

CABINET FOR HEALTH AND FAMILY SERVICES

Office of the Secretary (Amended After Comments)

915 KAR 2:030. Written certifications.

RELATES TO: KRS 218A.202, Chapter 218B

STATUTORY AUTHORITY: KRS 218B.140

NECESSITY, FUNCTION, AND CONFORMITY: KRS 218B.140 requires the Cabinet for Health and Family Services to promulgate administrative regulations creating a standardized written certification form for use by medicinal cannabis practitioners. This administrative regulation establishes the written certification form for the Kentucky Medical Cannabis Program.

Section 1. Medicinal Cannabis Practitioners.

- (1) The cabinet shall maintain a medicinal cannabis practitioner registry for the Kentucky Medical Cannabis Program as part of the state's designated electronic monitoring system.
- (2) Medicinal cannabis practitioners shall register with the state's medicinal cannabis practitioner registry in accordance with written instructions provided by the cabinet and properly enter written certifications and dosage recommendations for qualified patients into the registry.
- (3) Prior to providing a patient with a written certification, a medicinal cannabis practitioner shall comply with KRS 218B.050(4), including establishing a bona fide practitioner-patient relationship with the patient. A medicinal cannabis practitioner shall also comply with the respective administrative regulation promulgated by his or her state licensing board establishing professional standards for medicinal cannabis practitioners, 201 KAR 9:067 or 201 KAR 20:067, and be authorized to provide written certifications for use of medicinal cannabis to qualified patients by his or her state licensing board.

Section 2. Written Certification Form.

- (1) When issuing a written certification for the use of medicinal cannabis to a patient, the medicinal cannabis practitioner shall use the form prescribed by the cabinet and available in the medicinal cannabis practitioner registry. The written certification form shall include:
 - (a) The medicinal cannabis practitioner's full name, license type (such as MD or APRN), license number, office address, telephone number, and email address;
 - (b) The date of the medicinal cannabis practitioner's examination of the qualified patient;
 - (c) The qualified patient's full name, date of birth, Social Security number, and email address;
 - (d) If the qualified patient is a minor, the custodial parent or legal guardian's full name, date of birth, Social Security number, email address, and phone number;
 - (e) Identification of the diagnosed qualifying medical condition(s);
 - (f) Attestations that the medicinal cannabis practitioner has:
 1. Established a bona fide practitioner-patient relationship with the patient;
 2. Diagnosed the patient, or confirmed a diagnosis provided by another healthcare provider, with a qualifying medical condition for which the medicinal cannabis practitioner believes that the patient ~~is less likely to~~~~may~~ receive **safe and effective** therapeutic or palliative benefit from the use of medicinal cannabis;
 3. Reviewed a report of information from the electronic monitoring system established pursuant to KRS 218A.202 related to the patient for a period of time that covers at least the twelve (12) months immediately preceding the date of the report;

4. 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, 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

5. Obtained the consent of the patient's custodial parent or legal guardian responsible for providing consent to treatment if the patient is a minor;

(g) The medicinal cannabis practitioner's signature and the date signed.

(2) An initial written certification shall be provided by the medicinal cannabis practitioner to the qualified patient during the course of an in-person examination. Subsequent written certifications for the purpose of renewing a registry identification card may be provided electronically or during the course of a telehealth consultation.

(3) Pursuant to KRS 218B.050(6)(d), within twenty-four (24) hours of providing a patient with a written certification for the use of medicinal cannabis, a medicinal cannabis practitioner shall record the issuance of the written certification in the state's designated medicinal cannabis practitioner registry.

(4) Pursuant to KRS 218B.050(6)(c), for the purpose of initially applying for a registry identification card, a written certification shall be valid for a period of not more than sixty (60) days. A medicinal cannabis practitioner may renew a written certification for not more than three (3) additional periods of not more than sixty (60) days each. Thereafter, the medicinal cannabis practitioner may issue another written certification to the patient for use in the registry identification card application process only after an in-person examination or an examination conducted via telehealth of the patient by the medicinal cannabis practitioner.

(5) Pursuant to KRS 218B.055(10), for the purpose of renewing a registry identification card, a written certification issued by a medicinal cannabis practitioner shall be valid if issued within sixty (60)~~ninety (90)~~ days immediately preceding the date of a renewal application.

(6) When entering a written certification into the state's designated medicinal cannabis practitioner registry, a medicinal cannabis practitioner shall enter any recommendation or limitation as to the form and dosage of medicinal cannabis that can be dispensed to the registered qualified patient.

SAM FLYNN, Executive Director

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: June 3, 2024

FILED WITH LRC: June 10, 2024 at noon

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

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(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation creates a standardized written certification form for use by medicinal cannabis practitioners. The Amended After Comments version of the administrative regulation amends the language of Section 2(1)(f)(2) and Section 2(5) to reflect the changes necessitated by the passage of 2024 House Bill 829.

(b) The necessity of this administrative regulation:

This administrative regulation is necessary to carry out the requirements of KRS Chapter 218B, specifically KRS 218B.140.

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

KRS 218B.140 requires the Cabinet for Health and Family Services to promulgate administrative regulations for the medicinal cannabis program. This administrative regulation creates a standardized written certification form for use by medicinal cannabis practitioners.

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

This administrative regulation creates a standardized written certification form for use by 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:

Not applicable. This is a new administrative regulation.

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

Not applicable. This is a new administrative regulation.

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

Not applicable. This is a new administrative regulation.

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

Not applicable. This is a new administrative regulation.

