



1 CABINET FOR HEALTH AND FAMILY SERVICES

2 Office of the Secretary

3 (New Administrative Regulation)

4 915 KAR 1:030. Cultivator.

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 cultivator operations in the commonwealth. This
10 administrative regulation establishes those requirements and procedures.

11 Section 1. General requirements.

12 (1) No person or entity shall engage in the business of planting, growing, cultivating,
13 raising, harvesting, trimming, storing, testing, packaging, labeling, transferring, transporting,
14 selling, or offering to sell medicinal cannabis seeds, seedlings, medicinal cannabis plants,
15 medicinal cannabis, or medicinal cannabis products to a cannabis business without first being
16 issued a license by the cabinet. A cultivator shall not sell or transfer, or allow the sale or
17 transfer, of medicinal cannabis seeds, seedlings, medicinal cannabis plants, medicinal cannabis,
18 or medicinal cannabis products to any person or entity in the commonwealth who does not hold a
19 cannabis business license issued by the cabinet.

20 (2) A cultivator shall:

1 (a) Conduct cultivation activities in an enclosed, locked facility in accordance with KRS
2 218B.095(5);

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

7 (c) Comply with all applicable requirements of KRS Chapter 218B, specifically KRS
8 218B.095 and 218B.105, and 915 KAR Chapter 1.

9 (3) A cultivator shall not:

10 (a) Employ, take on as a volunteer, or have as a board member, principal officer, or agent
11 any person who was convicted of a disqualifying felony offense or is younger than twenty-one
12 (21) years of age; or

13 (b) Sell or transfer, or allow the sale or transfer, of medicinal cannabis seeds, seedlings,
14 medicinal cannabis plants, medicinal cannabis, or medicinal cannabis products to any person or
15 entity in the commonwealth who does not hold a cannabis business license issued by the cabinet.

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

18 Section 2. Plans of operation.

19 (1) Prior to its first day of cultivation activities in the commonwealth, a cultivator shall
20 establish standard operating procedures for the following:

21 (a) Employment policies and procedures;

22 (b) Security including:

23 1. Staff identification measures, including use of employee identification badges;

- 1 2. Monitoring of attendance of staff and visitors;
- 2 3. Alarm systems;
- 3 4. Video surveillance;
- 4 5. Monitoring and tracking inventory, including use of the commonwealth's electronic
- 5 monitoring system and seed to sale tracking system established pursuant to KRS 218B.140;
- 6 6. Personnel security;
- 7 7. Transportation of medicinal cannabis;
- 8 8. Cash management and anti-fraud procedures;
- 9 9. Measures to prevent loitering, which shall include signage; and
- 10 10. Storage of seeds, seedlings, medicinal cannabis plants, medicinal cannabis, or
- 11 medicinal cannabis products;
- 12 (c) The process for receiving, growing, cultivating, harvesting, handling, packaging,
- 13 labeling, storing, transporting, and disposing of seeds, seedlings, medicinal cannabis plants,
- 14 medicinal cannabis, or medicinal cannabis products and a process for handling, tracking,
- 15 transporting, storing, and disposing of medicinal cannabis waste;
- 16 (d) Workplace safety, including conducting safety checks;
- 17 (e) Contamination;
- 18 (f) Maintenance, cleaning, and sanitation of equipment used to grow and cultivate
- 19 medicinal cannabis;
- 20 (g) Maintenance and sanitation of the cultivator's facility;
- 21 (h) Application of pesticides, fertilizers, and herbicides to medicinal cannabis at any point
- 22 during the growing, cultivating, and harvesting processes;

1 (i) Proper handling and storage of any chemical or substance used in growing medicinal
2 cannabis;

3 (j) Logging the use of all pesticides and chemical applications applied to medicinal
4 cannabis and medicinal cannabis products;

5 (k) Quality control, including strict regulation of the amount of delta-9
6 tetrahydrocannabinol content in each medicinal cannabis harvest batch, proper labeling, and
7 minimization of medicinal cannabis contamination;

8 (l) Recordkeeping and inventory control;

9 (m) Investigation of complaints and potential adverse events received from other
10 cannabis businesses, cardholders, or medicinal cannabis practitioners regarding the cultivator's
11 operations;

12 (n) Preventing unlawful diversion of medicinal cannabis;

13 (o) Recall plan; and

14 (p) Any other standard operating procedures required for all cannabis businesses in KRS
15 Chapter 218B and 915 KAR Chapter 1;

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

18 Section 3. Cultivator facilities.

19 (1) A cultivator shall only plant, grow, cultivate, and harvest medicinal cannabis in an
20 enclosed, locked facility on the specific site licensed by the cabinet and identified on its license
21 issued by the cabinet.

