

CABINET FOR HEALTH AND FAMILY SERVICES

Office of the Secretary (Amended After Comments)

915 KAR 1:060. Safety compliance facility.

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 and procedures for safety compliance facilities that provide testing services to medicinal cannabis businesses in the Commonwealth. This administrative regulation sets out those requirements and procedures.

Section 1. General Requirements.

(1) A safety compliance facility shall not collect, handle, receive, or conduct tests on medicinal cannabis samples unless it has been issued a license by the cabinet. Prior to conducting any testing of a sample at the request of a cannabis business, a safety compliance facility shall enter into a written contract with the cannabis business for testing services. A safety compliance facility shall provide a copy of their contracts with cannabis businesses to the cabinet within two (2) business days of receipt of the request.

(2) The cabinet shall post a list of licensed safety compliance facilities on the Web site for the Kentucky Medical Cannabis Program, <https://kymedcan.ky.gov>.

(3) A safety compliance facility shall employ at least one (1) director to oversee and be responsible for the testing operations of the facility. A director shall have earned, from a college or university accredited by a national or regional accrediting authority, at least one of the following:

(a) A doctorate of science or an equivalent degree in chemistry, biology, or a subdiscipline of chemistry or biology;

(b) A master's level degree in a chemical or biological science and a minimum of two (2) years post-degree experience related to laboratory testing of medicinal or pharmaceutical products; or

(c) A bachelor's degree in a biological science and a minimum of four (4) years post-degree experience related to laboratory testing of medicinal or pharmaceutical products.

(4) A principal officer, board member, employee, volunteer, or agent of a cultivator, processor, producer, or dispensary shall not be employed by or affiliated with a safety compliance facility that has a contract with that respective cannabis business.

(5) A license issued by the cabinet to a safety compliance facility is valid only for the specific site licensed and identified on the license.

(6) A safety compliance facility shall:

(a) Conduct a criminal background check into the criminal history of each person seeking to become a principal officer, board member, agent, volunteer, or employee before that person begins work and shall retain records of these background checks for five (5) years and provide same to the cabinet during subsequent inspections or upon request;

(b) Maintain and adhere to proper standards of accuracy for testing and comply with the testing requirements contained in 915 KAR 1:110;

(c) Comply with all required analytes standards for the relevant test methods of cannabinoids, terpenoids, residual solvents and processing chemicals, residual pesticides, heavy metals, microbial impurities, mycotoxins, water activity, yeast, mold, and vitamin E acetate;

- (d) Accurately and honestly report all medicinal cannabis test results;
 - (e) Only allow authorized individuals to perform medicinal cannabis testing and sign reports;
 - (f) Only accept a sample or test sample from a cannabis business employee or agent, **or cardholder**, or an authorized representative of the cabinet;
 - (g) Maintain a certificate of accreditation in good standing from an accreditation body and provide a copy to the cabinet during subsequent inspections or upon request. The certificate of accreditation shall attest to the safety compliance facility's competence to perform testing, including all the required analytes for the relevant test methods required, and shall be obtained by the safety compliance facility prior to collecting, receiving, or testing any medicinal cannabis sample or test sample;
 - (h) Develop and maintain standard operating procedures for a laboratory approved by the accreditation body that issued the certificate of accreditation to the safety compliance facility and provide copies to the cabinet during subsequent inspections or upon request;
 - (i) Properly enter medicinal cannabis test results into the Commonwealth's designated electronic monitoring system and seed to sale tracking system as required by the cabinet and in accordance with written instructions provided by the cabinet; and
 - (j) Comply with all applicable requirements of KRS Chapter 218B, specifically KRS 218B.095 and 218B.125, and 915 KAR Chapter 1.
- (7) A safety compliance facility shall not employ, take on as a volunteer, or have as a board member, principal officer, or agent any person who was convicted of a disqualifying felony offense or is younger than twenty-one (21) years of age.
- (8) The qualifications that a safety compliance facility shall meet to receive a license are continuing qualifications to maintain the license throughout the licensure period.

