CABINET FOR HEALTH AND FAMILY SERVICES
Office of the Secretary
(Amended After Comments)

915 KAR 1:040. Processor.

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 processor operations in the Commonwealth. This administrative regulation sets out those requirements and procedures.

Section 1. General Requirements.

(1) No person or entity may engage in processing activities in the Commonwealth without first being issued a license by the cabinet. A processor shall not sell or transfer, or allow the sale or transfer, of medicinal cannabis or medicinal cannabis products to any person or entity in the Commonwealth who does not hold a cannabis business license issued by the cabinet.

(2) A processor shall:

(a) Only acquire or purchase raw plant material and medicinal cannabis from a cultivator, processor, or producer in the Commonwealth;

(b) Conduct processing activities in a secure facility on the specific site licensed by the cabinet and identified on its license issued by the cabinet;

(c) 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; and

(d) Comply with all applicable requirements of KRS Chapter 218B, specifically KRS 218B.095 and 218B.115, and 915 KAR Chapter 1.

(3) A processor 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.

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

Section 2. Plans of Operation.

(1) Prior to its first day of processing activities in the Commonwealth, a processor shall establish standard operating procedures for the following:

(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 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;

(c) The process for receiving, handling, processing, packaging, labeling, storing, transporting, and disposing of medicinal cannabis and medicinal cannabis products and a process for handling, tracking, transporting, storing, and disposing of medicinal cannabis waste;

(d) Workplace safety, including conducting safety checks;

(e) Contamination;

(f) Maintenance, cleaning, and sanitation of equipment used to process medicinal cannabis;

(g) Maintenance and sanitation of the processor's facility;

(h) Extraction method(s), including standards for processing of raw plant material, refining of medicinal cannabis extracts, and manufacturing of medicinal cannabis products, including safety protocols and equipment;

(i) Proper handling and storage of any solvent, gas, or other chemical or substance used in processing medicinal cannabis;

(j) Quality control, including strict regulation of the amount of delta-9 tetrahydrocannabinol content in each harvest or production batch in accordance with KRS 218B.115(2), proper labeling, and minimization of medicinal cannabis contamination;

(k) Recordkeeping and inventory control;

(l) Investigation of complaints and potential adverse events received from other cannabis businesses, cardholders, or medicinal cannabis practitioners regarding the processor's operations;

(m) Preventing unlawful diversion of medicinal cannabis;

(n) Recall plan; and

(o) Any other standard operating procedures required for all cannabis businesses in KRS Chapter 218B and 915 KAR Chapter 1.

(2) A processor shall make its standard operation procedures available to the cabinet upon request and during any inspection of the processor's site and facility.

Section 3. Processor Facilities.

(1) A processor shall only process medicinal cannabis within a building or secure structure 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 as well as the following requirements:

(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 locked and secure 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, solvents, gas, or other chemicals or substances used in processing medicinal cannabis in a manner that is in accordance with applicable local, state, and federal laws and regulations;

(h) Maintains exhaust and ventilation systems to mitigate noxious gasses or other fumes used or created as part of processing activities;

(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 processor 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 processor shall have a secure area for the loading and unloading of medicinal cannabis into and from a transport vehicle.

(4) On all perimeter doors, a processor shall post signs which shall not be less than twelve (12) inches wide and twelve (12) inches long, composed of letters not less than one-half inch in height, that clearly state the type of extraction method or methods used within the facility.

(5) A processor shall enact reasonable measures to ensure medicinal cannabis and medicinal cannabis products are not visible from outside the facility.

(6) If a processor intends to conduct medicinal cannabis processing and hemp processing at the same licensed location, the processor shall, prior to its first day of medicinal cannabis processing activities, provide the cabinet with:

(a) Proof that the processor is permitted to operate a hemp business by the appropriate permitting authority and is in good standing;

(b) A written plan for keeping strictly separated all medicinal cannabis processing activities from hemp processing activities; and

(c) A site map or blueprint showing which portions of the facility are designated for medicinal cannabis processing activities, including storage of medicinal cannabis, and which portions are designated for hemp processing activities, including storage of hemp and hemp products.

