



1 Cabinet for Health and Family Services

2 Office of the Secretary

3 (New Administrative Regulation)

4 915 KAR 1:040. Processor.

5 RELATES TO: KRS Chapter 218B

6 STATUTORY AUTHORITY: KRS 218B.140

7 NECESSITY, FUNCTION, AND CONFORMITY: KRS 218B.140 requires the Cabinet
8 for Health and Family Services to promulgate administrative regulations establishing requirements
9 and procedures for medicinal cannabis processor operations in the commonwealth. This
10 administrative regulation sets out those requirements and procedures.

11 Section 1. General requirements.

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

16 (2) A processor shall:

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

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

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

5 (d) Comply with all applicable requirements of KRS Chapter 218B, specifically KRS
6 218B.095 and 218B.115, and 915 KAR Chapter 1.

7 (3) A processor shall not employ, take on as a volunteer, or have as a board member,
8 principal officer, or agent any person who was convicted of a disqualifying felony offense or is
9 younger than twenty-one (21) years of age.

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

12 Section 2. Plans of operation.

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

15 (a) Employment policies and procedures;

16 (b) Security, including:

17 1. Staff identification measures and use of employee identification badges;

18 2. Monitoring of attendance of staff and visitors;

19 3. Alarm systems;

20 4. Video surveillance;

21 5. Monitoring and tracking inventory, including use of the commonwealth's electronic
22 monitoring system and seed to sale tracking system established pursuant to KRS 218B.140;

23 6. Personnel security;

1 7. Transportation of medicinal cannabis;

2 8. Cash management and anti-fraud procedures;

3 9. Measures to prevent loitering, which shall include signage; and

4 10. Storage of medicinal cannabis and medicinal cannabis products;

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

8 (d) Workplace safety, including conducting safety checks;

9 (e) Contamination;

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

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

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

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

18 (j) Quality control, including strict regulation of the amount of delta-9
19 tetrahydrocannabinol content in each harvest or production batch in accordance with KRS
20 218B.115(2), proper labeling, and minimization of medicinal cannabis contamination;

21 (k) Recordkeeping and inventory control;

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

- 1 (m) Preventing unlawful diversion of medicinal cannabis;
- 2 (n) Recall plan; and
- 3 (o) Any other standard operating procedures required for all cannabis businesses in KRS
- 4 Chapter 218B and 915 KAR Chapter 1.

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

7 Section 3. Processor facilities.

8 (1) A processor shall only process medicinal cannabis within a building or secure
9 structure on the specific site licensed by the cabinet and identified on its license issued by the
10 cabinet. The building or secure structure shall meet all applicable state and local building codes
11 and specifications as well as the following requirements:

12 (a) Has a complete roof enclosure supported by connecting permanent walls, constructed
13 of solid materials extending from the ground to the roof;

14 (b) Is secure against unauthorized entry;

15 (c) Has a foundation, slab, or equivalent base to which the floor is securely attached;

16 (d) Has commercial grade door locks on all external doors that are locked at all times;

17 (e) Restricts access to only authorized personnel to locked and secure areas identified
18 with signage and daily records of entry and exit;

19 (f) Contains adequate plumbing to carry sufficient quantities of water to locations
20 throughout the facility and convey sewage and waste from the facility without cross
21 contamination of potable water and waste;

1 (g) Stores toxic cleaning compounds, sanitizing agents, solvents, gas, or other chemicals
2 or substances used in processing medicinal cannabis in a manner that is in accordance with
3 applicable local, state, and federal laws and regulations;

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

6 (i) Maintains pest control;

7 (j) Maintains adequate indoor and exterior lighting to facilitate video surveillance at all
8 times; and

9 (k) Maintains adequate on-site parking for employees, agents, visitors, transporters of
10 medicinal cannabis, or cabinet staff.

11 (2) A processor shall clearly mark all limited access areas on its premises with proper
12 signage. All areas of ingress and egress to a limited access area shall be clearly identified by the
13 posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of
14 letters not less than one-half inch in height, which shall state: "Do Not Enter. Limited Access
15 Area. Access Limited to Authorized Personnel and Escorted Visitors."