Section 2. Selecting and Collecting Samples for Testing.

- (1) A sampler is 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 this administrative regulation. A sampler shall obtain an amount for a sample or test sample on behalf of his or her employer sufficient to be aliquoted into a primary sample and a reserve sample, which shall be equal in amount. The primary sample and reserve sample shall be in the amounts specified in the safety compliance facility's standard operating procedures.
- (2) A safety compliance facility shall ensure that samples and test samples are selected and collected in accordance with standard operating procedures established by the safety compliance facility and required by this administrative regulation. The standard operating procedures for sampling shall be written and provided to the cabinet and each cannabis business that the safety compliance facility contracts with for testing prior to collecting, receiving, or testing any medicinal cannabis. These standard operating procedures shall be in place prior to the first day that the safety compliance facility collects, receives, or tests a sample.
- (3) Samples shall consist of enough samples from a harvest batch or production batch to ensure that the required attributes in the products are homogenous and consistent with the safety compliance facility's standard operating procedures for selecting and collecting samples. Test samples shall consist of enough samples of the item identified for testing to ensure any required testing can be accomplished in accordance with the safety compliance facility's standard operating procedures.
- (4) The sampling policies and procedures shall include:
- (a) A step-by-step guide for obtaining samples and test samples;

- (b) Random taking of samples or test samples throughout the harvest batch or production batch;
 - (c) Using appropriate sampling equipment, including protocols relating to the sanitizing of equipment and tools, protective garb, and sampling containers;
 - (d) Using consistent collection procedures for samples and test samples;
 - (e) Transporting samples in a manner that does not endanger the integrity of the samples and that is in accordance with transportation requirements for samples contained in 915 KAR 1:080;
 - (f) Creating a unique sample identification number that will be linked to the harvest batch or production batch number assigned by the cultivator, processor, or producer in the Commonwealth's designated electronic monitoring system and seed to sale tracking system; and
 - (g) The process for properly documenting a chain of custody for each sample or test sample and retaining those records for a minimum of two (2) years.
- (5) An employee or agent of a safety compliance facility shall only enter a facility operated by a cultivator, processor, producer, or dispensary for the purpose of:
- (a) Selecting and collecting samples and test samples and shall have access to limited access areas in the facility for these purposes; and
 - (b) Providing training to cannabis business agents as provided in KRS 218B.125(7).
- (6) An employee or agent of a safety compliance facility shall comply with all visitor requirements for entry into the cultivator, processor, producer, or dispensary's facility.
- (7) An authorized cannabis business employee collecting any samples for testing shall follow the standard operating procedures established by the contracted safety compliance facility conducting the testing for sampling and documenting the chain of custody.

Section 3. Standards for testing. A safety compliance facility shall follow:

- (1) The methodologies and parameters that are contained in the scope of the certificate of accreditation issued to the safety compliance facility; and
- (2) The testing requirements contained in 915 KAR 1:110.

Section 4. Quality Assurance Program.

- (1) Prior to its first day of collecting or receiving samples or test samples in the Commonwealth, a safety compliance facility shall establish and implement a written quality assurance program to ensure that measurements are accurate, errors are controlled, and equipment, devices, or instruments used for testing are routinely and properly calibrated in accordance with the equipment, device, or instrument manufacturer recommendations regarding calibration and frequency.
- (2) The quality assurance program required under this section shall include the following components:
 - (a) An organizational chart that includes the testing responsibilities of employees;
 - (b) A description of sampling procedures to be utilized;
 - (c) Appropriate chain of custody protocols;
 - (d) Analytical procedures;
 - (e) Data reduction and validation procedures; and
 - (f) A plan for implementing corrective action, when necessary.
- (3) A safety compliance facility shall provide a copy of its written quality assurance program to the cabinet upon request or during subsequent inspections or investigations.

Section 5. Cabinet Request for Testing. If the cabinet requests that a safety compliance facility conduct tests on any samples or test samples collected by the cabinet, the safety compliance facility shall comply with the request and directions of the cabinet and provide the cabinet with a written report of the results from a sample tested under this section within seven (7) calendar days of receipt of the sample, or sooner if requested by the cabinet.