1 (2) All cultivation activities, excluding disposal, destruction, or transport of medicinal
2 cannabis, shall take place within a building or secure structure that meets all applicable state and
3 local building codes and specifications in addition to the following:

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

6 (b) Is secure against unauthorized entry;

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

8 (d) Restricts access to only authorized personnel to limited access areas identified with
9 signage and daily records of entry and exit;

10 (e) Contains adequate plumbing to carry sufficient quantities of water to locations
11 throughout the facility and convey any sewage and waste from the facility without cross
12 contamination of potable water and waste;

13 (f) Stores toxic cleaning compounds, sanitizing agents, pesticides, fertilizers, and
14 herbicides in a manner that is in accordance with applicable local, state, and federal laws and
15 regulations;

16 (g) Maintains proper ventilation;

17 (h) Maintains pest control;

18 (i) Maintains adequate indoor and exterior lighting to facilitate video surveillance at all
19 times; and

20 (j) Maintains adequate on-site parking for employees, agents, visitors, transporters of
21 medicinal cannabis, or cabinet staff.

22 (3) A cultivator shall clearly mark all limited access areas on its premises with proper
23 signage. All areas of ingress and egress to a limited access area shall be clearly identified by the

1 posting of a sign which shall be not less than 12 inches wide and 12 inches long, composed of
2 letters not less than one-half inch in height, which shall state: “Do Not Enter. Limited Access
3 Area. Access Limited to Authorized Personnel and Escorted Visitors.”

4 (4) A cultivator shall have a secure area for the loading and unloading of medicinal
5 cannabis seeds, seedlings, medicinal cannabis plants, and medicinal cannabis into and from a
6 transport vehicle.

7 Section 4. Inventory.

8 (1) A cultivator shall, within twenty-four (24) hours of receipt, record in the
9 commonwealth’s designated electronic monitoring system and seed to sale tracking system each
10 medicinal cannabis seed, seedling, or plant that it acquires.

11 (2) A cultivator shall only grow medicinal cannabis plants from seeds and seedlings
12 located physically in its facility.

13 (3) Canopy. A cultivator shall not exceed the indoor growth area specified in KRS
14 218B.105(3) for its respective cultivator tier. The surface area of the plant canopy shall be
15 calculated in square feet. Measurement shall include all of the area within the boundaries where
16 the cultivation of medicinal cannabis plants occurs. If a tiered or shelving system is used in the
17 cultivation area, the surface of each tier or shelf shall be included in the calculation. Calculation
18 of the area of the plant canopy shall not include square footage within a cultivator’s enclosed,
19 locked facility used for the storage of supplies, pesticides, fertilizers, or other products as well as
20 square footage used for quarantine, office space, or other non-cultivation activities.

21 Section 5. Employees records and identification.

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

23 (a) Full legal name;

- 1 (b) Detailed job description;
- 2 (c) Documentation of completed criminal background check;
- 3 (d) Record of all training received or acquired by the employee;
- 4 (e) Dates of employment;
- 5 (f) Records of days and hours worked; and
- 6 (g) Any disciplinary actions taken by the cultivator.

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

9 (3) A cultivator shall create an identification badge for each employee, agent, or
10 volunteer. The badge shall be conspicuously worn by employees, agents, or volunteers at all
11 times that they are on the licensed premises or during transport of medicinal cannabis. The
12 badge shall contain:

- 13 (a) The individual's name, photo, and employee identification number;
- 14 (b) A phone number and email address for the cultivator; and
- 15 (c) A phone number and email address for the Kentucky Medical Cannabis Program.

16 Section 6. Visitors to cultivator facilities.

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

18 (2) A cultivator shall complete the following steps when admitting a visitor to its site and
19 facility:

- 20 (a) Require the visitor to sign a visitor log upon entering and leaving the facility;
- 21 (b) Check the visitor's government-issued identification to verify that the name on the
22 identification provided matches the name in the visitor log;

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

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

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

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

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

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

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

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

4 Section 7. Security and surveillance.

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

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

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

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

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

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

21 5. Smoke and fire alarms;

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

1 7. The ability to ensure all access doors are not solely controlled by an electronic access
2 panel to prevent locks from becoming released during a power outage; and

3 8. Motion detectors for exterior lighting.

