

BOARDS AND COMMISSIONS
Kentucky Board of Medical Licensure
(Amended After Comments)

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

RELATES TO: KRS ~~13B.125~~, 218B.015, 218B.050, ~~218A.202~~, ~~+~~ 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 to promulgate administrative regulations to establish procedures for applying for authorization to provide written certifications; the conditions that ~~shall~~~~must~~ be met to be eligible for authorization to provide written certifications; the process and procedures for renewing authorization to provide written certifications; the continuing education requirements for medicinal cannabis practitioners; the reasons for which authorization to provide written certifications for the use of medicinal cannabis 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 indications of cannabis use disorder; 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 ~~that~~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 ~~shall~~~~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 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 **if,** ~~**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 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

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Leanne K. Diakov

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the qualifications, continuing education requirements, sanctions, and professional standards for physicians (MD/DO) authorized to practice as medicinal cannabis practitioners.

(b) The necessity of this administrative regulation:

This regulation is being promulgated as mandated by the General Assembly to establish standards for physicians (MD/DO) authorized to practice as medicinal cannabis practitioners in the Commonwealth of Kentucky pursuant to KRS Chapter 218B.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

This administrative regulation conforms to the content of the authorizing statutes by establishing the qualifications, continuing education requirements, sanctions, and professional standards for physicians (MD/DO) authorized to practice as medicinal cannabis practitioners.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

This administrative regulation assists in the effective administration of the statutes by setting forth the qualifications, continuing education requirements, sanctions, and professional standards for physicians (MD/DO) authorized to practice as medicinal cannabis practitioners. (2) If this is an amendment to an existing regulation, provide a brief summary of:

(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:

Not applicable.

(b) The necessity of the amendment to this administrative regulation:

Not applicable.

(c) How the amendment conforms to the content of the authorizing statutes:

Not applicable.

(d) How the amendment will assist in the effective administration of the statutes:

Not applicable.

(3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

This regulation may affect physicians with a Drug Enforcement Administration (DEA) registration and who choose to become authorized to practice as medicinal cannabis practitioners. At this time, the number is unknown. (4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this regulation, if new, or by the change, if it is an amendment, including:

(4) Provide an analysis of how the entities identified in question (3) 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 that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment:

No action is required. Physicians who wish to be authorized to practice as medicinal cannabis practitioners will have to submit an application, attest and provide documentation that they satisfy qualifications, and pay a fee.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3):

If a physician wishes to be authorized to practice as a medicinal cannabis practitioner there will be a \$100 initial fee, as well as a \$100 renewal fee each licensure period.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3):

The physician will be authorized to practice as a medicinal cannabis practitioner.

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

(a) Initially:

None

(b) On a continuing basis:

None

(6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation:

Agency funds.

(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:

An increase in fees is not required; however, new fees are established.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

An initial and renewal fee is established. The fee for each \$100.

(9) TIERING: Is tiering applied?

Tiering was not appropriate in this administrative regulation because the administrative regulation applies equally to all those individuals regulated by it.

FISCAL NOTE

(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 Medical Licensure will be impacted by this administrative regulation.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.

: KRS 311.565(1)(a) and KRS Chapter 218B.

(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.

None

(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?

None

(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?

None

(c) How much will it cost to administer this program for the first year?

None

(d) How much will it cost to administer this program for subsequent years?

None

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation:

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year?

None.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years?

None.

(c) How much will it cost the regulated entities for the first year?

The initial application fee is \$100.

(d) How much will it cost the regulated entities for subsequent years?

The annual renewal application fee is \$100.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Cost Savings (+/-):

Expenditures (+/-):

Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below.

"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies." [KRS 13A.010(13)]: This administrative regulation will not have a major economic impact.