
EMERGENCY RULE

TITLE 19 – DEPARTMENT OF HEALTH AND SENIOR SERVICES

Division 100 – Division of Cannabis Regulation Chapter 1 – Marijuana

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19 CSR 100-1.100 Facilities Generally

PURPOSE: Under Article XIV, Sections 1 and 2 of the Missouri Constitution, the Department of Health and Senior Services is authorized to regulate and control the operations of Medical and Marijuana Facilities. This rule explains general operating requirements applicable to all licensed and certificated facilities.

EMERGENCY STATEMENT: This emergency rule serves to implement and enforce Article XIV and to ensure the right to, availability, and safe use of marijuana product. This emergency rule is necessary to protect a compelling governmental interest since Amendment 3 to the Missouri Constitution made significant changes to the regulation of marijuana, and new rules will be needed to effectuate those changes. As a result, the Department of Health and Senior Services finds a compelling governmental interest, which requires emergency action. The scope of this emergency rule is limited to the circumstances creating the emergency and complies with the protections extended in the Missouri and United States Constitutions. The Department of Health and Senior Services believes this emergency rule is fair to all interested persons and parties under the circumstances. If an emergency is not enacted, there would be no rules explaining how the new provisions of Article XIV of the Missouri Constitution apply, and there would be much confusion as to the processes and procedures related to licensure and regulation of the marijuana industry. This emergency rule was filed January 20, 2023, becomes effective February 3, 2023, and expires August 1, 2023.

(1) Licensing and Location.

(A) An entity must obtain a separate license or certificate for each facility. Subject to department pre-approval, multiple licenses or certificates may be utilized at a single location. Testing facility licensees may not share space with any other facility.

(B) Each license or certification shall be charged an annual fee once the license or certification is granted. The first annual fee will be due thirty (30) days after a license or certification is issued and shall be due annually on that same date as long as the license or certification remains valid, except for in the case of microbusinesses whose first annual fee will be due on the anniversary of their licensure. The department shall publish the current fees, including any adjustments, on its website. The fees will be the amount that is effective as of that license or certification's annual fee due date.

(C) Unless expressly allowed by the local government, no medical or marijuana facility, including any offsite warehouses, shall be sited, at the time of application for license, certification, or local zoning approval, whichever is earlier, within one thousand feet (1,000') of any then-existing elementary or secondary school, daycare, or church. The method of measuring distances is governed by Article XIV.

(D) A medical or marijuana facility may not allow cultivation, manufacturing, sale, or display of marijuana product or marijuana accessories to be visible from a public place outside of the marijuana facility without the use of binoculars, aircraft, or other optical aids.

(2) Marijuana Facility Business Change Applications. Marijuana

facility licensees must apply for and obtain the department's approval before they may:

(A) Transfer their license to a different entity with the same ownership. Such a request must include at least the following:

1. Current legal name of the licensee, including fictitious business names, and proposed new legal name of the licensee, including fictitious business names;

2. All owners of the licensed entity and their individual ownership percentage, which must show the proposed new entity is owned by the same owners as is the licensee;

3. A visual representation of the licensee's ownership structure, including all owner entities;

4. Other documentation as requested to verify ownership; and

5. An administrative and processing fee of two thousand dollars (\$2000).

(B) Make any changes that would result in an individual becoming an owner of the licensed entity who was not previously an owner. Such requests must include at least the following:

1. All current and proposed owners of the licensed entity and their proposed individual ownership percentage;

2. A visual representation of the licensee's proposed ownership structure, including all owner entities;

3. A chart comparing the previously approved ownership percentages to the proposed ownership percentages;

4. Verification that the change will not result in any substantially common control, ownership, or management between a testing licensee and any other medical or marijuana licensee;

5. An attestation that all individuals subject to analysis for disqualifying felony offenses will submit fingerprints within two (2) weeks after the application submission, or have submitted such fingerprints within the last six (6) months, for a state and federal fingerprint-based criminal background check to be conducted by the Missouri State Highway Patrol;

6. For microbusinesses, if the proposed change affects eligibility, documentation sufficient to demonstrate eligibility for microbusiness facility ownership, as provided in the application and selection section of this chapter;

7. Other documentation as requested to verify ownership; and

8. An administrative and processing fee of five thousand dollars (\$5000), which shall only be assessed once on multiple licensed entities with identical ownership making the same changes in ownership.