Section 6. Ownership Prohibition. The following individuals shall not have a management or a direct or indirect financial or other ownership interest in a safety compliance facility:

- (1) An owner, principal officer, board member, financial backer, employee, volunteer, or agent of a cultivator, processor, producer, or dispensary; and
- (2) A medicinal cannabis practitioner.

Section 7. Plans of Operation.

(1) In addition to any other standard operating procedures required by this administrative regulation, a safety compliance facility shall establish standard operating procedures for the following prior to its first day of collecting or receiving samples or test samples in the Commonwealth:

- (a) Employment policies and procedures;
- (b) Security, including:
 1. Staff identification measures and use of employee identification badges;
 2. Monitoring of attendance of staff and visitors;
 3. Alarm systems;
 4. Video surveillance;
 5. Monitoring and tracking samples and test results, including use of the Commonwealth's electronic monitoring system and seed to sale tracking system established pursuant to KRS 218B.140;
 6. Personnel security;
 7. Transportation of medicinal cannabis **and how to properly secure medicinal cannabis in the event of a traffic collision or transport vehicle malfunction;**
 8. Cash management and anti-fraud procedures;
 9. Measures to prevent loitering, which shall include signage; and
 10. Storage of medicinal cannabis and medicinal cannabis products;
- (c) Recordkeeping;
- (d) The process for receiving, handling, packaging, labeling, storing, transporting, and disposing of medicinal cannabis samples;
- (e) Employee qualifications, supervision, and training;
- (f) Workplace safety;
- (g) Waste disposal and sanitation;
- (h) Inventory management, including intake, labeling, and storage of samples and test samples;
- (i) Contamination;
- (j) Maintenance, cleaning, and sanitation of equipment used to test samples;
- (k) Maintenance, cleaning, and sanitation of the safety compliance facility;
- (l) Proper handling and storage of any chemical or substance used in testing medicinal cannabis;
- (m) Investigation of complaints and potential adverse events received from other cannabis businesses, registered qualified patients, designated caregivers, or medicinal cannabis practitioners regarding the safety compliance facility's operations;
- (n) Preventing unlawful diversion of medicinal cannabis; and
- (o) Any other standard operating procedures required for all cannabis businesses in KRS Chapter 218B and 915 KAR Chapter 1.

(2) A safety compliance facility shall make its standard operation procedures available to the cabinet upon request and during any inspection or investigation.

Section 8. Facilities.

(1) A safety compliance facility shall only test samples in a facility on the specific site licensed by the cabinet and identified on its license issued by the cabinet. The facility shall meet all applicable state and local building codes and specifications in addition to the following:

- (a) Has a complete roof enclosure supported by connecting permanent walls, constructed of solid materials extending from the ground to the roof;
 - (b) Is secure against unauthorized entry;
 - (c) Has a foundation, slab, or equivalent base to which the floor is securely attached;
 - (d) Has commercial grade door locks on all external doors that are locked at all times;
 - (e) Restricts access to only authorized personnel to limited access areas identified with signage and daily records of entry and exit;
 - (f) Contains adequate plumbing to carry sufficient quantities of water to locations throughout the facility and convey sewage and waste from the facility without cross contamination of potable water and waste;
 - (g) Stores toxic cleaning compounds, sanitizing agents, and substances used in testing samples in a manner that is in accordance with applicable local, state, and federal laws and regulations;
 - (h) Maintains proper ventilation;
 - (i) Maintains pest control;
 - (j) Maintains adequate indoor and exterior lighting to facilitate video surveillance at all times; and
 - (k) Maintains adequate on-site parking for employees, agents, visitors, transporters of medicinal cannabis, or cabinet staff.
- (2) A safety compliance facility shall clearly mark all limited access areas on its premises with proper signage. All areas of ingress and egress to a limited access area shall be clearly identified by the posting of a sign which shall be not less than twelve (12) inches wide and twelve (12) inches long, composed of letters not less than one-half inch in height, which shall state: "Do Not Enter. Limited Access Area. Access Limited to Authorized Personnel and Escorted Visitors."
- (3) A safety compliance facility shall have a secure area for the loading and unloading of medicinal cannabis samples into and from a transport vehicle.

