

CABINET FOR HEALTH AND FAMILY SERVICES

Office of the Secretary (Amended After Comments)

915 KAR 1:070. Dispensary.

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 medicinal cannabis dispensaries in the Commonwealth. This administrative regulation establishes those requirements and procedures.

Section 1. General Requirements.

- (1) No person or entity may dispense, sell, or deliver medicinal cannabis to cardholders without first being issued a license by the cabinet.
- (2) The cabinet shall post a list of licensed dispensaries on the Web site for the Kentucky Medical Cannabis Program, <https://kymedcan.ky.gov>.
- (3) A dispensary 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) Not acquire medicinal cannabis for retail sale from any person or business other than a cannabis business licensed by the cabinet;
 - (c) Not sell or dispense medicinal cannabis products intended for consumption by vaporizing to a cardholder who is younger than twenty-one (21) years of age or to a designated caregiver for a registered qualified patient who is younger than twenty-one (21) years of age;
 - (d) Not sell medicinal cannabis directly to a minor;
 - (e) Not co-locate in a shared space or have any financial arrangement with a medicinal cannabis practitioner;
 - (f) Not acquire, possess, dispense, sell, offer for sale, transfer, or transport:
 1. Raw plant material with a delta-9 tetrahydrocannabinol (THC) content of more than thirty-five (35) percent;
 2. Medicinal cannabis products intended for oral consumption as an edible, oil, or tincture with more than ten (10) milligrams of THC per serving;
 3. Any medicinal cannabis product not otherwise described in this provision with a THC content of more than seventy (70) percent; or
 4. Any medicinal cannabis product that contains vitamin E acetate;
 - (g) Prohibit a cardholder from self-administering or a designated caregiver from assisting with administering medicinal cannabis on the premises of the licensed dispensary location;
 - (h) Only dispense or sell medicinal cannabis that has passed the testing requirements contained in 915 KAR 1:110;
 - (i) Only dispense or sell medicinal cannabis to a cardholder in a sealed and properly labeled package as required by 915 KAR 1:100;
 - (j) Maintain adequate on-site parking for employees, agents, visitors, transporters of medicinal cannabis, or cabinet staff; and
 - (k) Comply with all applicable requirements of KRS Chapter 218B, specifically KRS 218B.095 and 218B.110, and 915 KAR Chapter 1.

(4) A dispensary 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.

(5) The qualifications that a dispensary shall meet to receive a license are continuing qualifications to maintain the license throughout the licensure period.

(6) A dispensary shall not package medicinal cannabis and medicinal cannabis products for sale to cardholders.

Section 2. Dispensing Medicinal Cannabis.

(1) A dispensary shall only dispense medicinal cannabis to a registered qualified patient, visiting qualified patient, or designated caregiver who:

(a) Presents a valid registry identification card issued by the cabinet; or

(b) Presents a valid out-of-state registry identification card and documentation of having been diagnosed with a qualifying medical condition if the individual is a visiting qualified patient without a valid registry card issued by the cabinet.

(2) Prior to dispensing medicinal cannabis to registered qualified patients, designated caregivers, and visiting qualified patients who have a registry identification card issued by the cabinet, the dispensary shall:

(a) Verify the validity of the registry identification card through use of the Commonwealth's designated electronic monitoring system;

(b) Verify that the individual presenting the registry identification card is at least eighteen (18) years of age and is the person identified on the registry identification card by examining at least one (1) other form of government-issued photo identification; and

(c) Verify the amount of medicinal cannabis that the registered qualified patients, designated caregivers, and visiting qualified patients who have a registry identification card issued by the cabinet is legally permitted to purchase pursuant to KRS 218B.025 by checking the Commonwealth's designated electronic monitoring system. If a medicinal cannabis practitioner sets forth recommendations, requirements, or limitations as to the form or dosage of medicinal cannabis on the written certification issued to the individual, the medicinal cannabis dispensed shall conform to those recommendations, requirements, or limitations.