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

18 Section 4. Electronic monitoring system and seed to sale tracking system.

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

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

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

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

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

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

10 (3) A processor shall use the electronic monitoring system and seed to sale tracking
11 system prescribed by the cabinet containing the requirements in KRS Chapter 218B, specifically
12 KRS 218B.140. A processor shall use the electronic monitoring system and seed to sale tracking
13 system in accordance with written instructions provided by the cabinet.

14 (4) A processor shall record in the commonwealth's designated electronic monitoring
15 system and seed to sale tracking system all medicinal cannabis received, sold, disposed, or
16 otherwise transferred by the processor.

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

19 (a) A processor shall prepare quarterly physical inventory reports that includes any
20 necessary adjustments and the reason(s) for an adjustment and that demonstrates the physical
21 inventory reconciles with the inventory recorded in the commonwealth's designated electronic
22 monitoring system and seed to sale tracking system, including any medicinal cannabis that has
23 been or is in the process of being destroyed; and

1 (b) A written or electronic record shall be created and maintained of each inventory
2 conducted under this section that includes the date of the inventory, a summary of the inventory
3 findings, and the employee identification numbers and titles or positions of the individuals who
4 conducted the inventory.

5 Section 5. Employees records and identification.

6 (1) A processor shall keep an individual employment record for all employees, including:

7 (a) Full legal name;

8 (b) Detailed job description;

9 (c) Documentation of completed criminal background check;

10 (d) Record of all training received or acquired by the employee;

11 (e) Dates of employment;

12 (f) Records of days and hours worked; and

13 (g) Any disciplinary actions taken by the processor.

14 (2) Employment records shall be maintained, either electronically or in hard copy, for at
15 least five (5) years after the employee's last date of employment with the processor.

16 (3) A processor shall create an identification badge for each employee, agent, or
17 volunteer. This badge shall be conspicuously worn by employees, agents, or volunteers at all
18 times that they are on the licensed premises or during transport of medicinal cannabis or
19 medicinal cannabis products. The badge shall contain:

20 (a) The individual's name, photo, and employee identification number;

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

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

23 Section 6. Visitors to processor facilities.

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

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

4 (a) Require the visitor to sign a visitor log upon entering and leaving the facility;

5 (b) Check the visitor's government-issued identification to verify that the name on the
6 identification provided matches the name in the visitor log;

7 (c) Issue a visitor identification badge with the visitor's name and company, if
8 applicable, and a badge number;

9 (d) Escort the visitor while the visitor remains on the site or in the facility keeping a
10 record of the areas of the site and the facility visited; and

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

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

18 (4) A processor shall post a sign in a conspicuous location at each entrance of its site and
19 facility that states "THESE PREMISES ARE UNDER CONSTANT VIDEO SURVEILLANCE.
20 NO ONE UNDER THE AGE OF 18 IS PERMITTED TO ENTER."

21 (5) The processor shall maintain the visitor log required under this section for five (5)
22 years and make the visitor log available to the cabinet, law enforcement, and other federal or
23 state government officials upon request to perform the government officials' functions and

1 duties. The visitor log shall include the date, the full name of each visitor, the visitor
2 identification badge number, the time of arrival, the time of departure, and the purpose of the
3 visit, including the areas of the site and the facility visited.

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

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

10 Section 7. Security and surveillance.

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

14 (a) A professionally monitored security alarm system that includes:

15 1. Coverage of all facility entrances and exits; rooms with exterior windows, exterior
16 walls, roof hatches or skylights; storage rooms, including those that contain medicinal cannabis
17 and safes; and the perimeter of the facility.

18 2. An audible security alarm system signal, known as a panic alarm, generated by the
19 manual activation of a device intended to signal a life-threatening or emergency situation
20 requiring law enforcement response;

21 3. A silent alarm signal, known as a holdup alarm, generated by the manual activation of
22 a device intended to signal a robbery in progress;

1 4. A failure notification system that provides an audible, text, or visual notification of any
2 failure in the systems. The failure notification system shall provide by telephone, e-mail, or text
3 message an alert to a designated security person within the facility within five (5) minutes after
4 the failure;

5 5. Smoke and fire alarms;

6 6. Auxiliary power sufficient to maintain operation for at least twenty-four (24) hours
7 following a power outage;

8 7. The ability to ensure all access doors shall not be solely controlled by an electronic
9 access panel to prevent locks from becoming released during a power outage; and

10 8. Motion detectors for exterior lighting.