(C) Make any changes that would result in an overall change in ownership interests of fifty percent (50%) or more from the last approved ownership of the licensee. Such requests may only be submitted after the licensee's facility has received approval to operate and must include at least the following:

1. All current and proposed owners of the licensed entity and their proposed individual ownership percentage;

2. A chart comparing the previously approved ownership percentages to the proposed ownership percentages;

3. A visual representation of the licensee's proposed ownership structure including all owner entities;

4. Verification that the change will not result in any substantially common control, ownership, or management between a testing licensee and any other marijuana licensee;

5. An attestation that all new and proposed owners will submit fingerprints within two (2) weeks after the application submission, or have submitted such fingerprints within the last six (6) months, for a state and federal fingerprint-based criminal background check to be conducted by the Missouri State Highway Patrol;

6. In the case of full asset transfer to a different entity,

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applications must also include:

- A. Asset purchase agreement;
- B. Merger, sale, transfer, MOU, or other like agreement between the licensee and transferee;
- C. Brand, management, consultant agreements or contracts, or any other agreement or contracts; and
- D. Location lease agreement or proof of ownership.

7. For microbusinesses, documentation sufficient to demonstrate eligibility for microbusiness facility ownership, as provided in the application and selection section of this chapter;

8. Other documentation as requested to verify ownership; and

9. An administrative and processing fee of eight thousand dollars (\$8,000), which shall only be assessed once on multiple licensed entities with identical ownership making the same changes in ownership.

(D) Change the licensee's facility location. Such requests shall include at least the following:

1. Proposed blueprints for the facility that detail room purpose(s), camera locations, limited access areas, access permissions, and all premises under facility control;

2. Documentation from the local government with jurisdiction over the facility's location confirming that the proposed location complies with local distance requirements, or stating that there are none;

3. If the local government in which the facility will be located has enacted applicable zoning restrictions, documentation from the local government with jurisdiction over the facility's location confirming that the proposed location complies with applicable zoning restrictions;

4. Location lease agreement and/or proof of ownership; and

5. An administrative and processing fee of five thousand dollars (\$5000).

(E) Any administrative and processing fee for a microbusiness change application shall be half the amount listed in (A)-(D).

(F) Change applications will be approved if the request contains all of the documents, fees, and information required by this section, and the resulting change in ownership or ownership interests does not violate any provision of this chapter or Article XIV.

(3) Medical Facility Business Change Applications. Medical facility licensees must apply for and obtain the department's approval before they may:

(A) Transfer their license to a different entity with the same ownership. Such a request must include at least the following:

1. Current legal name of the licensee, including fictitious business names, and proposed new legal name of the licensee, including fictitious business names;

2. Any entity that owns any part of the licensed entity and their individual ownership percentage, which must show the proposed new entity is owned by the same entities as is the licensee;

3. A visual representation of the licensee's ownership structure, including all entities that own any part of the licensed entity;

4. Other documentation as requested to verify ownership; and

5. An administrative and processing fee of two thousand dollars (\$2000).

(B) Make any changes that would result in an overall change in financial or voting interests of fifty percent (50%) or more from the last approved ownership of the licensee. Such requests may only be submitted after the licensee's facility has

received approval to operate and must include at least the following:

1. All current and proposed entities with any financial or voting interest in the licensed entity and their proposed individual ownership percentage;

2. A chart comparing the previously approved ownership percentages to the proposed ownership percentages;

3. A visual representation of the licensee's proposed ownership structure including all entities;

4. Verification that the change will not result in any substantially common control, ownership, or management between a testing licensee and any other medical licensee;

