

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

PROPOSED RULE

19 CSR 100-1.030 Complaints, Inspections, and Investigations

PURPOSE: Article XIV, Sections 1 and 2 of the Missouri Constitution authorizes the Department of Health and Senior Services to promulgate rules for the implementation and enforcement of the Article and to ensure the right to, availability, and safe use of marijuana product. This section applies to complaints, inspections, and investigations of licensed or certified facilities and identification card holders.

(1) Complaints. The department may receive complaints related to any licensed or certified medical and marijuana facilities, or any individual holding a department issued identification card. Complaints may be submitted through the department website.

(A) Upon receipt of a complaint, the department will determine whether the allegations in the complaint warrant further investigation. The department can either close the complaint or conduct an investigation.

(B) The complaint shall remain confidential until either the complaint is closed or an investigation is completed.

(C) Employees or former employees of a licensee who, in good faith, report potential rule violations to the department may not be subjected to retaliation of any kind because of their report.

(2) Inspections and Investigations.

(A) The department may conduct an investigation related to an individual cardholder if the department has reason to believe the individual has or is violating any rule in this chapter or provision of Article XIV that could affect the individual's right to continue holding the authority granted by the department.

(B) The department may conduct an inspection or investigation of a licensee or facility at any time, including an inspection of any part of the premises or records of a licensed or certified entity.

1. No medical or marijuana facility licensee may refuse representatives of the department the right to inspect the licensed premises of the facility or to audit records of the facility, including records created or maintained by a third party under an agreement with a facility licensee.

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2. A department employee conducting an inspection or investigation may access all areas of the licensed or certified facility, including vehicles of the facility or any third party contractors, without a warrant and without prior notice to the licensee.

3. Licensed or certified entities must provide documents or records requested as part of an inspection or investigation within seven (7) days of the department issuing the request unless additional time is requested and granted.

A. Failure to timely provide requested documents or records may result in a fine of up to five thousand (5,000) dollars for every day the requested documents or records have not been provided after the deadline.

B. If a licensee fails to provide records, the department may impound, seize, assume control of, or summarily remove records from the licensed facility.

C. A department request for documents or records made as part of reviewing an application submitted by a licensee, such as a change request, shall be considered an inspection of records.

4. The department may request to interview any employees, contractors, owners, or volunteers of a licensed or certified facility, and the licensee shall arrange for the interview to occur as soon as possible but not later than seven (7) days after the department makes the request to the designated contact on file with the Department.

5. Upon receiving a notice of investigation, licensees must preserve all records of any type related to the subject of the investigation, including video camera recordings and facility access control records, until the licensee receives notice that the investigation is concluded.

6. As part of an investigation, the department may take any reasonable or appropriate action to enforce this chapter, including coordinating with law enforcement.

7. As part of an inspection or investigation, the department may direct the licensee to have marijuana product tested by a certified marijuana testing facility, at the cost of the licensee, when the department finds good cause to do so, which may include credible allegations of rule violations or other indications that the marijuana product does or would create a threat to the health or safety of the public.

8. In the course of any investigation of a licensee, the department may issue a subpoena or subpoena duces tecum to any individual or entity with documents or information related to an investigation. The department may enforce its subpoena by applying to the circuit court of Cole County or the county where the premises, records, or individuals are located.

(C) If the department determines a licensee presents a threat to the health or safety of the licensee's employees or the public, the department may require a licensee to immediately pause any part of its operations related to or causing the threat, including placing an administrative hold on marijuana product.

(D) Applicants and licensees must cooperate in any investigation conducted by the department. Failure to cooperate with a department investigation may be grounds for denial of an application or for administrative action against a licensee.

(3) Commencement Inspections.

(A) Facility licensees must request and pass a commencement inspection before they may do any of the following: begin operations under a new license or certification; occupy or utilize new space for which the licensee has not previously received approval to operate, including vehicles; begin sharing space with another licensee; change the use of spaces; or, in the case of microbusiness wholesale facilities, begin cultivating or manufacturing where that activity was not already approved after inspection.

1. Requests to begin operations under a new license or certification must be submitted when the licensee believes it will, within thirty (30) days, be ready to begin operations at the facility, and the request must include at least the following:

A. Blueprints of the facility showing the intended use of all spaces and how those spaces comply with the physical security requirements applicable to them;

B. All SOPs necessary for the facility licensee to show compliance with regulations applicable to it;

C. Documentation showing completion of all required training in use of the statewide track and trace system; and

D. Documentation showing compliance with all applicable federal, state, and local requirements for the facility.

2. Requests to occupy new space at an operational facility must be submitted prior to beginning construction or renovation, and the request must include at least the following:

A. The proposed blueprints for the facility showing the intended use of all spaces and how those spaces comply with the physical security requirements applicable to them;

B. SOPs and updated SOPs related to the new space;

C. A written explanation of any changes that will occur within the existing space due to the addition of new space and how those changes will comply with applicable regulations; and

D. An attestation that the proposed new space complies with the facility location requirements of this chapter and any location and zoning requirements of the local government.

