

CABINET FOR HEALTH AND FAMILY SERVICES

Office of the Secretary (Amended After Comments)

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

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 to administer the medicinal cannabis program in the Commonwealth. This administrative regulation establishes definitions of terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program.

Section 1. Definitions.

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

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

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

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

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

(4) **"Agent" means a person who acts on behalf of another person or group.**

~~(5)~~ "Applicant" means a person or entity, including any parent entity, who applies for a cannabis business license to operate as a cultivator, processor, producer, dispensary, or safety compliance facility in the Commonwealth.

~~(6)~~ ~~(5)~~ "Appropriate signs" means exterior signage that accurately reflects a cannabis business's legal name, business name, "doing business as" name, or trade name and contact information on record with the cabinet.

~~(7)~~ ~~(6)~~ "Cabinet" means the Cabinet for Health and Family Services.

~~(8)~~ ~~(7)~~ "Cannabis business" is defined by KRS 218B.010(3).

~~(9)~~ ~~(8)~~ "Cannabis business activities" means growing, cultivating, processing, producing, packaging, labeling, transporting, dispensing, or testing medicinal cannabis.

~~(10)~~ ~~(9)~~ "Cannabis business agent" is defined by KRS 218B.010(4).

~~(11)~~ ~~(10)~~ "Cannabis business category" means one (1) of the following: Tier I cultivator, Tier II cultivator, Tier III cultivator, Tier IV cultivator, processor, producer, dispensary, or safety compliance facility.

~~(12)~~ ~~(11)~~ "Canopy" means the total surface area within a cultivation area that is dedicated to live plant production.

~~(13)~~ ~~(12)~~ "Cardholder" is defined by KRS 218B.010(5).

~~(14)~~ ~~(13)~~ "Certificate of accreditation" means a document issued by an accreditation body evidencing that a safety compliance facility is in compliance with International Organization for Standardization Standard ISO and IEC 17025 and other requirements

relevant to the operation of laboratories conducting tests on medicinal cannabis and other items used in the growing, processing, or dispensing of medicinal cannabis.

~~(15) {(14)}~~ "Certificate of analysis" means a document that confirms that the test performed by a safety compliance facility on a harvest batch or production batch meets the testing requirements set forth by the cabinet.

~~(16) {(15)}~~ "Chain of custody" means the process used by employees or agents of a cannabis business or authorized agents of the cabinet to record the possession and transfer of medicinal cannabis samples or test samples from the time the samples are collected until testing is completed and the samples are destroyed.

~~(17) {(16)}~~ **"Controlled incineration" means the controlled burning of medicinal cannabis in an enclosed, secured limited access area capable of capturing and neutralizing any exhaust, fumes, or fugitive odors and is capable of protecting the operator and surrounding individuals from intoxication.**

~~(18) {(17)}~~ "Cultivation activities" means the activities involved with growing, cultivating, and selling medicinal cannabis, including planting, raising, harvesting, trimming, testing, packaging, labeling, transferring, transporting, and storing medicinal cannabis.

~~(19) {(18)}~~ "Cultivator" is defined by KRS 218B.010(6).

~~(20) {(19)}~~ "Daycare center" means "child-care center" as defined by KRS 199.894(3); ~~"family child-care home" as defined by KRS 199.894(5), and registered childcare providers in the Child Care Assistance Program as regulated by 922 KAR 2:180}.~~

~~(21) {(20)}~~ "Designated caregiver" is defined by KRS 218B.010(8).

~~(22) {(21)}~~ "Dispensary" is defined by KRS 218B.010(9).

~~(23) {(22)}~~ "Disqualifying felony offense" is defined by KRS 218B.010(11).

~~(24) {(23)}~~ "Enclosed, locked facility" is defined by KRS 218B.010(12).

~~(25) {(24)}~~ "Food grade" means a non-toxic material that is safe for direct contact with food.

~~(26) {(25)}~~ "Harvest batch" means a group of packages created from harvested medicinal cannabis plants of the same strain which were harvested at the same time. Packages of raw plant material are created from a harvest batch.

