Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.030 Qualifying Patient/Primary Caregiver

PURPOSE: Under Article XIV, Section 1 of the ***Missouri Constitution****, patients with qualifying medical conditions have the right to discuss freely with their physicians the possible benefits of medical marijuana use and the right to use medical marijuana for treatment under the supervision of a physician. Pursuant to the same article, the Department of Health and Senior Services is tasked with ensuring patient access to medical marijuana, subject to reasonable restrictions. This rule explains how the department will implement provisions of Article XIV related to Qualifying Patients and Primary Caregivers.*

(1) Physician Certification. A qualifying patient must obtain a new physician certification at least annually. In every application for which a physician certification is required, the physician certification must be less than thirty (30) days old at the time the application is submitted.

(2) Identification Card Applications. Qualifying patients and primary caregivers shall obtain identification cards from the department, which will include unique, identifying numbers for each patient and each caregiver-patient relationship. A qualifying patient or his or her primary caregivers may also obtain an identification card to cultivate up to six (6) flowering marijuana plants for the exclusive use of that qualifying patient. The department will receive applications for qualifying patients, primary caregivers, and patient cultivation electronically through a department-provided, web-based application system. In the event of application system unavailability, the department will arrange to accept applications in an alternative, department-provided format and will notify the public of those arrangements through its website at http://medicalmarijuana.mo.gov.

(A) All applications for qualifying patient identification cards and renewal of such identification cards shall include at least the following information:

1. The qualifying patient's name, date of birth, and Social Security number;

2. The qualifying patient's residence address and mailing address or, if the qualifying patient has no residence or mailing address, an address where the qualifying patient can receive mail;

3. A statement that the qualifying patient resides in Missouri and does not claim resident privileges in another state or country, as well as proof of current Missouri residency, which shall be shown by—

A. A copy of a valid Missouri driver's license, a Missouri Identification Card, a current Missouri motor vehicle registration, or a recent Missouri utility bill; or

B. If none of these proofs are available, some other evidence of residence in Missouri, which shall be approved or denied by the director of the medical marijuana program as sufficient proof of residency;

4. The qualifying patient's e-mail address;

5. A statement confirming that—

A. One (1) physician certification, which is less than thirty (30) days old, has been submitted on behalf of the qualifying patient; or

B. Two (2) physician certifications, which are less than thirty (30) days old, have been submitted on behalf of the qualifying patient in order to authorize possession limits other than those established by section (5) of this rule;

6. A legible copy of the qualifying patient's photo identification issued by a state or federal government entity;

7. If the qualifying patient is a non-emancipated qualifying patient, the name, Social Security number, and a Parental/Legal Guardian Consent Form, included herein, completed by a parent or legal guardian who will serve as primary caregiver for the qualifying patient;

8. A clear, color photo of the applicant's face taken within the prior three (3) months;

9. At the option of the applicant, a statement indicating whether the applicant is currently receiving assistance from any Missouri programs for low-income individuals, and if so, which programs;

10. If the patient is seeking authority to cultivate medical marijuana—

A. The address of the facility in which the qualifying patient will cultivate marijuana;

B. A description of the security arrangements and processes that will be used to restrict access to only qualifying patients and their primary caregivers;

C. The name and Patient License Number or Caregiver License Number, if applicable, of one (1) other qualifying patient or primary caregiver with whom the cultivating facility will be shared;

D. A statement affirming the applicant's agreement to immediately make available access to the patient cultivation facility upon request from the department. Such access will be only for purposes of confirming compliance with this rule and will be limited to the enclosed locked facility and any areas necessary to reach and enter the facility on a path of the patient's or primary caregiver's choosing;

11. An attestation that the information provided in the application is true and correct;

12. The signature of the qualifying patient and date the qualifying patient signed, or, in the case of a non-emancipated qualifying patient, the signature of the parent or legal guardian who will serve as primary caregiver for the qualifying patient and the date the parent or legal guardian signed; and

13. All applicable fees.

(B) All applications for primary caregiver identification cards and renewal of such identification cards shall include at least the following information:

1. The primary caregiver's name, date of birth, and Social Security number;

2. The primary caregiver's residence address and mailing address;

3. The primary caregiver's e-mail address;

4. The name and Patient License Number of the qualifying patient for whom the applicant seeks to serve as primary caregiver;

5. A legible copy of the primary caregiver's photo identification issued by a state or federal government entity;

6. If the qualifying patient is a non-emancipated qualifying patient, a statement that the primary caregiver is the qualifying patient's parent or legal guardian and—

A. A copy of a birth certificate or adoption record showing the primary caregiver as the qualifying patient's parent; or

B. A copy of documentation establishing legal guardianship of the primary caregiver over the qualifying patient;

7. A clear, color photo of the applicant's face taken within the prior three (3) months;

8. If the primary caregiver is seeking authority to cultivate medical marijuana on behalf of the patient—

A. The address of the facility in which the primary caregiver will cultivate marijuana;

B. A description of the security arrangements and processes that will be used to restrict access to only qualifying patients and their primary caregivers;

C. The name and Patient License Number or Caregiver License Number, if applicable, of one (1) other qualifying patient or primary caregiver with whom the cultivating facility will be shared; and

D. A statement affirming the applicant's agreement to immediately make available access to the patient cultivation facility upon request from the department. Such access will be only for purposes of confirming compliance with this rule and will be limited to the enclosed locked facility and any areas necessary to reach and enter the facility on a path of the patient's or primary caregiver's choosing;

9. An attestation that the information provided in the application is true and correct;

10. The signature of the primary caregiver and date the primary caregiver signed;

11. Except in the case of a non-emancipated qualifying patient, a Patient Authorization Form, included herein, completed by the qualifying patient who the primary caregiver will serve; and

12. All applicable fees.

(3) Application Processes.

(A) Upon receiving an application for a qualifying patient identification card, primary caregiver identification card, or patient cultivation identification card, the department shall, within thirty (30) days, either approve the application or provide a written explanation for its denial.

1. In the case of qualifying patient and patient cultivation identification cards, if the department fails to deny or fails to approve an application within thirty (30) days, a card will be issued that will be valid for one (1) year and will serve all the same functions as would a card issued after application approval.

2. An application for a qualifying patient or patient cultivation identification card will be considered received when an application is submitted to the department that includes all information required by section (2) of this rule. The department will notify an applicant once if an application is incomplete and will specify in that notification what information is missing.

(B) Denial and revocation.

1. Qualifying patient, primary caregiver, and patient cultivation identification cards may be denied or revoked.

A. If an applicant provides false or misleading information in an application, the identification card for which the applicant is applying will be denied.

B. If an applicant fails to provide a complete application within ten (10) days of being notified that an application is incomplete, the identification card for which the applicant is applying will be denied.

(I) An applicant will be considered notified on the date the department sends a written explanation of how the application is incomplete to a mailing or e-mail address provided by the applicant.

(II) If an applicant fails to provide either a mailing or e-mail address, the department will not issue notice but will hold the application for thirty (30) days before denying it.

C. If a card holder violates any provision of this rule, any medical marijuana identification cards currently held by that individual may be revoked.

D. If a card holder is found to be in possession of an amount of marijuana greater than the medical marijuana legal limit applicable to that individual, any medical marijuana identification cards currently held by that individual will be revoked. In such a case, the identification card may be revoked for up to one (1) year.

E. If a card holder is convicted of, pleads guilty to, or receives a suspended imposition of sentence for a violation of section 579.020, 579.065, or 579.068, RSMo or for a violation of a similar law of another state, any medical marijuana identification cards currently held by that individual will be revoked. In such a case, the revocation shall be permanent, absent a gubernatorial pardon or expungement.

F. If an applicant has applied for a qualifying patient, primary caregiver, or qualifying patient cultivation identification card and received two (2) denials within a twelve- (12-) month period, has any of these types of identification cards revoked twice within a twenty-four (24) month period, or applied for any of these types of identification cards and been denied once and also had any of these types of identification cards revoked once within a twenty-four- (24-) month period, the identification card for which the applicant is applying will be denied.

G. If a patient cultivation identification card holder fails to immediately make available access to his or her patient cultivation facility upon request from the department, the patient cultivation identification card will be revoked.

H. If medical marijuana is stolen or lost, is identifiable as medical marijuana purchased by a particular qualifying patient or primary caregiver, is discovered in the possession of an individual who is not the qualifying patient or primary caregiver authorized to possess that medical marijuana, and was not timely reported as stolen or lost by the qualifying patient or primary caregiver authorized to possess that medical marijuana, the qualifying patient's or primary caregiver's identification card may be revoked.

I. If a qualifying patient or primary caregiver uses combustible gases or other dangerous materials to extract resins from marijuana, the qualifying patient's or primary caregiver's identification card may be revoked for up to one (1) year.

J. If the department determines there is good cause to do so, an application for a patient cultivation identification card may be denied.

2. Any denial or revocation shall be issued by the department in writing to the qualifying patient or, in the case of a primary caregiver, to the qualifying patient and the primary caregiver, and shall include the specific reasons for the denial or revocation and the process for requesting review of the department's decision.

(C) Renewal. Qualifying patient, primary caregiver, and patient cultivation identification cards are valid for twelve (12) months from their date of issuance and shall be renewable by submitting, prior to expiration by at least thirty (30) days but no sooner than sixty (60) days, a new or updated application, which shall include any information required by section (2) that has changed since the date of the previous application, including a new physician certification.

(D) The department shall charge a fee for medical marijuana identification card applications.

1. There will be a separate fee for each application to be a qualifying patient, each application to be a primary caregiver on behalf of a specific qualifying patient, and each application to cultivate medical marijuana on behalf of a specific qualifying patient.

2. Requests for authority to cultivate medical marijuana on behalf of a qualifying patient may be made within a qualifying patient or primary caregiver application or may be made separately at a later time. However, the authorization to cultivate will be added to the qualifying patient or primary caregiver identification card and will only remain valid as long as the qualifying patient or primary caregiver's identification card is still valid.

3. Current fees, including any adjustments, will be posted on the department's website at http://medicalmarijuana.mo.gov.

(E) If the name or address of a qualifying patient or primary caregiver changes after an identification card is issued, the qualifying patient or primary caregiver shall notify the department within ten (10) days of the change.

(4) Qualifying Patient Cultivation.

(A) All qualifying patient cultivation shall take place in an enclosed, locked facility, as defined in 19 CSR 30-95.010.

(B) One (1) qualifying patient may cultivate up to six (6) flowering marijuana plants, six (6) nonflowering marijuana plants (over fourteen (14) inches tall), and six (6) clones (plants under fourteen (14) inches tall) at any given time in a single, enclosed locked facility. Two (2) qualifying patients, who both hold valid qualifying patient cultivation identification cards, may share one (1) enclosed, locked facility. No more than twelve (12) flowering marijuana plants, twelve (12) nonflowering plants, and twelve (12) clones may be cultivated in a single, enclosed locked facility, except when one (1) of

the qualifying patients, as a primary caregiver, also holds a patient cultivation identification card for a third qualifying patient, in which case that primary caregiver may cultivate six (6) additional flowering marijuana plants, six (6) additional nonflowering marijuana plants, and six (6) additional clones for a total of eighteen (18) flowering marijuana plants, eighteen (18) nonflowering marijuana plants, and eighteen (18) clones in a single, enclosed locked facility.

(C) Under no circumstance will a qualifying patient be entitled to cultivate, or have cultivated on his or her behalf, more than six (6) flowering marijuana plants.

(D) Nothing in this section shall convey or establish a right to cultivate medical marijuana in a facility where state law or a private contract would otherwise prohibit doing so.