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

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

9 a. All limited access areas;

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

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

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

17 e. Twenty (20) feet from the exterior of the perimeter of the facility.

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

20 3. Ability to operate under the normal lighting conditions of each area under surveillance;

21 4. Ability to immediately produce a clear, color, still photograph in a digital format that is
22 easily accessible;

1 5. Ability to clearly and accurately display the date and time. The date and time shall be
2 synchronized and set correctly and may not significantly obscure the picture;

3 6. Ability to record all images captured by each surveillance camera in a format that may
4 be easily accessed for a minimum of thirty (30) days, unless otherwise required for investigative
5 or litigation purposes. The recordings shall be kept:

6 a. At the cultivator's facility:

7 (i) In a locked cabinet, closet or other secure place to protect it from tampering or theft;

8 and

9 (ii) In a limited access area or other room to which access is limited to authorized
10 individuals; or

11 b. At a secure location other than the location of the cultivator's facility if approved by
12 the cabinet.

13 (2) Regarding inspection, servicing, alteration of, and any upgrade to, the security alarm
14 and surveillance systems:

15 (a) The systems shall be inspected and all devices tested once every year by a qualified
16 alarm system vendor and a qualified surveillance system vendor;

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

20 (c) A cultivator shall retain at the facility, for at least five (5) years, records of all
21 inspections, servicing, alterations, and upgrades performed on the security alarm and surveillance
22 systems and shall make the records available to the cabinet and its authorized agents within two

23 (2) business days following a request; and

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

5 (3) Regarding records retention, a cultivator shall:

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

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

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

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

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

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

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

- 1 (b) Federal, state, and local law enforcement;
- 2 (c) Security alarm and surveillance system service employees;
- 3 (d) The cabinet or its authorized agents; and
- 4 (e) Other persons with the prior written approval of the cabinet.

5 (7) A cultivator shall make available to the cabinet or its authorized agents, upon request,
6 a current list of authorized employees and service employees or contractors who have access to
7 areas containing the equipment operating the security alarm and surveillance monitoring
8 systems; and

9 (8) A cultivator shall keep rooms housing the equipment operating the security alarm and
10 surveillance monitoring systems locked at all times and shall not use these rooms for any other
11 purpose or function.

12 Section 8. Requirements for cultivating and growing medicinal cannabis.

13 (1) A cultivator who uses a pesticide on medicinal cannabis shall be certified to apply
14 pesticides by the Kentucky Department of Agriculture pursuant to KRS Chapter 217B and:

15 (a) A cultivator who is certified to apply pesticides by the Kentucky Department of
16 Agriculture shall not use, or be eligible to use, a Category 10 license to apply pesticides to
17 medicinal cannabis in violation of the product label;

18 (b) A cultivator shall not use any pesticide in violation of the product label;

19 (c) A cultivator who uses a pesticide on growth medium used for multiple medicinal
20 cannabis cultivation cycles shall comply with the longest of any planting restriction interval on
21 the product label prior to reusing the growth medium;

1 (d) The cabinet may perform pesticide testing on a random basis or if its authorized
2 agents have reason to believe that a pesticide may have been applied to medicinal cannabis in
3 violation of the product label; and

4 (e) Medicinal cannabis seeds, seedlings, plants, and materials bearing pesticide residue in
5 violation of the label or testing standards established by the cabinet shall be subject to forfeiture
6 or destruction without compensation.

7 (2) The cabinet shall publish a list of approved pesticides and any other chemical
8 applications for use in growing and cultivating medicinal cannabis on the website for the
9 Kentucky Medical Cannabis Program, <https://kymedcan.ky.gov>. This list shall be reviewed and
10 updated annually by the cabinet.

11 (3) A cultivator shall maintain a log of the use of all pesticides and any other chemical
12 applications applied to medicinal cannabis and medicinal cannabis products for a minimum of
13 five (5) years, including:

14 (a) The date of application;

15 (b) The name of the individual making the application;

16 (c) The product that was applied;

17 (d) The section, including the square footage, that received the application;

18 (e) The amount of product that was applied; and,

19 (f) A copy of the label of the product that was applied.

