218B.140 Electronic monitoring system required capabilities -- Administrative regulations -- Medicinal cannabis adverse drug effects reporting system -- Medicinal Cannabis Advisory Pamphlet.

(1) No later than July 1, 2024, the cabinet shall:

(a) Ensure that the electronic monitoring system established pursuant to KRS 218A.202 is designed or configured to enable:

1. Medicinal cannabis practitioners to record the issuance of written certifications to qualified patients, as required by KRS 218B.050;
2. The cabinet and state licensing boards to monitor the issuance of written certifications by medicinal cannabis practitioners;
3. Cabinet personnel, law enforcement personnel, and dispensary agents to verify the validity of registry identification cards issued by the cabinet by entering a registry identification number to determine whether or not the identification number corresponds with a current, valid registry identification card. The system shall only disclose whether the identification card is valid and whether the cardholder is a registered qualified patient, visiting qualified patient, or designated caregiver;
4. Law enforcement personnel and dispensary agents to access medicinal cannabis sales data recorded by dispensary agents pursuant to KRS 218B.110;
5. Dispensary agents to record the amount of medicinal cannabis that is dispensed to a cardholder during each transaction as required by KRS 218B.110; and
6. The sharing of dispensing data recorded by dispensary agents pursuant to KRS 218B.110 with all dispensaries in real time;

(b) Ensure that the electronic monitoring system established pursuant to KRS 218A.202 is designed to facilitate the tracking of medicinal cannabis from the point of cultivation to the point of sale to cardholders; and

(c) Promulgate administrative regulations in accordance with KRS Chapter 13A to establish:

1. Procedures for the issuance, renewal, suspension, and revocation of registry identification cards, including the creation of a standardized:
   a. Written certification form; and
   b. Application form which the cabinet shall require to be notarized;
2. Procedures for the issuance and revocation of registry identification cards;
3. Procedures for the issuance, renewal, suspension, and revocation of cannabis business licenses, including the creation of a uniform licensure application form which the cabinet shall require to be notarized and minimal performance standards for a biennial accreditation process with all such procedures subject to the requirements of KRS Chapters 13A and 13B;
4. A convenience fee to be assessed and collected by dispensaries for

visiting qualified patients who do not possess a valid registry identification card issued by the cabinet and who purchase medicinal cannabis with an out-of-state registry identification card and documentation of having been diagnosed with a qualifying medical condition. The convenience fee established pursuant to this subparagraph shall not exceed fifteen dollars ($15) per transaction;

5. In collaboration with the Board of Physicians and Advisors:
   a. A definition of the amount of medicinal cannabis or delta-9 tetrahydrocannabinol that constitutes a daily supply, an uninterrupted ten (10) day supply, and an uninterrupted thirty (30) day supply of medicinal cannabis; and
   b. The amount of raw plant material that medicinal cannabis products are considered to be equivalent to;
6. A process by which a medicinal cannabis practitioner may recommend, and a registered qualified patient or his or her designated caregiver may legally purchase and possess, an amount of medicinal cannabis in excess of the thirty (30) day supply of medicinal cannabis, if the medicinal cannabis practitioner reasonably believes that the standard thirty (30) day supply would be insufficient in providing the patient with uninterrupted therapeutic or palliative relief;
7. Provisions governing the following matters related to cannabis businesses with the goal of protecting against diversion and theft, without imposing any undue burden that would make cannabis business operations unreasonable or impractical on cannabis businesses or compromising the confidentiality of cardholders:
   a. Recordkeeping and inventory control requirements, including the use of the electronic monitoring systems established pursuant to KRS 218A.202;
   b. Procedures for the verification and validation of a registry identification card, or its equivalent, that was issued pursuant to the laws of another state, district, territory, commonwealth, or insular possession of the United States that allows for the use of medicinal cannabis in the jurisdiction of issuance;
   c. Security requirements for safety compliance facilities, processors, producers, dispensaries, and cultivators, which shall include at a minimum lighting, video security, alarm requirements, on-site parking, and measures to prevent loitering;
   d. Procedures for the secure transportation, including delivery services provided by dispensaries, and storage of medicinal cannabis by cannabis business licensees and their employees or agents;
   e. Employment and training requirements for licensees and their agents, including requiring each licensee to create an identification badge for each of the licensee's agents or employees; and

f. Restrictions on visits to licensed cultivation and processing facilities, including requiring the use of visitor logs;

8. Procedures to establish, publish, and annually update a list of varieties of cannabis that possess a low but effective level of tetrahydrocannabinol, including the substance cannabidiol, by comparing percentages of chemical compounds within a given variety against other varieties of cannabis;

9. A rating system that tracks the terpene content of at least the twelve (12) major terpenoids within each strain of cannabis available for medicinal use within the Commonwealth;

10. Requirements for random sample testing of medicinal cannabis to ensure quality control, including testing for cannabinoids, terpenoids, residual solvents, pesticides, poisons, toxins, mold, mildew, insects, bacteria, and any other dangerous adulterant;

