CABINET FOR HEALTH AND FAMILY SERVICES

Office of the Secretary

(New Administrative Regulation)

915 KAR 1:110. Medicinal cannabis testing.

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 requirements for random sample testing of medicinal cannabis to ensure quality control. This administrative regulation establishes those requirements and procedures.

Section 1. General requirements.

(1) To ensure the suitability and safety for human consumption of medicinal cannabis and medicinal cannabis products, cultivators, processors, and producers shall test medicinal cannabis in accordance with Section 2 of this administrative regulation.

(2) No laboratory may test medicinal cannabis under this administrative regulation without being issued a license to operate as a safety compliance facility. A safety compliance facility shall only send medicinal cannabis samples for testing to another licensed safety compliance facility in the commonwealth.

(3) Batch size.

(a) Cultivators and producers shall separate all harvested medicinal cannabis into harvest batches not to exceed fifteen (15) pounds with the exception of any raw plant material to be sold

to a processor or producer for the purposes of turning the raw plant material into concentrate which may be separated into harvest batches of no more than fifty (50) pounds.

(b) Processors and producers shall separate all medicinal cannabis product into production batches not to exceed four (4) liters of liquid medicinal cannabis concentrate or nine (9) pounds for nonliquid medicinal cannabis products and, for final medicinal cannabis products, no greater than one thousand (1,000) grams of delta-9-tetrahydrocannabinol.

(4) An authorized cannabis business employee or agent collecting any samples for testing shall follow the standard operating procedures established by the contracted safety compliance facility conducting the testing for:

(a) Sampling; and

(b) Documenting the chain of custody.

(5) Testing frequency.

(a) Harvest batch samples shall be obtained and tested post-harvest and prior to sell, transfer, or delivery of the medicinal cannabis from the respective harvest batch.

(b) Production batch samples shall be obtained and tested in their final form prepackaging and prior to sale, transfer, or delivery of the medicinal cannabis from the respective production batch.

(6) Prohibitions.

(a) Cultivators and producers shall not sell, transfer, or deliver any medicinal cannabis from a harvest batch to a dispensary, processor, cultivator, or producer until a sample of the harvest batch has passed all tests required by Section 2 of this administrative regulation.

(b) Processors and producers shall not sell, transfer, or deliver any medicinal cannabis from a production batch to a dispensary, processor, cultivator, or producer until a sample of the production batch has passed all tests required by Section 2 of this administrative regulation.

(c) Dispensaries shall not dispense or sell medicinal cannabis to cardholders until a sample of its harvest or production batch has passed all tests required by Section 2 of this administrative regulation.

(d) Following the collection of a sample from a harvest batch or production batch, medicinal cannabis shall not undergo any additional processing, transforming, or other changes that alter the substance of the medicinal cannabis or otherwise would result in different test results. Any medicinal cannabis that undergoes additional processing, transforming, or other changes that alters the substance of the medicinal cannabis following sample collection shall be tested as required by Section 2 of this administrative regulation prior to any sale, transfer, or delivery to a dispensary, processor, or producer.

(7) The cabinet may select and collect a sample or test sample from a cannabis business at any time. The cabinet may require a cultivator, processor, producer, or dispensary to submit a sample or test sample to a safety compliance facility upon request when the cabinet has reason to believe the medicinal cannabis is unsafe for cardholder consumption or inhalation or has not been tested in accordance with KRS Chapter 218B and Section 2 of this administrative regulation. A cultivator, processor, producer, or dispensary shall provide the samples for testing at their own expense.

(8) Except as authorized in Section 5 of this administrative regulation, cannabis businesses shall properly dispose of and shall not use, sell, or otherwise transfer medicinal cannabis that fails to meet any testing standard or requirement set forth in this administrative

regulation. Cannabis businesses shall dispose of this medicinal cannabis waste in accordance with the 915 KAR 1:030, 915 KAR 1:040, 915 KAR 1:060, and 915 KAR 1:070, as applicable.

Section 2. Medicinal cannabis tests.