Section 9. Employee Records and Identification.

- (1) A safety compliance facility shall keep an individual employment record for all employees, including:
- (a) Full legal name;
 - (b) Detailed job description;
 - (c) Documentation of completed criminal background check;
 - (d) Record of all training received or acquired by the employee;
 - (e) Dates of employment;
 - (f) Records of days and hours worked; and
 - (g) Any disciplinary actions taken by the safety compliance facility.
- (2) Employment records shall be maintained, either electronically or in hard copy, for at least five (5) years after the employee's last date of employment with the safety compliance facility.
- (3) A safety compliance facility shall create an identification badge for each employee, agent, or volunteer. This badge shall be conspicuously worn by employees or agents at all times that they are on the licensed premises or during transport of samples or test samples. The badge shall contain:
- (a) The individual's name, photo, ~~and~~ employee identification number, and the license number of the safety compliance facility;
 - (b) A phone number and email address for the safety compliance facility; and
 - (c) A phone number and email address for the Kentucky Medical Cannabis Program.

Section 10. Visitors to Safety Compliance Facilities.

- (1) A safety compliance facility shall not be open to the general public.

(2) A safety compliance facility shall complete the following steps when admitting a visitor to its site and facility:

- (a) Require the visitor to sign a visitor log upon entering and leaving the facility;
- (b) Check the visitor's government-issued identification to verify the visitor's age and that the name on the identification provided matches the name in the visitor log;
- (c) Issue a visitor identification badge with the visitor's name and company, if applicable, and a badge number;
- (d) Escort the visitor while the visitor remains in the facility ~~keeping a record of the areas of the facility visited~~; and
- (e) Ensure that the visitor does not touch any medicinal cannabis located in a limited access area.

(3) No one under the age of eighteen (18) shall be permitted to enter a safety compliance facility. A person who is at least eighteen (18) years of age may enter and remain on the premises if that person is present to perform contract work, including electrical, plumbing, or security maintenance, that does not involve handling medicinal cannabis or is a government employee and is at the facility in the course of his or her official duties.

(4) A safety compliance facility shall post a sign in a conspicuous location at each entrance of its facility that states "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE. NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER." The letters on the signs required by this provision shall be at minimum one-half inch in height.

(5) A safety compliance facility shall maintain the visitor log required under this section for five (5) years and make the visitor log available to the cabinet, law enforcement, and other federal or state government officials upon request to perform the government officials' functions and duties. The visitor log shall include the date, the full name of each visitor, the visitor identification badge number, the time of arrival, the time of departure, and the purpose of the visit, ~~including the areas of the site and the facility visited~~.

(6) This section does not limit the right of the cabinet or its authorized agents, or other federal, state, or local government officials from entering any area of a safety compliance facility if necessary to perform the governmental officials' functions and duties.

(7) A principal officer, board member, agent, financial backer, or employee of a safety compliance facility may not receive any type of consideration or compensation for allowing a visitor to enter a limited access area.

Section 11. Security and Surveillance.

(1) A safety compliance facility shall have security and surveillance systems, utilizing commercial-grade equipment, to prevent unauthorized entry and to prevent and detect an adverse loss. The security and surveillance systems shall include the following:

- (a) A professionally monitored security alarm system that includes:
 - 1. Coverage of all facility entrances and exits, storage rooms, including those that contain medicinal cannabis and safes, and the perimeter of the facility;
 - 2. Smoke and fire alarms;
 - 3. Auxiliary power sufficient to maintain operation for at least twenty-four (24) hours following a power outage;
 - 4. The ability to ensure all access doors are not solely controlled by an electronic access panel to prevent locks from becoming released during a power outage; and
 - 5. Motion detectors for exterior lighting.
- (b) A professionally monitored security surveillance system that is operational twenty-four (24) hours a day, seven (7) days a week, and records all activity in images capable of clearly revealing facial detail. The security and surveillance system shall include:
 - 1. Fixed camera placement that allows for a clear image of all individuals and activities in and around the following:

- a. All limited access areas;
 - b. A room or area containing a security alarm and surveillance system storage device or equipment;
 - c. Entrances to and exits from the facility; and
 - d. Twenty (20) feet from the exterior of the perimeter of the facility.
2. Ability to operate under the normal lighting conditions of each area under surveillance;
3. Ability to immediately produce a clear, color, still photograph in a digital format that is easily accessible;
4. Ability to display the date and time clearly and accurately. The date and time shall be synchronized and set correctly and may not significantly obscure the picture;~~;~~
and
5. Ability to record all images captured by each surveillance camera in a format that may be easily accessed for a minimum of ~~sixty (60)~~~~(thirty (30))~~ days, unless otherwise required for investigative or litigation purposes. The recordings shall be kept:
- a. At the safety compliance facility:
 - (i) In a locked cabinet, closet or other secure place to protect it from tampering or theft; and
 - (ii) In a limited access area or other room to which access is limited to authorized individuals; or
 - b. At a secure location other than the location of the safety compliance facility if approved by the cabinet;~~and~~~~;~~

6. Ability to easily export video recordings and still photographs requested by the cabinet, law enforcement, and other federal or state government officials and provide same in a standard file format that is easily accessible.

- (2) The following requirements apply to the inspection, servicing or alteration of, and any upgrade to, the security alarm and surveillance systems:
- (a) The systems shall be inspected and all devices tested once every year by a qualified alarm system vendor and a qualified surveillance system vendor;
 - (b) A safety compliance facility shall conduct maintenance inspections once every month to ensure that any repairs, alterations, or upgrades to the security alarm and surveillance systems are made for the proper operation of the systems. **No more than thirty (30) calendar days shall lapse between the inspections required under this provision;**
 - (c) A safety compliance facility shall retain at the facility, for at least five (5) years, records of all inspections, servicing, alterations, and upgrades performed on the security alarm and surveillance systems and shall make the records available to the cabinet and its authorized agents within two (2) business days following a request; and
 - (d) In the event of a mechanical malfunction of the security alarm or surveillance system that a safety compliance facility anticipates will exceed an eight (8) hour period, the safety compliance facility shall notify the cabinet immediately via electronic mail to kymedcanreporting@ky.gov, with cabinet approval, provide alternative security measures that may include closure of the facility.
- (3) A safety compliance facility shall meet the following requirements regarding records retention:
- (a) Have a secure electronic back-up system for all electronic records;
 - (b) Within three (3) business days following a request for records under this paragraph, provide up to four (4) screen captures of an unaltered copy of a video surveillance recording to the cabinet or its authorized agents, law enforcement, or other federal, state, or local government officials if necessary to perform the governmental officials' functions and duties; and

- (c) If a safety compliance facility has been notified in writing by the cabinet or its authorized agents, law enforcement, or other federal, state, or local government officials of a pending criminal or administrative investigation for which a recording may contain relevant information, retain an unaltered copy of the recording for two (2) years or until the investigation or proceeding is closed or the entity conducting the investigation or proceeding notifies the cultivator that it is not necessary to retain the recording, whichever is later.
- (4) During all non-working hours, all entrances to and exits from the safety compliance facility shall be securely locked.
- (5) A safety compliance facility shall install lighting to ensure proper surveillance inside and outside of the facility.
- (6) A safety compliance facility shall limit access to a room containing the equipment operating the security alarm and surveillance monitoring systems to:
- (a) Persons who are essential to maintaining security and surveillance operations;
 - (b) Federal, state, and local law enforcement;
 - (c) Security alarm and surveillance system service employees;
 - (d) The cabinet or its authorized agents; and
 - (e) Other persons with the prior written approval of the cabinet.
- (7) A safety compliance facility shall make available to the cabinet or its authorized agents, upon request, a current list of authorized employees and service employees or contractors who have access to areas containing the equipment operating the security alarm and surveillance monitoring systems **and place a copy of this list on or next to the doors that access those areas.**
- (8) A safety compliance facility shall keep rooms housing the equipment operating the security alarm and surveillance monitoring systems locked at all times and may not use these rooms for any other purpose or function.