(7) Pursuant to KRS 218B.100(1), a cannabis business that co-locates with a hemp business shall be subject to reasonable inspection by the cabinet and the cabinet may inspect the entire facility as part of an inspection.

Section 4. Electronic Monitoring System and Seed to Sale Tracking System.

(1) Except as provided in this section, a processor shall not possess, process, produce, or manufacture:

(a) Raw plant material with a delta-9 tetrahydrocannabinol content of more than thirty-five (35) percent;

(b) Medicinal cannabis products intended for oral consumption as an edible, oil, or tincture with more than ten (10) milligrams of delta-9 tetrahydrocannabinol per serving;

(c) Any medicinal cannabis product not described in this section with a delta-9 tetrahydrocannabinol content of more than seventy (70) percent; or

(d) Any medicinal cannabis product that contains vitamin E acetate.

(2) A processor may possess unfinished medicinal cannabis products not ready for retail sale that exceed the delta-9 tetrahydrocannabinol limits in this section. However, all finished medicinal cannabis products intended for sale to cardholders shall comply with the delta-9 tetrahydrocannabinol limits in this section.

(3) A processor 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 processor shall use the electronic monitoring system and

seed to sale tracking system in accordance with written instructions provided by the cabinet.

(4) A processor shall record in the Commonwealth's designated electronic monitoring system and seed to sale tracking system all medicinal cannabis received, sold, disposed, or otherwise transferred by the processor and ensure the inventory is accurate in real-time.

(5) A processor shall establish inventory controls and procedures to conduct inventory reviews and comprehensive inventories at its facility to include:

(a) A processor shall prepare monthly physical inventory reports 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 5. Employees Records and Identification.

(1) A processor 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 processor.

(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 processor.

(3) A processor 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 or medicinal cannabis products. The badge shall contain:

(a) The individual's name, photo, employee identification number, and the license number of the processor;

(b) A phone number and email address for the processor; and

(c) A phone number and email address for the Kentucky Medical Cannabis Program.

Section 6. Visitors to Processor Facilities.

(1) A processor site and facility shall not be open to the general public.

(2) A processor 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 on the site or in the facility; and

(e) Ensure that the visitor does not touch any medicinal cannabis or medicinal cannabis product located in a limited access area.

(3) No one under the age of eighteen (18) shall be permitted to enter a processor's site or facility. A person who is at least eighteen (18) years of age or older may enter and remain on the processor's 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 cannabis business in the course of his or her official duties.

(4) A processor shall post a sign in a conspicuous location at each entrance of its site and 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) The processor 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.

(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 processor's site and facility if necessary to perform the governmental officials' functions and duties.

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

Section 7. Security and Surveillance.

(1) A processor 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; 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 (5) 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 shall not be 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) 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 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;

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) days, unless otherwise required for investigative or litigation purposes. The recordings shall be kept:

a. At the processor's 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 processor's facility 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) Regarding inspection, servicing or alteration of, and any upgrade to, the site's and facility's 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 processor 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 processor 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 processor anticipates shall exceed an eight (8) hour period, the processor 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) Regarding records retention, a processor shall:

(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 processor 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 processor 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 processor's facility shall be securely locked.

(5) A processor shall install lighting to ensure proper surveillance inside and outside of the facility.

(6) A processor 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 processor 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 processor 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 8. Forms of Medicinal Cannabis.

(1) A processor may process medicinal cannabis for sale to a cannabis business in forms including:

(a) Edible;

(b) Oil;

(c) Topical forms, including gel, creams, ointments, and cosmetics;

(d) A form medically appropriate for administration by vaporization or nebulization;

(e) Tincture;

(f) Dermal patch;

(g) Suppositories;

(h) Beverages;

(i) Raw plant material; and

(j) Capsules.

(2) In addition to other packaging and labeling requirements established in 915 KAR 1:100, all raw plant material packaged and sold by a processor in this Commonwealth shall be marked or labeled as "NOT INTENDED FOR CONSUMPTION BY SMOKING." Processors delivering raw plant material to dispensaries for sale shall comply with the requirements contained in 915 KAR 1:030, Section 14.