(1) Medicinal cannabis shall be tested for:

(a) Tetrahydrocannabinol (THC) and cannabinoid concentration;

(b) Terpenoid type and concentration;

(c) Residual solvents and processing chemicals (for production batches);

(d) Residual pesticides;

(e) Heavy metals;

(f) Microbial impurities;

(g) Mycotoxins;

(h) Water activity (for harvest batches);

(i) Yeast and mold; and

(i) Vitamin E acetate.

(2) The cabinet may conduct additional tests on samples or test samples at its discretion.

Section 3. Maximum allowable limits for medicinal cannabis tests.

(1) Cannabinoid and terpenoid concentration. KRS Chapter 218B, specifically KRS 218B.095, KRS 218B.105, KRS 218B.115, and KRS 218B.120, establishes the maximum delta-9 tetrahydrocannabinol content for raw plant material and medicinal cannabis products in the commonwealth. Cultivators, processors, and producers shall test harvest batch and production batch samples for levels of total THC and cannabinoid concentration and terpenoid type and concentration.

(a) For THC and cannabinoid concentration, the testing shall include:

1. Total THC;

2. Total cannabidiol (CBD);

2. Total cannabinoids;

3. Tetrahydrocannabinolic acid (THCa);

4. Delta-9-tetrahydrocannabinol (Delta-9-THC);

5. Delta-8-tetrahydrocannabinol (Delta-8-THC);

6. Cannabidiolic acid (CBDA);

7. Cannabidiol (CBD);

8. Cannabinol (CBN);

9. Cannabigerolic acid (CBGa);

10. Cannabigerol (CBG);

11. Tetrahydrrocannabivarin (THCV);

12. Cannabichromene (CBC);

(b) For terpenoid type and concentrate concentration, the testing shall include:

1. Total terpenes;

2. Limonene;

3. Myrcene;

4. Pinene;

5. Linalool;

6. Eucalyptol;

7. Delta-terpinene (terpinolene);

8. Caryophyllene

9. Nerolidol;

10. Humulene;

11. Bisabolol;

12. Camphene;

13. Delta 3 Carene;

14. Borneol;

15. Geraniol; and

16. Terpineol;

(c) In accordance with KRS 218B.140(1)(c)(9), cultivators and producers shall track the terpene content of the twelve (12) major terpenoids within each strain of medicinal cannabis that they cultivate in the commonwealth and provide a written summary of this information to the cabinet upon request.

(2) Residual solvents and processing chemicals. Production batch samples shall be tested for residual solvents and processing chemicals and shall not exceed the maximum allowable concentration for each solvent or chemical used as set forth in Appendix A, which is incorporated by reference.

(3) Residual Pesticides. Harvest batch samples and production batch samples shall be tested for residual pesticides and shall not exceed the maximum allowable concentration for each pesticide used as set forth in Appendix B, which is incorporated by reference.

(4) Heavy Metals. All harvest batch and production batch samples shall be tested for heavy metals, which shall include arsenic, cadmium, lead, and mercury, as follows:

(a) For inhaled medicinal cannabis products, including administration by metered dose nasal spray or pressurized metered dose inhaler, harvest and production batches shall be tested

for the following heavy metal analytes and shall comply with the maximum allowable concentration:

1. Arsenic, maximum allowable concentration: zero and two-tenths (0.2) parts per million (ppm);

2. Cadmium, maximum allowable concentration: zero and two-tenths (0.2) ppm;

3. Lead, maximum allowable concentration: zero and five-tenths (0.5) ppm; and

4. Mercury, maximum allowable concentration: zero and one-tenths (0.1) ppm.

(b) For medicinal cannabis products not intended to be inhaled, harvest and production batches shall be tested for the following heavy metal analytes and shall comply with the maximum allowable concentration:

1. Arsenic, maximum allowable concentration: zero and four-tenths (0.4) ppm;

2. Cadmium, maximum allowable concentration: zero and four-tenths (0.4) ppm;

3. Lead, maximum allowable concentration: one (1) ppm; and

4. Mercury, maximum allowable concentration: one and two-tenths (1.2) ppm.

(5) Microbial impurities. Harvest batch samples and production batch samples shall be tested for the presence of microbial impurities. Harvest batch and production batch samples shall be deemed to have passed the microbial impurities testing if the following conditions are met:

(a) Total Escherichia coli is not detected above one hundred (100) colony forming units/gram;

(b) Shiga toxin–producing Escherichia coli is not detected in one (1) gram;

(c) Salmonella spp. is not detected in one (1) gram; and

(d) Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, and A. terreus are not detected in one (1) gram.

