

BOARDS AND COMMISSIONS

Board of Nursing

(Amended After Comments)

201 KAR 20:067. Professional standards for medicinal cannabis.

RELATES TO: KRS 218B.010, 218B.015, 218B.050, 218B.080, 314.011, 314.042, 314.085, 314.089, 314.091

STATUTORY AUTHORITY: KRS 218B.010, 218B.015, 218B.050, 218B.080, 314.131

NECESSITY, FUNCTION, AND CONFORMITY: KRS 314.131 authorizes the Board to promulgate administrative regulations to regulate the conduct of its licensees. This administrative regulation establishes the professional standards for APRNs practicing as a medicinal cannabis practitioner.

Section 1. Definitions.

- (1) "Advanced Practice Registered Nurse" or "APRN" is defined by KRS 314.011(7).
- (2) "Authorization" means a credential that authorizes the APRN to provide written certifications under KRS 218B.050 and this administrative regulation.
- (3) "Bona fide practitioner-patient relationship" is defined by KRS 218B.010(1).
- (4) "Cabinet" means the Cabinet for Health and Family Services.
- (5) "Controlled substance" means any Schedule II, III, IV, or V controlled substance and does not include medicinal cannabis.
- (6) "Good standing" means a license that at the time of initial application or renewal, is not:
 - (a) Limited, suspended, probated, revoked, or otherwise disciplined;
 - (b) Under investigation;
 - (c) Subject to monitoring, alternative discipline, or peer assistance; or
 - (d) Held by a person who has ever been subject to disciplinary action by any licensing entity, including the board of any jurisdiction or the United States Drug Enforcement Administration (DEA) that was based, in whole or in part, on the person's inappropriate prescribing, personally furnishing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug.
- (7) "Medicinal cannabis" is defined by KRS 218B.010(15).
- (8) "Medicinal cannabis practitioner" means an APRN who is holds an authorization under this administrative regulation.
- (9) "Minor" means a person less than eighteen (18) years of age.
- (10) "Immediate family member" is defined by 201 KAR 20:057, Section 1(5).
- (11) "Prescription Drug Monitoring Program" or "PDMP" is defined by 201 KAR 20:057, Section 1(11).
- (12) "Qualifying medical condition" is defined by KRS 218B.010(26).
- (13) "Qualified patient" is defined by KRS 218B.010(25).
- (14) "Telehealth" is defined by KRS 211.332(5).
- (15) "Use of medicinal cannabis" is defined by KRS 218B.010(37).
- (16) "Written certification" means a written certification for the use of medicinal cannabis and is defined by KRS 218B.010(39).

Section 2. Applicability. This administrative regulation does not apply to an APRN who recommends treatment with cannabis or a drug derived from cannabis under any of the following that are approved by an investigational review board or equivalent entity, the United States Food and Drug Administration, or the National Institutes for Health or any of its cooperative groups or centers under the United States Department of Health and Human Services:

- (1) A research protocol;

- (2) A clinical trial;
- (3) An investigational new drug application; or
- (4) An expanded access submission.

Section 3. Eligibility for an Authorization.

- (1) An APRN applicant for an authorization shall meet the following requirements:
 - (a) Holds an active, unrestricted Kentucky license as an APRN that is in good standing;
 - (b) Has a DEA registration and a current registration certificate is on file with the board;
 - (c) Has an active account with the PDMP, a current PDMP registration certificate is on file with the board;
 - (d) Has not been denied a license to prescribe, possess, dispense, administer, supply, or sell a controlled substance by the DEA or appropriate issuing body of any state or jurisdiction, based, in whole or in part, on the applicant's inappropriate prescribing, personally furnishing, dispensing, administering, supplying or selling a controlled substance or other dangerous drug;
 - (e) Has not held a license issued by the DEA or a state licensing administration in any jurisdiction, under which the person may prescribe, personally furnish, dispense, possess, administer, supply or sell a controlled substance, that has ever been restricted, based, in whole or in part, on the applicant's inappropriate prescribing, dispensing, administering, supplying, or selling a controlled substance or other dangerous drug;
 - (f) The applicant has not been subject to disciplinary action by any licensing entity that was based, in whole or in part, on the applicant's inappropriate prescribing, personally furnishing, dispensing, diverting, administering, supplying or selling a controlled substance or other dangerous drug; and
 - (g) The applicant has completed the continuing education requirements in Section 6 of this administrative regulation.
 - (h) The applicant has no ownership or investment interest in or compensation agreement with a cannabis business licensed under KRS Chapter 218B.
- (2) The board shall provide the cabinet with the names of all APRNs authorized to provide written certifications.
- (3) An APRN who fails to renew the authorization or is otherwise unable to legally practice as a registered nurse or APRN shall not practice as or use the title of medicinal cannabis practitioner until an authorization has been issued by the board.
- (4) An APRN shall not provide written certifications unless authorized to do so under this section.
- (5) It is not within the scope of practice for an APRN to provide written certifications, unless the APRN is authorized to do so under this section.
- (6) The board shall notify the cabinet immediately with the name of any APRN whose authorization is lapsed, surrendered, suspended, revoked or otherwise not renewed.