(3) Prior to dispensing medicinal cannabis to visiting qualified patients that do not have a registry identification card issued by the cabinet, the dispensary shall:

(a) Review the out-of-state registry identification card presented by the individual to determine any issues with its validity, including checking any expiration date;

(b) Verify that the individual presenting the registry identification card is at least eighteen (18) years of age and is the person identified on the registry identification card by examining at least one (1) other form of government-issued photo identification;

(c) Examine documentation provided by the individual of having been diagnosed with a qualifying medical condition. This documentation shall consist of contemporaneous records containing an express statement of diagnosis of a qualifying medical condition and may include a written certification from a physician, patient history and physical report, or a physician summary report; and

(d) Inform the individual that he or she is not be permitted to purchase more medicinal cannabis than the amount determined by the cabinet to constitute an uninterrupted ten (10) day supply of medicinal cannabis during a given eight (8) day period.

(4) A dispensary shall maintain records that include specific notations of the type and amount of medicinal cannabis being dispensed to a cardholder and whether it was dispensed directly to a registered qualified patient or visiting qualified patient, or to a registered qualified patient's designated caregiver. Each entry shall include the date and

time the medicinal cannabis was dispensed. The data required to be recorded by this provision shall be entered into the Commonwealth's designated electronic monitoring system and seed to sale tracking system in accordance with written instructions provided by the cabinet.

(5) Prior to the completion of the transaction, the employee conducting the transaction at the dispensary shall prepare a receipt of the transaction, provide a **hardcopy or electronic** copy of the receipt to the cardholder, and retain a **hardcopy or electronic** copy of the receipt for the dispensary's records for a minimum of two (2) years. The receipt shall include the following information:

- (a) The dispensary's name, address, and license number;
- (b) The name of the cardholder;
- (c) The date and time the medicinal cannabis was dispensed;
- (d) ~~Any requirement or limitation noted by the medicinal cannabis practitioner on the cardholder's written certification as to the form or amount of medicinal cannabis that the individual should use;~~
- ~~(e)~~ The form and the quantity of medicinal cannabis dispensed;
- ~~(e)~~ ~~(f)~~ Any medicinal cannabis accessories or educational materials included in the transaction; and
- ~~(f)~~ ~~(g)~~ The amount paid by the cardholder for the medicinal cannabis and other items.

(6) When dispensing medicinal cannabis to visiting qualified patients with an out-of-state registry identification card and required documentation of having been diagnosed with a qualifying medical condition, a dispensary may assess a convenience fee to be collected by the dispensary as part of the transaction. The convenience fee shall not exceed fifteen (15) dollars per transaction.

Section 3. Limitations on Dispensing Medicinal Cannabis. In addition to other dispensing requirements contained in KRS Chapter 218B and this administrative regulation, a dispensary shall not dispense to a cardholder:

- (1) A quantity of medicinal cannabis that is greater than the amount indicated on the individual's written certification, if any;
- (2) A form or dosage of medicinal cannabis that is listed as a restriction or limitation on the individual's written certification;
- (3) A quantity of medicinal cannabis that is greater than the cardholder is legally permitted to purchase at the time of the transaction;
- (4) Any expired medicinal cannabis or medicinal cannabis products; and
- (5) Any medicinal cannabis or medicinal cannabis products that have been identified as part of a recall.

Section 4. Dispensary Facilities.

(1) A dispensary shall only sell medicinal cannabis within a building or secure structure located on the specific site licensed by the cabinet and identified on its license issued by the cabinet. The building or secure structure 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) Properly stores toxic cleaning compounds or sanitizing agents in a manner that is in accordance with applicable local, state, and federal laws and regulations;
 - (h) Maintains pest control; and
 - (i) Maintains adequate indoor and exterior lighting to facilitate video surveillance at all times.
- (2) A dispensary shall only dispense medicinal cannabis to a cardholder in an indoor, enclosed, secure facility between the hours of 8 a.m. and 8 p.m.
- (3) A dispensary shall not be located at the same site and location used for growing, cultivating, or processing medicinal cannabis, ~~for~~ in the same office space as a medicinal cannabis practitioner or other physician, **or in the same location as a hemp business.**
- (4) A dispensary shall not permit a person under eighteen (18) years of age to enter or remain on its premises. A dispensary shall not permit an individual who is not a cardholder to enter or remain its premises except in accordance with KRS 218B.095(6) and Section 10 of this administrative regulation.
- (5) A dispensary shall post a sign in a conspicuous location at each entrance of the facility that reads: "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.**
- (6) A dispensary 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."
- (7) A dispensary shall have a secure area for the loading and unloading of medicinal cannabis into and from a transport vehicle.