(6) Mycotoxins. Harvest batch and production batch samples shall be tested for the following mycotoxins: aflatoxin B1, B2, G1, and G2 ochratoxin A. A production batch shall be deemed to have passed mycotoxin testing if the following conditions are met:

1. Total of aflatoxin B1, B2, G1, and G2 does not exceed twenty (20) microgram per kilogram (µg/kg) of substance; and

2. Ochratoxin A does not exceed twenty (20) µg/kg of substance.

(7) Water activity. Harvest batch samples shall be tested to determine the level of water activity. Harvest batch samples shall have a water activity (aw) rate of less than 0.65.

(8) Yeast and mold. Harvest batch and production batch samples shall be tested to determine the level of yeast and mold. Harvest batch and production batch samples shall have a total combined yeast and mold not to exceed 100,000 colony forming units per gram.

(9) Vitamin E acetate. Harvest batches and production batches shall be tested for any detectable level of vitamin E acetate.

Section 4. Failed testing.

(1) A harvest batch or production batch sample that fails any initial testing may be reanalyzed by the safety compliance facility using the reserve sample for that harvest or production batch.

(2) If the reserve sample passes the required testing, an authorized cannabis business employee or agent shall resample the harvest batch or production batch in question and send the new sample to a different safety compliance facility than the one that performed the initial testing. In order for the harvest batch or production batch in question to pass testing under this

administrative regulation, the new safety compliance facility shall test the resample and confirm the resample passed all required tests.

(3) A harvest batch or production batch shall fail testing if the respective sample exceeds any maximum allowable limit established in Section 3 of this administrative regulation or the maximum allowable delta-9 tetrahydrocannabinol content for raw plant material and medicinal cannabis products established in KRS Chapter 218B:

(a) During an initial test where no reanalysis is requested; or

(b) Upon reanalysis as described in this section.

(4) If a harvest batch or production batch sample fails a test or a reanalysis, the harvest batch or production batch:

1. May be remediated or sterilized if allowed by Section 5 of this administrative regulation; or

2. If it cannot be remediated or sterilized in accordance with Section 5 of this administrative regulation, the harvest or production batch shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance with 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(4) Medicinal cannabis from a harvest or production batch that failed testing shall not be combined with another harvest or production batch. Mixed products shall be considered adulterated and shall not be sold, transferred, or otherwise delivered to a cannabis business.

Section 5. Remediation.

(1) THC concentration.

(a) If a harvest batch sample exceeds the THC content limit imposed on raw plant material in KRS 218B.095, KRS 218B.105, 218B.115, or 218B.120, the harvest batch shall be

deemed medicinal cannabis waste and destroyed by the cultivator or producer in accordance with 915 KAR 1:030.

(b) If a production batch sample exceeds the THC content limits imposed on edibles, oils, tincture, and other medicinal cannabis products by KRS 218B.095, 218B.115, or 218B.120, the production batch may be remediated using procedures that would reduce the concentration of THC to allowable levels provided that the remediation method does not impart any toxic or deleterious substance to the medicinal cannabis in the production batch.

(c) A production batch that is remediated in accordance with this subsection shall be sampled and tested in accordance with Sections 2 and 3 of this administrative regulation.

(d) A processor or producer shall inform the safety compliance facility conducting the retesting prior to samples being taken that the production batch has previously failed testing and is being retested after undergoing remediation. Any remediation methods or remediation solvents used on the production batch being retested shall be disclosed to the safety compliance facility conducting the retesting.

(e) A production batch that exceeds the required THC content limits that is not remediated or that if remediated fails testing shall be deemed medicinal cannabis waste and destroyed by the processor or producer in accordance with 915 KAR 1:040.