5. An attestation that all individuals subject to analysis for disqualifying felony offenses will submit fingerprints within two (2) weeks after the application submission, or have submitted such fingerprints within the last six (6) months, for a state and federal fingerprint-based criminal background check to be conducted by the Missouri State Highway Patrol;

6. In the case of full asset transfer to a different entity, applications must also include:

A. Asset purchase agreement;

B. Merger, sale, transfer, MOU, or other like agreement between the licensee and transferee;

C. Brand, management, consultant agreements or contracts, or any other agreement or contracts; and

D. Location lease agreement or proof of ownership.

7. Other documentation as requested to verify ownership; and

8. An administrative and processing fee of eight thousand dollars (\$8,000), which shall only be assessed once on multiple licensed entities with identical ownership making the same changes in ownership.

(C) Change the licensee's facility location. Such requests shall include at least the following:

1. Proposed blueprints for the facility that detail room purpose(s), camera locations, limited access areas, access permissions, and all premises under facility control;

2. Documentation from the local government with jurisdiction over the facility's location confirming that the proposed location complies with local distance requirements, or stating that there are none;

3. If the local government in which the facility will be located has enacted applicable zoning restrictions, documentation from the local government with jurisdiction over the facility's location confirming that the proposed location complies with applicable zoning restrictions;

4. Location lease agreement and/or proof of ownership; and

5. An administrative and processing fee of five thousand dollars (\$5000).

(D) Change applications will be approved if the request contains all of the documents and information required by this section and the resulting change in ownership or ownership interests does not violate any provision of this chapter or Article XIV.

(4) General Operations.

(A) Licenses shall be displayed within twenty feet (20') of the main entrance to a facility at all times.

(B) All licensees must comply at all times with applicable state, local, and federal requirements.

(C) Licensees shall implement a quality management system using a published standard, such as those offered by International Organization for Standardization, ASTM International, Cannabis Safety and Quality, or Foundation of Cannabis Unified Standards, within one (1) year of the date the

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facility receives department approval to operate. The chosen standard shall be applicable to the licensee's facility type and be implemented with emphasis on regulatory compliance.

(D) All licensees must receive approval to operate within one (1) year of being issued a license or certification; except microbusiness licensees, which must receive approval to operate within two (2) years of issuance. Absent a granted waiver or variance, licenses may be revoked or sanctioned if not operational and active within the required time frame.

(E) All marijuana-infused products shall be manufactured in a licensed manufacturing facility. Any facility that extracts resins from marijuana using combustible gases or other dangerous materials, without a manufacturing facility license, shall incur a penalty of ten thousand dollars (\$10,000).

(F) All marijuana product sold in Missouri, including plants, flowers, pre-rolls, and infused products, shall have originated from marijuana grown and cultivated in a licensed cultivation facility located in Missouri.

(G) All licensees shall establish and follow SOPs in the event the facility is suspended or ordered to cease operations.

(H) All licensees shall establish and follow detailed SOPs for marijuana product remediation.

(I) All licensees shall establish and follow SOPs to ensure marijuana remains free from contaminants. The systems, equipment, and documentation necessary to follow procedures must address, at a minimum:

1. The flow through a facility of any equipment or supplies that will come in contact with marijuana including receipt and storage;

2. Employee health and sanitation; and

3. Environmental factors, such as:

A. Floors, walls, and ceilings made of smooth, hard surfaces that are easily cleaned;

B. Temperature and humidity controls;

C. A system for monitoring environmental conditions;

D. A system for cleaning and sanitizing rooms and equipment;

E. A system for maintaining any equipment used to control sanitary conditions; and

F. For cultivation and manufacturing facilities, an air supply filtered through high-efficiency particulate air filters under positive pressure.

(J) All licensees shall post a sign and outline in policy that consumption of marijuana product is not allowed on the licensed premises, including in any approved transport vehicles.