Section 5. Items and Services Provided at a Dispensary.

- (1) **Unless expressly authorized by this administrative regulation,** a dispensary shall **not sell, offer for sale, or dispense any product except** ~~dispense~~ medicinal cannabis, medicinal cannabis products, and medicinal cannabis accessories in accordance with this administrative regulation. **A dispensary shall not sell prerolled medicinal cannabis products, such as joints or blunts or any other products that are solely intended for consumption by smoking.**
- (2) A dispensary may operate a delivery service for registered qualified patients and designated caregivers in accordance with the delivery service requirements established in 915 KAR 001:080, Section 2.
- (3) A dispensary may dispense medicinal cannabis to cardholders via a drive-thru window or curbside pickup service if:
- (a) The dispensary notifies the cabinet via electronic mail to kymedcanreporting@ky.gov of its intent to dispense medicinal cannabis via a drive-thru window or curbside pickup service;
 - (b) The dispensary provides the cabinet with detailed written plans and procedures for drive-thru and curbside pickup operations, including operating hours, how payment will be accomplished, how medicinal cannabis products will be provided to cardholders, and safety and security measures to ensure safe operations;
 - (c) The cabinet approves the dispensary's proposed written plans and procedures; and
 - (d) The dispensary complies with the dispensing requirements contained in Sections 2 and 3 of this administrative regulation.
- (4) A dispensary may display product examples that have been designated by the dispensary for the purpose of product education for cardholders if:

- (a) There is a sign or label conspicuously displayed on or near the product example that clearly states "PRODUCT EXAMPLE FOR DISPLAY PURPOSES ONLY. NOT FOR SALE OR CONSUMPTION" in bold, capital letters;
 - (b) The product example is packaged in a secure jar protected by a plastic, glass, or metal mesh screen to allow cardholders to see the medicinal cannabis or medicinal cannabis product;
 - (c) The product example is recorded in the Commonwealth's electronic monitoring system and seed to sale tracking system as a product example; and
 - (d) At the point a product example has noticeably degraded to where it is no longer representative of a new product, the dispensary shall destroy the product example in accordance with Section 14 of this administrative regulation.
- (5) Dispensaries may utilize inducements to assist cardholders. Inducements shall not persuade or influence the use of medicinal cannabis outside of medicinal cannabis practitioner recommendations or limitations or the amounts allowed by KRS Chapter 218B. Authorized inducements are as follows:
- (a) The use of coupons, **loyalty programs**, and discounts; and
 - (b) The giving away of educational materials and branded merchandise.
- (6) Pursuant to KRS 218B.110(1)(e), a dispensary may accept returns of medicinal cannabis and medicinal cannabis products from a cardholder, ~~but only~~ for the purpose of disposal. A dispensary may not offer anything of monetary value in return for medicinal cannabis or medicinal cannabis products received from a cardholder, **except clearly defective products may be exchanged for the same or similar product of equal or lesser value with no monetary refund**. All medicinal cannabis and medicinal cannabis product returns and their subsequent destruction shall be documented by the dispensary.
- (7) A dispensary may sell branded merchandise, including t-shirts, mugs, water bottles, and hats.
- (8) A dispensary shall not sell any medicinal cannabis accessory that is used solely for the purpose of smoking medicinal cannabis, including rolling papers and lighters.

Section 6. Educational Materials and Product Information.

