or provide additional information deemed appropriate for the board to make an informed decision about the licensee's qualifications.

(c) If the board or its staff determines that the licensee is not qualified to become a medicinal cannabis practitioner or if the board or its staff is unable to independently verify whether the licensee meets the qualifications to become a medicinal cannabis practitioner, the board shall notify the licensee of the grounds upon which the initial application cannot be approved.

(3) A licensee shall become an authorized medicinal cannabis practitioner effective upon written or electronic notification from the board the initial application has been processed and approved.

(4) Unless initially issued or annually renewed between January 1 and March 1 in accordance with Section 5 of this administrative regulation, the authorization to provide written certifications for the use of medicinal cannabis shall expire on March 1.

(5) If a medicinal cannabis practitioner fails to renew before March 1 of any subsequent year, the practitioner may apply as an initial applicant in accordance with the procedures established in this section.

Section 5. Process and Procedures for Renewing Authorization to Provide Written Certifications.

(1) If a medicinal cannabis practitioner fails to renew his or her medical license and authorization by March 1 of any calendar year following the calendar year of initial application, the authorization shall become inactive.

(2) On or about January 1 of each calendar year after initial issuance, the board shall send notification to all medicinal cannabis practitioners that annual renewal of their authorization must be executed on or before March 1. The notification shall indicate the annual renewal fee and shall advise the medicinal cannabis practitioner that failure to timely renew by March 1 shall cause his or her authorization to become inactive. (3)

(a) All notifications required to be sent by this administrative regulation shall be sent either:

1. By mail to the medicinal cannabis practitioner's last known address of which the board has record; or

2. Electronically to the medicinal cannabis practitioner 's last known email address of which the board has record.

(b) Failure of the medicinal cannabis practitioner to receive notice if sent to the last known address or last known email address shall not excuse the medicinal cannabis practitioner from compliance with KRS Chapter 218B or this administrative regulation.

(4) To renew an authorization to provide written certifications, a medicinal cannabis practitioner shall:

(a) Submit to the board a completed Renewal Application for Authorization to Provide Written Certifications for the Use of Medicinal Cannabis;

(b) Attest to the completion of three (3) hours of education established in Section 6 of this administrative regulation; and

(c) Submit payment of a non-refundable fee of \$100.

Section 6. Continuing Education.

(1) A medicinal cannabis practitioner shall not issue a written certification for use of medicinal cannabis to any patient unless that licensee has completed the minimum hours of continuing medical education established in this section.

(2) Within the immediate twelve (12) months prior to submitting an initial application, a medicinal cannabis practitioner shall complete at least six (6) hours of continuing medical education certified in Category I specific to the following:

(a) Diagnosing qualifying medical conditions;

(b) Treating qualifying medical conditions with medicinal cannabis; and

(c) The characteristics of medicinal cannabis and possible drug interactions.

(3) Within the immediate twelve (12) months prior to submitting a renewal application, a medicinal cannabis practitioner shall complete at least three (3) hours of continuing medical education certified in Category I specific to the following:

(a) Diagnosing qualifying medical conditions;

(b) Treating qualifying medical conditions with medicinal cannabis; and

(c) The characteristics of medicinal cannabis and possible drug interactions.

Section 7. Reasons for which Authorization to Provide Written Certifications for the Use of Medicinal Cannabis may be Suspended or Revoked.

(1) The board may probate, restrict, suspend, or revoke a medicinal cannabis practitioner's authorization to provide written certifications upon proof that the medicinal cannabis practitioner has violated any of the provisions established in KRS 311.595 or violations in accordance with KRS 218B.015(3)(b).

(2) The board may probate, restrict, suspend, or revoke a medicinal cannabis practitioner's authorization to provide written certifications upon proof that the medicinal cannabis practitioner has provided a written certification to an immediate family member of the medicinal cannabis practitioner.

(3) Notwithstanding subsections (1) and (2) of this section, the board may issue an emergency order, in accordance with KRS 311.592 and KRS 13B.125, suspending, limiting, or restricting a medicinal cannabis practitioner's authorization to provide written certifications at any time that the board has probable cause to believe that:

(a) In accordance with KRS 218B.015(3)(b), the medicinal cannabis practitioner has violated any provision of KRS Chapter 218B;

(b) The medicinal cannabis practitioner has actively engaged in the practice of medicine or osteopathy or operated a motor vehicle while under the influence of or while consuming medicinal cannabis;

(c) The medicinal cannabis practitioner has become impaired by or otherwise abused medicinal cannabis;

(d) The medicinal cannabis practitioner has a medically diagnosable disease that is characterized by chronic, habitual or periodic use of medicinal cannabis resulting in interference with his or her professional, social, or economic functions in the community or the loss of powers of self-control regarding the use of medicinal cannabis;

(e) The medicinal cannabis practitioner has violated the terms of an agreed order or a disciplinary order; or

(f) The medicinal cannabis practitioner's practice constitutes a danger to the health, welfare, and safety of patients or the general public.