(3) Unless specifically authorized in writing by the cabinet, all hard medicinal cannabis products intended for oral consumption as an edible shall be stamped with the

standardized symbol indicating a product contains medicinal cannabis provided in Appendix A to 915 KAR 1:100. If the medicinal cannabis product intended for oral consumption as an edible contains multiple servings, the processor shall ensure a cardholder can easily separate out a single serving from the whole.

(4) Except for transfer of samples to a safety compliance facility for testing, no medicinal cannabis shall be sold or transferred to another cannabis business until all required testing is complete and the representative sample passed inspection. Processors shall not sell medicinal cannabis directly to cardholders.

Section 9. Requirements for Processing Medicinal Cannabis.

(1) A processor may only use the methods, equipment, solvents, and gases set forth in this section in the processing and manufacture of medicinal cannabis and medicinal cannabis products.

(2) A processor may use hydrocarbon solvent-based extraction methods in a spark-free and properly ventilated environment, isolated from any open flame or ignition source, and may use the following solvents, at a minimum of ninety-nine per cent purity, in a professional grade, closed-loop extraction system designed to recover the solvents:

(a) Propane;

(b) N-butane;

(c) Isobutane; and

(d) Heptane.

(3) A processor may use carbon dioxide-based extraction methods using food grade carbon dioxide at a minimum of ninety-nine percent (99%) purity in a professional grade, closed-loop system in which each vessel is rated to a minimum pressure to accommodate the specific extraction protocol, including supercritical, liquid, and subcritical.

(4) A processor may use ethanol at a minimum of ninety-nine percent (99%) purity to produce extracts for use in the manufacture of medicinal cannabis products.

(5) A processor may use food grade glycerin and propylene glycol in the manufacture of medicinal cannabis products.

(6) A processor may use non-solvent extraction methods involving the mechanical separation of cannabinoids from plant material to produce medicinal cannabis extracts for use in the manufacture of medicinal cannabis products.

(7) A processor may use non-cannabis ingredients in the manufacture of medicinal cannabis products that meet the following conditions:

(a) The non-cannabis ingredients are nontoxic and safe for human consumption; and

(b) The non-cannabis ingredients were not prepared or stored in a private residence.

(8) A processor using hydrocarbon solvent-based or carbon dioxide extraction methods shall designate at least one (1) individual to train and supervise employees in the use of extraction equipment and associated solvents who has earned, at minimum, a Bachelor's Degree in engineering or physical sciences from an accredited university, or who has at least three (3) years of experience in the operation of the equipment being used in the facility or similar equipment.

(9) A processor shall maintain a log of the use of all extraction methods, equipment, solvents, and gases used in the processing and manufacture of medicinal cannabis products for a minimum of five (5) years.

(10) A processor may only process the parts of the medicinal cannabis plant that are free of dirt, sand, debris, or other foreign matter.

(11) Prior to processing, a processor shall perform visual inspections of the raw plant material to ensure there are no visible insects, mold, mildew, pests, rot, grey or black plant material, or inorganic material, including plastic, glass, and metal shavings.

(12) A processor shall have a separate and secure area for temporary storage of medicinal cannabis that is awaiting disposal by the processor.

(13) A processor shall process medicinal cannabis in a safe and sanitary manner, which includes:

(a) Medicinal cannabis, raw plant material, and other product used in the processing of medicinal cannabis shall be handled on food-grade stainless steel benches or tables;

(b) Proper sanitation shall be maintained;

(c) Proper rodent, bird and pest exclusion practices shall be employed;

(d) Prior to packaging, the medicinal cannabis shall have passed all required testing established within 915 KAR 1:110; and

(e) Any person making human-consumable products or substances that will be used to make human-consumable products, shall be Good Manufacturing Practices-compliant and permitted by the Department of Public Health within the cabinet.

(14) A processor shall establish procedures to monitor, record, and regulate:

(a) Temperature;

(b) Humidity;

(c) Ventilation;

(d) Lighting; and

(e) Water supply.

Section 10. Equipment, Operation and Maintenance.