(E) All cultivated flowering marijuana plants in the possession of a qualifying patient or primary caregiver shall be clearly labeled with the qualifying patient's name.

(F) The department shall provide each qualifying patient or primary caregiver who receives a qualifying patient cultivation identification card with a cultivation authorization, which shall be clearly displayed within the enclosed cultivation area and in close proximity to the marijuana plants. The authorization shall list the name of the qualifying patient or primary caregiver and the address of the facility in which that qualifying patient or primary caregiver is authorized to cultivate marijuana.

(5) Purchase and Possession Limitations.

(A) Qualifying patients may only purchase, or have purchased on their behalf by their primary caregivers, four (4) ounces of dried, unprocessed marijuana per qualifying patient, or its equivalent, in a thirty- (30-) day period.

(B) Qualifying patients may only possess, or instruct a primary caregiver to possess on their behalf—

1. In the case of qualifying patients who do not cultivate or have medical marijuana cultivated on their behalf, up to a sixty- (60-) day supply of dried, unprocessed marijuana per qualifying patient, or its equivalent; or

2. In the case of qualifying patients who are cultivating marijuana for medical use or whose primary caregivers are cultivating marijuana on their behalf, up to a ninety- (90-) day supply of dried, unprocessed marijuana or its equivalent, so long as the supply of medical marijuana cultivated by the qualifying patients or primary caregivers remains on property under their control.

(C) All medical marijuana purchased from a dispensary must be stored in or with its original packaging.

(D) Primary caregivers may possess a separate legal limit for each qualifying patient under their care and a separate legal limit for themselves if they are a qualifying patient, each of which shall be stored separately for each qualifying patient and labeled with the qualifying patient's name.

(E) Purchase and possession limits established in this section shall not apply to a qualifying patient with written certification from two (2) independent physicians that there are compelling reasons why the qualifying patient needs a greater amount than the limits established in this section.

1. In such a case, both independent physicians must state in their certifications what amount the qualifying patient requires, which shall then be that patient's limit.

2. If the two (2) independent physicians disagree on what amount should be the patient's limit, the lower of the two (2) amounts shall be that patient's limit.

3. If the patient's limit is increased after receiving a qualifying patient identification card, the qualifying patient or primary caregiver shall notify the department within ten (10) days of the change.

(6) Non-Emancipated Qualifying Patient.

(A) A physician shall not issue a certification for the medical use of marijuana for a non-emancipated qualifying patient under the age of eighteen (18) without the written consent of a parent or legal guardian of the qualifying patient.

(B) The department shall not issue a qualifying patient identification card on behalf of a non-emancipated qualifying patient under the age of eighteen (18) without the written consent of a parent or legal guardian of the qualifying patient. Such card shall be issued to the parent or guardian and not directly to the patient.

(C) Only a parent or guardian may serve as a primary caregiver for a non-emancipated qualifying patient under the age of eighteen (18).

(D) Only the qualifying patient's parent or guardian who holds a primary caregiver identification card shall purchase or possess medical marijuana for a non-emancipated qualifying patient under the age of eighteen (18).

(E) A parent or guardian who holds a primary caregiver identification card shall supervise the administration of medical marijuana to a non-emancipated qualifying patient under the age of eighteen (18).

(7) Qualifying Patient Responsibilities.

(A) No qualifying patient shall consume marijuana for medical use in a public place, unless provided by law.

(B) No qualifying patient who is under the care of a primary caregiver may serve as the primary caregiver for another qualifying patient.

(C) If a qualifying patient is no longer entitled to medical marijuana or no longer wishes to hold a medical marijuana identification card, he or she must notify the department within ten (10) days of that change. The department will confirm in writing that the qualifying patient has voluntarily surrendered the identification card and that the identification card is no longer valid.

(D) If a qualifying patient's medical marijuana is stolen or lost, the qualifying patient must notify the department within two (2) days.

(8) Primary Caregiver Responsibilities.

(A) No individual shall serve as the primary caregiver for more than three (3) qualifying patients.

(B) No individual shall serve as a primary caregiver for a qualifying patient who is already served by two (2) primary caregivers.

(C) If a primary caregiver is no longer entitled to serve as a primary caregiver or no longer wishes to hold a primary caregiver identification card, he or she must notify the department within ten (10) days of that change. The department will confirm in writing that the primary caregiver has voluntarily surrendered the identification card and that the identification card is no longer valid.

(D) If medical marijuana in possession of a primary caregiver is stolen or lost, the primary caregiver must notify the department in a department-approved format within two (2) days.

(9) Disposal of Qualifying Patient Medical Marijuana.

(A) In any case where a qualifying patient is no longer entitled to medical marijuana under any provision of state law or is deceased, any excess medical marijuana or marijuana plants in the possession of the qualifying patient or the patient's primary caregiver or discovered by a third party shall be turned over to a licensed dispensary for disposal within thirty (30) days of the event that makes the qualifying patient ineligible.

1. Before delivering the excess medical marijuana to a dispensary, the individual in possession of the excess medical marijuana must contact the department, and the department will coordinate delivery arrangements between the individual and a dispensary.

2. The individual in possession of excess medical marijuana shall receive from the department written, temporary authorization to transport medical marijuana, which shall include details regarding the delivery arrangements approved by the department.

(B) The possession and transportation of medical marijuana under this section shall not subject the possessor to arrest, criminal or civil liability, or sanctions under Missouri law, provided that the possessor produces on demand to the appropriate authority a copy of the

temporary authorization for transport or evidence of communication with the department regarding delivery arrangements.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION FOR MEDICAL MARIJUANA REGULATION
MEDICAL MARIJUANA REGULATORY PROGRAM

PARENT / LEGAL GUARDIAN CONSENT FORM

A Parental/Legal Guardian Consent Form is required by 19 CSR 30-95.030 as proof of consent by a parent or legal guardian for a minor's use of marijuana for medical use and must be submitted with any Patient Registration Application for a non-emancipated qualifying patient. Please ensure information provided is consistent with the applicable Patient Registration Application and the applicable Primary Caregiver Application.

PATIENT NAME:

LAST NAME:	FIRST NAME:	MIDDLE NAME:

PATIENT / LEGAL GUARDIAN WHO WILL SERVE AS PRIMARY CAREGIVER NAME:

LAST NAME:	FIRST NAME:	MIDDLE NAME:

SOCIAL SECURITY NUMBER:	DATE OF BIRTH:

I, _____, affirm I am the parent or legal guardian of _____, and this is my written consent for the Department of Health and Senior Services to issue a Patient Identification Card for his/her medical use of marijuana under my supervision.

PARENT / LEGAL GUARDIAN SIGNATURE:	DATE:

MO 580-3272 (5-19)

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION FOR MEDICAL MARIJUANA REGULATION
MEDICAL MARIJUANA REGULATORY PROGRAM

PATIENT AUTHORIZATION FORM

A Patient Authorization Form is required by 19 CSR 30-95.030 as proof of a patient's desire that a particular individual serve as the patient's primary caregiver and must be submitted with a Primary Caregiver Registration Application. Please ensure information provided is consistent with the applicable Primary Caregiver Registration Application.

PATIENT NAME:

LAST NAME:	FIRST NAME:	MIDDLE NAME:

PRIMARY CAREGIVER NAME:

LAST NAME:	FIRST NAME:	MIDDLE NAME:

SOCIAL SECURITY NUMBER:	DATE OF BIRTH:

I, _____, affirm that it is my desire that _____, serve as my primary caregiver in order to assist me in the medical use of marijuana.

PATIENT SIGNATURE:	DATE:

MO 580-3271 (5-19)

AUTHORITY: Sections 1.3.(1)(b) and 1.3.(2) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule has an estimated cost to state agencies or political subdivisions of $4,154,908 in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $3,500,000 in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PUBLIC COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.030 Qualifying Patient / Primary Caregiver
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Department of Health & Senior Services' costs =	**$4,154,908 for the first three year period and $1,228,706 for annually thereafter**
Total =	**$4,154,908 for the first three year period and $1,228,706 for annually thereafter**

III. WORKSHEET

Patient Services Director

One (1) FTE with an annual salary of $70,000 and with estimated fringe benefits of $33,941.

One-Time First Year expense (computer, office, furniture etc.) for one FTE listed above - $4,661

On-going expenses (including travel, office supplies, network, printing, etc.) for one FTE - $13,277.

$70,000 (salary) + $33,941 (fringe benefits) + $13,277 (on-going expenses) X 3 year = $351,654 + $4,761 (one-time first year expense) = $356,415 for the first three year period.

$70,000 (salary) + $33,941 (fringe benefits) + $13,777 (on-going expenses) = $117,718 annually thereafter.

Patient Services Team Lead

Two (2) FTE's with total annual salaries of $71,000 and with estimated fringe benefits of $46,858.

One-Time First Year expense (computer, office, furniture etc.) for two (2) FTEs listed above - $15,974

On-going expenses (including travel, office supplies, network, printing, etc.) for two (2) FTEs - $30,633.

$71,000 (salary) + $46,858 (fringe benefits) + $30,633 (on-going expenses) X three (3) = $445,473 + $19,338 (one-time first year expense) = $464,811 for the first three year period.

$71,000 (salary) + $46,858 (fringe benefits) + $30,633 (on-going expenses) = $148,491 annually thereafter.

Patient Services Specialists

Twelve (12) FTE's with total annual salaries of $426,000 and with estimated fringe benefits of $281,146.

One-Time First Year expense (computer, office, furniture etc) for twelve (12) FTEs listed above - $116,028

On-going expenses (including travel, office supplies, network, printing, etc.) for twelve (12) FTEs - $183,797.

$426,000 (salary) + $281,146 (fringe benefits) + $183,797 (on-going expenses) X three (3) = $2,672,829 + $116,028 (one-time first year expense) = $2,788,857 for the first three year period.

$426,000 (salary) + $281,146 (fringe benefits) + $183,797 (on-going expenses) = $890,943 annually thereafter.

Administrative Office Support Assistant

One (1) FTE with an annual salary of $35,000 and with estimated fringe benefits of $23,277.

One-Time First Year expense (computer, office, furniture etc.) for one FTE listed above - $7,969

On-going expenses (including travel, office supplies, network, printing, etc.) for one FTE - $13,277.

$35,000 (salary) + $23,277 (fringe benefits) + $13,277 (on-going expenses) X three (3) = $214,662 + $7,969 (one-time first year expense) = $222,631 for the first three year period.

$35,000 (salary) + $23,277 (fringe benefits) + $13,277 (on-going expenses) = $71,554 annually thereafter.

Patient Registry System Contract

Estimated contract cost of $308,194 for one year.
Call Center installation cost of $14,000 for year one.

IV. ASSUMPTIONS

In order to process the patient, caregiver, and patient cultivation applications; answer patient, caregiver, and physician inquiries related to these applications; answer public inquiries about patient services; process issues related to lost or stolen cards; and process patient or caregiver rule violations and any resultant ID card revocations, the department will need a Patient Services Director, two Patient Services Team Leads, twelve Patient Services Specialists, and one Administrative Office Support Assistant.

In order to receive and maintain records related to patient, caregiver, and patient cultivation applications, including physician certifications tied to patient applications, the department will need a Patient Registry System, which is an IT solution specifically designed for medical marijuana program functions, including protection of health information and integration with the state system for tracking medical marijuana purchases. All functions of this system referenced throughout Chapter 95 stem from requirements in this rule.

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.030 Qualifying Patient / Primary Caregiver
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
20,000	**Patients**	**$3,500,000 - unknown for the first year**
unknown	**Caregivers**	**unknown**
Total =		**$3,500,000 - unknown for the first year**

III. WORKSHEET

Patients and Patient Caregivers

Twenty thousand (20,000) patients x $25 for patient identification card = $500,000 for one year.