(2) Residual solvents and processing chemicals.

(a) If a production batch sample fails residual solvent testing, the production batch may be remediated using procedures that would reduce the concentration of solvents to less than the action level provided that the remediation method does not impart any toxic or deleterious substance to the medicinal cannabis in the production batch.

(b) A production batch that is remediated in accordance with this subsection shall be sampled and tested in accordance with Sections 2 and 3 of this administrative regulation.

(c) A processor or producer shall inform the safety compliance facility conducting the retesting prior to samples being taken that the production batch has previously failed testing and is being retested after undergoing remediation or decontamination. Any remediation methods or remediation solvents used on the production batch being retested shall be disclosed to the safety compliance facility conducting the retesting.

(d) A production batch that fails solvent testing that is not remediated or that if remediated fails testing shall be deemed medicinal cannabis waste and destroyed by the processor or producer in accordance with the 915 KAR 1:040.

(3) Residual Pesticides. A harvest batch or production batch that fails residual pesticide testing shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance with 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(4) Heavy metals. A harvest batch or production batch that fails heavy metals testing shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance with the 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(5) Microbial impurities.

(a) If a harvest batch or production batch sample fails microbial impurities testing, the harvest batch or production batch may be further processed if the processing method effectively sterilizes the batch and does not impart any toxic or deleterious substance to the medicinal cannabis in the batch.

(b) A harvest batch or production batch that is sterilized in accordance with this subsection shall be sampled and tested in accordance with Sections 2 and 3 of this administrative regulation.

(c) A cultivator, processor, or producer shall inform the safety compliance facility conducting the retesting prior to samples being taken that the harvest or production batch has previously failed testing and is being retested after undergoing sterilization. Any sterilization methods or sterilization solvents used on the harvest or production batch being retested shall be disclosed to the safety compliance facility conducting the retesting.

(d) A harvest batch or production batch that fails microbiological contaminant testing after undergoing a sterilization process in accordance with this subsection shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance with 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(6) Mycotoxins. A harvest batch or production batch that fails mycotoxins testing shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance with 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(7) Water activity. If a harvest batch sample fails water activity testing, the harvest batch may be further dried and cured by the cultivator or producer. A harvest batch that is further dried and cured shall be sampled and retested in accordance with Sections 2 and 3 of this administrative regulation.

(8) Yeast and mold. A harvest batch or production batch sample that fails yeast and mold testing shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(9) Vitamin E acetate. A harvest batch or production batch that fails vitamin E acetate testing shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance with 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(10) Where remediation is allowed, a harvest or production batch shall only be remediated twice. If the harvest or production batch fails testing after a second remediation attempt and the second retesting, the harvest or production batch shall be deemed medicinal cannabis waste and destroyed by the cultivator, processor, or producer in accordance with 915 KAR 1:030 or 915 KAR 1:040 as applicable for their respective business.

(11) Prior to taking any remediation efforts, cultivators, processors, and producers shall:

(a) Create and maintain detailed written procedures for all remediation processes used by the cannabis business and provide those procedures to the cabinet upon request within three (3) business days of receiving the request or during an inspection; and

(b) Document all remediation, sterilization, resampling, retesting, and disposal of medicinal cannabis that fails testing required by Section 2 of this administrative regulation.

Section 6. Certificate of analysis.

(1) A safety compliance facility shall:

(a) Generate a certificate of analysis (COA) for each harvest batch and production batch sample that the safety compliance facility analyzes; and

(b) Ensure the COA contains the results of all required analyses performed for the harvest batch or production batch sample.

(2) The COA shall contain, at minimum:

(a) The safety compliance facility's name, address, and license number;

(b) The cultivator, processor, or producer's name, address, and license number;

(c) The harvest batch or production batch number from which the sample was obtained;

(d) Sample identifying information, including matrix type and unique sample identifiers;

(e) Sample history, including the date collected, the date received by the safety compliance facility, and the date of all sample analyses and corresponding testing results;

(f) The analytical methods, analytical instrumentation used, and corresponding limit of detection (LOD) and limits of quantitation (LOQ);

(g) An attestation from an authorized employee of the safety compliance facility that all testing required by Section 2 of this administrative regulation was performed; and

(h) Analytes detected during the analyses of the harvest batch or production batch sample that are unknown, unidentified, or injurious to human health if consumed, if any.