~~(27) {(26)}~~ "Licensee" means the recipient of a license from the cabinet authorizing a cannabis business to operate in Kentucky for the term of the license.

~~(28) {(27)}~~ "Limited access area" means:

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

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

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

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

~~(29) {(28)}~~ "Local government" means a city, county, urban-county government, consolidated local government, charter county government, or unified local government.

~~(30)~~ ~~(28)~~ "Medicinal cannabis" is defined by KRS 218B.010(15).

~~(31)~~ ~~(29)~~ "Medicinal cannabis accessories" is defined by KRS 218BH.010(16).

~~(32)~~ ~~(30)~~ "Medicinal cannabis practitioner" is defined by KRS 218B.010(17).

~~(33)~~ ~~(31)~~ "Medicinal cannabis product" is defined by KRS 218B.010(18).

~~(34)~~ ~~(32)~~ "Medicinal cannabis waste" means:

- (a) Solid, liquid, semi-solid, or contained gaseous materials that are generated by a cultivator, processor, producer, or safety compliance facility;
- (b) Unused, surplus, returned, recalled, contaminated, or expired medicinal cannabis;
- (c) Medicinal cannabis plant material that is not used in the growing, harvesting, processing, or testing of medicinal cannabis, including flowers, stems, trim, leaves, seeds, dead medicinal cannabis plants, dead seedlings, unused medicinal cannabis plant parts, unused seedling parts, or roots;
- (d) Medicinal cannabis that exceeds any maximum allowable testing limit or fails to meet any other standards or requirements set forth in 915 KAR 001:110;
- (e) Spent hydroponic nutrient solution;
- (f) Containers used for:
 - 1. Growing seedlings or medicinal cannabis plants or for use in the growing of medicinal cannabis; and
 - 2. Processing of medicinal cannabis.
- (g) Used or unused fertilizers and pesticides;
- (h) Used or unused solvents, chemicals, or excipients;
- (i) Samples that have been tested;
- (j) Excess samples that will not be tested; and
- (k) Wastewater.

~~(35)~~ ~~(33)~~ "Minor" is defined by KRS 218B.010(19).

~~(36)~~ ~~(34)~~ "Pesticide" means:

- (a) Any substance or mixture of substances intended to prevent, destroy, control, repel, attract, or mitigate any pest;
- (b) Any substance or mixture of substances intended to be used as a plant regulator, defoliant, or desiccant;
- (c) Any herbicide used to manipulate or control undesirable vegetation;
- (d) Any fungicide used to kill or prevent the growth of fungi and their spores; and
- (e) Any substance or mixture of substances intended to be used as a spray adjuvant, once they have been mixed with an EPA-registered product.

~~(37)~~ **"Principal officer" means a person who has ultimate responsibility for implementing the decisions of the cannabis business's governing body, or for supervising the management, administration, or operation of the cannabis business.**

~~(38)~~ ~~(35)~~ "Processing activities" means the activities involved with processing raw plant material and medicinal cannabis into medicinal cannabis products, including acquiring, purchasing, possessing, processing, preparing, manufacturing, manipulating, blending, packaging, labeling, transferring, transporting, supplying, or selling medicinal cannabis or medicinal cannabis products to other cannabis businesses in the Commonwealth.

~~(39)~~ ~~(36)~~ "Processor" is defined by KRS 218B.010(21).

~~(40)~~ ~~(37)~~ "Producer" is defined by KRS 218B.010(23).

~~(41)~~ ~~(38)~~ "Product example" means a limited amount of medicinal cannabis or medicinal cannabis product that has been designated by a dispensary for display on its premises for the sole purpose of product education for cardholders.

~~(42)~~ ~~(39)~~ "Production batch" means a group of packages created from a production run of medicinal cannabis and indicates the medicinal cannabis in the packages has changed forms chemically or physically, which severs previous test results from those packages and requires new testing to be completed.

~~(43)~~ ~~(40)~~ "Qualifying medical condition" is defined by KRS 218B.010(26).