Twenty thousand (20,000) patients x $150 for physician certification = $3,000,000 for one year.

IV. ASSUMPTIONS

Each patient or caregiver who chooses to apply to the department for authorization to purchase and possess medical marijuana will be charged an application fee in the amount of twenty-five (25) dollars. If that individual also applies for authorization to cultivate medical marijuana, he or she will be charged an application fee of one hundred (100) dollars. If individuals choose to renew their authorizations, they will be charged these fees again at the time of their application for renewal.

The University of Missouri conducted a market analysis to try to predict, among other things, how many patients would apply for medical marijuana access in the first year the program is functioning. The analysis concluded Missouri can expect approximately twenty thousand patients in the first year.

Unfortunately, this number is only an estimate, and there are no estimates for the number of caregivers or number of individuals who will apply to cultivate.

In addition to application fees, patients or caregivers who are authorized to cultivate medical marijuana will incur costs to comply with regulations in this rule regarding secure cultivation areas. There are not reliable estimates for what it will cost any particular individual to comply with the regulations as there are many way to comply, and in addition to that, as mentioned above, there are no estimates for the number of patient/caregiver cultivators the department should expect.

The final private cost required by this regulation is the cost of obtaining a certification from a physician for the medical use of marijuana. The department is estimating the cost to patients for such visits based on anecdote and media reports, which indicate visits can cost between $50 and $250, with an average of $150.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.040 Medical Marijuana Facilities Generally

*PURPOSE: Under Article XIV, Section 1 of the **Missouri Constitution**, the Department of Health and Senior Services is authorized to regulate and control the operations of Cultivation, Infused Product Manufacturing, Dispensary, Testing, and Transportation facilities, and to grant, refuse, suspend, fine, restrict, or revoke the licenses and certifications for such facilities. This rule explains how this authority will be exercised.*

(1) Application Processes. The department will begin accepting applications for licensing and certification of cultivation, infused products manufacturing, dispensary, testing, and transportation facilities on August 3, 2019.

(A) The department will receive applications for facility licenses or certifications electronically through a department-provided, web-based application system. In the event of application system unavailability, the department will arrange to accept applications in an alternative, department-provided format and will notify the public of those arrangements through its website.

(B) For cultivation, manufacturing, dispensary, and testing facilities, the department will publish on its website time periods during which it will accept applications for review. All complete applications received by the department that are submitted during the application time periods will be approved or denied within one hundred fifty (150) days of that application's submission.

1. Any application fees submitted before or during the first application time period and during any subsequent application period are nonrefundable.

2. After the first application time period, any application fees submitted outside of an application time period will not be accepted.

3. If licenses or certifications are available after a time period for accepting applications has passed, the department will determine when to publish on its website a new time period during which it will accept applications and will publish that new time period on its website at least six (6) months prior to the beginning of that time period.

4. Applications will be considered complete if they include all information required for applications by this rule and by 19 CSR 30-95.025(4). The department will notify an applicant if an application is incomplete and will specify in that notification what information is missing. Applicants will be given seven (7) days to provide missing information.

(C) For transportation facilities, all complete applications received by the department that are submitted on or after August 3, 2019, will be approved or denied within one hundred fifty (150) days of that application's submission. Applications will be considered complete if they include all information required for applications by this rule. The department will notify an applicant if an application is incomplete and will specify in that notification what information is missing. Applicants will be given seven (7) days to provide missing information.

(D) The issuance of a facility license or certification does not authorize the facility to begin cultivating, manufacturing, dispensing, testing, or transporting medical marijuana. A facility will be granted final approval to operate upon passing a commencement inspection.

(E) The department will not license or certify a cultivation, dispensary, manufacturing, transportation, or testing facility that is owned by or affiliated with an entity that currently holds a contract with the state of Missouri for any product or service related to the department's medical marijuana program.

(F) Licenses and certification for facilities may be suspended, denied, or revoked.

1. If a facility provides false or misleading information in an application, its application may be denied or, if the information is later discovered to have been false or misleading, its license or certification may be revoked. Plans, assurances, and projections offered in answers to 19 CSR 30-95.025(4) evaluation criteria questions may be considered false or misleading if, upon application for license renewal, the department determines the facility has not made a reasonable effort to implement or follow-through on those plans, assurances, or projections.

2. If a facility violates any provision in this chapter or fails to comply with a corrective action plan, its license or certification may be suspended or revoked.

3. If an applicant fails to provide a complete application within seven (7) days of being notified that an application is incomplete, the license or certification for which the applicant is applying will be denied.

4. If a facility is granted a license or certification but has not passed a commencement inspection within one (1) year of the department issuing the license or certification, the license or certification may be revoked.

5. If a facility fails to comply with a department order to immediately suspend all or a part of its operations, the license or certification shall be revoked.

6. If an application does not meet the minimum standards for licenses and certifications pursuant to 19 CSR 30-95.025(4), the license or certification for which the applicant is applying will be denied.

7. If a facility uses combustible gases or other dangerous materials to extract resins from marijuana without a manufacturing facility license, the facility's license may be suspended for up to one (1) year.

8. If a facility packages medical marijuana in a false or misleading manner, or in any manner designed to cause confusion between a marijuana product and any product not containing marijuana, the facility's license may be suspended or revoked.

9. If a facility or a facility employee fails to comply with seed-to-sale tracking requirements or intentionally misuses or falsifies seed-to-sale tracking data, the facility's license may be revoked.

(G) Cultivation, infused product manufacturing, and dispensary licenses and testing and transportation certifications are valid for three (3) years from the date the license or certification is issued and shall, except for good cause, be renewable by submitting, prior to expiration by at least one hundred fifty (150) days but no sooner than two hundred fifty (250) days, an updated application, which shall include any information required by section (2) of this rule or section (4) of 19 CSR 30-95.025 that has changed since the date of the previous application.

(H) The department shall charge an application or renewal fee for a facility license or certification and also an annual fee once a 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 facility's license or certification remains valid. The department shall publish the current fees, including any adjustments, on its website. The amount of fees due for each facility will be the amount that is effective as of that facility's due date.

(2) Application Requirements. Facilities must obtain a license or certification to cultivate, manufacture, dispense, test, and transport medical marijuana in Missouri. All applications for facility licenses or certifications and for renewals of licenses or certifications shall include at least the following information:

(A) Name and address of the primary contact for the applicant facility;

(B) Legal name of the facility, including fictitious business names,

and a certificate of good standing from the Missouri Office of the Secretary of State;

(C) A completed Ownership Structure Form, included herein, which must show the applicant entity is majority owned by Missouri residents, and a written description or visual representation of the facility's ownership structure including all entities listed on the Ownership Structure Form;

(D) For each owner claiming Missouri residency for purposes of subsection (C) of this section, a statement that the owner has resided in Missouri for at least one (1) year and does not claim resident privileges in another state or country, as well as proof of current Missouri residency, which shall be shown by—

1. A copy of a valid Missouri driver's license, a Missouri Identification Card, a current Missouri motor vehicle registration, or a recent Missouri utility bill; or

2. If none of these proofs are available, some other evidence of residence in Missouri, which shall be approved or denied at the discretion of the director of the medical marijuana program as sufficient proof of residency;

(E) A list of all facilities licensed or certified or applying for licensure or certification in Missouri to cultivate, manufacture, dispense, or test medical marijuana that are or will be under substantially common control, ownership, or management as the applicant. For each facility listed, a written explanation of how the facility is under substantially common control, ownership, or management as the applicant, with supporting documentation;

(F) Proposed address of the facility and—

1. A map of the surrounding area that shows compliance with the facility location requirements of subsection (4)(B) of this rule or 19 CSR 30-95.100(2)(C); or

2. Documentation showing a local government requirement different than the requirement in subsection (4)(B) of this rule or 19 CSR 30-95.100(2)(C) and a map of the surrounding area that shows compliance with the facility location requirements of the local government; and

3. An attestation that the proposed address of the facility complies with the facility location requirements of subsection (4)(B) of this rule or 19 CSR 30-95.100(2)(C);

(G) Descriptions, schematics, or blueprints for the facility;

(H) If the city, town, or county in which the facility will be located has enacted zoning restrictions applicable to the facility, the text of the restrictions and a description of how the facility plans to comply with those restrictions;

(I) An attestation that no individual who owns the facility, in whole or in part, has a disqualifying felony offense;

(J) A statement confirming that all owners who hold any portion of the economic or voting interest of the facility who will also have access to medical marijuana or the medical marijuana facility, and all officers, directors, board members, managers, and employees identified in the application, have submitted fingerprints within the previous six (6) months for a state and federal fingerprint-based criminal background check to be conducted by the Missouri State Highway Patrol;

(K) All facility evaluation information required by 19 CSR 30-95.025(4); and

(L) All applicable fees or proof that all applicable fees have already been paid.

(3) Facility Ownership and Employment.

(A) Cultivation, infused products manufacturing, dispensary, testing, and transportation facilities shall not be owned by, in whole or in part, or have as an officer, director, board member, manager, or employee, any individual with a disqualifying felony offense.

(B) Cultivation, infused products manufacturing, dispensary, testing, and transportation facilities shall be held by entities that are majority owned by natural persons who have been citizens of the state of Missouri for at least one (1) year prior to applying for a facility license or certification. For the purposes of this requirement, citizen means resident.

(C) No more than three (3) cultivation, no more than three (3) manufacturing, and no more than five (5) dispensary licenses shall be issued to any entity under substantially common control, ownership, or management. Any entity under substantially common control, ownership, or management that has applied for more than three (3) cultivation, three (3) manufacturing, or five (5) dispensary licenses shall contact the department at the time of application submission to identify for the department the applications associated with that entity. The department will use this information, once application scoring is complete pursuant to 19 CSR 30-95.025(4), solely for determining how many licenses the department may issue any particular entity.

(D) No testing facility shall be owned by an entity under substantially common control, ownership, or management as a cultivation, manufacturing, or dispensary facility.

(E) Facility Agent Identification Cards. Each owner, officer, manager, contractor, employee, and other support staff of a licensed or certified cultivation, dispensary, manufacturing, testing, or transportation facility shall obtain an agent identification card, which shall be assigned and display a unique, identifying number. For all such individuals associated with an entity at the time it is licensed or certified, any work they are performing for that entity may continue, but application for an agent identification card must be made within thirty (30) days of a license or certification being granted. For all other such individuals, applications for agent identification cards will be accepted only after an individual receives an offer of employment from a licensed or certified facility, and for those individuals, agent identification cards must be granted before they may begin employment with a licensed or certified entity.

1. All applications for agent identification cards and renewals of agent identification cards shall include at least the following information in a department-approved format:

A. Name, address, and Social Security number of the applicant;

B. A statement confirming that the applicant has submitted fingerprints within the previous six (6) months for a state and federal fingerprint-based criminal background check to be conducted by the Missouri State Highway Patrol;

C. A copy of a written offer of employment from a licensed or certified facility; and

D. All applicable fees.

2. Agent identification cards shall be valid for three (3) years.

3. If arrested for a disqualifying felony offense, agent identification card holders must notify the department within thirty (30) days of the arrest.

4. For purposes of this section, a contractor is a person or company that undertakes a contract with a licensed or certified facility to perform work that would include access to medical marijuana or related equipment or supplies for a time period greater than fourteen (14) days.

5. For purposes of this section, an owner is a person who holds any portion of the economic or voting interests of a facility and who will have access to medical marijuana or a medical marijuana facility.

6. Agent identification card holders must have their cards accessible to them at all times while performing work in or on behalf of a facility.