Section 12. Electronic Monitoring System and Seed to Sale Tracking System.

- (1) A safety compliance facility shall use the electronic monitoring system and seed to sale tracking system prescribed by the cabinet containing the requirements in KRS Chapter 218B, specifically KRS 218B.140. A safety compliance facility shall use the electronic monitoring system and seed to sale tracking system in accordance with written instructions provided by the cabinet.
- (2) **A safety compliance facility shall record in the commonwealth's designated electronic monitoring system and seed to sale tracking system all medicinal cannabis received, disposed, or otherwise transferred by the safety compliance facility and ensure the inventory is accurate in real-time.**
- (3) **A safety compliance facility shall establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility to include:**
- (a) A safety compliance facility shall prepare monthly physical inventory reports that include any necessary adjustments and the reason(s) for an adjustment and that demonstrate the physical inventory reconciles with the inventory recorded in the commonwealth's designated electronic monitoring system and seed to sale tracking system, including any medicinal cannabis that has been or is in the process of being destroyed. No more than thirty (30) calendar days shall lapse between the preparation of a report required under this provision; and**
 - (b) A written or electronic record shall be created and maintained of each inventory conducted under this section that includes the date of the inventory, a summary of the inventory findings, and the employee identification numbers and titles or positions of the individuals who conducted the inventory.**

Section 13. Equipment, Operation, and Maintenance.

(1) A safety compliance facility shall have a written process in place to maintain the sanitation and operation of equipment that comes into contact with samples to prevent contamination. A safety compliance facility shall provide a copy of the written process to the cabinet upon request.

(2) As part of the written process required under this section, a safety compliance facility shall:

(a) Routinely check and inspect automatic, mechanical, or electronic equipment as well as any measurement devices used in the safety compliance facility's operations to ensure accuracy; and

(b) Maintain an accurate log recording the:

1. Maintenance of equipment;
2. Cleaning of equipment; and
3. Calibration of equipment.

Section 14. Sanitation and Safety in a Safety Compliance Facility.

(1) A safety compliance facility shall maintain its site and facility in a sanitary condition to limit the potential for contamination of samples. The following requirements shall apply:

(a) Equipment and surfaces, including floors, counters, walls, and ceilings, shall be cleaned and sanitized as frequently as necessary to protect against contamination, using a sanitizing agent registered by the United States Environmental Protection Agency, in accordance with the instructions printed on the label. All equipment and utensils used by a safety compliance facility shall be capable of being adequately cleaned;

(b) Trash shall be properly and routinely removed;

(c) Floors, walls, and ceilings shall be kept in good repair;

(d) Adequate protection against pests shall be provided; and

(e) Toxic cleaning compounds, sanitizing agents, and other chemicals shall be labeled and stored in a manner that prevents contamination of samples, and in a manner that otherwise complies with other applicable laws, rules, and regulations.

(2) All employees shall conform to sanitary practices while on duty, including:

(a) Maintaining adequate personal cleanliness;

(b) Washing hands thoroughly in an adequate hand-washing area before starting work and at any other time when hands may have become soiled or contaminated;

(c) Wearing proper clothing, including gloves, hair nets, headbands, caps, beard covers, or other effective hair restraints where appropriate;

(d) Removing all unsecured jewelry and other objects that might fall into medicinal cannabis, equipment, or containers, and removing hand jewelry that cannot be adequately sanitized during periods in which medicinal cannabis is manipulated by hand. If such hand jewelry cannot be removed, it may be covered by material which can be maintained in an intact, clean, and sanitary condition and which effectively protects the medicinal cannabis from contamination by these objects;

(e) Storing clothing or other personal belongings in areas other than where medicinal cannabis is exposed or where equipment is cleaned;

(f) Confining the following to areas other than where medicinal cannabis may be exposed or where equipment is cleaned: eating food, chewing gum, drinking beverages, or using tobacco; and

(g) Taking any other necessary precautions to protect against contamination of medicinal cannabis with microorganisms or foreign substances including perspiration, hair, cosmetics, tobacco, chemicals, and medicines applied to the skin.