(3) The safety compliance facility shall report test results for each representative harvest batch or production batch sample on the COA as an overall "pass" or "fail" for the entire batch.

(a) When reporting qualitative results for each analyte, the safety compliance facility shall indicate "pass" or "fail";

(b) When reporting quantitative results for each analyte, the testing facility shall use the appropriate units of measurement for testing the analyte;

(c) When reporting results for each test method, the testing facility shall indicate "pass" or "fail";

(d) When reporting results for any analytes that were detected below the analytical method LOQ, indicate "<LOQ," notwithstanding cannabinoid and terpenoid results;

(e) When reporting results for any analytes that were not detected or detected below the LOD, indicate "ND"; and

(f) Indicate "NT" for any test that the safety compliance facility did not perform.

(4) The safety compliance facility shall retain a reserve sample for each harvest or production batch consisting of any portion of a sample that was not used in the testing process. The reserve sample shall be kept for a minimum of forty-five (45) calendar days after the analyses, after which time it may be destroyed as medicinal cannabis waste by the safety compliance facility in accordance with 915 KAR 1:060.

(5) The safety compliance facility shall securely store the reserve sample in a manner that minimizes the risk of sample degradation, contamination, and tampering.

(6) The safety compliance facility shall provide any reserve samples to the cabinet upon request within three (3) business days of receiving the request.

(7) All certificates of analysis prepared by safety compliance facilities shall be documented in the commonwealth's designated electronic monitoring system and seed to sale tracking system in accordance with instructions provided by the cabinet.

(8) On any informational website that they maintain in accordance with 915 KAR 1:090, Section 2, cultivators, processors, and producers shall publish or provide links to the COAs that they receive from safety compliance facilities for their respective harvest batches and production batches. The information required to be provided under this provision shall be presented in such a way that cardholders can easily access the specific COA for the harvest batch or production batch referenced on the medicinal cannabis product label.

Section 7. Incorporation by reference.

(1) The following material is incorporated by reference:

(a) "Appendix A: List of residual solvents for medicinal cannabis testing", dated January 4, 2024; and

(b) "Appendix B: List of residual pesticides for medicinal cannabis testing", dated January 4, 2024.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Cabinet for Health and Family Services, Office of the Secretary, 275 East Main Street, Frankfort, Kentucky, 40621, Monday through Friday, 8:30 AM to 4:30 PM. This material may also be viewed on the Kentucky Medical Cannabis Program's website at https://kymedcan.ky.gov.

915 KAR 1:110

REVIEWED:

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Sam Flynn
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1/2/2024

Sam Flynn
Executive Director
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Cabinet for Health and Family Services

Date

APPROVED:

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1/2/2024

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 1:110
Agency Contact: Oran S. McFarlan, III
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Contact Person: Krista Quarles
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(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements for random sample testing of medicinal cannabis to ensure quality control.

(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 authorizes the Cabinet for Health and Family Services to promulgate administrative regulations establishing requirements for random sample testing of medicinal cannabis to ensure quality control. This administrative regulation sets out those requirements and procedures.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation provides the requirements for random sample testing of medicinal cannabis to ensure quality control.

(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 that have applied for and subsequently received licenses to conduct medicinal cannabis activities in the commonwealth.

(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: Cannabis businesses must review and comply with the testing requirements contained in this administrative regulation.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (3): Cultivators, processors, and producers will contract with safety compliance facilities to conduct the required testing of medicinal cannabis harvest and production lots.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (3): Cultivators, processors, producers, and safety compliance facilities will be able to properly sample and test medicinal cannabis in the commonwealth.

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

(a) Initially: It is anticipated that an increase in funding will be necessary to implement this administrative regulation as additional staff and resources are necessary to administer and enforce testing requirements. The cabinet estimates that the total staffing costs for the program in the first year will be approximately $1,800,000, and a portion of those staffing costs will go toward regulating testing requirements.