3. Requests to begin sharing space with another licensee must be submitted prior to making any changes to the existing space or most recently approved plan for a space, and the request must include at least the following:

A. Descriptions, schematics, or blueprints for the facility clearly indicating what spaces will be shared;

B. A written explanation of the operations that will occur in each shared space for each licensee sharing the space and how those operations and any related changes to existing space will comply with applicable regulations;

C. SOPs and updated SOPs related to the shared space;

D. Copies of agreements between the licensees concerning their respective roles and their relationship for management, operation, and maintenance of the shared spaces, including an acknowledgment that all licensees sharing space will be jointly responsible for compliance with the applicable department regulations for the shared spaces; and

E. An attestation that the proposed sharing of space complies with any zoning requirements of the local government.

4. Requests to change the use of spaces must be submitted prior to making any changes to the existing space or most recently approved plan for a space, and the request must include at least the following:

A. Descriptions, schematics, or blueprints for the facility clearly indicating the spaces that will be used differently than the most recently approved use of the space;

B. A written explanation of the proposed changes and how all affected spaces will comply with applicable regulations; and

C. SOPs and updated SOPs related to the new use of space.

5. Requests by microbusiness wholesale licensees to begin cultivation or manufacturing processes not already approved during a prior commencement inspection must be submitted prior to beginning construction or renovation or making any changes to the existing space or most recently approved plan for a space, and the request must include at least the following:

A. Descriptions, schematics, or blueprints for the facility showing the intended use of all spaces and how those spaces comply with the physical security requirements applicable to them;

B. A written explanation of any changes that will occur within the existing space due to the addition of new processes and how those changes will comply with applicable regulations;

C. SOPs and updated SOPs related to the new space or new use of space;

D. Documentation showing all required training in use of the statewide track and trace system; and

E. Documentation showing compliance with all applicable federal, state, and local requirements for the facility.

(B) In any commencement inspection process, if the department determines the licensee who requested the commencement inspection was not prepared to complete the commencement inspection process when it made the request, the department may set aside the request and require the licensee to make a new request once it is ready to proceed.

(C) Licensees who are constructing or renovating in an operational facility are responsible for ensuring the approved spaces are secured while the unapproved spaces are being constructed, which must include at a minimum, ensuring that all access requirements for limited access areas are maintained during construction and that operational spaces are protected from all potential contaminants related to construction.

(D) Licensees may not commence any operations that are subject to a commencement inspection until the department issues written approval to do so.

(E) Licensees shall notify the department that an approved change will be complete at least sixty (60) days prior to expected completion.

(4) Notices of Violation.

(A) If the department determines that a licensee is not in compliance with the department's regulations, the department may issue a warning or an Initial Notice of Violation to the licensee that explains how the licensee has violated the department's regulations and what remedial actions the department expects the licensee to take.

(B) Once a licensee has been issued an Initial Notice of Violation, the licensee shall, within fifteen (15) days, complete the specified remedial actions and notify the department in writing of that completion, or request additional time for remediation if necessary.

(C) If the department conducts a follow up inspection or review of the licensee or its response to the Initial Notice of Violation and determines violations have not been cured or remedial actions have not been taken, the department may issue a Final Notice of Violation to the licensee explaining how the licensee continues to violate the department's regulations, what remedial actions the department expects the licensee to take, and that the license may be suspended if the specified remedial actions are not taken or the violations cured within thirty (30) days.

(D) If the violations have not been cured or specified remedial actions taken within thirty (30) days after a Final Notice of Violation is sent, the department may suspend or fine the licensee, up to an amount equal to the daily gross receipts of the facility per day, until the corrective or remedial actions have been taken by the licensee.

(5) Licensees that receive more than three (3) notices of violation in a twelve (12) month period or that have ever received more than one (1) notice of violation for violating the same regulation may be required by the department to:

(A) Acquire certification or accreditation to a quality management system standard chosen by the department; or

(B) Be subject to an audit of the licensee's processes or practices relevant to the violations by a third party auditor chosen by the department.

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 three million, seventy-four thousand, two hundred ninety-eight dollars (\$3,074,298) for the first three years, and one million, seven thousand, four hundred thirteen dollars (\$1,007,413) annually thereafter.

PRIVATE COST: This proposed rule will not cost private entities more than five hundred dollars (\$500) in the aggregate.

*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.*