

CABINET FOR HEALTH AND FAMILY SERVICES

Office of the Secretary

(New Administrative Regulation)

915 KAR 2:020. Supply limits and equivalency formula.

RELATES TO: KRS 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 establishing supply limits and an equivalency formula for medicinal cannabis. This administrative regulation establishes the supply limits and equivalency formula for the Kentucky Medical Cannabis Program.

Section 1. Medicinal Cannabis Supply Limits.

(1) For the purpose of establishing supply limits for the Kentucky Medical Cannabis Program:

- (a) A daily supply of medicinal cannabis for cardholders consists of 3.75 grams of raw plant material, 1 gram of concentrate, or 130 milligrams of delta-9 tetrahydrocannabinol (THC) infused into a medicinal cannabis product, such as an edible, pill, capsule, oil, liquid, or tincture;
- (b) An uninterrupted ten (10) day supply of medicinal cannabis for cardholders consists of 37.5 grams of raw plant material, 9.5 grams of concentrate, or 1,300 milligrams of THC infused into a medicinal cannabis product; and
- (c) An uninterrupted thirty (30) day supply of medicinal cannabis for cardholders consists of 112 grams of raw plant material, 28 grams of concentrate, or 3,900 milligrams of THC infused into a medicinal cannabis product.

(2) The following non-consumable medicinal cannabis products shall not count toward a patient's supply limits:

- (a) Ointments;
- (b) Soaps;
- (c) Lotions; and
- (d) Other topical agents.

(3) In making recommendations for dosage of medicinal cannabis, a medicinal cannabis practitioner may recommend, and a registered qualified patient or his or her designated caregiver may legally purchase and possess, an amount of medicinal cannabis in excess of the thirty (30) day supply of medicinal cannabis established in this section if the medicinal cannabis practitioner reasonably believes that the standard thirty (30) day supply would be insufficient in providing the patient with uninterrupted therapeutic or palliative relief. If a medicinal cannabis practitioner makes the determination to increase the qualified patient's dosage above the thirty (30) day supply limit, the medicinal cannabis practitioner shall:

- (a) Document the dosage recommendation and the rationale in the qualified patient's medical record; and
- (b) Document the dosage recommendation and the rationale in the qualified patient's written certification in the state's designated medicinal cannabis practitioner registry.

(4) Beginning January 1, 2026, the cabinet shall annually review the supply limits established in this section to determine if any adjustments should be made. In making this determination, the cabinet shall consider standards and procedures that have been found to be best practices relative to the use of medicinal cannabis, any scientific research studies regarding dosage and the health effects of medicinal cannabis, and any input from

the Board of Physicians and Advisors, the Kentucky Board of Medical Licensure, the Kentucky Board of Nursing, and the Kentucky Center for Cannabis.

Section 2. Standards for Determining Equivalency.

(1) The following potency equivalency formula shall be used for determining the amount of raw plant material that medicinal cannabis products are considered the equivalent to:

(a) Step 1. Weight of raw plant material (in grams) x average THC potency percentage of raw plant material = amount of concentrate (in grams).

(b) Step 2. Convert amount of concentrate in grams to milligrams.

(c) Step 3. Amount of concentrate (in milligrams) x average THC potency percentage of concentrate = preliminary amount of THC infused medicinal cannabis products (in milligrams).

(d) Step 4. Preliminary amount of THC infused medicinal cannabis products (in milligrams) / 5 = final amount of THC infused medicinal cannabis products (in milligrams).

(2) In Step 4 of the equivalency formula, the preliminary amount of THC infused medicinal cannabis products (in milligrams) is reduced by a factor of five (5) based on pharmacokinetic equivalency research showing one (1) milligram of THC in edible form is equivalent to approximately five (5) milligrams of THC in inhalable form.

(3) For example:

(a) 28 grams of raw plant material x 25% average THC potency = 7 grams of concentrate.

(b) 7 grams is equivalent to 7,000 milligrams.

(c) 7,000 milligrams of concentrate x 70% average THC potency = 4,900 milligrams.

(d) 4,900 milligrams / 5 = 980 milligrams of THC infused medicinal cannabis products.

(50 Ky.R. 2128; eff. 8-28-2024.)

SAM FLYNN, Executive Director

ERIC C. FRIEDLANDER, Secretary

APPROVED BY AGENCY: March 6, 2024

FILED WITH LRC: March 14, 2024 at 11:50 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall, if requested, be held on May 22, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by May 15, 2024, 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 attends virtually 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 this proposed administrative regulation until May 31, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

CONTACT PERSON: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, Kentucky 40621; phone 502-564-7476; fax 502-564-7091; email CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:Oran S. McFarlan, III or Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes supply limits of medicinal cannabis and an equivalency formula for medicinal cannabis.

(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 establishes supply limits of medicinal cannabis and an equivalency formula for medicinal cannabis.

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

This administrative regulation establishes supply limits of medicinal cannabis and an equivalency formula for medicinal cannabis.

(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 will use the supply limits when making dosage recommendations for patients, and cannabis businesses will use the equivalency formula for their products.

(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 will use the supply limits when making dosage recommendations for patients, and cannabis businesses may determine the amount of raw plant material to which medicinal cannabis products are considered to be equivalent.

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

(a) Initially:

This administrative regulation establishes supply limits and an equivalency formula for medicinal cannabis. There is no anticipated cost to implement this administrative regulation.

(b) On a continuing basis:

This administrative regulation establishes supply limits and an equivalency formula for medicinal cannabis. 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 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?

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

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

KRS 218B.140.

(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?

This administrative regulation is not expected to generate revenue for state or local government in the first year.

(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 administrative regulation is not expected to generate revenue for state or local government for subsequent years.

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

This administrative regulation establishes supply limits and an equivalency formula for medicinal cannabis. There is no anticipated cost to implement this administrative regulation.

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

This administrative regulation establishes supply limits and an equivalency formula for medicinal cannabis. There is no anticipated cost to implement this administrative regulation on a continuing basis.

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?

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

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

The cabinet does not anticipate any cost savings in subsequent years.

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

The cabinet does not anticipate any cost for the first year.

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

The cabinet does not anticipate any cost in subsequent years.

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)] It is not anticipated that this administrative regulation will have an overall negative or adverse economic impact of \$500,000 or more on the Cabinet for Health and Family Services.