(3) A safety compliance facility shall provide its employees and visitors with adequate and convenient hand-washing facilities furnished with running water at a temperature

suitable for sanitizing hands. Effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices shall also be provided.

(4) A safety compliance facility shall provide its employees and visitors with adequate, readily accessible restrooms that are maintained in a sanitary condition and in good repair.

(5) A safety compliance facility shall ensure that its facility is provided with a water supply sufficient for its operations, which shall be derived from a source that is a public water system, or a nonpublic system that is capable of providing a safe, potable, and adequate supply of water to meet the operational needs of the facility.

(6) A safety compliance facility shall comply with all other applicable federal, state, and local building code requirements and occupational safety and health requirements.

Section 15. Storage Requirements.

(1) A safety compliance facility shall have separate locked limited access areas for storage of all samples and test samples until they can be tested and destroyed or otherwise disposed of as required under Section 16 of this administrative regulation.

(2) A safety compliance facility shall maintain all storage areas in a clean and orderly condition and free from infestation by insects, rodents, birds, and pests.

Section 16. Management and Disposal of Medicinal Cannabis Waste.

(1) A safety compliance facility shall dispose of samples in such a manner as to render the medicinal cannabis unusable. A safety compliance facility shall record medicinal cannabis waste as required in the Commonwealth's designated electronic monitoring system and seed to sale tracking system.

(2) Medicinal cannabis that is rendered unusable shall be discarded into a ~~locked~~ dumpster with commercial grade locks or other approved, locked container for removal from the facility by a waste removal company selected by the safety compliance facility, except that ashes resulting from the controlled incineration of medicinal cannabis may be placed in an unlocked dumpster. Medicinal cannabis shall be rendered unusable by:

(a) Controlled incineration; or

(b) Grinding and incorporating the medicinal cannabis with one (1) or more of the non-consumable, solid wastes listed below, such that the resulting mixture is majority non-cannabis waste:

1. Paper waste;
2. Cardboard waste;
3. Food waste;
4. Yard or garden waste;
5. Grease or other compostable oil waste; or
6. Soil or other used growth media.

(3) The disposal of medicinal cannabis shall be performed under video surveillance from the time the destruction begins to when it is placed in a locked dumpster or other approved, locked container and removed from the safety compliance facility location.

(4) A minimum of two (2) employees shall oversee ~~The employee overseeing~~ the disposal of medicinal cannabis and shall maintain and make available a separate record of every disposal indicating the following:

(a) The date and time of disposal;

(b) The manner of disposal;

(c) Any ~~The~~ unique identification codes associated with the medicinal cannabis scheduled for destruction;

(d) The reasoning for and description of the disposal;

(e) The names~~name~~, employee identification numbers~~number~~, and signatures~~signature~~ of the employees~~employee~~ overseeing the disposal of the

medicinal cannabis; and

(f) The harvest batch or production batch number and weight of the **medicinal cannabis**~~plant material~~ being disposed of.

(5) The disposal of other waste from the safety compliance facility that does not include medicinal cannabis, including hazardous waste and liquid waste, shall be performed in a manner consistent with applicable federal, state, and local requirements.

Section 17. Duty to Report.