11 (b) A professionally monitored security surveillance system that is operational twenty-
12 four (24) hours a day, seven (7) days a week, and records all activity in images capable of clearly
13 revealing facial detail. The security and surveillance system shall include:

14 1. Fixed camera placement that allows for a clear image of all individuals and activities in
15 and around the following:

16 a. All limited access areas;

17 b. A room or area containing a security alarm and surveillance system storage device or
18 equipment;

19 c. Entrances to and exits from the facility. Entrances and exits shall be recorded from
20 both indoor and outdoor vantage points;

21 d. Rooms with exterior windows, exterior walls, roof hatches, or skylights and storage
22 rooms, including those that may contain medicinal cannabis and safes and excluding restrooms;
23 and

- 1 e. Twenty (20) feet from the exterior of the perimeter of the facility.
- 2 2. Auxiliary power sufficient to maintain operation for at least twenty-four (24) hours
- 3 following a power outage;
- 4 3. Ability to operate under the normal lighting conditions of each area under surveillance;
- 5 4. Ability to immediately produce a clear, color, still photograph in a digital format that is
- 6 easily accessible;
- 7 5. Ability to display the date and time clearly and accurately. The date and time shall be
- 8 synchronized and set correctly and may not significantly obscure the picture;
- 9 6. Ability to record all images captured by each surveillance camera in a format that may
- 10 be easily accessed for a minimum of thirty (30) days, unless otherwise required for investigative
- 11 or litigation purposes. The recordings shall be kept:
- 12 a. At the processor's facility:
- 13 (i) In a locked cabinet, closet, or other secure place to protect it from tampering or theft;
- 14 and
- 15 (ii) In a limited access area or other room to which access is limited to authorized
- 16 individuals; or
- 17 b. At a secure location other than the location of the processor's facility if approved by
- 18 the cabinet.
- 19 (2) Regarding inspection, servicing or alteration of, and any upgrade to, the site's and
- 20 facility's security alarm and surveillance systems:
- 21 (a) The systems shall be inspected and all devices tested once every year by a qualified
- 22 alarm system vendor and a qualified surveillance system vendor;

1 (b) A processor shall conduct maintenance inspections once every month to ensure that
2 any repairs, alterations, or upgrades to the security alarm and surveillance systems are made for
3 the proper operation of the systems;

4 (c) A processor shall retain at the facility, for at least five (5) years, records of all
5 inspections, servicing, alterations, and upgrades performed on the security alarm and surveillance
6 systems and shall make the records available to the cabinet and its authorized agents within two
7 (2) business days following a request; and

8 (d) In the event of a mechanical malfunction of the security alarm or surveillance system
9 that a processor anticipates shall exceed an eight (8) hour period, the processor shall notify the
10 cabinet immediately via electronic mail to kymedcanreporting@ky.gov and, with cabinet
11 approval, provide alternative security measures that may include closure of the facility.

12 (3) Regarding records retention, a processor shall:

13 (a) Have a secure electronic back-up system for all electronic records;

14 (b) Within three (3) business days following a request for records under this paragraph,
15 provide up to four (4) screen captures of an unaltered copy of a video surveillance recording to
16 the cabinet or its authorized agents, law enforcement, or other federal, state, or local government
17 officials if necessary to perform the governmental officials' functions and duties; and

18 (c) If a processor has been notified in writing by the cabinet or its authorized agents, law
19 enforcement, or other federal, state, or local government officials of a pending criminal or
20 administrative investigation for which a recording may contain relevant information, retain an
21 unaltered copy of the recording for two (2) years or until the investigation or proceeding is
22 closed or the entity conducting the investigation or proceeding notifies the processor that it is not
23 necessary to retain the recording, whichever is later.

1 (4) During all non-working hours, all entrances to and exits from the processor's facility
2 shall be securely locked.

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

5 (6) A processor shall limit access to a room containing the equipment operating the
6 security alarm and surveillance monitoring systems to:

7 (a) Persons who are essential to maintaining security and surveillance operations;

8 (b) Federal, state, and local law enforcement;

9 (c) Security alarm and surveillance system service employees;

10 (d) The cabinet or its authorized agents; and

11 (e) Other persons with the prior written approval of the cabinet.

12 (7) A processor shall make available to the cabinet or its authorized agents, upon request,
13 a current list of authorized employees and service employees or contractors who have access to
14 areas containing the equipment operating the security alarm and surveillance monitoring
15 systems.