(K) If a licensee enters into a contract with a management company or other entity to run all or part of the regulated marijuana operations under this chapter, the contract must permit the licensee to access the records of the management company or other entity at request of the department during an investigation or inspection.

(L) All licensees shall maintain any records required by this chapter for at least five (5) years.

(M) The department may issue notice of marijuana product recall to licensees or the public if, in its judgment, any particular marijuana product presents a threat or potential threat to the health and safety of qualifying patients or consumers. All facilities are responsible for complying with recall notices. Recalled items must be immediately pulled from production or inventory and quarantined until such time as the department determines the item is safe, may be remediated, or must be destroyed.

(5) Signage and advertising must comply with the following:

(A) A marijuana product may only be advertised or marketed in compliance with all applicable municipal ordinances,

state law, and rules that regulate signs and advertising.

(B) No advertisement of marijuana may contain:

1. Any representation that is false or misleading in any way;

2. Any statement representing that the use of marijuana has curative or therapeutic effects or tending to create an impression that it has curative or therapeutic effects unless such statement has been evaluated and approved by the Food and Drug Administration;

3. Any content that appeals to children, including but not limited to the shape or any part of the shape of a human, animal, or fruit, including realistic, artistic, caricature, or cartoon renderings; or

4. Any statement concerning a brand of marijuana that is inconsistent with any statement on the labeling.

(C) Outdoor signage and, if visible from a public right of way, interior signage, must comply with any local ordinances for signs or advertising.

(6) Facility Licensee Notification and Reporting. Licensees have a duty to keep the department apprised of certain information. Failure of a licensee to report required information to the department may result in administrative penalties, to include a fine of up to \$10,000, suspension, or revocation of the license.

(A) Licensees have a continuing duty to provide the department with up-to-date contact information, including the individual who shall be the designated contact for all department communications.

1. Licensees shall notify the department in writing of any changes to the mailing addresses, phone numbers, email addresses, and other contact information they provide the department.

2. Licensees and applicants are deemed to have received all communications and notifications from the department on the date the department sends an email to the email address of the designated contact for the licensee or applicant.

(B) Licensees must report, at least annually:

1. For marijuana facility licensees, all owners, with ownership percentage.

2. For medical facility licensees, all entities that own any part of the licensed entity, with ownership percentage.

(C) The licensee shall notify the department within five (5) days of the initiation and conclusion of any legal proceedings, government investigations, or any other activity that would negatively affect the licensee's ability to operate in accordance with department regulations, including a petition for receivership, loss of lease or location, or disputes relating to the ownership of the facility license.

(D) The licensee shall notify the department when a facility agent has been terminated for misconduct related to handling of marijuana product, including but not limited to, inventory, product integrity, marijuana product sales, theft, health and safety, or facility security.

(E) The licensee shall notify the department within twenty-four (24) hours following the occurrence of an event that affects the health and safety of the facility or its employees, including injury to employees or other persons at the facility resulting in medical care being administered by a medical professional.

(F) The licensee shall notify the department within twenty-four (24) hours of discovery of any theft or attempted theft of marijuana product.

(G) The licensee shall notify the department within twenty-four (24) hours of discovery of any criminal misconduct of an employee, contractor, owner, or volunteer, as it pertains to the operation of the facility.

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(H) A cultivation licensee shall notify the department before changing its cultivation practice (indoor, outdoor, or greenhouse) or modifying the ratios of cultivation practices it uses, as provided in the cultivation section of this chapter.

(I) After the department approves a change in location, the licensee shall notify the department it has completed its location change within ninety (90) days of moving the location of the licensed facility.

(J) The licensee shall notify the department of any entity name changes or fictitious name changes.

*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 Jan. 20, 2023, effective Feb. 3, 2023, expires Aug. 1, 2023. An emergency rule and a proposed rule covering this same material will be published in the March 1, 2023, issue of the **Missouri Register**.*

PUBLIC COST: This emergency rule will not cost state agencies or political subdivisions more than five hundred dollars (\$500) in the time the emergency is effective.