(b) On a continuing basis: It is anticipated that an increase in funding will be necessary to administer this administrative regulation as additional staff and resources are necessary to enforce testing requirements. The cabinet estimates that the total staffing costs for the program on a continuing basis following the first year will be approximately $2,400,000, and a portion of those staffing costs will go toward regulating testing requirements.

(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 anticipated that an increase in funding will be necessary to implement this regulation as additional staff and resources are necessary to administer and enforce the testing requirements.

(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 1:110
Agency Contact: Oran S. McFarlan, III
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Phone Number: (502) 564-7476
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(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? It is anticipated that an increase in funding will be necessary to implement this administrative regulation as additional staff and resources are necessary to administer and enforce testing requirements. The cabinet estimates that the total staffing costs for the program in the first year will be approximately $1,800,000, and a portion of those staffing costs will go toward regulating testing requirements.

(d) How much will it cost to administer this program for subsequent years? It is anticipated that an increase in funding will be necessary to administer this administrative regulation as additional staff and resources are necessary to enforce the testing requirements. The cabinet estimates that the total staffing costs for the program on a continuing basis following the first year will be approximately $2,400,000, and a portion of those staffing costs will go toward regulating packaging and labeling requirements.

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? Cultivators, processors, and producers will contract with safety compliance facilities to conduct the required testing of medicinal cannabis harvest and production lots.

(d) How much will it cost the regulated entities for subsequent years? Cultivators, processors, and producers will contract with safety compliance facilities to conduct the required testing of medicinal cannabis harvest and production lots.

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)]* 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 licensing and enforcement of cannabis businesses operating in the commonwealth as well implementation and continued operation of the electronic monitoring system and seed to sale tracking system required by KRS 218B.140. 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 1 related to cannabis businesses.

COMMONWEALTH OF KENTUCKY
CABINET FOR HEALTH AND FAMILY SERVICES
OFFICE OF THE SECRETARY
915 KAR 1:110
Medicinal cannabis testing.
Summary of Material Incorporated by Reference

The "Appendix A: List of residual solvents for medicinal cannabis testing", dated January 4, 2024, contains the testing requirements for residual solvents and processing chemicals in medicinal cannabis products and establishes the maximum allowable concentration for each solvent or chemical. Appendix A contains one (1) page. The "Appendix B: List of residual pesticides for medicinal cannabis testing", dated January 4, 2024, contains the testing requirements for residual pesticides in medicinal cannabis and establishes the maximum allowable concentration for each pesticide. Appendix B contains two (2) pages.

The total number of pages incorporated by reference for this administrative regulation is three (3) pages.

APPENDIX A

LIST OF RESIDUAL SOLVENTS FOR MEDICINAL CANNABIS TESTING:

Solvent or processing chemical	**Chemical Abstract Service (CAS) assigned number**	**Maximum allowable concentration stated in parts per million (ppm)**
Acetone	67-64-1	1,000 ppm
Benzene	71-43-2	2 ppm
Butanes, (measured as the cumulative residue of n-butane and iso-butane),	106-97-8 and 75-28-5	1,000 ppm
Ethanol	64-17-5	5,000 ppm
Ethyl Acetate	141-78-6	1,000 ppm
Heptanes	142-82-5	1,000 ppm
Hexanes (measured as the cumulative residue of n-hexane, 2-methylpentane, 3-methylpentane, 2,2-dimethylbutane, and 2,3-dimethylbutane)	110-54-3, 107-83-5 and 79-29-8	60 ppm
Methanol	67-56-1	600 ppm
Pentanes (measured as the cumulative residue of n-pentane, iso-pentane, and neo-pentane)	109-66-0, 78-78-4 and 463-82-1	1,000 ppm
2-Propanol (IPA)	67-63-0	1,000 ppm
Propane	74-98-6	1,000 ppm
Toluene	108-88-3	180 ppm
Total Xylenes (measured as the cumulative residue of 1,2-dimethylbenzene, 1,3-dimethylbenzene, and 1,4-dimethylbenzene, and the non-xylene, ethylbenzene),	1330-20-7 (95-47-6, 108-38-3 and 106-42-3 and 100-41-4)	430 ppm