16 (8) A processor shall keep rooms housing the equipment operating the security alarm and
17 surveillance monitoring systems locked at all times and may not use these rooms for any other
18 purpose or function.

19 Section 8. Forms of medicinal cannabis.

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

22 (a) Edible;

23 (b) Oil;

- 1 (c) Topical forms, including gel, creams, ointments, and cosmetics;
- 2 (d) A form medically appropriate for administration by vaporization or nebulization;
- 3 (e) Tincture;
- 4 (f) Dermal patch;
- 5 (g) Suppositories;
- 6 (h) Beverages; and
- 7 (i) Raw plant material.

8 (2) In addition to other packaging and labeling requirements established in 915 KAR
9 1:100, all raw plant material packaged and sold by a processor in this commonwealth shall be
10 marked or labeled as “NOT INTENDED FOR CONSUMPTION BY SMOKING.” Processors
11 delivering raw plant material to dispensaries for sale shall comply with the requirements
12 contained in 915 KAR 1:030, Section 14.

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

17 Section 9. Requirements for processing medicinal cannabis.

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

21 (2) A processor may use hydrocarbon solvent-based extraction methods in a spark-free
22 and properly ventilated environment, isolated from any open flame or ignition source, and may

1 use the following solvents, at a minimum of ninety-nine per cent purity, in a professional grade,
2 closed-loop extraction system designed to recover the solvents:

- 3 (a) Propane;
- 4 (b) N-butane;
- 5 (c) Isobutane; and
- 6 (d) Heptane.

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

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

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

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

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

- 20 (a) The non-cannabis ingredients are nontoxic and safe for human consumption; and
- 21 (b) The non-cannabis ingredients were not prepared or stored in a private residence.

22 (8) A processor using hydrocarbon solvent-based or carbon dioxide extraction methods
23 shall designate at least one (1) individual to train and supervise employees in the use of

1 extraction equipment and associated solvents who has earned, at minimum, a Bachelor's Degree
2 in engineering or physical sciences from an accredited university, or who has at least three (3)
3 years of experience in the operation of the equipment being used in the facility or similar
4 equipment.

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

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

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

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

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

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

19 (b) Proper sanitation shall be maintained;

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

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

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

4 (14) A processor shall install a system to monitor, record, and regulate:

5 (a) Temperature;

6 (b) Humidity;

7 (c) Ventilation;

8 (d) Lighting; and

9 (e) Water supply.

10 Section 10. Equipment, operation and maintenance.

11 (1) A processor shall have a written process in place to maintain the sanitation and
12 operation of equipment that comes into contact with medicinal cannabis to prevent
13 contamination. The processor shall provide a copy of the written process to the cabinet upon
14 request.

15 (2) As part of the written process required under this section, a processor shall:

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

19 (b) Maintain an accurate log recording:

20 1. Maintenance of equipment;

21 2. Cleaning of equipment; and

22 3. Calibration of equipment.

23 Section 11. Sanitation and safety in a processor facility.

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

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

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

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

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

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

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

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

20 (a) Maintaining adequate personal cleanliness;

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

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

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

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

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

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

17 (3) A processor shall:

18 (a) Provide its employees, volunteers, and visitors with adequate and convenient hand-
19 washing facilities furnished with running water at a temperature suitable for sanitizing hands.

20 Effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices shall
21 also be provided;

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

1 (c) Ensure that its facility is provided with a water supply sufficient for its operations,
2 which shall be derived from a source that is a public water system, or a nonpublic system that is
3 capable of providing a safe, potable, and adequate supply of water to meet the operational needs
4 of the facility; and

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

7 Section 12. Storage requirements.

8 (1) A processor shall have separate locked limited access areas for storage of medicinal
9 cannabis that is expired, damaged, deteriorated, mislabeled, contaminated, recalled, or whose
10 containers or packaging have been opened or breached until the medicinal cannabis is destroyed
11 or otherwise disposed of as required under Section 13 of this administrative regulation.

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

14 Section 13. Management and disposal of medicinal cannabis waste.

15 (1) A processor shall dispose of undesired, excess, unauthorized, obsolete, adulterated,
16 misbranded, or deteriorated medicinal cannabis in such a manner as to render the medicinal
17 cannabis unusable. A processor shall record medicinal cannabis waste as required in the
18 commonwealth's designated electronic monitoring system and seed to sale tracking system.