Section 4. Procedures for submitting an initial application for authorization.

- (1) An applicant for a certificate to recommend medicinal cannabis shall:
 - (a) Submit to the board an Application for Authorization to Provide Written Certifications for the Use of Medicinal Cannabis;
 - (b) Submit to the board a copy of the APRN's DEA registration certificate;
 - (c) Submit a copy of the PDMP master account registration certificate to the board;
 - (d) Submit proof of completion of the education requirements in Section 6(1) of this administrative regulation; and
 - (e) Pay a nonrefundable fee of \$100.
- (2) An application shall be considered complete if all the following requirements are met:

- (a) Evidence of all the requirements in subsection (1) of this section are received by the board; and
- (b) The APRN is not under investigation pursuant to 201 KAR 20:161 of evidence appearing to show that the applicant has violated KRS 314.091(1).
- (3) Upon receipt of the application:
 - (a) The board shall review all application materials submitted.
 - (b) The board may contact individuals, agencies, or organizations for information about the applicant. As part of the application process, the board may request an applicant to appear before the board to answer questions or provide additional information.
 - (c) An applicant shall not withdraw an application for the authorization to provide written certifications without the approval of the board.
- (4) The following processes apply if an application is not complete within (6) six months of the date the application is received by the board:
 - (a) If the application is not complete because required information or materials have not been received by the board, the board may notify the applicant that it intends to consider the application abandoned if the application is not completed. If an application is abandoned, the board may close the application.
 - 1. The notice shall specifically identify the information or materials required to complete the application and inform the applicant that the information or materials must be received by a specified date.
 - 2. The notice shall also inform the applicant that if the application remains incomplete at the close of business on the specified date the application may be deemed to be abandoned.
 - 3. If all of the information or materials are received by the board by the specified date and the application is determined to be complete, the board shall process the application. The board may require updated information, as it deems necessary.
 - (b) If the application is not complete because the board is investigating the applicant for a violation of KRS 314.091(1), the Board shall do both of the following:
 - 1. Notify the applicant that although otherwise complete, the application shall not be processed pending completion of the investigation; and
 - 2. Upon completion of the investigation and the determination that the applicant is not in violation of KRS 314.091(1), process the application. The board may require updated information, as it deems necessary.
- (5) Once submitted, the Application for Authorization to Provide Written Certifications for the Use of Medicinal Cannabis shall follow the periods for length and renewal in accordance with 201 KAR 20:085, Sections 1 and 2.
- (6) All supporting documentation required under this section shall be submitted via the KBN Nurse Portal at <https://kbn.ky.gov>.

Section 5. Renewal of the Authorization.

- (1) If the APRN fails to renew the authorization in accordance with 201 KAR 20:085, Sections 1 and 2, the authorization shall lapse.
- (2) If the APRN fails to timely renew the authorization, the APRN may reapply as an initial applicant in accordance with the procedures set forth in Section 4 of this administrative regulation.
- (3) The authorization may be renewed after an APRN's license to practice is has been renewed or restored, if the APRN:
 - (a) Meets the requirements in Section 3 of this administrative regulation;
 - (b) Pays a nonrefundable fee of \$100; and
 - (c) Has completed the continuing education requirements in Section 6(2) of this administrative regulation.

(4) All supporting documentation required under this section shall be submitted via the KBN Nurse Portal at <https://kbn.ky.gov>.

Section 6. Continuing Education.

(1) An applicant for an initial authorization shall have completed within the immediate twelve (12) months a one(1) ~~+~~ time requirement of six (6) contact hours within in the following subjects:

- (a) Diagnosing qualifying medical conditions;
- (b) Treating qualifying medical conditions with medicinal cannabis; and
- (c) The pharmacological characteristics of medicinal cannabis and possible drug interactions.

(2) Thereafter, an APRN renewing the authorization shall have obtained during the earning period three (3) continuing education hours in the subjects listed in subsection (1) of this section.

Section 7. Sanctions.