(4) A medicinal cannabis practitioner may be ordered by the board to submit to a mental or physical examination, including impairment evaluation, in accordance with KRS 311.599.

Section 8. Minimal Standards of Care for Providing Written Certifications.

(1) A medicinal cannabis practitioner shall only provide a patient with a written certification after the medicinal cannabis practitioner has complied with the requirements established by KRS 218B.050(4).

(2) A bona fide practitioner-patient relationship may be established pursuant to KRS 218B.050(5).

(3) A medicinal cannabis practitioner shall comply with the written certification requirements established by KRS 218B.050(6).

(4) A medicinal cannabis practitioner shall comply with the professional standards established in this subsection.

(a) Prior to providing a written certification, the medicinal cannabis practitioner shall obtain and document all relevant information in a patient's medical record in a legible manner and in sufficient detail to enable the board to determine whether the licensee is conforming to the requirements of KRS Chapter 218B and this administrative regulation. Relevant information shall include as appropriate:

1. The patient's medical history, including:

a. The patient's mental health and psychiatric history;

b. The patient's history of drug use, including a documented review of the patient's current medication to identify possible drug interactions, including benzodiazepines and opioids;

c. Prior treatments; and

d. Diagnostic, therapeutic, and laboratory results;

2. A focused physical examination relevant to the patient's medical condition;

3. Evaluations and consultations;

4. Diagnosis of the patient's qualifying medical condition;

5. Treatment objectives with use of medicinal cannabis;

6. Discussion of risk, benefits, limitations, and alternatives to the of use of medicinal cannabis;

7. Written informed consent;

8. Instructions and agreements;

9. Periodic reviews of the patient's file;

10. Follow up evaluations; and

11. Results and analysis of the patient's PDMP information.

(b) Prior to providing an initial written certification or renewing a written certification, the medicinal cannabis practitioner shall query and review a PDMP report for the patient for the twelve (12) month period immediately preceding the written certification and appropriately utilize that information in the evaluation and treatment of the patient.

(c) If the patient is a female of childbearing potential and age, the medicinal cannabis practitioner shall require the patient to submit to a pregnancy test and shall factor the results of that test into the clinical decision as to the appropriateness of the use of medicinal cannabis.

(d) Based on evidence or behavioral indications of addiction or drug abuse, the medicinal cannabis practitioner shall obtain a drug screen on the patient. It shall be within the medicinal cannabis practitioner's discretion to decide the nature of the screen and which type of drug to be screened.

(e) A medicinal cannabis practitioner shall be available to provide follow-up care and treatment to the patient, including physical examinations relevant to the patient's condition to determine the efficacy of medicinal cannabis in treating the patient's qualifying medical condition. If the qualifying condition was indicated as a terminal illness in the prior six (6) months, the medicinal cannabis practitioner shall confirm whether the patient's condition continues to be a terminal illness.

(f) A medicinal cannabis practitioner shall terminate or decline to issue a new written certification to a patient, and shall notify the cabinet in writing of the patient's name, under any of the following circumstances:

1. The patient no longer has the diagnosis of or symptoms of the qualifying medical condition;

2. The medicinal cannabis practitioner is not authorized to issue a written certification;

3. The medicinal cannabis practitioner's has reason to believe that the patient or a caregiver is abusing or diverting medicinal cannabis; or

4. The patient is deceased.

(g) If the medicinal cannabis practitioner is unable to conform to professional standards established in this administrative regulation due to circumstances beyond the licensee's control, or the medicinal cannabis practitioner makes a professional determination that it is not appropriate to comply with a specific standard established in this administrative regulation based upon the individual facts applicable to a specific patient's diagnosis and treatment, the medicinal cannabis practitioner shall document those circumstances in the patient's record and only provide a written certification to

the patient if the patient record appropriately justifies the use of medicinal cannabis under the circumstances.

Section 9. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Initial Application for Authorization to Provide Written Certifications for the Use of Medicinal Cannabis"; and

(b) "Renewal Application for Authorization to Provide Written Certifications for the Use of Medicinal Cannabis."

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, Monday through Friday, 8:00 a.m. to 4:30 p.m. This material is also available on the board's Web site at http://kbml.ky.gov.

WILLIAM C. THORNBURY, JR., M.D., Board President

APPROVED BY AGENCY: October 5, 2023

FILED WITH LRC: October 9, 2023 at 10:10 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on December 21, 2023 at 9:30 a.m. at the offices of the Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222. Individuals interested in being heard at this hearing shall notify this agency in writing by December 14, 2023, 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, 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 December 31, 2023. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Leanne K. Diakov, General Counsel, Kentucky Board of Medical Licensure, 310 Whittington Parkway, Suite 1B, Louisville, Kentucky 40222, phone (502) 429-7943, fax (502) 429-7118, email leanne.diakov@ky.gov.