7. The department shall charge a fee for identification cards, which shall be seventy-five dollars ($75), due at the time of application or renewal.

(4) Facility Operation, Policies, and Procedures.

(A) Each cultivation, infused product manufacturing, or dispensary facility in operation must obtain a separate license, but multiple licenses may be utilized in a single facility. All licenses shall be displayed at all times within twenty feet (20') of the main entrance to a facility.

(B) Unless expressly allowed by the local government, no new cultivation, infused products manufacturing, dispensary, or testing facility shall be sited, at the time of application for license or for local zoning approval, whichever is earlier, within one thousand feet (1,000') of any then-existing elementary or secondary school, daycare, or church.

1. In the case of a freestanding facility, the distance between the facility and the school, daycare, or church shall be measured from the external wall of the facility structure closest in proximity to the school, daycare, or church to the closest point of the property line of the school, daycare, or church. If the school, daycare, or church is part of a larger structure, such as an office building or strip mall, the distance shall be measured to the entrance or exit of the school, daycare, or church closest in proximity to the facility.

2. In the case of a facility that is part of a larger structure, such as an office building or strip mall, the distance between the facility and the school, daycare, or church shall be measured from the property line of the school, daycare, or church to the facility's entrance or exit closest in proximity to the school, daycare, or church. If the school, daycare, or church is part of a larger structure, such as an office building or strip mall, the distance shall be measured to the entrance or exit of the school, daycare, or church closest in proximity to the facility.

3. Measurements shall be made along the shortest path between the demarcation points that can be lawfully traveled by foot.

(C) All licensed or certified cultivation, dispensary, manufacturing, testing, and transportation facilities must seek and obtain the department's approval before they may—

1. Assign, sell, give, lease, sublicense, or otherwise transfer its license to any other entity.

A. If the entity to which the license or certification will be transferred is owned by the same entities as was the entity to which the department originally issued the license or certification, the request may be submitted after the facility at issue has been granted a license and must include at least the following:

(I) Legal name of the facility, including fictitious business names, and a certificate of good standing from the Missouri Office of the Secretary of State; and

(II) A completed Ownership Structure Form, included herein, which must show the applicant entity is owned by the same entities as was the entity to which the department originally issued the license or certification;

B. If the entity to which the license or certification will be transferred is not owned by the same entities as was the entity to which the department originally issued the license or certification, the request may be submitted beginning January 1, 2021, and shall include at least the same information required for an initial application for license or certification;

2. Make any changes to ten percent (10%) or more of the ownership interests of the facility. Such requests may be submitted after the facilities at issue have been granted a license and must include at least the following:

A. Name of each new owner, if any;

B. An updated Ownership Structure Form, included herein, which must show the applicant entity is majority owned by Missouri residents, and a written description or visual representation of the facility's ownership structure including all entities listed on the Ownership Structure Form;

C. For each owner claiming Missouri residency for purposes of subparagraph B of this paragraph, a statement that the owner has resided in Missouri for at least one (1) year and does not claim resident privileges in another state or country, as well as proof of current Missouri residency, which shall be shown by—

(I) A copy of a valid Missouri driver's license, a Missouri Identification Card, a current Missouri motor vehicle registration, or a recent Missouri utility bill; or

(II) If none of these proofs are available, some other evidence of residence in Missouri, which shall be approved or denied at the discretion of the director of the medical marijuana program as sufficient proof of residency;

D. A list of all facilities licensed or certified or applying for licensure or certification in Missouri to cultivate, manufacture, dispense, or test medical marijuana that are or will be under substantially common control, ownership, or management as the applicant. For each facility listed, an explanation of how the facility is under substantially common control, ownership, or management as the applicant, with supporting documentation;

E. An attestation that no individual who owns the facility, in whole or in part, has a disqualifying felony offense; and

F. A statement confirming that all owners who hold any portion of the economic or voting interest of a facility who will also have access to medical marijuana or a medical marijuana facility, and all officers, directors, board members, managers, and employees identified in the application have submitted fingerprints within the previous six (6) months for a state and federal fingerprint-based criminal background check to be conducted by the Missouri State Highway Patrol;

3. Materially deviate from the proposed physical design or make material changes to the current physical design of the facility, including its location. Such requests may be submitted after the facilities at issue have been granted a license and shall include at least the following:

A. New or updated descriptions, schematics, or blueprints for the facility;

B. An attestation that the proposed changes to the facility comply with the facility location requirements of subsection (4)(B) of this rule or 19 CSR 30-95.100(2)(C) and any facility location requirements of the local government;

C. If the city, town, or county in which the facility will be located has enacted zoning restrictions applicable to the facility, the text of the restrictions and a description of how the changes to the facility comply with those restrictions; and

D. For location change requests, an explanation for why the facility's original location is no longer possible and proof that claims made in the facility's initial licensure application regarding benefits of its original location also apply to the facility's newly proposed location;

4. Combine licensed facilities at a single location. Such requests may be submitted after the facilities at issue have been granted a license and shall include at least the following:

A. Descriptions, schematics, or blueprints for the combined facilities;

B. An attestation that the proposed combination of facilities complies with the facility location requirements of subsection (4)(B) of this rule or 19 CSR 30-95.100(2)(C) and any location requirements of the local government;

C. If the city, town, or county in which the combined facilities will be located has enacted zoning restrictions applicable to the combined facilities, the text of the restrictions and a description of how the combined facilities will comply with those restrictions; and

D. If the combination of facilities is between two (2) or more entities with different ownership, documents showing the agreements between the entities concerning their respective roles and their relationship in regard to management, operation, and maintenance of the combined facility. Such agreements shall include an acknowledgment that all entities sharing management, operations, or maintenance of the combined facility shall be jointly responsible for compliance with the applicable department regulations for the shared spaces of the combined facility; or

5. Begin construction on a warehouse sited at a location other than the approved location of the facility. Such requests may be submitted after the facility at issue has been granted a license and shall include at least the following:

A. Descriptions, schematics, or blueprints for the warehouse;

B. An attestation that the proposed location for the warehouse complies with the facility location requirements of subsection (4)(B)

of this rule or 19 CSR 30-95.100(2)(C) and any location requirements of the local government that would apply to the facility for which the warehouse is being constructed;

C. If the city, town, or county in which the warehouse will be located has enacted zoning restrictions applicable to the facility for which the warehouse is being constructed, the text of the restrictions and a description of how the warehouse will comply with those restrictions; and

D. An attestation that the warehouse will comply with all other rules applicable to the facility for which the warehouse is being constructed.

(D) All marijuana for medical use, including plants, flowers, and infused products, sold in Missouri shall be cultivated in a licensed cultivation facility located in Missouri. After December 31, 2020, marijuana for medical use shall be grown from seeds or plants obtained from a Missouri licensed cultivation or dispensary facility.

(E) Any excess or unusable medical marijuana or medical marijuana byproduct of a cultivation, manufacturing, dispensary, testing, or transportation facility shall be disposed of in the following manner, as applicable:

1. Solid and liquid wastes generated during medical marijuana production and processing must be stored, managed, and disposed of in accordance with applicable state, tribal, local, and municipal laws and regulations. Facilities must keep records of the final disposal destinations of all such wastes for at least five (5) years;

2. Wastewater generated during medical marijuana production and processing must be disposed of in compliance with applicable state, tribal, local, and municipal laws and regulations;

3. Wastes from the production and processing of medical marijuana plants must be evaluated against state hazardous waste regulations to determine if those wastes qualify as hazardous waste. It is the responsibility of each waste generator to properly evaluate their waste to determine if it is a hazardous waste per 40 CFR 262.11. If a generator's waste does qualify as a hazardous waste, then that waste is subject to the applicable hazardous waste management standards.

A. All solid waste, as defined by 40 CFR 261.2, must be evaluated under the hazardous waste regulations, including:

(I) Waste from medical marijuana flowers, trim, and solid plant material used to create an extract;

(II) Waste solvents, pesticides, and other similar materials used in the cultivation, manufacturing, or testing process;

(III) Discarded plant waste, spent solvents, and laboratory wastes from any medical marijuana processing or quality assurance testing; and

(IV) Medical marijuana extract that fails to meet quality testing.

B. Medical marijuana flowers, trim, and solid plant material are not in themselves considered hazardous waste unless they have been treated or contaminated with a hazardous waste constituent;

4. Medical marijuana waste that does not qualify as hazardous waste per 40 CFR 262.11 must be rendered unusable prior to leaving a facility, including plant waste, such as roots, stalks, leaves, and stems;

5. Medical marijuana plant waste that does not qualify as hazardous may be rendered unusable by grinding and incorporating the medical marijuana plant waste with other nonhazardous ground materials so the resulting mixture is at least fifty percent (50%) non-marijuana waste by volume. Material used to grind with the medical marijuana may be either compostable waste or noncompostable waste. Other methods to render medical marijuana waste unusable must be approved by the department before implementation.

A. Compostable mixed waste: Medical marijuana waste to be disposed as compost feedstock or in another organic waste method (for example, anaerobic digester) may be mixed with the following types of waste materials:

(I) Food waste;

(II) Yard waste; or

(III) Vegetable based grease or oils.

B. Noncompostable mixed waste: Medical marijuana waste to be disposed in a landfill or another disposal method (for example, incinerator) may be mixed with the following types of waste materials:

(I) Paper waste;

(II) Cardboard waste;

(III) Plastic waste; or

(IV) Soil;

6. Medical marijuana waste that has been rendered unusable may be delivered to a permitted solid waste facility for final disposition. Examples of acceptable permitted solid waste facilities include:

A. For compostable mixed waste: Compost, anaerobic digester, or other facility with approval of the local health department; and

B. For noncompostable mixed waste: Landfill, incinerator, or other facility with approval of the local health department; or

7. All facility waste of any type must be stored securely before final disposition, which can be done within the facility in areas designated for disposal activities or, if necessary, outside the facility in a locked, tamper-resistant receptacle.

(F) All cultivation, manufacturing, dispensary, testing, and transportation facilities must establish and follow procedures to ensure medical marijuana remains free from contaminants. The procedures must address, at a minimum:

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

2. Employee health and sanitation;

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.

(G) All cultivation, infused products manufacturing, dispensary, testing, and transportation facilities shall implement inventory control systems and procedures as follows:

1. Each facility shall designate in writing a facility agent who is generally responsible for the inventory control systems and procedures for that facility;

2. All weighing and measuring of medical marijuana required by this rule must be conducted with a National Type Evaluation Program approved scale, which shall be capable of weighing and measuring accurately at all times and recalibrated at least yearly;

3. Each facility shall use a department-certified seed-to-sale tracking system to track medical marijuana from seed or immature plant stage until the medical marijuana is purchased by a qualifying patient or primary caregiver or destroyed. Records entered into the seed-to-sale tracking system must include each day's beginning inventory, harvests, acquisitions, sales, disbursements, remediations, disposals, transfers, ending inventory, and any other data necessary for inventory control records in the statewide track and trace system;

4. Each infused product manufacturing facility shall—

A. Establish and maintain a perpetual inventory system that documents the flow of materials through the manufacturing process;

B. Establish procedures to reconcile the raw material used to the finished product on the basis of each process lot. Significant variances must be documented, investigated by management personnel, and reported to the department and to the facility that ordered the infused product within twenty-four (24) hours of discovering the variances; and

C. Provide for quarterly physical inventory counts to be performed by facility employees who do not participate in the manufacturing process, which shall be reconciled to the perpetual inventory records. Significant variances must be documented, investigated by management personnel, and reported to the department within twenty-four (24) hours of discovering the variances;

5. Each dispensary facility shall be responsible for ensuring that every amount of medical marijuana sold or disbursed to a qualifying patient or primary caregiver is recorded in the seed-to-sale tracking system as a purchase by or on behalf of the applicable qualifying patient. Amounts of medical marijuana shall be recorded—

A. For dried, unprocessed marijuana, in ounces or grams;

B. For concentrates, in grams; or

C. For infused products, by milligrams of THC;

6. If a facility identifies a reduction in the amount of medical marijuana in the inventory of the facility, the facility must document where in the facility's processes the loss has occurred, if possible, and take and document corrective action. If the reduction in the amount of medical marijuana in the inventory of the facility is due to suspected criminal activity by a facility agent, the facility 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;

7. A medical marijuana facility shall maintain all records required by this subsection for at least five (5) years; and

8. In case of seed-to-sale system failure or loss of connection to the statewide track and trace system, the facility may continue performing for up to five (5) hours all actions that are required to be tracked, except sales of medical marijuana or transfers of medical marijuana from the facility, as long as the facility records all necessary tracking information and enters that information into its seed-to-sale tracking system upon restoration of the system or into the statewide track and trace system upon restoration of the connection.