- (1) When dispensing medicinal cannabis, a dispensary shall disseminate evidence-based educational materials and product information regarding dosage, directions for use, and impairment to cardholders who purchase medicinal cannabis as follows:
- (a) A dispensary may provide the educational material and product information required under this section to cardholders through the use of a quick response (QR) code that links to the information required under this section. The QR code shall be labeled as "Educational Materials" directly above or below the code and shall be large enough to be smart-phone readable. The QR code may appear on the receipt provided to the cardholder or on a separate sheet of paper provided to the cardholder;
 - (b) Upon request of the cardholder purchasing the medicinal cannabis, a dispensary shall provide hardcopies of any materials required under this provision; and
 - (c) Upon request of the cabinet, a dispensary shall provide the cabinet with copies of the educational material required under this section within five (5) business days of receipt of the request.
- (2) The educational materials and product information required by this section shall include the following information:
- (a) The method or methods for administering individual servings of medicinal cannabis;
 - (b) Dosage or serving size information;
 - (c) ~~Side~~ Effects and impairment;
 - (d) How to obtain appropriate services or treatment for medicinal cannabis abuse;

- (e) Any ~~known[side effects and]~~ contraindications associated with medicinal cannabis that may cause harm to the patient; and
- (f) How to properly store medicinal cannabis and medicinal cannabis products.

Section 7. Secret Shoppers. The cabinet may utilize secret shoppers to assist with reviewing a dispensary's compliance with KRS Chapter 218B and 915 KAR Chapter 1, including attempting to purchase medicinal cannabis or medicinal cannabis products. The cabinet may conduct an inspection or investigation resulting from a secret shopper's experience.

Section 8. Plans of Operation.

(1) Prior to its first day of selling or dispensing medicinal cannabis in the Commonwealth, a dispensary shall establish standard operating procedures for the following:

- (a) Employment policies and procedures;
- (b) Security, including:
 - 1. Staff identification measures, including use of identification badges;
 - 2. Monitoring of attendance of staff and visitors;
 - 3. Alarm systems;
 - 4. Video surveillance;
 - 5. Monitoring and tracking inventory, 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; and
 - 11. Customer service, including procedures for halting a sale;**
- (c) Recordkeeping;
- (d) The process for receiving, handling, transporting, storing, selling, and disposing of medicinal cannabis;
- (e) Employee qualifications, supervision, and training;
- (f) Workplace safety;
- (g) Waste disposal;
- (h) Maintenance, cleaning, and sanitation of facility;
- (i) Investigation of complaints and potential adverse events received from other cannabis businesses, cardholders, or medicinal cannabis practitioners;
- (j) Preventing unlawful diversion of medicinal cannabis;
- (k) Recall plan;
- (l) Contamination;
- (m) Maintaining confidentiality of cardholder information, including information and documentation provided by visiting qualified patients; and
- (n) Any other standard operating procedures required for all cannabis businesses in KRS Chapter 218B and 915 KAR Chapter 1.

(2) A dispensary shall make its standard operation procedures available to the cabinet upon request and during any inspection of the dispensary.

Section 9. Employees Records and Identification.

- (1) A dispensary 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 dispensary.
- (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 dispensary.
- (3) A dispensary shall create an identification badge for each employee, agent, or volunteer. This badge shall be conspicuously worn by employees, agents, or volunteers at all times that they are on the licensed premises or during transport of medicinal cannabis. The badge shall contain:
- (a) The individual's name, photo, ~~and~~ employee identification number, **and the license number of the dispensary;**
 - (b) The phone number and email address for the dispensary; and
 - (c) The phone number and email address for the Kentucky Medical Cannabis Program.

Section 10. Visitor Access to Limited Access Areas.

- (1) Except as provided in this section, only authorized employees or agents of a dispensary shall enter a limited access area.
- (2) A dispensary shall require visitors requiring access to a limited access area in the dispensary's facility to:
- (a) Sign a visitor log upon entering and leaving the limited access area and detail the need for entry;
 - (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 **at the dispensary location**~~in a limited access area~~; and
 - (e) Ensure that the visitor does not touch any medicinal cannabis located in a limited access area.
- (3) The visitor log required by this section shall:
- (a) Be maintained for five (5) years and available to the cabinet, law enforcement, and other federal or state government officials upon request to perform the government officials' functions and duties; and
 - (b) Include 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 facility visited~~.
- (4) 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 dispensary if necessary to perform the government officials' functions and duties.
- (5) A principal officer, board member, agent, financial backer, employee, or volunteer of a dispensary 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 dispensary 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 the following:
 1. Coverage of all facility entrances and exits; rooms with exterior windows, exterior walls, roof hatches or skylights; storage rooms, including those that contain medicinal cannabis, and safes; and the perimeter of the facility;