(1) The board may probate, restrict, suspend, revoke, or otherwise discipline an APRN's license or credential to issue authorizations for violations of KRS 314.091(1), or violations in accordance with KRS 218B.015(3)(b).

(2) An investigation against the APRN under this administrative regulation shall be conducted in accordance with 201 KAR 20:161.

(3) A disciplinary proceeding against the APRN under this administrative regulation shall be conducted in accordance with KRS 314.091 and 201 KAR 20:162.

(4) APRN may be ordered by the board to undergo a substance use evaluation and be subject to an immediate temporary suspension, in accordance with KRS 218B.015(4), 314.085, and 314.089.

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

(1) An APRN authorized by the board to provide written certifications may only provide a patient with a written certification after the APRN:

- (a) Has established a bona fide practitioner-patient relationship with the patient in an in-person visit that complies with this administrative regulation and for which there is an expectation that the APRN will provide a plan of care for the patient;
- (b) Has diagnosed the patient, or confirmed a diagnosis provided by another medicinal cannabis practitioner, with a qualifying medical condition for which the medicinal cannabis practitioner believes that the patient may receive therapeutic or palliative benefit from the use of medicinal cannabis;
- (c) Has reviewed a report of information from the PDMP related to the patient for a period of time that covers at least the twelve (12) months immediately preceding the date of the report;
- (d) Consulted with the patient, or the patient's custodial parent or legal guardian responsible for providing consent to treatment if the patient is a minor child, with respect to the possible risks and side effects associated with medicinal cannabis, including possible interactions between medicinal cannabis and any other drug or medication that the patient is taking at that time; and
- (e) Obtained the written consent of the patient's custodial parent or legal guardian responsible for providing consent to treatment, if the patient is a minor child.

(2) A bona fide practitioner-patient relationship may be established following a referral from the patient's primary care provider and may be maintained via telehealth. However, a bona fide practitioner-patient relationship shall not be established via telehealth.

(3)

- (a) When issuing a written certification to a patient, the APRN shall use the Cabinet's Written Certification Form in accordance with KRS 218B.050(6);

(b) An initial written certification shall be provided during the course of an in-person examination of the patient by the APRN. Subsequent written certifications, including for the purpose of renewing a registry identification card, may be provided electronically or during the course of a telehealth consultation.

(c) For the purpose of applying for a registry identification card, a written certification provided under this section shall:

1. Be valid for a period of not more than sixty (60) days;
2. The APRN may renew a written certification for not more than three (3) additional periods of not more than sixty (60) days each; and
3. The APRN shall not issue another certification to the patient until an examination of the patient has been conducted by the APRN.

(d) Within twenty-four (24) hours of providing a patient with a written certification, the APRN shall record the issuance of the written certification in the PDMP.

(4)

(a) An APRN who provides written certifications shall comply with the professional standards established in this section.

(b) Prior to providing a written certification, the APRN shall:

1. Obtain, review, and record a complete and appropriate evaluation of the patient, which shall include:
 - a. The patient's name;
 - b. Date or dates of office visits or treatments, and responses to treatments;
 - c. The patient's medical history, including relevant prescription history and diagnostic results;
 - d. 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;
 - e. Based on evidence or behavioral indications of addiction or drug abuse, the APRN shall obtain a drug screen on the patient. It is within the APRN's discretion to decide the nature of the screen and which type of drug to be screened;
 - f. The patient's social and family history;
 - g. A physical examination relevant to the current medical condition;
 - h. The patient's psychiatric history;
 - i. A focused physical examination of the patient relevant to the patient's current medical condition;
 - j. Documented review that standard medical treatment has been attempted or considered. If standard medical treatment is not attempted, the APRN shall document the reasons that standard medical treatment is not appropriate for this patient;
 - k. The APRN's diagnosis of the patient's qualifying medical condition; and
 - l. If the patient has been previously diagnosed with a qualifying medical condition by **another healthcare provider pursuant to KRS 314.050(4) [a medicinal cannabis practitioner]**, the APRN may confirm the diagnosis if:
 - (i) The APRN obtains a copy of the medical records or a detailed written summary indicating the diagnosis; and
 - (ii) The APRN is satisfied that those records confirm a diagnosis of a qualifying condition.
 - (iii) The APRN shall maintain a copy of any record or report of any medicinal cannabis practitioner on which the practitioner relied for purposes of meeting the requirements under this paragraph.
 - (iv) Document a plan to obtain the patient's consent in order to obtain and discuss the patient's prior medical records within thirty (30) days of initiating treatment. Upon receipt of the medical records, the APRN shall review and

incorporate the information from the records into the evaluation and treatment of the patient. If the APRN is unable, despite best efforts, to obtain the patient's prior medical records, the APRN shall document those efforts in the patient's chart.

