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Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 100—Division of Cannabis Regulation
Chapter 1—Marijuana

JAN 20 2023

SECRETARY OF STATE
ADMINISTRATIVE RULES

PROPOSED RULE

19 CSR 100-1.130 Inventory Control and Seed-to-Sale Tracking

PURPOSE: Under Article XIV, Sections 1 and 2 of the Missouri Constitution, the Department of Health and Senior Services has the authority to regulate and control Medical and Marijuana licensees. This rule explains what regulations apply to medical and marijuana facility inventory control systems and procedures as well as to certification and operations of seed-to-sale tracking systems.

(1) Inventory control systems and procedures. All facility licensees shall implement inventory control systems and procedures as follows:

(A) Each licensee shall designate, in writing, a facility agent who is generally responsible for the inventory control systems and procedures for that facility;

(B) Licensees shall maintain all records required by this section for at least five (5) years;

(C) All weighing and measuring of marijuana product required by this rule must be conducted with a National Type Evaluation Program (NTEP) approved scale that complies with Accuracy Class I & II parameters, which shall be recalibrated by a certified entity at least yearly;

1. Facility agents shall inspect and log the inspection of each scale prior to use and verify the scale is clean and reading accurately.

2. Each licensee shall maintain a scale inspection log indicating the date, method of accuracy verification, and by whom the accuracy is verified.

3. The licensee's NTEP scale shall be designed for the type of weighing or measuring needed for the licensee's facility type.

(D) Each facility licensee shall use the statewide track and trace system as its system of record to track marijuana product from seed or immature plant stage until the marijuana product is either purchased by a consumer, qualifying patient, or primary caregiver; expended during testing; or destroyed;

(E) All marijuana product in a medical or marijuana facility must be traceable in the statewide track and trace system at all times;

1. All immature plants at least eight (8) inches tall or eight (8) inches wide shall be tagged with traceability information.

2. All packaged marijuana product shall bear a tag with traceability information.

3. Licensees shall place a new package tag on marijuana product any time—

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A. A marijuana product changes product category; or

B. The marijuana product is incorporated into a different marijuana product.

(F) Licensees must enter into the statewide track and trace system each day's beginning inventory, harvests, acquisitions, sales, disbursements, remediations, disposals, transfers, deliveries, ending inventory, and any other data necessary to complete the inventory control records in the statewide track and trace system. Records will not be considered complete unless all available fields for a particular action are completed, including the identity of the facility agent making the record;

(G) Discrepancies in marijuana product inventory records shall not be corrected by entering an inventory adjustment without first being documented, investigated by management personnel, and reported to the department within twenty-four (24) hours of discovering the discrepancy;

(H) If a licensee identifies a reduction in the amount of marijuana product in the inventory of the facility due to suspected criminal activity by a facility agent, the licensee shall report the facility agent to the department and to the appropriate law enforcement agencies within twenty-four (24) hours of discovering the suspected criminal activity;

(I) Cultivation facility licensees must—

1. Report in the statewide track and trace system all seeds and all plants of any size;

2. Report in the statewide track and trace system, by plant or location—

A. All pesticides, herbicides, fertilizers, and other agricultural chemicals applied to marijuana plants and growing medium during production and processing at its facility; and

B. All ingredients contained in each pesticide, herbicide, fertilizer, and other agricultural chemical applied to the marijuana plants and growing medium during production and processing at its facility; and

3. Provide to the department a monthly physical inventory report that includes all adjustments and adjustment reasons. The physical inventory shall be reconciled with the inventory recorded in the statewide track and trace system.

(J) Manufacturing facility licensees shall—

1. Establish and maintain a perpetual inventory system that documents the flow of all non-marijuana materials through the manufacturing process;

2. Establish procedures to reconcile the raw marijuana material with the finished product on the basis of each process lot;

3. Record in the statewide track and trace system all active and inactive ingredients in each final manufactured product;

4. Record in the statewide track and trace system the serving or, in the case of medical marijuana product, dosage amounts for each final manufactured product; and

5. Provide to the department a monthly physical inventory report that includes all adjustments and adjustment reasons. The physical inventory shall be reconciled with the inventory recorded in the statewide track and trace system.

(K) Dispensary licensees shall be responsible for ensuring that every amount of marijuana product sold or disbursed to a consumer, qualifying patient, or primary caregiver is immediately recorded in the statewide track and trace system. Amounts of marijuana product shall be recorded—

1. For dried, unprocessed marijuana and prerolls, in grams;
2. For concentrates and infused prerolls, in grams; or
3. For infused products, by milligrams of THC;

(L) All facility licensees must ensure the accuracy of information entered into the statewide track and trace system on a daily basis;

1. Errors identified within the system must be immediately corrected. All corrections should be accompanied with a detailed note in the system clearly outlining the error that occurred and the corrective action taken.