2. An audible security alarm system signal, known as a panic alarm, generated by the manual activation of a device intended to signal a life-threatening or emergency situation requiring law enforcement response;
3. A silent alarm signal, known as a holdup alarm, generated by the manual activation of a device intended to signal a robbery in progress;
4. A failure notification system that provides an audible, text, or visual notification of any failure in the systems. The failure notification system shall provide by telephone, e-mail, or text message an alert to a designated security person within the facility within five minutes after the failure;
5. Smoke and fire alarms;
6. Auxiliary power sufficient to maintain operation for at least twenty-four (24) hours following a power outage;
7. 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
8. 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. Entrances and exits shall be recorded from both indoor and outdoor vantage points;
 - d. Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage rooms, including those that may contain medicinal cannabis and safes and excluding restrooms; and
 - e. Twenty (20) ~~Five (5)~~ feet from the exterior of the perimeter of the facility;
2. Auxiliary power sufficient to maintain operation for at least twenty-four (24) hours following a power outage;
3. Ability to operate under the normal lighting conditions of each area under surveillance;
4. Ability to immediately produce a clear, color, still photograph in a digital format that is easily accessible;
5. Ability to clearly and accurately display the date and time. The date and time shall be synchronized and set correctly and may not significantly obscure the picture;
6. 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 dispensary:
 - (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 dispensary if approved by the cabinet; ~~and~~ ~~;~~

7. 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) The dispensary 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) The dispensary 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 dispensary anticipates will exceed an eight (8) hour period, the dispensary shall notify the cabinet immediately via electronic mail to kymedcanreporting@ky.gov and, with cabinet approval, provide alternative security measures that may include closure of the facility.

(3) A dispensary 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 dispensary 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 dispensary that it is not necessary to retain the recording, whichever is later.

(4) A dispensary shall install commercial-grade, nonresidential doors and door locks on each external door of the facility. Keys or key codes for all doors shall remain in the possession of designated authorized individuals.

(5) During all non-working hours, all entrances to and exits from the dispensary shall be securely locked.

(6) A dispensary 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 dispensary 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 dispensary 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.

(9) A dispensary shall routinely inspect its point of sale systems to confirm no malicious software, programs, or applications have been downloaded that affect cardholder or sales information and shall document each inspection in writing. The documentation required under this provision shall be retained by the dispensary for a minimum of two (2) years from the date of the inspection.

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

(1) A dispensary 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, and in accordance with written instructions provided by the cabinet.

(2) A dispensary shall establish inventory controls and procedures to conduct inventory reviews at its facility **and ensure its inventory is accurate in real-time in the commonwealth's designated electronic monitoring system and seed to sale tracking system.**

(a) A dispensary shall prepare a ~~monthly~~**quarterly** physical inventory report that includes any necessary adjustments, and the reason(s) for an adjustment, and that demonstrates 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. Storage Requirements.

(1) A dispensary shall have separate locked limited access areas for storage of:

(a) Medicinal cannabis and medicinal cannabis products that are ready for sale to cardholders; and

(b) Medicinal cannabis that is expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been opened or breached until the medicinal cannabis is returned to another cannabis business, destroyed, or otherwise disposed of as required under Section 14 of this administrative regulation.

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

(3) A dispensary shall store medicinal cannabis and medicinal cannabis products in a manner that prevents degradation of active compounds and spoilage.

(4) A dispensary shall routinely review medicinal cannabis and medicinal cannabis products in its inventory available for sale to identify any products that are past their respective expiration date and remove those products from the saleable inventory.

Section 14. Management and Disposal of Medicinal Cannabis Waste.

(1) A dispensary shall dispose of expired, undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated medicinal cannabis in such a manner as to render the medicinal cannabis unusable. A dispensary 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~~**locked** dumpster **with commercial grade locks** or other approved, locked container for removal from the dispensary by a waste removal company selected by the dispensary, **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 dispensary's 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 code(s) 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) ~~{If the medicinal cannabis waste for disposal contains raw plant material that was prepared for sale at the dispensary,}~~ The harvest **or production** batch, strain, volume, **number of units if applicable**, and weight of the **medicinal cannabis**~~{plant material}~~ being disposed.
- (5) The disposal of other waste from the dispensary 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 15. Sanitation and Safety in a Dispensary.