20 (4) A cultivator shall:

21 (a) Use appropriate nutrient practices;

22 (b) Use a fertilizer or hydroponic solution of a type, formulation, and at a rate to support
23 healthy growth of plants; and

1 (c) Maintain a log of the type and amounts of fertilizer and any growth additives used.

2 (5) A cultivator shall perform visual inspections of growing medicinal cannabis plants
3 and harvested medicinal cannabis plant material to ensure there are no visible insects, mold,
4 mildew, pests, rot, grey or black plant material, or inorganic material, including plastic, glass,
5 and metal shavings.

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

8 (7) A cultivator shall install a system to monitor, record, and regulate:

9 (a) Temperature;

10 (b) Humidity;

11 (c) Ventilation;

12 (d) Lighting; and

13 (e) Water supply.

14 Section 9. Electronic monitoring system and seed to sale tracking system.

15 (1) A cultivator shall use the electronic monitoring system and seed to sale tracking
16 system prescribed by the cabinet containing the requirements in KRS Chapter 218B, specifically
17 KRS 218B.140, and in accordance with written instructions provided by the cabinet.

18 (2) A cultivator shall establish inventory controls and procedures to conduct inventory
19 reviews at its facility.

20 (a) A cultivator shall prepare quarterly physical inventory reports that includes any
21 necessary adjustments and the reason(s) for an adjustment and that demonstrates the physical
22 inventory reconciles with the inventory recorded in the commonwealth's designated electronic

1 monitoring system and seed to sale tracking system, including any medicinal cannabis that has
2 been or is in the process of being destroyed; and

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

7 Section 10. Equipment, operation, and maintenance.

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

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

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

16 (b) Maintain an accurate log recording the:

17 1. Maintenance of equipment;

18 2. Cleaning of equipment; and

19 3. Calibration of equipment.

20 Section 11. Sanitation and safety in a cultivator facility.

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

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

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

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

8 (d) Equipment, counters, and surfaces used for packaging and labeling of medicinal
9 cannabis shall be food grade quality;

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

13 (f) Toxic cleaning compounds, sanitizing agents, pesticides, herbicides, and other
14 chemicals shall be labeled and stored in a manner that prevents contamination of seeds,
15 seedlings, medicinal cannabis plants, and medicinal cannabis.

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

18 (a) Maintaining adequate personal cleanliness;

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

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

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

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

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

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

15 (3) A cultivator shall:

16 (a) Provide its employees, volunteers, and visitors with adequate and convenient hand-
17 washing facilities furnished with running water at a temperature suitable for sanitizing hands.
18 Effective nontoxic sanitizing cleansers and sanitary towel service or suitable drying devices shall
19 also be provided;

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

22 (c) Ensure that its facility is provided with a water supply sufficient for its operations,
23 which shall be derived from a source that is a public water system, or a nonpublic system that is

1 capable of providing a safe, potable, and adequate supply of water to meet the operational needs
2 of the facility; and

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

5 Section 12. Storage requirements.

6 (1) A cultivator shall have separate locked limited access areas for storage of seeds,
7 seedlings, medicinal cannabis plants, and medicinal cannabis that are expired, damaged,
8 deteriorated, mislabeled, contaminated, recalled, or whose containers or packaging have been
9 opened or breached until the seeds, seedlings, medicinal cannabis plants, and medicinal cannabis
10 are destroyed or otherwise disposed of as required under Section 15 of this administrative
11 regulation.

12 (2) A cultivator 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 cultivator 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 cultivator 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 cultivator or may be composted in a secured area at the cultivation site
22 for future use at the facility. Medicinal cannabis shall be rendered unusable by:

23 (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 cultivator'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:

- 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 or processor, the harvest batch number, strain, volume, and weight of the
3 plant material being disposed of.

4 (5) The disposal of other waste from the cultivator 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. Requirements for cultivators to deliver raw plant material to dispensaries for
8 sale.

9 (1) A cultivator that delivers medicinal cannabis to licensed dispensaries for sale to
10 cardholders shall comply with the requirements of KRS Chapter 218B and 915 KAR Chapter 1,
11 including 915 KAR 1:080, 915 KAR 1:100, and 915 KAR 1:110.