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

This administrative regulation affects medicinal cannabis practitioners, patients, designated caregivers, and the Kentucky Medical Cannabis Program within the Cabinet for Health and Family Services.

(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:

Medicinal cannabis practitioners shall use the written certification form prescribed by the cabinet.

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

There is no anticipated cost to comply with this administrative regulation.

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

Medicinal cannabis practitioners can provide patients with written certifications required to become cardholders in the Kentucky Medical Cannabis Program.

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

(a) Initially:

This administrative regulation creates a standardized written certification form for use by medicinal cannabis practitioners. There is no anticipated cost to implement this administrative regulation.

(b) On a continuing basis:

This administrative regulation creates a standardized written certification form for use by medicinal cannabis practitioners. There is no anticipated cost to implement this administrative regulation on a continuing basis.

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

State general funds provided by the commonwealth

(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:

It is not anticipated that an increase in funding will be necessary to implement this regulation.

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

This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied?

Tiering is not applied. All medicinal cannabis practitioners will be treated equally.

FISCAL IMPACT STATEMENT

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

KRS 218B.140(1)(c).

(2) Identify the promulgating agency and any other affected state units, parts, or divisions:

This administrative regulation is promulgated by the Kentucky Medical Cannabis Program within the Cabinet for Health and Family Services.

(a) Estimate the following for the first year:

Expenditures:The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward implementation and continued operation of the electronic monitoring system required by KRS 218B.140, including the patient and caregiver registry and the medicinal cannabis practitioner registry, which houses the written certifications.

Revenues:This administrative regulation is not expected to generate revenue for the state in the first year.

Cost Savings:The cabinet does not anticipate any cost savings in the first year.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward implementation and continued operation of the electronic monitoring system required by KRS 218B.140, including the patient and caregiver registry and the medicinal cannabis practitioner registry, which houses the written certifications. This administrative regulation is not expected to generate revenue for the state in subsequent years. The cabinet does not anticipate any cost savings in subsequent years.

(3) Identify affected local entities (for example: cities, counties, fire departments, school districts):

Medicinal cannabis practitioners that issue written certifications will reside within a city or county in the commonwealth.

(a) Estimate the following for the first year:

Expenditures:It is not anticipated that affected local entities will have significant expenditures arising out of medicinal cannabis practitioners residing in their respective county or city.

Revenues:Unknown at this time. This response will depend on the number of licensed cannabis businesses located in a respective city or county, any ordinances and fees established by local authorities regulating licensed cannabis businesses in their jurisdiction as allowed by KRS 218B.130, and the number of cardholders and medicinal cannabis practitioners in their area.

Cost Savings:The cabinet does not anticipate any cost savings in the first year.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

It is not anticipated that affected local entities will have significant expenditures arising out of medicinal cannabis practitioners residing in their respective county or

city. Regarding revenues, this response will depend on the number of licensed cannabis businesses located in a respective city or county, any ordinances and fees established by local authorities regulating licensed cannabis businesses in their jurisdiction as allowed by KRS 218B.130, and the number of cardholders and medicinal cannabis practitioners in their area. The cabinet does not anticipate any cost savings in subsequent years.

(4) Identify additional regulated entities not listed in questions (2) or (3):

Medicinal cannabis practitioners.

(a) Estimate the following for the first year:

Expenditures: There is no fee for medicinal cannabis practitioners to register with the state's medicinal cannabis practitioner registry and enter written certifications and dosage recommendations for qualified patients into the registry.

Revenues: This response will depend on the fees established by medicinal cannabis practitioners for appointments with patients.

Cost Savings: The cabinet does not anticipate any cost savings in the first year.

(b) How will expenditures, revenues, or cost savings differ in subsequent years?

There is no fee for medicinal cannabis practitioners to register with the state's medicinal cannabis practitioner registry and enter written certifications and dosage recommendations for qualified patients into the registry. Revenues will continue to depend on the fees established by medicinal cannabis practitioners for appointments with patients. The cabinet does not anticipate any cost savings in subsequent years.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward implementation and continued operation of the electronic monitoring system required by KRS 218B.140, including the patient and caregiver registry and the medicinal cannabis practitioner registry, which houses the written certifications. It is anticipated that an increase in funding will be necessary to administer all of the administrative regulations contained in 915 KAR Chapter 2.

(b) Methodology and resources used to determine the fiscal impact:

As part of its Biennial Budget Request, the Cabinet for Health and Family Services analyzed the cost to administer all aspects of the Kentucky Medical Cannabis Program, including estimated costs for staffing and implementation and ongoing maintenance and operations costs for the electronic monitoring system and seed to sale tracking system required by KRS 218B.140.

(6) Explain:

(a) Whether this administrative regulation will have an overall negative or adverse major economic impact to the entities identified in questions (2) - (4). (\$500,000 or more, in aggregate)

. The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward approving implementation and continued operation of the electronic monitoring system required by KRS 218B.140, including the patient and caregiver registry and the medicinal cannabis practitioner registry, which houses the written certifications. The Kentucky Medical Cannabis Program will have a major economic impact on the

Cabinet for Health and Family Services, and it is anticipated that an increase in funding will be necessary to administer all of the administrative regulations contained in 915 KAR Chapter 2.

(b) The methodology and resources used to reach this conclusion:

As part of its Biennial Budget Request, the Cabinet for Health and Family Services analyzed the cost to administer all aspects of the Kentucky Medical Cannabis Program, including estimated costs for staffing and implementation and ongoing maintenance and operations costs for the electronic monitoring system required by KRS 218B.140.