- (1) A dispensary shall maintain its facility in a sanitary condition to limit the potential for contamination or adulteration of the medicinal cannabis stored in or dispensed at the facility. The following requirements shall apply:
 - (a) Trash shall be properly and routinely removed;
 - (b) Floors, walls, and ceilings shall be kept in good repair;
 - (c) Adequate protection against pests shall be provided; and
 - (d) Toxic cleaning compounds, sanitizing agents, and other chemicals shall be labeled and stored in a manner that prevents contamination of medicinal cannabis, 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; and
 - (c) Confining the following to areas other than where medicinal cannabis may be exposed: eating food, chewing gum, drinking beverages, or using tobacco.
- (3) A dispensary 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 dispensary shall provide employees, agents, volunteers, cardholders, and visitors with adequate, readily accessible restrooms that are maintained in a sanitary condition and in good repair.

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

Section 16. Complaints About or Recall of Medicinal Cannabis and Medicinal Cannabis Products.

(1) A dispensary shall immediately notify the cabinet via electronic mail to kymedcanreporting@ky.gov as well as the cannabis business from which it received any medicinal cannabis in question upon becoming aware of any defects or quality issues with the medicinal cannabis or any complaint made to the dispensary by another cannabis business, a cardholder, or medicinal cannabis practitioner who reports an adverse event from using medicinal cannabis purchased from the dispensary. A dispensary shall investigate the report as follows:

(a) A dispensary shall immediately investigate a complaint to determine if a voluntary or mandatory recall of medicinal cannabis and medicinal cannabis products is necessary or if any further action is required;

(b) If a dispensary determines that further action is not required, the dispensary shall notify the cabinet of its decision via electronic mail to kymedcanreporting@ky.gov and, within twenty-four (24) hours, submit a written report to the cabinet stating its rationale for not taking further action. The cabinet shall review the written report and consult with the dispensary as needed. If the cabinet disagrees with the dispensary's decision, the cabinet shall take all necessary steps allowable under KRS Chapter 218B and 915 KAR Chapter 1 to ensure public health and safety, including issuing a cease and desist order to pause the sale and distribution of the medicinal cannabis at issue until resolution of the matter; and

(c) If a dispensary determines that further action is required, the dispensary shall initiate a voluntary or mandatory recall in accordance with the requirements of this section.

(2) Voluntary recalls. If a dispensary voluntarily initiates a recall, the dispensary shall recall medicinal cannabis from the market at its discretion for reasons that do not pose a risk to public health and safety and shall notify the cabinet at the time the dispensary begins the recall via electronic mail to kymedcanreporting@ky.gov.

(3) Mandatory recalls. If a dispensary discovers that a condition relating to medicinal cannabis sold at its facility poses a risk to public health and safety, the dispensary shall:

(a) Immediately notify the cabinet by phone and electronic mail to kymedcanreporting@ky.gov; and

(b) Secure, isolate, and prevent the distribution of the medicinal cannabis that may have been affected by the condition and remains in its possession. The dispensary shall not dispose of affected medicinal cannabis prior to notifying the cabinet and coordinating the disposal with the cabinet.

(4) If a dispensary fails to cooperate with the cabinet in a recall, or fails to immediately notify the cabinet of a need for a recall under this section, the cabinet may seek a cease and desist order and the dispensary may be subject to any other penalties or sanctions provided for in KRS Chapter 218B and 915 KAR Chapter 1:020.

(5) A dispensary's recall plan as required under this administrative regulation shall include the following:

(a) Designation of one (1) or more employees to serve as the recall coordinators. A recall coordinator shall be responsible for, among other duties, accepting the recalled

medicinal cannabis;

(b) Procedures for identifying and isolating the affected medicinal cannabis to prevent or minimize its distribution cardholders and other cannabis businesses;

(c) Procedures to retrieve and dispose of the medicinal cannabis;

(d) A communications plan to notify those affected by the recall, including:

1. The manner in which the dispensary shall notify other cannabis businesses in possession of medicinal cannabis subject to the recall; and

2. The use of press releases and other appropriate notifications to ensure that cardholders shall be notified of the recall if affected medicinal cannabis was dispensed to cardholders.