19 (2) Medicinal cannabis that is rendered unusable shall be discarded into a locked
20 dumpster or other approved, locked container for removal from the facility by a waste removal
21 company selected by the processor. Medicinal cannabis shall be rendered unusable by:

22 (a) Controlled incineration; or

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

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

10 (3) The disposal of medicinal cannabis shall be performed under video surveillance from
11 the time the destruction begins to when it is placed in a locked dumpster or other approved,
12 locked container and removed from the processor's site and facility.

13 (4) The employee overseeing the disposal of medicinal cannabis shall maintain and make
14 available a separate record of every disposal indicating the following:

- 15 (a) The date and time of disposal;
- 16 (b) The manner of disposal;
- 17 (c) The unique identification codes associated with the medicinal cannabis scheduled for
18 destruction;
- 19 (d) The reasoning for and description of the disposal;
- 20 (e) The name, employee identification number, and signature of the employee overseeing
21 the disposal of the medicinal cannabis; and

1 (f) If the medicinal cannabis waste for disposal contains plant material that was prepared
2 for sale to a dispensary, the harvest or production batch number, strain, volume, and weight of
3 the plant material being disposed of.

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

7 Section 14. Complaints about or recall of medicinal cannabis and medicinal cannabis
8 products.

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

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

19 (b) If a processor determines that further action is not required, the processor shall notify
20 the cabinet of its decision via electronic mail to kymedcanreporting@ky.gov and, within twenty-
21 four (24) hours, submit a written report to the cabinet stating its rationale for not taking further
22 action. The cabinet shall review the written report and consult with the processor as needed. If
23 the cabinet disagrees with the processor's decision, the cabinet shall take all necessary steps

1 allowable under KRS Chapter 218B and 915 KAR Chapter 1 to ensure public health and safety,
2 including issuing a cease and desist order to pause the sale and distribution of the medicinal
3 cannabis at issue until resolution of the matter; and

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

6 (2) Voluntary recalls. If a processor voluntarily initiates a recall, the processor shall
7 recall seeds, seedlings, medicinal cannabis plants, postharvest plant material, or medicinal
8 cannabis from the market at its discretion for reasons that do not pose a risk to public health and
9 safety and shall notify the cabinet at the time the processor begins the recall via electronic mail
10 to kymedcanreporting@ky.gov.

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

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

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

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

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

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

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

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

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

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

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

14 (e) Procedures for notifying the cabinet; and

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

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

22 (7) A processor shall coordinate the disposal of recalled medicinal cannabis with the
23 cabinet. The cabinet or its authorized agents may oversee the disposal to ensure that the recalled

1 medicinal cannabis is disposed of in a manner that will not pose a risk to public health and
2 safety.

3 (8) The processor shall enter information relevant to the recall into the commonwealth's
4 designated electronic monitoring system and seed to sale tracking system as part of the
5 inventory, which may include the following:

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

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

10 (c) The names of the recall coordinators;

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

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

13 (f) The reason for the recall;

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

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

18 1. The name of the individual overseeing the disposal of the recalled medicinal cannabis;

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

20 3. The method of disposal;

21 4. The date of disposal; and

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

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

4 Section 15. Duty to report.

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

8 (a) Any significant issues with the supply and demand of medicinal cannabis experienced
9 by the processor;

10 (b) The total amount of raw plant material processed during the current licensure period
11 and the average price per pound; and

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

13 (2) A processor shall participate in market surveys distributed by the cabinet throughout a
14 licensure period and provide full and complete responses.

915 KAR 1:040

REVIEWED:

DocuSigned by:
Sam Flynn 1/2/2024
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Sam Flynn Date
Executive Director
Kentucky Medical Cannabis Program
Cabinet for Health and Family Services

APPROVED:

DocuSigned by:
Eric Friedlander 1/2/2024
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Eric C. Friedlander Date
Secretary
Cabinet for Health and Family Services

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

A public hearing on this administrative regulation shall, if requested, be held on March 25, 2024, at 9:00 a.m. using the CHFS Office of Legislative and Regulatory Affairs Zoom meeting room. The Zoom invitation will be emailed to each requestor the week prior to the scheduled hearing. Individuals interested in attending this virtual hearing shall notify this agency in writing by March 18, 2024, five (5) workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who attends virtually will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on this proposed administrative regulation until March 31, 2024. Send written notification of intent to attend the public hearing or written comments on the proposed administrative regulation to the contact person. Pursuant to KRS 13A.280(8), copies of the statement of consideration and, if applicable, the amended after comments version of the administrative regulation shall be made available upon request.