(v) Obtain and review a PDMP report for that patient for the twelve (12) month period immediately preceding the initial patient encounter and appropriately utilize that information in the evaluation and treatment of the patient;

(vi) Explain treatment alternatives, the risks, and the benefits of medicinal cannabis with the patient;

(vii) Obtain written informed consent from the patient for treatment;

(viii) Discuss and document the patient's treatment with the patient's other providers;

(ix) If the patient is a female of childbearing potential and age, meet the requirements of subparagraph 2. of this paragraph.

2.

a. Prior to initiating treatment, the APRN shall ~~recommend~~**require** that female patients of childbearing age submit to a pregnancy test and, if pregnant, the APRN shall provide counseling. The APRN shall document a patient's decision to decline to take a pregnancy test and the stated rationale for the patient's decision.

b. Prior to providing a written certification to a patient who is pregnant or breastfeeding, the APRN shall document the patient's decision to decline consultation referenced in this subsection, and the stated rationale for the patient's decision.

(5) The written certification shall include a statement from the APRN certifying that:

(a) A bona fide practitioner-patient relationship exists between the APRN and patient.

(b) The patient has been diagnosed with at least one (1) qualifying medical condition for which the APRN believes the patient may receive medical, therapeutic, or palliative benefit; and

(c) In the APRN's professional medical opinion, the patient may receive medical, therapeutic, or palliative benefit from the use of medicinal cannabis.

(6) An APRN who authorizes a written certification 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 APRN shall confirm whether the patient's condition continues to be a terminal illness.

(7) The APRN shall terminate or decline to issue a new written certification under any of the following circumstances:

(a) The patient no longer has the diagnosis of, or symptoms of, the qualifying medical condition.

(b) The APRN is not authorized to issue a written certification.

(c) Based on the APRN's clinical judgement, the patient or caregiver is abusing or diverting medicinal cannabis.

(d) The patient is deceased.

(8) The APRN shall notify the cabinet in writing within thirty (30) days the name of any patient for whom the APRN has terminated or declined to issue a written certification.

(9) The records required for the recommendation for a written certification may be kept with the patient's other medical records and shall be retained for at least five (5) years following the last office visit by the patient.

(10) An APRN medicinal cannabis practitioner shall not:

(a) Dispense medicinal cannabis; or

(b) Provide a written certification to an immediate family member or for himself or herself.

Section 9. Documented Deviation from Professional Standards for Providing Written Certifications. If an APRN is unable to conform to professional standards for providing written certifications set forth in this administrative regulation due to circumstances beyond the APRN's control, or the APRN makes a professional determination that it is not appropriate to comply with a specific standard, based upon the individual facts applicable to a specific patient's diagnosis and treatment, the APRN 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 providing of a written certification under the circumstances.

Section 10. Material Incorporated by reference.

(1) "Application for Authorization to Provide Written Certifications for the Use of Medicinal Cannabis", 09/2023.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Nursing, 312 Whittington Parkway, Suite 300, Louisville, Kentucky 40222, Monday through Friday, 8 a.m. to 4:30 p.m. This material is also available on the Board's Web site at <https://kbn.ky.gov/General/Pages/Document-Library.aspx>.

AUDRIA DENKER, President

APPROVED BY AGENCY: January 5, 2024

FILED WITH LRC: January 11, 2024 at 10:05 a.m.

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Jeffrey Prather

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes the credentialing, continuing education requirements, sanctions, and professional standards for APRNs authorized to practice as medicinal cannabis practitioners.

(b) The necessity of this administrative regulation:

It is necessary to promulgate this regulation to establish standards for APRNs 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 setting standards.

(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 standards for APRNs authorized to practice as medicinal cannabis practitioners.

(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.

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

This is a new regulation.

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

This is a new regulation.

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

This is a new regulation.

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

This regulation may affect APRNs with a Drug Enforcement Administration (DEA) registration, at this time, approximately 2300

(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. The APRNs that wish to be authorized to practice as medicinal cannabis practitioners will have to submit an application, provide documentation or otherwise complete the credentialing requirements, 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 an APRN 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 APRN 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:

No additional cost, beyond staff processing of authorization applications.

(b) On a continuing basis:

No additional cost, beyond staff processing of authorization applications.

(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 is not applied because all applicants are in the same class and treated the same.

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?

Board of Nursing.

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

KRS 314.131 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.

(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?

No additional cost.

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

No additional cost.

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.