(1) At the time a safety compliance facility submits a license renewal application to the cabinet, a safety compliance facility shall report to the cabinet via electronic mail to kymedcanreporting@ky.gov the following:

(a) A list of the cannabis businesses that the safety compliance facility has contracted with for sample testing;

(b) A list of non-testing activities allowed under KRS 218B.125 that the safety compliance facility engaged in during the licensure period, a list of its customers for each activity, and the compensation received for each activity. If the safety compliance facility produced and sold educational materials related to the use of medicinal cannabis, the safety compliance facility shall provide copies of those educational materials to the cabinet upon request;

(c) Any issues with accomplishing sample testing in a timely manner;~~and~~

(d) The number of current employees, their respective job titles, and hourly wage;~~and~~

(e) The number of samples tested during the previous twelve (12) months; and

(f) The number of samples that failed testing during the previous twelve (12) months and a breakdown of the reason(s) the tests failed.

(2) A safety compliance facility shall participate in surveys distributed by the cabinet throughout a licensure period and provide full and complete responses.

SAM FLYNN, Executive Director

ERIC FRIEDLANDER, Secretary

APPROVED BY AGENCY: May 14, 2024

FILED WITH LRC: May 15, 2024 at 11:15 a.m.

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:Krista Quarles

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes requirements and procedures for safety compliance facilities that provide testing services to medicinal cannabis businesses in the commonwealth. In response to comments received by the cabinet, the Amended After Comments version of the administrative regulation will be amended to clarify and address security, facility, and recordkeeping requirements.

(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 and procedures for safety compliance facilities that provide testing services to medicinal cannabis businesses in the commonwealth. 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 and procedures for safety compliance facilities to operate in the commonwealth.

(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 safety compliance facilities that have applied for and subsequently received licenses to provide testing services to medicinal cannabis businesses 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:

The requirements to operate as a safety compliance facility and remain in good standing throughout the licensure period are provided 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):

Safety compliance facilities will have to pay an initial application fee, and if approved for a license, an initial license fee and then a renewal license fee if it desires to continue operating as a cannabis business following the expiration of its initial license.

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

A safety compliance facility that receives a license from the Cabinet for Health and Family Services is authorized to provide testing and other services to medicinal cannabis businesses in the commonwealth for the term of the license (i.e., 1 year from the date of license issuance).

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

(a) Initially:

\$1,200,000

(b) On a continuing basis:

\$1,200,000

(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 licensure of safety compliance facilities.

(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 safety compliance facilities 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.010, 218B.080, 218B.085, 218B.090, 218B.095, 218B.100, 218B.125, 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:The cabinet estimates that it will cost \$1,200,000 to license and regulate safety compliance facilities in the first year.

Revenues:The cabinet will receive initial application fees and initial license fees paid by safety compliance facilities during the first year.

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

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

The cabinet estimates that it will cost \$1,200,000 to regulate licensed safety compliance facilities in each subsequent year. The cabinet will receive annual renewal license fees from safety compliance facilities that desire to continue operating in the commonwealth following the expiration of their existing license. The cabinet may also receive additional initial application fees and initial license fees if additional licenses are made available 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 safety compliance facility will locate within a city or county in the commonwealth.

(a) Estimate the following for the first year:

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

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

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?

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

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

Licensed safety compliance facilities.

(a) Estimate the following for the first year:

Expenditures:The initial license fee for a safety compliance facility is \$12,000 for each licensed location.

Revenues:Unknown at this time. This response will depend on how many licensed cannabis businesses are contracted with a respective safety compliance facility to test samples as well as other allowable activities under KRS 218B.125.

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

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

The annual renewal license fee for a safety compliance facility is \$12,000 for each licensed location. Revenues will continue to depend on how many licensed cannabis businesses are contracted with a respective safety compliance facility to test samples as well as other allowable activities under KRS 218B.125. Cost savings may occur in subsequent years as licensed safety compliance facilities gain experience and efficiency in their operations while still remaining fully compliant with the applicable administrative regulations.

(5) Provide a narrative to explain the:

(a) Fiscal impact of this administrative regulation:

The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward 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. A portion of the estimated staffing costs will go toward regulating licensed safety compliance facilities.

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

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

(6) Explain:

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

The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward licensing and enforcement of cannabis businesses operating in the commonwealth, including safety compliance facilities, 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.

(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.