- ~~(44)~~ ~~((41))~~ "Raw plant material" is defined by KRS 218B.010(27).
- ~~(45)~~ ~~((42))~~ "Registered qualified patient" is defined by KRS 218B.010(28).
- ~~(46)~~ ~~((43))~~ "Registry identification card" is defined by KRS 218B.010(29).
- ~~(47)~~ ~~((44))~~ "Safety compliance facility" is defined by KRS 218B.010(30).
- ~~(48)~~ ~~((45))~~ "Sample" means medicinal cannabis randomly selected from a harvest batch or production batch and collected by an employee or agent of a cannabis business or an authorized agent of the cabinet for testing by a safety compliance facility. "Sample" includes both a primary sample and a reserve sample.
- ~~(49)~~ ~~((46))~~ "Sampler" means an employee or agent of a cultivator, processor, producer, safety compliance facility, or dispensary that is authorized by his or her employer to collect samples or test samples in accordance with the contracted safety compliance facility's standard operating procedures and 915 KAR 1:060.
- (50) "School" means a public elementary or secondary school of the state and non-public schools certified by the Kentucky Department of Education.**
- ~~(51)~~ ~~((47))~~ "Seedling" is defined by KRS 218B.010(32).
- ~~(52)~~ ~~((48))~~ "Serious violation" is defined by KRS 218B.010(33).
- ~~(53)~~ ~~((49))~~ "Smoking" is defined by KRS 218B.010(34).
- ~~(54)~~ ~~((50))~~ "Test sample" means an amount of medicinal cannabis or medicinal cannabis products, or amount of soil, growing medium, water, or solvents used to grow or process medicinal cannabis, dust, or other particles obtained from the swab of a counter or equipment used in the growing or processing of medicinal cannabis, or other item used in the growing or processing of medicinal cannabis in a facility taken by an employee or agent of a cannabis business or an authorized agent of the cabinet and provided to a safety compliance facility for testing.
- ~~(55)~~ ~~((51))~~ "Transport vehicle" means a vehicle that is used to transport seeds, seedlings, medicinal cannabis plants, medicinal cannabis, and medicinal cannabis products between cannabis businesses or between a dispensary and registered qualified patients or designated caregivers.
- ~~(56)~~ ~~((52))~~ "Visiting qualified patient" is defined by KRS 218B.010(38).

SAM FLYNN, Executive Director
ERIC FRIEDLANDER, Secretary

APPROVED BY AGENCY: May 14, 2024

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REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

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

(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. The Amended After Comments version of the administrative regulation includes four (4) additional definitions and amends the definition of “daycare center” in response to comments received by the cabinet.

(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?

Tiering is not applied. All cannabis businesses 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.

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

Revenues: This administrative regulation is not expected to generate revenue 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?

This administrative regulation establishes definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. There are no anticipated expenditures to implement this administrative regulation in subsequent years. This administrative regulation is not expected to generate revenue 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):

If its application is approved, a proposed cannabis business will locate within a city or county in the commonwealth.

(a) Estimate the following for the first year:

Expenditures: This administrative regulation establishes definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. There are no anticipated expenditures to implement this administrative regulation.

Revenues: This administrative regulation is not expected to generate revenue 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?

This administrative regulation establishes definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. There are no anticipated expenditures to implement this administrative regulation in subsequent years. This administrative regulation is not expected to generate revenue in subsequent years. The cabinet does not anticipate any cost savings in subsequent years.

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

Proposed and licensed cannabis businesses.

(a) Estimate the following for the first year:

Expenditures: There are no anticipated expenditures to implement this administrative regulation.

Revenues: This administrative regulation is not expected to generate revenue 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?

This administrative regulation establishes definitions for terms used by the cabinet in administrative regulations pertaining to cannabis businesses and the medicinal cannabis program. There are no anticipated expenditures to implement this administrative regulation in subsequent years. This administrative regulation is not expected to generate revenue in subsequent years. 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:

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 fiscal impact of this administrative regulation.

(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)

. 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.

(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.