(H) All cultivation, infused products manufacturing, and dispensary facilities shall ensure the security of medical marijuana and facility employees by taking at least the following measures:

1. Facilities shall install and maintain security equipment designed to prevent unauthorized entrance into limited access areas and to prevent diversion and inversion of medical marijuana including:

A. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular or private radio signals, or other mechanical or electronic devices;

B. Except in the case of outdoor cultivation, exterior lighting to facilitate surveillance, which shall cover the exterior and perimeter of the facility;

C. Electronic video monitoring, including—

(I) At least one (1) call-up monitor that is nineteen inches (19") or more;

(II) A printer capable of immediately producing a clear still photo from any video camera image;

(III) Video cameras with a recording resolution of at least 1920 x 1080, or the equivalent, at a rate of at least fifteen (15) frames per second, that operate in such a way as to allow identification of people and activities in the monitored space, in all lighting levels, that are capable of being accessed remotely by the department or a law enforcement agency in real-time upon request, and that provide coverage of—

(a) All entrances and exits of the facility, including windows, and all entrances and exits from limited access areas;

(b) The perimeter and exterior areas of the facility, including at least twenty feet (20') of space around the perimeter of an outdoor grow area;

(c) Each point-of-sale location;

(d) All vaults or safes; and

(e) All medical marijuana, from at least two (2) angles, where it is cultivated, cured, trimmed, processed, rendered unusable, and disposed;

(IV) A method for storing recordings from the video cameras for at sixty (60) days in a secure on-site or off-site location or through a service or network that provides on-demand access to the recordings and that allows for providing copies of the recordings to the department upon request and at the expense of the facility;

(V) A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system; and

(VI) Sufficient battery backup for video cameras and recording equipment to support at least sixty (60) minutes of recording in the event of a power outage;

D. Controlled entry to limited access areas, which shall be controlled by electronic card access systems, biometric identification systems, or other equivalent means, except that, in addition to these means, all external access doors shall be equipped with a locking mechanism that may be used in case of power failure. Access information shall be recorded, and all records of entry shall be maintained for at least one (1) year;

E. A method of immediate, automatic notification to alert local law enforcement agencies of an unauthorized breach of security at the facility; and

F. Manual, silent alarms at each point-of-sale, reception area, vault, and electronic monitoring station with capability of alerting local law enforcement agencies immediately of an unauthorized breach of security at the facility;

2. Facilities shall establish policies and procedures—

A. For restricting access to the areas of the facility that contain medical marijuana to only persons authorized to be in those areas, which shall include, when necessary for business purposes, contractors hired for no more than fourteen (14) days and other visitors, all of which may enter the restricted area if they sign in and sign out of a visitor log and are escorted at all times by facility agents in a ratio of no less than one (1) facility agent per five (5) visitors;

B. For identifying persons authorized to be in the areas of the facility that contain medical marijuana;

C. For identifying facility agents responsible for inventory control activities;

D. For limiting the amount of money available in any retail areas of the facility and for notifying the public that there is a minimal amount of money available, including by posting of a sign;

E. For electronic monitoring;

F. For the use of the automatic or electronic notification and manual, silent alarms to alert local law enforcement agencies of an unauthorized breach of security at the facility, including designation of on-call facility personnel to respond to, and to be available to law enforcement personnel who respond to, any alarms; and

G. For keeping local law enforcement updated on whether the facility employs armed security personnel and how law enforcement can identify such personnel on sight;

3. Facilities with outdoor cultivation shall construct an exterior barrier around the perimeter of the marijuana cultivation area that consists of a fence that is—

A. Constructed of six (6) gauge metal or stronger chain link;

B. Topped with razor wire or similar security wire;

C. At least eight feet (8') in height; and

D. Screened such that the cultivation area is not easily viewed from outside the fence;

4. Facilities with windows in a limited access area must ensure either that the window cannot be opened and is designed to prevent intrusion or that the window is otherwise inaccessible from the outside;

5. Facilities shall ensure that each video camera used pursuant to this section—

A. Includes a date and time generator which possesses the capability to accurately display the date and time of recorded events on the recording in a manner that does not significantly obstruct the recorded view; and

B. Is installed in a manner that will prevent the video camera from being readily obstructed, tampered with, or disabled;

6. A facility shall make a reasonable effort to repair any malfunction of security equipment within seventy-two (72) hours after the malfunction is discovered. A facility shall notify the department within twenty-four (24) hours after a malfunction is discovered and provide a plan of correction.

A. If a video camera used pursuant this section malfunctions, the facility shall immediately provide alternative video camera coverage or use other security measures until video camera coverage can be restored, such as assigning additional supervisory or security personnel, to provide for the security of the facility. If the facility uses other security measures, the facility must immediately notify the department, and the department will determine whether the other security measures are adequate and for what amount of time those other security measures will be acceptable.

B. Each facility shall maintain a log that documents each malfunction and repair of the security equipment of the facility. The log must state the date, time, and nature of each malfunction; the efforts taken to repair the malfunction and the date of each effort; the reason for any delay in repairing the malfunction; the date the malfunction is repaired and; if applicable, any alternative security measures that were taken. The log must also list, by date and time, all communications with the department concerning each malfunction and corrective action. The facility shall maintain the log for at least one (1) year after the date of last entry in the log;

7. Each facility shall employ a security manager who shall be responsible for:

A. Conducting a semiannual audit of security measures to ensure compliance with this subsection and to identify potential security issues;

B. Training employees on security measures, emergency response, and theft prevention and response within one (1) week of hiring and on an annual basis;

C. Evaluating the credentials of any contractors who intend to provide services to the facility before the contractor is hired by or enters into a contract with the facility; and

D. Evaluating the credentials of any third party who intends to provide security to the facility before the third party is hired by or enters into a contract with the facility; and

8. Each facility shall ensure that the security manager of the facility, any facility agents who provide security for the facility, and the employees of any third party who provides security to the facility have completed the following training:

A. Training in theft prevention or a related subject;

B. Training in emergency response or a related subject;

C. Training in the appropriate use of force or a related subject that covers when the use of force is and is not necessary;

D. Training in the protection of a crime scene or a related subject;

E. Training in the control of access to protected areas of a facility or a related subject;

F. Not less than eight (8) hours of training at the facility in providing security services; and

G. Not less than eight (8) hours of classroom training in providing security services.

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

(J) Medical marijuana that fails testing or is subject to a recall must either be destroyed by any facility in possession of that medical marijuana or, at the election of the facility from which the failed test or recalled item originated, and with approval of the department, may be remediated, if possible.

1. Remediated medical marijuana must pass all testing required by 19 CSR 30-95.070;

2. Facilities may only elect to remediate any particular medical marijuana once.

(K) All cultivation, infused products manufacturing, and dispensary facilities shall ensure that all medical marijuana is packaged and labeled in a manner consistent with the following:

1. Facilities shall not manufacture, package, or label marijuana—

A. In a false or misleading manner;

B. In any manner designed to cause confusion between a marijuana product and any product not containing marijuana; or

C. In any manner designed to appeal to a minor;

2. Marijuana and marijuana-infused products shall be sold in containers clearly and conspicuously labeled, in a font size at least as large as the largest other font size used on the package, with:

A. "Marijuana" or a "Marijuana-infused Product"; and

B. "Warning: Cognitive and physical impairment may result from the use of Marijuana";

3. Any marijuana or marijuana-infused products packaged for retail sale before delivery to a dispensary must be packaged in opaque, re-sealable packaging designed or constructed to be significantly difficult for children under five (5) years of age to open but not normally difficult for adults to use properly. Any marijuana or marijuana-infused products not packaged for retail sale before delivery to a dispensary must be packaged by the dispensary upon sale to a qualifying patient or primary caregiver in opaque, re-sealable packaging designed or constructed to be significantly difficult for children under five (5) years of age to open but not normally difficult for adults to use properly. All edible marijuana-infused products must be packaged for retail by the infused-products manufacturer before transfer to a dispensary;

4. Marijuana and marijuana-infused products shall bear a label displaying the following information, in the following order:

A. The total weight of the marijuana included in the package:

(I) For dried, unprocessed marijuana, weight shall be listed in ounces or grams;

(II) For concentrates, weight shall be listed in grams; or

(III) For infused products, weight shall be listed by milligrams of THC;

B. Dosage amounts, instructions for use, and estimated length of time the dosage will have an effect;

C. The THC, tetrahydrocannabinol acid, cannabidiol, cannabidiol acid, and cannabinol concentration per dosage;

D. All active and inactive ingredients, which shall not include groupings of ingredients that obscure the actual ingredients, such as "proprietary blend" or "spices";

E. In the case of dried, unprocessed marijuana, the name, as recorded with the Missouri Office of the Secretary of State, of the cultivating facility from which the marijuana in the package originated and, in the case of infused products, the name of the infused-product manufacturer, as recorded with the Missouri Office of the Secretary of State; and

F. A "best if used by" date;

5. No branding, artwork, or other information or design elements included on marijuana or marijuana-infused products shall be placed in such a way as to obscure any of the information required by this section;

6. Marijuana and marijuana-infused product packaging shall not include claims of health benefits but may include health warnings; and

7. Marijuana and marijuana-infused products must, at all times, be tagged with traceability information generated by the statewide track and trace system.

(L) Cultivation, manufacturing, dispensary, and testing facilities that transport medical marijuana must also comply with 19 CSR 30-95.100(2)(D) in doing so.

(M) Signage and advertising on facility premises must comply

with the following:

1. A facility may not display marijuana, marijuana paraphernalia, or advertisements for these items in a way that is visible to the general public from a public right-of-way; and

2. Outdoor signage and, if visible to the public, interior signage, must comply with any local ordinances for signs or advertising and—

A. May not display any text other than the facility's business name or trade name, address, phone number, and website; and

B. May not utilize images or visual representations of marijuana plants, products, or paraphernalia, including representations that indicate the presence of these items, such as smoke.

(5) Facility Inspections.

(A) Submission of an application for a facility license or certification constitutes consent to inspection by the department. A department inspector conducting an inspection pursuant to this section need not give prior notice of the inspection and, during the inspection, must be given access to all areas and property of the facility, including vehicles, wherever located, without delay.

1. The department will enter and inspect at least annually, with or without notice, to ensure compliance with this chapter.

2. The department may also, at any time it determines an inspection is needed, conduct an inspection, including an inspection of any part of the premises, qualifications of personnel, methods of operation, records, and policies and procedures of a licensed or certified facility.