Contact Person: Krista Quarles, Policy Analyst, Office of Legislative and Regulatory Affairs, 275 East Main Street 5 W-A, Frankfort, KY 40621; Phone: 502-564-7476; Fax: 502-564-7091; CHFSregs@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 915 KAR 1:040
Agency Contact: Oran S. McFarlan, III
Phone Number: (502) 564-5313
Email: oran.mcfarlan@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-7476
Email: CHFSregs@ky.gov

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation establishes requirements and procedures for medicinal cannabis processors to operate in the commonwealth.

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

(4) Provide an analysis of how the entities identified in question (3) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (3) will have to take to comply with this administrative regulation or amendment: The requirements to operate

as a processor 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): Processors 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): Processors that receive a license from the Cabinet for Health and Family Services are authorized to conduct medicinal cannabis processing activities 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 processors.

(8) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish or increase any fees.

(9) TIERING: Is tiering applied? Explain why or why not. Tiering is not applied. All processors will be treated equally.

FISCAL NOTE

Administrative Regulation: 915 KAR 1:040
Agency Contact: Oran S. McFarlan, III
Phone Number: (502) 564-5313
Email: oran.mcfarlan@ky.gov

Contact Person: Krista Quarles
Phone Number: (502) 564-7476
Email: CHFSregs@ky.gov

(1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? This administrative regulation impacts the Kentucky Medical Cannabis Program within the Cabinet for Health and Family Services.

(2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation. KRS 218B.010, 218B.080, 218B.085, 218B.090, 218B.095, 218B.100, 218B.115, 218B.140.

(3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect.

(a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? The cabinet will receive initial application fees and initial license fees paid by processors during the first year.

(b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? The cabinet will receive annual renewal license fees from processors that desire to continue operating in the commonwealth following the expiration of their existing license.

(c) How much will it cost to administer this program for the first year? The cabinet estimates that it will cost \$1,200,000 to license and regulate processors in the first year.

(d) How much will it cost to administer this program for subsequent years? The cabinet estimates that it will cost \$1,200,000 to regulate licensed processors in subsequent years.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-):

Expenditures (+/-):

Other Explanation: 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 processors.

(4) Estimate the effect of this administrative regulation on the expenditures and cost savings of regulated entities for the first full year the administrative regulation is to be in effect.

(a) How much cost savings will this administrative regulation generate for the regulated entities for the first year? The cabinet does not anticipate any cost savings in the first year.

(b) How much cost savings will this administrative regulation generate for the regulated entities for subsequent years? The cabinet does not anticipate any cost savings in subsequent years.

(c) How much will it cost the regulated entities for the first year? A processor will pay an initial application fee and, if issued a license, an initial license fee in order to conduct processing activities in the commonwealth.

(d) How much will it cost the regulated entities for subsequent years? If it desires to continue cannabis business operations in the commonwealth, a processor will pay an annual renewal license fee. The renewal license fee is refundable if the renewal application is denied.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

- Cost Savings(+/-):
- Expenditures (+/-):
- Other Explanation:

(5) Explain whether this administrative regulation will have a major economic impact, as defined below. *"Major economic impact" means an overall negative or adverse economic impact from an administrative regulation of five hundred thousand dollars (\$500,000) or more on state or local government or regulated entities, in aggregate, as determined by the promulgating administrative bodies. [KRS 13A.010(13)]* The annual cost estimate to administer all aspects of the Kentucky Medical Cannabis Program is \$9,135,398. A significant portion of those funds will go toward licensing and enforcement of cannabis businesses operating in the commonwealth, including processors, as well implementation and continued operation of the electronic monitoring system and seed to sale tracking system required by KRS 218B.140. The Kentucky Medical Cannabis Program will have a major economic impact on the Cabinet for Health and Family Services, and it is anticipated that an increase in funding will be necessary to administer all of the administrative regulations contained in 915 KAR Chapter 1 related to cannabis businesses.