(1) A processor shall have a written process in place to maintain the sanitation and operation of equipment that comes into contact with medicinal cannabis to prevent contamination. The processor 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 processor shall:

(a) Routinely calibrate, check and inspect automatic, mechanical, or electronic equipment as well as any scales, balances, or other measurement devices used in the processor's operations to ensure accuracy; and

(b) Maintain an accurate log recording:

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

Section 11. Sanitation and Safety in a Processor Facility.

(1) A processor shall maintain its site and facility in a sanitary condition to limit the potential for contamination of the medicinal cannabis processed in the facility, including:

(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 processor shall be capable of being adequately cleaned;

(b) Trash shall be properly and routinely removed to prevent pest infestation;

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

(d) Equipment, counters, and surfaces for processing shall be food grade quality and may not react adversely with any solvent being used;

(e) Adequate protection against pests shall be provided through the use of integrated pest management practices and techniques that identify and manage plant pathogens and pest problems; and

(f) Toxic cleaning compounds, sanitizing agents, solvents, and any other allowable chemicals used in the processing of medicinal cannabis shall be labeled and stored in a manner that prevents contamination of medicinal cannabis.

(2) All employees and volunteers 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 processor shall:

(a) Provide its employees, volunteers, 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;

(b) Provide its employees, volunteers, and visitors with adequate, readily accessible restrooms that are maintained in a sanitary condition and in good repair;

(c) 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; and

(d) Comply with all other applicable federal, state, and local building code requirements and occupational safety and health requirements.

Section 12. Storage Requirements.

(1) A processor shall have separate locked limited access areas for storage of 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 destroyed or otherwise disposed of as required under Section 13 of this administrative regulation.

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

Section 13. Management and Disposal of Medicinal Cannabis Waste.

(1) A processor shall dispose of undesired, excess, unauthorized, obsolete, adulterated, misbranded, or deteriorated medicinal cannabis in such a manner as to render the medicinal cannabis unusable. A processor 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 dumpster with commercial grade locks or other approved, locked container for removal from the facility by a waste removal company selected by the processor, 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 processor's site and facility.

(4) A minimum of two (2) employees shall oversee 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 unique identification codes associated with the medicinal cannabis scheduled for destruction;

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

(e) The names, employee identification numbers, and signatures of the employees overseeing the disposal of the medicinal cannabis; and

(f) If the disposal contains medicinal cannabis that was prepared for sale to a dispensary, the harvest or production batch number, strain, volume, weight, and number of units if applicable of the medicinal cannabis being disposed of.

(5) The disposal of other waste from the processor 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 14. Complaints About or Recall of Medicinal Cannabis and Medicinal Cannabis Products.

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

(a) A processor 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 processor determines that further action is not required, the processor 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 processor as needed. If the cabinet disagrees with the processor'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 processor determines that further action is required, the processor shall initiate a voluntary or mandatory recall in accordance with the requirements of this section.

(2) Voluntary recalls. If a processor voluntarily initiates a recall, the processor shall recall seeds, seedlings, medicinal cannabis plants, postharvest plant material, or 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 processor begins the recall via electronic mail to kymedcanreporting@ky.gov.

(3) Mandatory recalls. If a processor discovers that a condition relating to medicinal cannabis processed at its facility poses a risk to public health and safety, the processor 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 processor shall not dispose of affected medicinal cannabis prior to notifying the cabinet and coordinating the disposal with the cabinet.

(4) If a processor 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 processor may be subject to any other penalties or sanctions provided for in KRS Chapter 218B and 915 KAR Chapter 1:020.

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

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

(7) A processor 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.

(8) The processor 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 processor, 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 of the individuals 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.

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

Section 15. Duty to Report.

(1) At the time a processor submits a license renewal application to the cabinet, a processor shall report to the cabinet via electronic mail to kymedcanreporting@ky.gov the following:
(a) Any significant issues with the supply and demand of medicinal cannabis experienced by the processor;
(b) The total amount of raw plant material purchased and processed during the current licensure period and the average price per pound as well as the total amount of raw plant material purchased and sold as raw plant material and the average price per pound; and
(c) The number of current employees, their respective job titles, and hourly wage; and

(2) A processor shall participate in market 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.
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