(e) Procedures for notifying the cabinet; and

(f) Procedures for entering information relating to the recall into the Commonwealth's designated electronic monitoring system and seed to sale tracking system.

(6) A dispensary shall follow the procedures outlined in its recall plan unless the dispensary obtains prior written approval of the cabinet or the cabinet notifies the dispensary in writing to perform other procedures. A dispensary shall conduct recall procedures in a manner that maximizes the recall of affected medicinal cannabis and minimizes risks to public health and safety.

(7) Upon receiving notification of a recall from a cannabis business or the cabinet, a dispensary shall cease dispensing the affected medicinal cannabis immediately.

(8) A dispensary shall coordinate the disposal of recalled medicinal cannabis with the cabinet. The cabinet or its authorized agents may oversee the disposal to ensure that the recalled medicinal cannabis is disposed of in a manner that will not pose a risk to public health and safety.

(9) The dispensary shall enter information relevant to the recall into the Commonwealth's designated electronic monitoring system and seed to sale tracking system as part of the inventory, which may include the following:

(a) The total amount of recalled medicinal cannabis, including types, harvest batches, and production batches, if applicable;

(b) The total amount of recalled medicinal cannabis returned to the dispensary, including types, forms, harvest batches, and production batches, if applicable;

(c) The names of the recall coordinators;

(d) From whom the recalled medicinal cannabis was received;

(e) The means of transport of the recalled medicinal cannabis;

(f) The reason for the recall;

(g) The number of recalled samples, types, forms, harvest batches, and production batches, if applicable, sent to safety compliance facilities, the names and addresses of the safety compliance facilities, the dates of testing, and the results by sample; and

(h) The manner of disposal of the recalled medicinal cannabis, including:

1. The ~~names~~~~{name}~~ of the ~~individuals~~~~{individual}~~ overseeing the disposal of the recalled medicinal cannabis;

2. The name of the disposal company, if applicable;

3. The method of disposal;

4. The date of disposal; and

5. The amount disposed of by types, forms, harvest batches, and production batches, if applicable.

(10) The cabinet may initiate a mandatory recall upon receipt of information that a condition relating to the medicinal cannabis sold by the dispensary poses a risk to public health and safety.

Section 17. Duty to Report.

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

(a) A list of the cannabis businesses whose medicinal cannabis products are sold at the dispensary;

(b) A list of the forms of medicinal cannabis sold at the dispensary and their average sale price;

(c) **The amount of medicinal cannabis purchased by the dispensary during the current licensure period, including a breakdown by product type;**

(d) The amount of medicinal cannabis sold by the dispensary during the current licensure period, including a breakdown by product type;

(e) Any significant issues with the supply and demand of medicinal cannabis experienced by the dispensary; and

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

(2) A dispensary 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 medicinal cannabis dispensaries to operate 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 dispensaries to operate 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 dispensaries 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 dispensaries that have applied for and subsequently received licenses to dispense and sell medicinal cannabis to cardholders 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 dispensary 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):

Dispensaries will have to pay an initial application fee, and if approved for a license, an initial license fee and 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):

Dispensaries that receive a license from the Cabinet for Health and Family Services are authorized to dispense and sell medicinal cannabis 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 dispensaries.

(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 dispensaries 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.110, 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 dispensaries in the first year.

Revenues:The cabinet will receive initial application fees and initial license fees paid by dispensaries 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 dispensaries in each subsequent year. The cabinet will receive annual renewal license fees from dispensaries 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 dispensary 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 dispensaries.

(a) Estimate the following for the first year:

Expenditures:The initial license fee for a dispensary is \$30,000 for each licensed location.

Revenues:Unknown at this time. This response will depend upon how much medicinal cannabis is sold by a licensed dispensary, including the sale price.

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 dispensary is \$15,000 for each licensed location. Revenues will continue to depend on how much medicinal cannabis is sold by a licensed dispensary, including the sale price. Cost savings may occur in subsequent years as licensed dispensaries 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 dispensaries.

(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 dispensaries, 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.