(B) Once a licensed or certified facility believes it will, within a month, be ready to begin operations and meet all state and local requirements for its facility, it shall request that the department conduct a commencement inspection to confirm the facility is in compliance with all requirements of this chapter.

(C) Violations, Compliance Verification Inspections, and Suspension.

1. If the department determines, during an inspection or otherwise, that a facility is not in compliance with the department's regulations, the department will issue an Initial Notice of Violation to the facility that explains how the facility has violated the department's regulations and what remedial actions the department expects the facility to take to correct the violation(s).

2. Once a facility has been notified of violation(s), the facility shall correct the violations within fifteen (15) days, and the department will conduct a follow-up inspection within fifteen (15) to thirty (30) days to confirm the facility has corrected the violation(s). The facility shall notify the department if it believes it needs additional time to correct the violation(s), which the department may grant for good cause.

3. If the department's follow-up inspection reveals the violation(s) have not been corrected, the department will issue a Final Notice of Violation to the facility explaining how the facility continues to violate the department's regulations, what remedial actions the department expects the facility to take, and notifying the facility that its license or certifications will be suspended if the specified remedial action is not taken and the violation(s) corrected within thirty (30) days.

4. If the violation(s) have not been corrected thirty (30) days after a Final Notice of Violation and no extension of this deadline has been granted by the department, the facility's license or certification will be suspended, the facility will be required to cease operations, and the facility must sign a corrective action plan designed to bring the facility into compliance.

(D) Upon receipt of complaint against a facility, the department will determine whether an inspection is warranted to investigate the allegations in the complaint, and, if so, the department will, at the time of inspection, provide the facility with a copy of the complaint and an opportunity to respond to the complaint. Employees of a facility who report potential violations by a facility to the department may not be subjected to retaliation of any kind, including termination, because of their report.

(E) If, at any time, the department determines a facility presents an immediate and serious threat to the health and safety of the public or of the facility's employees, the department may order the facility to immediately suspend all or a part of its operations until the threat has been eliminated.

MISSOURI DEPARTMENT OF HEALTH AND SENIOR SERVICES
SECTION FOR MEDICAL MARIJUANA REGULATION
MEDICAL MARIJUANA REGULATORY PROGRAM

OWNERSHIP STRUCTURE FORM

OWNER INFORMATION – Pursuant to 19 CSR 30-95.040, all entities that own any portion of the economic or voting interests of the applicant facility must be listed on this form. Natural persons whose ownership interest contributes to the facility's claim that it is majority owned by Missouri residents must be listed on this form in their individual capacity and must include a residence address in the "Address" field as well as the name of the business entity in which he or she holds an economic or voting interest. Refer to 19 CSR 30-95.010 for applicable definitions. Use additional sheets as necessary.

BUSINESS ENTITY NAME AND TAX NUMBER		% ECONOMIC INTEREST	% VOTING INTEREST
LAST NAME	FIRST NAME		MIDDLE INITIAL
SOCIAL SECURITY NUMBER		DATE OF BIRTH (MM-DD-YYYY)	
ADDRESS			UNIT/APT NO
CITY	STATE	COUNTY	ZIP CODE
PHONE NUMBER	EMAIL ADDRESS		
NATURAL PERSON CLAIMING RESIDENCY FOR PURPOSES OF MAJORITY OWNERSHIP CALCULATION? ☐ YES ☐ NO			

BUSINESS ENTITY NAME AND TAX NUMBER		% ECONOMIC INTEREST	% VOTING INTEREST
LAST NAME	FIRST NAME		MIDDLE INITIAL
SOCIAL SECURITY NUMBER		DATE OF BIRTH (MM-DD-YYYY)	
ADDRESS			UNIT/APT NO
CITY	STATE	COUNTY	ZIP CODE
PHONE NUMBER	EMAIL ADDRESS		
NATURAL PERSON CLAIMING RESIDENCY FOR PURPOSES OF MAJORITY OWNERSHIP CALCULATION? ☐ YES ☐ NO			

BUSINESS ENTITY NAME AND TAX NUMBER		% ECONOMIC INTEREST	% VOTING INTEREST
LAST NAME	FIRST NAME		MIDDLE INITIAL
SOCIAL SECURITY NUMBER		DATE OF BIRTH (MM-DD-YYYY)	
ADDRESS			UNIT/APT NO
CITY	STATE	COUNTY	ZIP CODE
PHONE NUMBER	EMAIL ADDRESS		
NATURAL PERSON CLAIMING RESIDENCY FOR PURPOSES OF MAJORITY OWNERSHIP CALCULATION? ☐ YES ☐ NO			

MO 580-3270 (5-19)

AUTHORITY: Sections 1.3.(1)(b) and 1.3.(2) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule has an estimated cost to state agencies or political subdivisions of $1,895,829 in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $176,318,000 in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PUBLIC COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.040 Medical Marijuana Facilities Generally
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Department of Health & Senior Services' costs =	**$1,895,829 for the first three year period and $477,187 for annually thereafter**
Total =	**$1,895,829 for the first three year period and $477,187 for annually thereafter**

III. WORKSHEET

Facility Licensing & Compliance Director

Three quarters (3/4) of one (1) FTE with an annual salary of $56,250 and with estimated fringe benefits of $26,598.

Three quarters (3/4) of One-Time First Year expense (computer, office, furniture etc.) for one FTE listed above - $3,496.

On-going expenses (including travel, office supplies, network, printing, etc.) for one FTE - $9,959.

$56,250 (salary) + $26,598 (fringe benefits) + $9,959 (on-going expenses) X three (3) = $278,421 – $3,496 (one-time first year expense) = $281,917 for the first three year period.

$56,250 (salary) + $26,598 (fringe benefits) + $9,959 (on-going expenses) = $92,807 annually thereafter.

Facility Licensing Managers

Half (1/2) of one (1) FTE with an annual salary of $30,000 and with estimated fringe benefits of $15,447.

One-Time First Year expense (computer, office, furniture etc.) for half (1/2) of one (1) FTE listed above - $2,331

On-going expenses (including travel, office supplies, network, printing, etc.) for half (1/2) of one (1) FTE - $6,639

$30,000 (salary) + $15,447 (fringe benefits) + $6,639 (on-going expenses) X three (3) = $156,258 + $2,331 (one-time first year expense) = $158,589 for the first three year period.

$30,000 (salary) + $15,447 (fringe benefits) + $6,639 (on-going expenses) = $52,086 annually thereafter.

Facility Licensing Specialists

Two (2) FTE's with total annual salaries of $104,000 and with estimated fringe benefits of $56,913.

One-Time First Year expense (computer, office, furniture etc.) for two (2) FTEs listed above - $9,322

On-going expenses (including travel, office supplies, network, printing, etc.) for two (2) FTEs - $28,273

$104,000 (salary) + $56,913 (fringe benefits) + $28,273 (on-going expenses) X three (3) = $567,558 + $9,322 (one-time first year expense) = $576,880 for the first three year period.

$104,000 (salary) + $56,913 (fringe benefits) + $28,273 (on-going expenses) = $189,186 annually thereafter.

Administrative Office Support Assistant

Two (2) FTE's with total annual salaries of $70,000 with estimated fringe benefits of $46,554.

One-Time First Year expense (computer, office, furniture etc.) for two FTEs listed above - $15,938

On-going expenses (including travel, office supplies, network, printing, etc.) for two FTEs - $26,554.

$70,000 (salary) + $46,554 (fringe benefits) + $26,554 (on-going expenses) X three (3) = $429,324 + $15,938 (one-time first year expense) = $445,262 for the first three year period.

$70,000 (salary) + $46,554 (fringe benefits) + $26,554 (on-going expenses) = $143,108 annually thereafter.

Facility Licensing System Contract

Estimated contract cost of $203,132.for one year.

Seed-to-Sale System Contract

Estimated contract cost of $230,049 for one year.

IV. ASSUMPTIONS

In order to process the facility license applications and the applications for various approvals post-licensing described in this rule, the department will need a Facility Licensing Manager, who will also perform other duties not covered by this proposed rule, and two (2) Facility Licensing Specialists.

In order to conduct the inspections and enforcement activities described by this rule, the department will need fourteen (14) Inspectors.

In order to supervise the fourteen (14) Inspectors and to conduct and support escalated or complex compliance/enforcement actions, the department will need four (4) Compliance Managers.

In order to supervise the work of the Facility Licensing Manager; to review and analyze escalated or complex issues; to issue, deny, revoke, and suspend licenses; to supervise the work of the Compliance Managers; and to review and analyze escalated or complex compliance/inspection issues, the department will need a Facility Licensing & Compliance manager, who will also perform other duties not covered by this proposed rule.

In order to administratively support the work of all FTEs required for this rule, the department will need two (2) Administrative Office Support Assistants.

In order to receive, process, and maintain records related to facility applications and licensed/certified facilities, the department will need a Facility Licensing System, which is an IT solution specifically designed for medical marijuana program functions, including integration with the state system for tracking medical marijuana purchases.

In order to facilitate the inventory control provisions of this rule and all facility requirements related to tracking medical marijuana from seed to sale, the department will need a Seed-to-Sale System, which is an IT solution specifically designed for tracking and tracing medical marijuana from immature plants stage to sale by a dispensary to a qualified patient or primary caregiver. The Seed-to-Sale system is necessary to determine whether any given individual may purchase any given amount of medical marijuana. All functions of this system referenced throughout Chapter 95 stem from requirements in this rule.

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.040 Medical Marijuana Facilities Generally
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
192	**Dispensaries**	**$1,152,000 in first year and $1,920,000 for two additional years in total**
60	**Cultivators**	**$600,000 in first year and $3,000,000 for two additional years in total**
86	**Manufacturing**	**$516,000 in first year and $1,720,000 for two additional years in total**
10	**Testing**	**$50,000 in first year and $100,000 for two additional years in total**
unknown	**Transportation**	**unknown**
348	**Dispensaries, Cultivators, Manufacturing, Testing**	**$174,000,000 – $1,740,000,000 for first year**
unknown	**Transportation**	**unknown**
Total =		**At least $176,318,000 for the first year and unknown for additional years**

III. WORKSHEET

Dispensary Facility

One hundred ninety-two (192) dispensary facilities x six thousand (6,000) dollars for application fee in year one = 1,152,000.

One hundred nine-two (192) dispensary facilities x ten thousand (10,000) dollars for annual fee in years two and three =.1,920,000 x 2 years = 3,840,000.

Cultivation Facility

Sixty (60) cultivation facilities x ten thousand (10,000) dollars for application fee in year one = 600,000.

Sixty (60) cultivation facilities x twenty-five thousand (25,000) dollars for annual fee in years two and three = 1,500,000 x 2 = 3,000,000.

Manufacturing Facility

Eighty-six (86) manufacturing facilities x six thousand (6,000) dollars for application fee in year one = 516,000.

Eighty-six (86) manufacturing facilities x ten thousand (10,000) dollars for annual fee in years two and three = 860,000 x 2 = 1,720,000.

Testing Facility

Ten (10) testing facilities x five thousand (5,000) dollars for application fee and for annual fee in years one, two, and three = 150,000.

Transportation Facility

Unknown number of transportation facilities x five thousand (5,000) dollars for application fee and for annual fee in years one, two, and three = 150,000.

All Facilities

Three hundred forty-eight known facilities x $500,000 - $5,000,000 for compliance with all regulations applicable to all facilities in the first year = $174,000,000 – $1,740,000,000.

Unknown number of transportation facilities x $500,000 - $1,000,000 for compliance with all regulations applicable to transportation facilities in the first year = unknown.