11. Requirements for licensed cultivators, producers, and processors to contract with an independent safety compliance facility to test the medicinal cannabis before it is sold at a dispensary. The cabinet may approve the safety compliance facility chosen by a cultivator, producer, or processor and require that the safety compliance facility report test results for a designated quantity of medicinal cannabis to the cultivator, producer, or processor and cabinet;

12. Standards for the operation of safety compliance facilities which may include:
    a. Requirements for equipment;
    b. Personnel qualifications; and
    c. Requiring facilities to be accredited by a relevant certifying entity;

13. Standards for the packaging and labeling of medicinal cannabis sold or distributed by cannabis businesses which shall comply with 15 U.S.C. secs. 1471 to 1476 and shall include:
    a. Standards for packaging that requires at least a two (2) step process of initial opening;
    b. A warning label which may include the length of time it typically takes for the product to take effect, how long the effects of the product typically last, and any other information deemed appropriate or necessary by the cabinet;
    c. The amount of medicinal cannabis the product is considered the equivalent to;
    d. Disclosing ingredients, possible allergens, and certain bioactive components, including cannabinoids and terpenoids, as determined by the cabinet;
    e. A nutritional fact panel;
    f. Opaque, child-resistant packaging;
    g. A requirement that all raw plant material packaged or sold in this

state be marked or labeled as "NOT INTENDED FOR CONSUMPTION BY SMOKING";

h. A requirement that medicinal cannabis products be clearly marked with an identifiable and standardized symbol indicating that the product contains cannabis;

i. A requirement that all medicinal cannabis product packaging include an expiration date; and

j. A requirement that medicinal cannabis products and their packaging not be visually reminiscent of major brands of edible noncannabis products or otherwise present an attractive nuisance to minors;

14. Health and safety requirements for the processing of medicinal cannabis and the indoor cultivation of medicinal cannabis by licensees;

15. Restrictions on:

a. Additives to medicinal cannabis that are toxic, including vitamin E acetate, or increase the likelihood of addiction; and

b. Pesticides, fertilizers, and herbicides used during medicinal cannabis cultivation which pose a threat to human health and safety;

16. Standards for the safe processing of medicinal cannabis products created by extracting or concentrating compounds from raw plant material;

17. Standards for determining the amount of unprocessed raw plant material that medicinal cannabis products are considered the equivalent to;

18. Restrictions on advertising, marketing, and signage in regard to operations or establishments owned by licensees necessary to prevent the targeting of minors;

19. The requirement that evidence-based educational materials regarding dosage and impairment be disseminated to registered qualified patients, visiting qualified patients, and designated caregivers who purchase medicinal cannabis products;

20. Policies governing insurance requirements for cultivators, dispensaries, processors, producers, and safety compliance facilities; and

21. Standards, procedures, or restrictions that the cabinet deems necessary to ensure the efficient, transparent, and safe operation of the medicinal cannabis program, except that the cabinet shall not promulgate any administrative regulation that would impose an undue burden or make cannabis business operations unreasonable or impractical.

(2) No later than January 1, 2025, the cabinet shall:

(a) Establish a medicinal cannabis adverse drug effects reporting system for the purpose of allowing cardholders to report adverse drug effects via telephone or online; and

(b) In collaboration with the Board of Physicians and Advisors, produce the Medicinal Cannabis Advisory Pamphlet which shall include but not be limited

to:

1. Information on the risks, dangers, and possible side effects of the use of medicinal cannabis;
2. Information on the medicinal cannabis adverse drug effects reporting system and how to report adverse drug effects; and
3. A detachable signature page which shall be:
   a. Signed by a cardholder each time he or she receives a copy of the Medicinal Cannabis Advisory Pamphlet as required under KRS 218B.110(2)(d); and
   b. Retained by the dispensary for a period of at least thirty-six (36) months.

(3) The cabinet shall provide each licensed dispensary with an adequate number of Medicinal Cannabis Advisory Pamphlets to ensure that the dispensary is able to comply with the requirements of KRS 218B.110(2)(d).

(4) Except as provided in KRS 218B.035(1)(g), 218B.095(2)(b), 218.110(2)(e), 218B.115(2), 218B.120(3), and subsection (1)(c)10., 13., 15., and 16. of this section, the cabinet shall not restrict or limit methods of delivery, use, or consumption of medicinal cannabis or the types of products that may be acquired, produced, processed, possessed, sold, or distributed by a cannabis business.

(5) If a need for additional cannabis cultivation in this state is demonstrated by cannabis businesses or the cabinet's own analysis, the cabinet may through the promulgation of administrative regulations increase the cultivation area square footage limits for either cultivators or producers, or both by up to three (3) times the limits established in KRS 218B.105 and 218B.120. Any increase in the cultivation square footage limits adopted by the cabinet pursuant to this section shall not result in an increase in the licensure application or renewal fees established by the cabinet.

(6) When promulgating administrative regulations under this section, the cabinet shall consider standards, procedures, and restrictions that have been found to be best practices relative to the use and regulation of medicinal cannabis.

Effective: April 17, 2024

History: Amended 2024 Ky. Acts ch. 195, sec. 14, effective April 17, 2024. -- Created 2023 Ky. Acts ch. 146, sec. 27, effective June 29, 2023.