12 (2) A cultivator that delivers medicinal cannabis to a licensed dispensary for sale to
13 cardholders shall not:

14 (a) Deliver, transfer, or sell raw plant material to a dispensary for more than fair market
15 value;

16 (b) Supply a dispensary with more than the amount of raw plant material reasonably
17 required by a dispensary to maintain an inventory sufficient for normal retail operations; and

18 (c) Deliver, transfer, or sell raw plant material to a dispensary with a delta-9
19 tetrahydrocannabinol content of more than thirty-five percent (35%).

20 (3) Any raw plant material to be sold as a medicinal cannabis product by a cultivator to a
21 dispensary shall:

22 (a) Be free of seeds and stems;

23 (b) Be free of dirt, sand, debris, or other foreign matter; and

1 (c) Not contain a level of pesticides, herbicides, poisons, toxins, mold, mildew, insects,
2 bacteria, or any other chemical substance higher than the levels established in the standards for
3 testing within 915 KAR 1:110.

4 (4) A cultivator shall prepare raw plant material for sale to dispensaries in a safe and
5 sanitary manner, including:

6 (a) Raw plant material shall be handled on food grade stainless steel benches or tables;

7 (b) Proper sanitation shall be maintained;

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

9 (d) Prior to packaging, the raw plant material shall have passed all required safety
10 compliance facility tests established in 915 KAR 1:110.

11 (5) In addition to other packaging and labeling requirements established in 915 KAR
12 1:100, all raw plant material packaged and sold by a cultivator in the commonwealth shall be
13 marked or labeled as "NOT INTENDED FOR CONSUMPTION BY SMOKING."

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

18 Section 15. Complaints about or recall of medical medicinal cannabis products.

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

1 medicinal cannabis purchased by the cannabis business from the cultivator. A cultivator shall
2 investigate the report as follows:

3 (a) A cultivator shall immediately investigate a complaint to determine if a voluntary or
4 mandatory recall of seeds, seedlings, medicinal cannabis plants, postharvest plant material, or
5 medicinal cannabis is necessary or if any further action is required;

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

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

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

21 (3) Mandatory recalls. If a cultivator discovers that a condition relating to the seeds,
22 seedlings, medicinal cannabis plants, postharvest plant material, or medicinal cannabis grown at
23 its facility poses a risk to public health and safety, the cultivator shall:

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

3 (b) Secure, isolate, and prevent the distribution of the seeds, seedlings, medicinal
4 cannabis plants, postharvest plant material, or medicinal cannabis that may have been affected by
5 the condition and remains in its possession. The cultivator shall not dispose of affected seeds,
6 seedlings, medicinal cannabis plants, postharvest plant material, or medicinal cannabis prior to
7 notifying the cabinet and coordinating the disposal with the cabinet.

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

12 (5) A cultivator's recall plan as required under this administrative regulation shall
13 include:

14 (a) Designation of one or more employees to serve as the recall coordinator(s). A recall
15 coordinator shall be responsible for, among other duties, accepting the recalled seeds, seedlings,
16 medicinal cannabis plants, postharvest plant material, or medicinal cannabis;

17 (b) Procedures for identifying and isolating the affected seeds, seedlings, medicinal
18 cannabis plants, postharvest plant material, or medicinal cannabis to prevent or minimize its
19 distribution to cardholders and other cannabis businesses;

20 (c) Procedures to retrieve and dispose of the affected seeds, seedlings, medicinal cannabis
21 plants, postharvest plant material, or medicinal cannabis;

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

1 1. The manner in which the cultivator shall notify other cannabis businesses in possession
2 of seeds, seedlings, medicinal cannabis plants, postharvest plant material, or medicinal cannabis
3 subject to the recall; and

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

6 (e) Procedures for notifying the cabinet; and

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

9 (6) A cultivator shall follow the procedures outlined in its recall plan unless the cultivator
10 obtains prior written approval of the cabinet, or the cabinet notifies the cultivator in writing to
11 perform other procedures. A cultivator shall conduct recall procedures in a manner that
12 maximizes the recall of affected seeds, seedlings, medicinal cannabis plants, postharvest plant
13 material, and medicinal cannabis and minimizes risks to public health and safety.

14 (7) A cultivator shall coordinate the disposal of recalled seeds, seedlings, medicinal
15 cannabis plants, postharvest plant material, and medicinal cannabis with the cabinet. The cabinet
16 or its authorized agents may oversee the disposal to ensure that the recalled seeds, seedlings,
17 medicinal cannabis plants, postharvest plant material, and medicinal cannabis are disposed of in
18 a manner that shall not pose a risk to public health and safety.