2. Errors involving consumer and patient allotments must be reported to the department and corrected in the statewide track and trace system within twenty-four (24) hours of being identified.

(M) In order to facilitate the use of the statewide track and trace system, facilities may also employ a department-certified seed-to-sale tracking system that integrates with the statewide track and trace system; and

(N) In case of seed-to-sale system failure or loss of connection between the seed-to-sale system and the statewide track and trace system, a licensee must cease performing all actions that are required to be tracked.

1. Upon system restoration, the licensee must confirm all inventory and tracking information is accurately reflected in the statewide track and trace system.

2. Any such system failure or loss of connection must be reported to the department within three (3) hours of identifying the seed-to-sale system failure or loss of connection between the seed-to-sale system and the statewide track and trace system.

(2) Seed-to-Sale Tracking.

(A) Access to Seed-to-Sale Tracking System Certifications.

1. Any entity certified to conduct seed-to-sale tracking for medical marijuana product as of the effective date of this section shall be deemed certified to conduct those activities with respect to all marijuana product.

2. The department will accept applications for seed-to-sale tracking system certifications via the online application system.

3. Incomplete applications for certification of seed-to-sale tracking systems may be denied.

4. The department shall charge an application fee for a seed-to-sale certification and also an annual fee once a certification is granted.

A. The first annual fee will be due thirty (30) days after a certification is issued and shall be due annually on that same date as long as the certification remains valid.

B. The department shall publish the current fees, including any adjustments, on its website at <http://cannabis.mo.gov>. The fees due will be the fee that is effective as of the due date for the fee.

(B) Application Requirements. All applications for seed-to-sale tracking system certifications shall include at least the following information:

1. Name and address of the applicant;
2. Legal name of the entity, including any fictitious business names;
3. An attestation by an owner or principle of the entity that the seed-to-sale tracking system can and will comply with this rule; and
4. All applicable fees or proof that all applicable fees have already been paid.

(C) Seed-to-Sale Tracking System Requirements. All seed-to-sale tracking systems used by licensees shall be capable of—

1. Interfacing with the statewide track and trace system such that a licensee's employees may enter and access information in the statewide track and trace system as required for inventory control and tracking and for purchase limitations set forth in this chapter;

2. Providing the department with access to all information stored in the system's database;

3. Maintaining the confidentiality of all patient and consumer data and records accessed or stored by the system such that all persons or entities other than the department may only access the information in the system that they are authorized by law to access; and

4. Producing analytical reports to the department regarding—

A. Total quantity of daily, monthly, and yearly sales at the facility per product type;

B. Average prices of daily, monthly, and yearly sales at the facility per product type;

C. Total inventory or sales record adjustments at the facility; and

D. API error report showing how many times the seed-to-sale tracking system failed to upload information to the statewide track and trace system, or failed in some other way.

(D) Seed-to-Sale Tracking System Prohibitions.

1. No certified seed-to-sale tracking system entities may begin operations before signing the department's Marijuana Application Programming Interface User Agreement.

2. No seed-to-sale tracking system entity may be owned by or affiliated with an entity that holds a contract with the state of Missouri for any product or service related to the department's marijuana program.

(E) Tracking-related discipline.

1. The department may impose a fine of up to \$5,000, and may restrict, suspend, or revoke a seed-to-sale tracking system entity certification for the following reasons:

A. Failure of a seed-to-sale tracking system entity to comply with this rule;

B. Failure to abide by the department's Marijuana Application Programming Interface User Agreement;

C. Failure of a seed-to-sale tracking system entity to timely interface with the statewide track and trace system;

D. Persistent failure to interface with the statewide track and trace system; or

E. Providing false or misleading information to the statewide track and trace system.

2. If a facility licensee or its employees or contractors fail to comply with the statewide track and trace system requirements or intentionally misuses or falsifies statewide track and trace system tracking data, the department may impose a fine of up to fifty thousand dollars (\$50,000), and may restrict, suspend, or revoke the facility's license.

AUTHORITY: Sections 1.3.(1)(b), 1.3.(2), 2.4(1)(b), and 2.4(4) of Article XIV, Mo. Const. Emergency rule filed January 20, 2023, effective February 3, 2023, expires August 1, 2023. Original rule filed January 20, 2023.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions one million, seven hundred thirty-nine thousand, nine hundred ninety-six dollars (\$1,739,996) for the first and second year.

PRIVATE COST: This proposed rule will cost private entities between seven hundred twenty-five thousand dollars (\$725,000) and one million, five hundred ninety-five thousand dollars (\$1,595,000) in the first year, and one hundred forty-five thousand dollars (\$145,000) annually thereafter.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with the Department of Health and Senior Services, MMPublicComment@health.mo.gov. To be considered, comments must be received within thirty (30) days after publication of this notice in the *Missouri Register*. No public hearing is scheduled.*