PRIVATE COST: This emergency rule will cost private entities at least two hundred ten million, five hundred ninety-one thousand dollars (\$210,591,000), and up to eight hundred fifty-five million, seven hundred fifty-one thousand, two hundred eight dollars (\$855,751,208) in the time the emergency is effective.

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FISCAL NOTE PRIVATE COST

- I. Department Title: Department of Health and Senior Services
Division Title: Division of Cannabis Regulation
Chapter Title: Marijuana**

Rule Number and Title:	19 CSR 100-1.100 Facilities Generally
Type of Rulemaking:	Emergency

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Classification by types of the business entities which would likely be affected:	Estimate in the aggregate as to the cost of compliance with the rule by the affected entities
Facilities : new entity same owner		\$20,000 in the six month emergency rule period
Facilities : new owner		\$570,000 in the six month emergency rule period
Facilities : ownership change greater than 50%		\$304,000 in the six month emergency rule period
Facilities : location change		\$120,000 in the six month emergency rule period
213	Dispensaries Annual Fee	\$1,491,000 in the six month emergency rule period
67	Cultivators Annual Fee	\$804,000 in the six month emergency rule period
87	Manufacturing Annual Fee	\$609,000 in the six month emergency rule period
10	Testing Annual Fee	\$50,000 in the six month emergency rule period
26	Transportation Annual Fee	\$130,000 in the six month emergency rule period
454	Dispensaries, Cultivators, Manufacturing, Testing, Transportation Compliance	\$207,000,000 – \$828,000,000 for first year
Total =		\$210,591,000 to \$855,751,208 in the six month emergency rule period

III. WORKSHEET

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Manufacturing Facility

Eighty-seven (87) manufacturing facilities x two thousand (2,000) dollars for comprehensive change request application fee in year one = \$174,000.

Warehouses

10 facilities applying in the first year x two thousand (2,000) dollars for application fee = \$50,000

Microbusiness Facility

Forty-eight (48) microbusiness facility x one thousand five hundred (1,500) dollars for application fee in year one = \$72,000

IV. ASSUMPTIONS

Each facility that applies for and receives a business license or certification from the department will incur application fees and annual fees. There are currently department will issue 213 dispensary licenses, 67 cultivation facility licenses, 87 manufacturing facility licenses, 10 testing facility certifications, and 26 transportation certifications. It is anticipated that all of these licenses that currently exist will convert from their current medical facility to a comprehensive facility. The department does not plan on adding any new licenses in the next three years and as such there is no revenue from applications. Additionally, the department does not anticipate any new applications for transportation or labs at this time.

Additionally, the Department has no means of knowing with the facilities will request to convert to comprehensive and as such full numbers appear in both the emergency rule and the proposed rule.

Microbusinesses are to be licensed incrementally with the first round of applications to be turned in October 2023, the second in June 2024, and the third round in April 2025. Microbusinesses do not incur an annual fee for one year, thus the first round of microbusinesses will not incur an annual fee until late 2024. These facilities must comply with all rules and as such will incur compliance expenses.

While there has been a request for warehouses there is no means to determine how many individuals will request a warehouse, or if they will request multiple warehouses. As such the department is anticipating ten new warehouses based on only one being asked for in the past.

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Each license holder is required to pay annual fees as set forth in the worksheet.

Finally, each licensed or certificated entity will incur costs to comply with all of the regulations in this rule and all other rules with which this rule requires compliance, including warehouses. The department has no basis on which to estimate what those costs will be except anecdotal reports from states with somewhat similar regulations to the proposed rules. This number is also reliant upon how many warehouses the division receives applications for. The department estimates that 10 warehouses will be applied for based on past applications.

It is unknown when the businesses will spend their money for the compliance. As such it is shown both in the emergency rule and the proposed rule.

Much of the compliance for these businesses has already been met. However, due to rescinding 19 CSR 35-90 and the implementation of 19 CSR 100 these requirements are considered all new requirements. As such, the actual cost implementation of these rules will not be as high as is reflected.