IV. ASSUMPTIONS

Each facility that applies for and receives a business license or certification from the department will incur application fees and annual fees. The department will issue 192 dispensary licenses, 60 cultivation facility licenses, 86 manufacturing facility licenses, and 10 testing facility certifications. It is unknown how many transportation certifications will be issued.

Additionally, every entity that applies for a business license or certification that does not receive one will incur a non-refundable application fee. It is unknown at this time how many of these entities will submit applications.

Finally, each licensed or certificated entity will incur costs to comply with all of the regulations in this rule and all other rules in Chapter 95 related to this one. However, these costs are currently unknown and cannot be reasonably estimated. More specifically, because these rules establish an entirely new regulated industry unrelated to any existing industry in Missouri, the department does not know and cannot estimate what any facility or any type of facility within this industry will need to expend to comply with these regulations. No two facilities will be the same in size or operations, and with no facilities existing yet, the department is unable even to calculate an average of estimated costs. For example, an indoor cultivation facility may be built to cultivate a very small amount of marijuana or up to thirty thousand square feet of flowering marijuana canopy space, which are two vastly different operations. Taking the security camera requirement alone, the facility may require several cameras or several hundred cameras, and at this time, the department is unable even to estimate an average size of facility for Missouri as there is no reliable date on which to base such an estimate.

For purposes of this rule, which includes the bulk of the cost-causing regulations for each of the facilities at issue, the department has used anecdotal reports from states with somewhat similar regulations to estimate total costs of building and operating each type of facility. However, these cost estimates are not tied specifically to Missouri's regulations and are known to include costs that are unrelated to Missouri's regulations.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.050 Cultivation Facility

*PURPOSE: Under Article XIV, Section 1 of the **Missouri Constitution**, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply only to Cultivation Facilities.*

(1) Cultivation Facility Licenses.

(A) The number of cultivation facility licenses will be limited to sixty (60) unless the department determines the limit must be increased in order to meet the demand for medical marijuana by qualifying patients.

(B) A facility license will be issued for a single facility in a single location. Combinations of licenses at the same location must be approved pursuant to 19 CSR 30-95.040(4)(C).

(2) Cultivation Facility Requirements. In addition to the requirements for cultivation facilities in 19 CSR 30-95.040, cultivation facilities shall also comply with the following;

(A) Cultivation facilities may cultivate medical marijuana in indoor, outdoor, or greenhouse facilities.

1. Each indoor facility utilizing artificial lighting will be limited to no more than thirty thousand (30,000) square feet of flowering plant canopy space.

2. Each outdoor facility utilizing natural lighting will be limited to no more than two thousand eight hundred (2,800) flowering plants.

3. Each greenhouse facility using a combination of natural and artificial lighting will be limited to, at the election of the licensee, either no more than two thousand eight hundred (2,800) flowering plants or no more than thirty thousand (30,000) square feet of flowering plant canopy space.

4. If a cultivation facility is operating with multiple cultivation licenses in the same location, the size limitations of the cultivation facility will be multiplied by the number of licenses;

(B) Facilities must keep records, by month and by batch, of all pesticides, herbicides, fertilizers, and other agricultural chemicals applied to marijuana plants and growing medium during production and processing at its facility for at least five (5) years;

(C) Facilities, except those in rural, unincorporated agricultural areas, must develop, implement, and maintain an odor control plan, which shall address odor mitigation practices including, but not limited to, engineering controls, such as system design and operational processes, which shall be reviewed and certified by a professional engineer or a certified industrial hygienist as sufficient to effectively mitigate odors for all odor sources;

(D) Cultivation facilities must ensure all facility employees are trained in at least the following:

1. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of marijuana;

2. Proper use of the statewide track and trace system;

3. Procedures for responding to an emergency, including severe weather, fire, natural disasters, and unauthorized intrusions;

4. Standards for maintaining the confidentiality of information related to the medical use of marijuana, including, but not limited to, compliance with the Health Insurance Portability and Accountability Act of 1996;

5. The methods of cultivation used by the facility; and

6. The facility's safety and sanitation procedures;

(E) Cultivation facilities shall not transfer medical marijuana from the facility, except to a testing facility, until the medical marijuana has been tested by a testing facility, according to the provisions of 19 CSR 30-95.070, and the cultivation facility has received verification from the testing facility that the medical marijuana passed all required testing;

(F) Cultivation facilities may only transport medical marijuana—

1. That the facility cultivated;

2. To a dispensary, testing, or manufacturing facility; and

3. If the facility complies with the requirements of 19 CSR 30-95.100(2); and

(G) Cultivation facilities shall store all medical marijuana—

1. At the approved location of the facility; or

2. In offsite warehouses that comply with the security requirements of 19 CSR 30-95.040(4)(H), the location requirements of 19 CSR 30-95.040(4)(B), and that have been approved pursuant to 19 CSR 30-95.040(3)(C).

AUTHORITY: Sections 1.3.(1)(b) and 1.3.(2) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $3,000,000 in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.050 Cultivation Facility
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
60	**Cultivation Facilities**	**$3,000,000 - $30,000,000 in the first year**
Total =		**At least $3,000,000 in the first year**

III. WORKSHEET

Cultivation Facility

Sixty (60) cultivation facilities x $50,000 - $500,000 for compliance with the regulations applicable to only this facility type in the first year = $3,000,000 - $30,000,000.

IV. ASSUMPTIONS

Each licensed entity will incur costs to comply with all of the regulations in this rule and all other rules in Chapter 95 related to this one. However, these costs are currently unknown. More specifically, because these rules establish an entirely new regulated industry unrelated to any existing industry in Missouri, the department does not know and can only speculate what any facility or any type of facility within this industry will need to expend to comply with these regulations. No two facilities will be the same in size or operations, and with no facilities existing yet, the department is unable to calculate an average of costs.

As noted in the private fiscal note for 19 CSR 30-95.040, which includes the bulk of the cost-causing regulation for each of the facility types in Chapter 95, the department has collected anecdotal reports from states with somewhat similar regulations to estimate

total cost of building and operating each type of facility. These cost estimates are not tied specifically to Missouri's regulations and are known to include costs that are unrelated to Missouri's regulations. However, as a starting point, the department assumes the costs in other states will be similar to the costs in Missouri. Since this rule represents only a fraction of the total regulatory costs to be incurred, a fraction (specifically, a tenth) of the total costs noted for 19 CSR 30-95.040 are assumed for this rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.060 Infused Products Manufacturing Facility

*PURPOSE: Under Article XIV, Section 1 of the **Missouri Constitution**, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply only to Infused Products Manufacturing Facilities.*

(1) Infused Products Manufacturing Facility Licenses.

(A) The number of manufacturing facility licenses will be limited to eighty-six (86) unless the department determines the limit must be increased in order to meet the demand for medical marijuana by qualifying patients.

(B) A facility license will be issued for a single facility in a single location. Combinations of licenses at the same location must be approved pursuant to 19 CSR 30-95.040(4)(C).

(2) Manufacturing Facility Requirements. In addition to the requirements for manufacturing facilities in 19 CSR 30-95.040, manufacturing facilities shall also comply with the following:

(A) Facilities must ensure all facility employees are trained in at least the following:

1. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of marijuana;

2. Proper use of the statewide track and trace system;

3. Procedures for responding to an emergency, including severe weather, fire, natural disasters, and unauthorized intrusions;

4. The differences between the types of infused products manufactured at that facility and their methods of production; and

5. The facility's safety and sanitation procedures;

(B) Facilities must develop, implement, and maintain an odor control plan, which shall address odor mitigation practices including, but not limited to, engineering controls, such as system design and operational processes, which shall be reviewed and certified by a professional engineer or a certified industrial hygienist as sufficient to effectively mitigate odors for all odor sources;

(C) Manufacturing facilities shall not transfer medical marijuana from the facility, except to a testing facility, until the medical marijuana has been tested by a testing facility, according to the provisions of 19 CSR 30-95.070, and the manufacturing facility has received verification from the testing facility that the medical marijuana passed all required testing;

(D) Manufacturing facilities may only transport medical marijuana—

1. That the facility manufactured;

2. To a dispensary, testing, or other manufacturing facility; and

3. If the facility complies with the requirements of 19 CSR 30-95.100(2);

(E) Manufacturing facilities that produce ingestible medical marijuana-infused products shall comply with the applicable food safety standards set forth in 19 CSR 20-1.025, 19 CSR 20-1.040, and 19 CSR 20-1.050, as applicable. Such facilities are prohibited from producing frozen desserts, as defined by 19 CSR 20-1.030, or acidified foods, as defined by 19 CSR 20-1.042;

(F) Manufacturing facilities shall store all medical marijuana—

1. At the approved location of the facility; or

2. In offsite warehouses that comply with the security requirements of 19 CSR 30-95.040(4)(H), the location requirements of 19 CSR 30-95.040(4)(B), and that have been approved pursuant to 19 CSR 30-95.040(3)(C); and

(G) Manufacturing facilities that use volatile solvents shall install air-handling systems and other controls designed to minimize the risks of explosions and fires. These controls should include systems to prevent ignition; plans for safe storage, use, and disposal of solvents; and policies for continuous staff monitoring of all processes involving volatile solvents.

AUTHORITY: Sections 1.3.(1)(b), 1.3.(2), and 1.3.(3) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $4,300,000 in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.060 Infused Products Manufacturing
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
86	**Manufacturing**	**$4,300,000 - $43,000,000 in the first year.**
Total =		**At least $4,300,000 in the first year.**

III. WORKSHEET

Manufacturing Facility

Eighty-six (86) manufacturing facilities $50,000 - $500,000 for compliance with the regulations applicable to only this facility type in the first year = $4,300,000 - $43,000,000.

IV. ASSUMPTIONS

Each licensed entity will incur costs to comply with all of the regulations in this rule and all other rules in Chapter 95 related to this one. However, these costs are currently unknown. More specifically, because these rules establish an entirely new regulated industry unrelated to any existing industry in Missouri, the department does not know and can only speculate what any facility or any type of facility within this industry will need to expend to comply with these regulations. No two facilities will be the same in size or operations, and with no facilities existing yet, the department is unable to calculate an average of costs.

As noted in the private fiscal note for 19 CSR 30-95.040, which includes the bulk of the cost-causing regulation for each of the facility types in Chapter 95, the department has

collected anecdotal reports from states with somewhat similar regulations to estimate total cost of building and operating each type of facility. These cost estimates are not tied specifically to Missouri's regulations and are known to include costs that are unrelated to Missouri's regulations. However, as a starting point, the department assumes the costs in other states will be similar to the costs in Missouri. Since this rule represents only a fraction of the total regulatory costs to be incurred, a fraction (specifically, a tenth) of the total costs noted for 19 CSR 30-95.040 are assumed for this rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.070 Testing Facility

PURPOSE: Under Article XIV, Section 1 of the ***Missouri Constitution****, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply only to Testing Facilities.*

(1) Access to Testing Facility Certifications. The number of testing facility certifications will be limited to ten (10) unless the department determines the limit must be increased in order to meet the demand for medical marijuana by qualifying patients.

(2) Testing Facility Requirements. In addition to the requirements of 19 CSR 30-95.040, testing facilities shall also comply with the following:

(A) Testing facilities must ensure all facility employees are trained in at least the following:

1. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of marijuana;

2. Proper use of the statewide track and trace system; and

3. Procedures for responding to an emergency, including severe weather, fire, natural disasters, and unauthorized intrusions;

(B) Testing facilities shall comply with International Organization for Standardization (ISO) 17025 standards for personnel at all times;

(C) During any periods of time when a facility no longer complies with ISO 17025 standards for personnel, the facility shall not conduct testing of medical marijuana. Upon return to compliance, the facility shall not resume testing until the department conducts an inspection of the facility;

(D) Testing facilities shall become fully accredited to the standard set forth by ISO 17025 by an International Laboratory Accreditation Cooperation recognized accreditation body. Testing facilities shall achieve such accreditation within one (1) year of the date the facility receives department approval to operate and shall maintain its accreditation as long the facility holds a certification.

