



1 Cabinet for Health and Family Services

2 Office of the Secretary

3 (New Administrative Regulation)

4 915 KAR 1:001. Definitions for 915 KAR Chapter 1.

5 RELATES TO: KRS Chapter 218B

6 STATUTORY AUTHORITY: KRS 218B.140

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 218B.140 requires the Cabinet
8 for Health and Family Services to promulgate administrative regulations to administer the
9 medicinal cannabis program in the commonwealth. This administrative regulation establishes
10 definitions of terms used by the cabinet in administrative regulations pertaining to cannabis
11 businesses and the medicinal cannabis program.

12 Section 1. Definitions.

13 (1) “Accreditation Body” means an impartial non-profit organization that operates in
14 conformance with the International Organization for Standardization (ISO) and International
15 Electrotechnical Commission (IEC) standard 17011 and is a signatory to the International
16 Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement (MRA) for
17 Testing.

18 (2) “Advertising” means the publication, dissemination, solicitation, or circulation, for a
19 fee, that is visual, oral, written, or electronic to induce directly or indirectly an individual to
20 patronize a cannabis business or to purchase medicinal cannabis.

1 (3) "Advertising device" means any billboard, sign, notice, poster, display, or other device,
2 including the structure erected or used in connection with the display or device and all lighting or
3 other attachments used in connection with the display or device, that is:

4 (a) Operated or owned by a person or entity who is earning compensation directly or
5 indirectly from a third party or parties for the placement of a message on the device; and

6 (b) Intended to attract the attention of operators of motor vehicles on the highways.

7 (4) "Applicant" means a person or entity, including any parent entity, who applies for a
8 cannabis business license to operate as a cultivator, processor, producer, dispensary, or safety
9 compliance facility in the commonwealth.

10 (5) "Appropriate signs" means exterior signage that accurately reflects a cannabis
11 business's legal name, business name, "doing business as" name, or trade name and contact
12 information on record with the cabinet.

13 (6) "Cabinet" means the Cabinet for Health and Family Services.

14 (7) "Cannabis business" is defined by KRS 218B.010(3).

15 (8) "Cannabis business activities" means growing, cultivating, processing, producing,
16 packaging, labeling, transporting, dispensing, or testing medicinal cannabis.

17 (9) "Cannabis business agent" is defined by KRS 218B.010(4).

18 (10) "Cannabis business category" means one of the following: Tier I cultivator, Tier II
19 cultivator, Tier III cultivator, Tier IV cultivator, processor, producer, dispensary, or safety
20 compliance facility.

21 (11) "Canopy" means the total surface area within a cultivation area that is dedicated to
22 live plant production.

23 (12) "Cardholder" is defined by KRS 218B.010(5).

1 (13) "Certificate of accreditation" means a document issued by an accreditation body
2 evidencing that a safety compliance facility is in compliance with International Organization for
3 Standardization Standard ISO and IEC 17025 and other requirements relevant to the operation of
4 laboratories conducting tests on medicinal cannabis and other items used in the growing,
5 processing, or dispensing of medicinal cannabis.

6 (14) "Certificate of analysis" means a document that confirms that the test performed by
7 a safety compliance facility on a harvest batch or production batch meets the testing
8 requirements set forth by the cabinet.

9 (15) "Chain of custody" means the process used by employees or agents of a cannabis
10 business or authorized agents of the cabinet to record the possession and transfer of medicinal
11 cannabis samples or test samples from the time the samples are collected until testing is
12 completed and the samples are destroyed.

13 (16) "Cultivation activities" means the activities involved with growing, cultivating, and
14 selling medicinal cannabis, including planting, raising, harvesting, trimming, testing, packaging,
15 labeling, transferring, transporting, and storing medicinal cannabis.

16 (17) "Cultivator" is defined by KRS 218B.010(6).

17 (18) "Daycare center" means "child-care center" as defined by KRS 199.894(3), "family
18 child-care home" as defined by KRS 199.894(5), and registered childcare providers in the Child
19 Care Assistance Program as regulated by 922 KAR 2:180.

20 (19) "Designated caregiver" is defined by KRS 218B.010(8).

21 (20) "Dispensary" is defined by KRS 218B.010(9).

22 (21) "Disqualifying felony offense" is defined by KRS 218B.010(11).