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

22 (a) The total amount of recalled seeds, seedlings, medicinal cannabis plants, postharvest
23 plant material, and medicinal cannabis, including types and harvest batches, if applicable;

1 (b) The total amount of recalled seeds, seedlings, medicinal cannabis plants, postharvest
2 plant material, or medicinal cannabis returned to the cultivator, including types, forms, and
3 harvest batches, if applicable;

4 (c) The names of the recall coordinators;

5 (d) From whom the recalled seeds, seedlings, medicinal cannabis plants, postharvest plant
6 material, or medicinal cannabis were received;

7 (e) The means of transport of the recalled seeds, seedlings, medical medicinal cannabis
8 plants, postharvest plant material, medicinal cannabis, or medicinal cannabis products;

9 (f) The reason for the recall;

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

13 (h) The manner of disposal of the recalled seeds, seedlings, medicinal cannabis plants,
14 postharvest plant material, and medicinal cannabis, including:

15 1. The name of the individual overseeing the disposal of the recalled seeds, seedlings,
16 medicinal cannabis plants, postharvest plant material, or medicinal cannabis;

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

18 3. The method of disposal;

19 4. The date of disposal; and

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

21 (9) The cabinet may initiate a mandatory recall upon receipt of information that a
22 condition relating to the seeds, seedlings, medicinal cannabis plants, postharvest plant material,
23 or medicinal cannabis grown or sold by a cultivator poses a risk to public health and safety.

1 Section 16. Increase of canopy limits.

2 (1) Pursuant to KRS 218B.140(3), if a need for additional medicinal cannabis cultivation
3 in the commonwealth is demonstrated by cannabis businesses or the cabinet's own analysis, the
4 cabinet may through the promulgation of administrative regulations increase the canopy size
5 limits for cultivators by up to three (3) times the limits established in KRS 218B.105. Any
6 increase in the canopy size limits adopted by the cabinet shall not result in an increase in
7 licensure application or renewal fees established by the cabinet.

8 (2) In making its determination whether to increase canopy limits for cultivators, the
9 cabinet may consider factors including the population of the commonwealth, the number of
10 active cardholders, changes to the list of qualifying medical conditions for medicinal cannabis,
11 market supply and demand, the amount of medicinal cannabis being sold by dispensaries, the
12 amount of allowable canopy space being utilized by cultivators, workforce development
13 opportunities, and any other factors that the cabinet deems relevant to its analysis.

14 Section 17. Duty to report.

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

18 (a) The average amount of allowable canopy space being utilized by the cultivator during
19 the current licensure period. If a cultivator is not utilizing the full amount of allowable canopy
20 space during the current licensure period, the cultivator shall provide a written explanation to the
21 cabinet of the reasons for not utilizing all available canopy space;

22 (b) The total amount of raw plant material sold during the current licensure period and
23 the average price per pound; and

- 1 (c) The number of current employees, respective job titles, and hourly wage; and
- 2 (2) A cultivator shall participate in market surveys distributed by the cabinet throughout a
- 3 licensure period and provide full and complete responses.

915 KAR 1:030

REVIEWED:

DocuSigned by:
Sam Flynn
72326208BAA58414

1/2/2024

Sam Flynn
Executive Director
Kentucky Medical Cannabis Program
Cabinet for Health and Family Services

Date

APPROVED:

DocuSigned by:
Eric Friedlander
0AFA1D6C15D6431

1/3/2024

Eric C. Friedlander
Secretary
Cabinet for Health and Family Services

Date

PUBLIC HEARING AND PUBLIC COMMENT PERIOD:

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

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

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Administrative Regulation: 915 KAR 1:030
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 cultivators 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 cultivators 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 cultivators 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 cultivators that have applied for and subsequently received licenses to conduct medicinal cannabis cultivation 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 cultivator 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): Cultivators 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): Cultivators that receive a license from the Cabinet for Health and Family Services are authorized to conduct medicinal cannabis cultivation 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 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 cultivators.

(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 cultivators will be treated equally.

FISCAL NOTE

Administrative Regulation: 915 KAR 1:030
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.105, 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 cultivators 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 cultivators 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 cultivators 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 cultivators 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 cultivators.

(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 cultivator will pay an initial application fee and, if issued a license, an initial license fee in order to conduct cultivation 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 cultivator 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 cultivators, 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.