APPENDIX B

LIST OF RESIDUAL PESTICIDES FOR MEDICINAL CANNABIS TESTING:

Residual pesticide	**Chemical Abstract Service (CAS) assigned number**	**Maximum allowable concentration stated in parts per million (ppm)**
Abamectin	71751-41-2	0.5 ppm
Acephate	30560-19-1	0.4 ppm
Acequinocyl	57960-19-7	2.0 ppm
Acetamiprid	135410-20-7	0.2 ppm
Aldicarb	116-06-3	0.4 ppm
Azoxystrobin	131860-33-8	0.2 ppm
Bifenazate	149877-41-8	0.2 ppm
Bifenthrin	82657-04-3	0.2 ppm
Boscalid	188425-85-6	0.4 ppm
Carbaryl	63-25-2	0.2 ppm
Carbofuran	1563-66-2	0.2 ppm
Chlorantraniliprole	500008-45-7	0.2 ppm
Chlorfenapyr	122453-73-0	1.0 ppm
Chlormequat chloride	7003-89-6	0.2 ppm
Chlorpyrifos	2921-88-2	0.2 ppm
Clofentezine	74115-24-5	0.2 ppm
Cyfluthrin	68359-37-5	1.0 ppm
Cypermethrin	52315-07-8	1.0 ppm
Daminozide	1596-84-5	1.0 ppm
DDVP (Dichlorvos)	62-73-7	0.1 ppm
Diazinon	333-41-5	0.2 ppm
Dimethoate	60-51-5	0.2 ppm
Ethoprophos	13194-48-4	0.2 ppm
Etofenprox	80844-07-1	0.4 ppm
Etoxazole	153233-91-1	0.2 ppm
Fenoxycarb	72490-01-8	0.2 ppm
Fenpyroximate	134098-61-6	0.4 ppm
Fipronil	120068-37-3	0.4 ppm
Flonicamid	158062-67-0	1.0 ppm
Fludioxonil	131341-86-1	0.4 ppm
Hexythiazox	78587-05-0	1.0 ppm
Imazalil	35554-44-0	0.2 ppm
Imidacloprid	138261-41-3	0.4 ppm
Kresoxim-methy	143390-89-0	0.4 ppm
Malathion	121-75-5	0.2 ppm
Metalaxyl	57837-19-1	0.2 ppm
Methiocarb	2032-65-7	0.2 ppm
Methomyl	16752-77-5	0.4 ppm

Methyl parathion	298-00-0	0.2 ppm
Myclobutanil,	88671-89-0	0.2 ppm (prohibited at any concentration for inhalation)
Naled	300-76-5	0.5 ppm
Oxamyl	23135-22-0	1.0 ppm
Paclobutrazol	76738-62-0	0.4 ppm
Permethrins (measured as the cumulative residue of cis- and trans-isomers)	52645-531 (54774-45-7 and 51877-74-8)	0.2 ppm
Phosmet	732-11-6	0.2 ppm
Piperonyl_butoxide	51-03-6	2.0 ppm
Prallethrin	23031-36-9	0.2 ppm
Propiconazole	60207-90-1	0.4 ppm
Propoxur	114-26-1	0.2 ppm
Pyrethrins (measured as the cumulative residue of pyrethrin 1, cinerin 1 and jasmolin 1)	8003-34-7(121-21-1,25402-06-6 and 4466-14-2)	1.0 ppm
Pyridaben	96489-71-3	0.2 ppm
Spinosad	168316-95-8	0.2 ppm
Spiromesifen	283594-90-1	0.2 ppm
Spirotetramat	203313-25-1	0.2 ppm
Spiroxamine	118134-30-8	0.4 ppm
Tebuconazole	107534-96-3	0.4 ppm
Thiacloprid	111988-49-9	0.2 ppm
Thiamethoxam	153719-23-4	0.2 ppm
Trifloxystrobin	141517-21-7	0.2 ppm