23 (22) "Enclosed, locked facility" is defined by KRS 218B.010(12).

1 (23) "Food grade" means a non-toxic material that is safe for direct contact with food.

2 (24) "Harvest batch" means a group of packages created from harvested medicinal
3 cannabis plants of the same strain which were harvested at the same time. Packages of raw plant
4 material are created from a harvest batch.

5 (25) "Licensee" means the recipient of a license from the cabinet authorizing a cannabis
6 business to operate in Kentucky for the term of the license.

7 (26) "Limited access area" means:

8 (a) An area on a cultivator or producer's site or within its facility where seedlings or
9 medicinal cannabis plants are growing; seedlings, medicinal cannabis plants, or medicinal
10 cannabis are being loaded into or out of transport vehicles; medicinal cannabis is being packaged
11 for sale or stored; medicinal cannabis waste is processed, stored or destroyed; and security alarm
12 and surveillance system devices are stored or maintained;

13 (b) An area on a processor or producer's site or within its facility where medicinal
14 cannabis is being processed; medicinal cannabis is being loaded into or out of transport vehicles;
15 medicinal cannabis is being packaged for sale or stored; medicinal cannabis waste is processed,
16 stored or destroyed; and security alarm and surveillance system devices are stored or maintained;

17 (c) An area on a safety compliance facility's site or within its facility where medicinal
18 cannabis is being loaded into or out of transport vehicles, stored, tested, or destroyed and where
19 security alarm and surveillance system devices are stored or maintained; or

20 (d) An area on a dispensary's site or within its building where medicinal cannabis is
21 being loaded into or out of transport vehicles, stored, or destroyed and where security alarm and
22 surveillance system devices are stored or maintained.

1 (27) "Local government" means a city, county, urban-county government, consolidated
2 local government, charter county government, or unified local government.

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

4 (29) "Medicinal cannabis accessories" is defined by KRS 218BH.010(16).

5 (30) "Medicinal cannabis practitioner" is defined by KRS 218B.010(17).

6 (31) "Medicinal cannabis product" is defined by KRS 218B.010(18).

7 (32) "Medicinal cannabis waste" means:

8 (a) Solid, liquid, semi-solid, or contained gaseous materials that are generated by a
9 cultivator, processor, producer, or safety compliance facility;

10 (b) Unused, surplus, returned, recalled, contaminated, or expired medicinal cannabis;

11 (c) Medicinal cannabis plant material that is not used in the growing, harvesting,
12 processing, or testing of medicinal cannabis, including flowers, stems, trim, leaves, seeds, dead
13 medicinal cannabis plants, dead seedlings, unused medicinal cannabis plant parts, unused
14 seedling parts, or roots;

15 (d) Medicinal cannabis that exceeds any maximum allowable testing limit or fails to meet
16 any other standards or requirements set forth in 915 KAR 001:110;

17 (e) Spent hydroponic nutrient solution;

18 (f) Containers used for:

19 1. Growing seedlings or medicinal cannabis plants or for use in the growing of medicinal
20 cannabis; and

21 2. Processing of medicinal cannabis.

22 (g) Used or unused fertilizers and pesticides;

23 (h) Used or unused solvents, chemicals, or excipients;

1 (i) Samples that have been tested;

2 (j) Excess samples that will not be tested; and

3 (k) Wastewater.

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

5 (34) "Pesticide" means:

6 (a) Any substance or mixture of substances intended to prevent, destroy, control, repel,
7 attract, or mitigate any pest;

8 (b) Any substance or mixture of substances intended to be used as a plant regulator,
9 defoliant, or desiccant;

10 (c) Any herbicide used to manipulate or control undesirable vegetation;

11 (d) Any fungicide used to kill or prevent the growth of fungi and their spores; and

12 (e) Any substance or mixture of substances intended to be used as a spray
13 adjuvant, once they have been mixed with an EPA-registered product.

14 (35) "Processing activities" means the activities involved with processing raw plant
15 material and medicinal cannabis into medicinal cannabis products, including acquiring,
16 purchasing, possessing, processing, preparing, manufacturing, manipulating, blending,
17 packaging, labeling, transferring, transporting, supplying, or selling medicinal cannabis or
18 medicinal cannabis products to other cannabis businesses in the commonwealth.

19 (36) "Processor" is defined by KRS 218B.010(21).

20 (37) "Producer" is defined by KRS 218B.010(23).

21 (38) "Product example" means a limited amount of medicinal cannabis or medicinal
22 cannabis product that has been designated by a dispensary for display on its premises for the sole
23 purpose of product education for cardholders.

1 (39) "Production batch" means a group of packages created from a production run of
2 medicinal cannabis and indicates the medicinal cannabis in the packages has changed forms
3 chemically or physically, which severs previous test results from those packages and requires
4 new testing to be completed.

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

6 (41) "Raw plant material" is defined by KRS 218B.010(27).

7 (42) "Registered qualified patient" is defined by KRS 218B.010(28).

8 (43) "Registry identification card" is defined by KRS 218B.010(29).

9 (44) "Safety compliance facility" is defined by KRS 218B.010(30).

10 (45) "Sample" means medicinal cannabis randomly selected from a harvest batch or
11 production batch and collected by an employee or agent of a cannabis business or an authorized
12 agent of the cabinet for testing by a safety compliance facility. "Sample" includes both a
13 primary sample and a reserve sample.

14 (46) "Sampler" means an employee or agent of a cultivator, processor, producer, safety
15 compliance facility, or dispensary that is authorized by his or her employer to collect samples or
16 test samples in accordance with the contracted safety compliance facility's standard operating
17 procedures and 915 KAR 1:060.

18 (47) "Seedling" is defined by KRS 218B.010(32).

19 (48) "Serious violation" is defined by KRS 218B.010(33).

20 (49) "Smoking" is defined by KRS 218B.010(34).

21 (50) "Test sample" means an amount of medicinal cannabis or medicinal cannabis
22 products, or amount of soil, growing medium, water, or solvents used to grow or process
23 medicinal cannabis, dust, or other particles obtained from the swab of a counter or equipment

1 used in the growing or processing of medicinal cannabis, or other item used in the growing or
2 processing of medicinal cannabis in a facility taken by an employee or agent of a cannabis
3 business or an authorized agent of the cabinet and provided to a safety compliance facility for
4 testing.

5 (51) "Transport vehicle" means a vehicle that is used to transport seeds, seedlings,
6 medicinal cannabis plants, medicinal cannabis, and medicinal cannabis products between
7 cannabis businesses or between a dispensary and registered qualified patients or designated
8 caregivers.

9 (52) "Visiting qualified patient" is defined by KRS 218B.010(38).

915 KAR 1:001

REVIEWED:

<small>DocuSigned by:</small> <i>Sam Flynn</i> <small>7228208BA50414...</small>	1/2/2024
<hr/>	
Sam Flynn Executive Director Kentucky Medical Cannabis Program Cabinet for Health and Family Services	Date

APPROVED:

<small>DocuSigned by:</small> <i>Eric Friedlander</i> <small>0AEA1D6C15D6431...</small>	1/3/2024
<hr/>	
Eric C. Friedlander Secretary Cabinet for Health and Family Services	Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on March 25, 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 March 18, 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 March 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, KY 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 915 KAR 1:001
Agency Contact: Oran S. McFarlan, III
Phone Number: (502) 564-5313
Email: oran.mcfarlan@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-7476
Email: CHFSregs@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes definitions of terms used by the Cabinet for Health and Family Services in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program.

(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 sets out definitions of terms used in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides the definitions of terms used in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program.

(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 cannabis businesses 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: None.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): None.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Not applicable.

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

(a) Initially: This administrative regulation establishes definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. There is no anticipated cost to implement this administrative regulation.

(b) On a continuing basis: This administrative regulation establishes definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. 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: Not applicable.

(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? Explain why or why not. Tiering is not applied. All cannabis businesses will be treated equally.

FISCAL NOTE

Administrative Regulation: 915 KAR 1:001
Agency Contact: Oran S. McFarlan, III
Phone Number: (502) 564-5313
Email: oran.mcfarlan@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-7476
Email: CHFSregs@ky.gov

(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 definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. 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 definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. 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 cannabis businesses arising out of this administrative regulation in the first year.

(d) How much will it cost the regulated entities for subsequent years? The cabinet does not anticipate any cost for the cannabis businesses arising out of this administrative regulation 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.