1. The scope of the accreditation shall include all medical marijuana testing performed at the facility.

2. Loss of accreditation shall be reported to the department by the testing facility within twenty-four (24) hours of the testing facility receiving notice of the loss.

3. Inspection and audit reports from the accrediting body shall be submitted to the department by the testing facility within ten (10) days of receipt;

(E) Testing facilities shall participate in a proficiency testing program provided by an organization that operates in conformance with the requirements of ISO/IEC 17043 at least twice in a calendar year.

1. The facility shall notify the department of the proficiency testing provider the facility chooses, and the department will work with the proficiency testing provider to determine the schedule the provider will follow when sending proficiency testing samples to facilities for analysis.

2. The facility shall analyze proficiency test samples using the same procedures and equipment as used for testing medical marijuana.

3. Upon receipt of proficiency test results, the facility shall submit copies of those results to the department;

(F) Testing facilities shall install and maintain security equipment designed to prevent unauthorized entrance into limited access areas, which shall include any area where medical marijuana is tested, stored, or disposed, and to prevent diversion and inversion of medical marijuana including:

1. Devices or a series of devices to detect unauthorized intrusion, which may include a signal system interconnected with a radio frequency method, such as cellular or private radio signals, or other mechanical or electronic devices;

2. Electronic monitoring, including:

A. At least one (1) call-up monitor that is nineteen inches (19") or more;

B. A printer capable of immediately producing a clear still photo from any video camera image;

C. Video cameras with a recording resolution of at least 1920 x 1080, or the equivalent, at a rate of at least fifteen (15) frames per second, that operate in such a way as to allow identification of people and activities in the monitored space, and that provide coverage of—

(I) All entrances and exits from limited access areas, including windows; and

(II) All areas in which medical marijuana is tested, stored, or disposed, from at least two (2) angles;

D. A method for storing recordings from the video cameras for at least sixty (60) days in a secure on-site or off-site location or through a service or network that provides on-demand access to the recordings and that allows for providing copies of the recordings to the department upon request and at the expense of the facility;

E. A failure notification system that provides an audible and visual notification of any failure in the electronic monitoring system; and

F. Sufficient battery backup for video cameras and recording equipment to support at least sixty (60) minutes of recording in the event of a power outage;

3. Controlled entry to limited access areas, which shall be controlled by electronic card access systems, biometric identification systems, or other equivalent means. Access information shall be recorded, and all records of entry to limited access areas shall be maintained for at least one (1) year;

(G) Testing facilities shall maintain all sampling and testing records for five (5) years; and

(H) Testing facilities may only transport medical marijuana—

1. That the facility intends to test;

2. From cultivation, dispensary, manufacturing, and other testing facilities;

3. If the facility complies with the requirements of 19 CSR 30-95.100(2).

(3) Sampling Requirements.

(A) Sampling and testing of medical marijuana shall be done at the lot level.

(B) Sampling and testing of each harvest lot or process lot shall be conducted with representative samples such that there is assurance that all lots are adequately assessed for contaminants and that the cannabinoid profile is consistent throughout.

1. In the case of dry, unprocessed marijuana, the maximum amount of marijuana from which a sample may be selected is fifteen pounds (15 lbs.), and a minimum of zero point five percent (0.5%) of a harvest lot will be sampled for testing.

2. In the case of concentrates and extracts, the amount of material required for sampling is—

Process Lot Weight		Sample Increments Required (1±0.2 g)
Pounds	Kilograms	
0-0.50	0-0.23	4
0.51-1.5	0.24-0.68	8
1.51-3.00	0.69-1.36	12
3.01-6.00	1.37-2.72	16
6.01-10.00	2.73-4.58	20
10+	4.58+	32

3. In the case of all other infused products, the amount of material required for sampling is—

Units for Sale	Sample Increments
2-15	2
16-50	3
51-150	5
151-500	8
501-3,200	13
3,201 – 35,000+	20

(4) Testing Requirements.

(A) Testing facilities shall test all lots of medical marijuana produced by cultivation or infused products manufacturing facilities. Testing shall only be performed on the final medical marijuana product equivalent to what will be dispensed to the patient.

(B) Mandatory testing requirements may only be met through testing of samples collected by the testing facility according to section (3) of this rule.

(C) Upon request from a licensed cultivation, manufacturing, or dispensary facility, testing facilities may also test material received directly from the facility, including:

1. Medical marijuana plants at any stage of growth;

2. Infused products at any stage of production; and

3. Components used for the production of final medical marijuana product, such as water or growing materials.

(D) Within five (5) business days of collecting a sample, the testing facility shall file a report in the statewide track and trace system detailing all test results and stating whether the lot passed or failed each required test. Filing of this report must coincide with or precede any notice of test results to the originating facility.

(E) Testing of the cannabinoid profile of the final medical marijuana product shall include those analytes listed below, and the acceptable limits for each analyte will be a percentage deviation from the mean in concentration throughout the lot of fifteen percent (15%) or less:

1. Delta-9 tetrahydrocannabinol (THC), CAS number 1972-08-3;

2. Tetrahydrocannabinol acid (THCA), CAS number 23978-85-0;

3. Cannabidiol (CBD), CAS number 13956-29-1;

4. Cannabidiolic acid (CBDA), CAS number 1244-58-2; and

5. Cannabinol (CBN), CAS number 521-35-7.

(F) Testing for contaminants in the final medical marijuana product shall include, but shall not be limited to:

1. Microbial screening. A test will fail if it shows—

A. A mycotoxin concentration, including aflatoxins and ochratoxin A, of greater than 20 micrograms per kilogram;

B. Pathogenic E. coli or salmonella concentrations detectable in 1 gram; and

C. Pathogenic Aspergillus species A. fumigatus, A. flavus, A. niger, or A. terreus detectable in 1 gram;

2. Chemical residue screening. A test will fail if it shows—

Banned Analytes	Chemical Abstract Services (CAS) Registry number	Action Limit (ppm)
Abamectin	71751-41-2	> 0.5
Acephate	30560-19-1	> 0.4
Acequinocyl	57960-19-7	> 2
Acetamiprid	135410-20-7	> 0.2
Aldicarb	116-06-3	> 0.4
Azoxystrobin	131860-33-8	> 0.2
Bifenazate	149877-41-8	> 0.2
Bifenthrin	82657-04-3	> 0.2
Boscalid	188425-85-6	> 0.4
Carbaryl	63-25-2	> 0.2
Carbofuran	1563-66-2	> 0.2
Chlorantraniliprole	500008-45-7	> 0.2
Chlorfenapyr	122453-73-0	> 1
Chlormequat Chloride	7003-89-6	> 0.2
Chlorpyrifos	2921-88-2	> 0.2
Clofentezine	74115-24-5	> 0.2
Cyfluthrin	68359-37-5	> 1
Cypermethrin	52315-07-8	> 1
Daminozide	1596-84-5	> 1
DDVP (Dichlorvos)	62-73-7	> 1
Diazinon	333-41-5	> 0.2
Dimethoate	60-51-5	> 0.2
Ethoprophos	13194-48-4	> 0.2
Etofenprox	80844-07-1	> 0.4
Etoxazole	153233-91-1	> 0.2
Fenoxycarb	72490-01-8	> 0.2
Fenpyroximate	134098-61-6	> 0.4
Fipronil	120068-37-3	> 0.4
Flonicamid	158062-67-0	> 1
Fludioxonil	131341-86-1	> 0.4
Hexythiazox	78587-05-0	> 1
Imazalil	35554-44-0	> 0.2
Imidacloprid	138261-41-3	> 0.4
Kresoxim-methyl	143390-89-0	> 0.4
Malathion	121-75-5	> 0.2
Metalaxyl	57837-19-1	> 0.2
Methiocarb	2032-65-7	> 0.2
Methomyl	16752-77-5	> 0.4
Methyl parathion	298-00-0	> 0.2
MGK-264	113-48-4	> 0.2
Myclobutanil	88671-89-0	> 0.2
Naled	300-76-5	> 0.5
Oxamyl	23135-22-0	> 1
Paclobutrazol	76738-62-0	> 0.4
Permethrins*	52645-53-1	> 0.2
Prallethrin	23031-36-9	> 0.2
Phosmet	732-11-6	> 0.2
Piperonyl_butoxide	51-03-6	> 2
Propiconazole	60207-90-1	> 0.4
Propoxur	114-26-1	> 0.2
Pyridaben	96489-71-3	> 0.2
Pyrethrins+	8003-34-7	> 1
Spinosad	168316-95-8	> 0.2
Spiromesifen	283594-90-1	> 0.2
Spirotetramat	203313-25-1	> 0.2
Spiroxamine	118134-30-8	> 0.4
Tebuconazole	80443-41-0	> 0.4
Thiacloprid	111988-49-9	> 0.2
Thiamethoxam	153719-23-4	> 0.2
Trifloxystrobin	141517-21-7	> 0.2
Spirotetramat	203313-25-1	> 0.2
Spiroxamine	118134-30-8	> 0.4
Tebuconazole	80443-41-0	> 0.4
Thiacloprid	111988-49-9	> 0.2
Thiamethoxam	153719-23-4	> 0.2
Trifloxystrobin	141517-21-7	> 0.2

* Permethrins cumulative residue of cis- and trans-permethrin isomers
\+ Pyrethrins cumulative residues of pyrethrin 1, cinerin 1 and jasmolin 1

3. Heavy metal screening. A test will fail if it shows—

Metal	Failure Level for Medical Marijuana (Meant for Inhalation) (ppm)	Failure Level for Medical Marijuana-Infused Products (ppm)
Inorganic Arsenic	> 0.2	> 1.5
Cadmium	> 0.2	> 0.5
Total Chromium	> 0.6	> 2.0
Lead	> 0.5	> 0.5
Mercury	> 0.1	> 3.0

4. Residual solvents. A test will fail if it shows—

Solvent	Chemical Abstract Services (CAS) Registry number	Failure Level for Medical Marijuana (Inhalation) (ppm)	Failure Level for Medical Marijuana-Infused Products (ppm)
1,2-Dichloroethane	107-06-2	> 2	> 5
Acetone	67-64-1	> 750	> 5000
Acetonitrile	75-05-8	> 60	> 410
Benzene	71-43-2	> 1	> 2
Butanes (all isomers)	106-97-8	> 800	> 5000
Chloroform	67-66-3	> 2	> 60
Ethanol	64-17-5	> 1000	> 5000
Ethyl acetate	141-78-6	> 400	> 5000
Ethyl ether	60-29-7	> 500	> 5000
Ethylene Oxide	75-21-8	> 5	> 50
Heptane	142-82-5	> 500	> 5000
Hexanes (all isomers)	11054-3	> 50	> 290
Isopropyl alcohol	67-63-0	> 500	> 5000
Methanol	67-56-1	> 250	> 3000
Methylene chloride	75-09-2	> 125	> 600
Pentanes (all isomers)	109-66-0	> 750	> 5000
Propane	74-98-6	> 2100	> 5000
Toluene	79-01-6	> 150	> 890
Trichloroethylene	108-88-3	> 25	> 80
Total Xylenes (ortho-, meta-, para-)	1330-20-7	> 150	> 2170

5. Water activity and moisture content screening. A test will fail if it shows, for dry, unprocessed marijuana, water activity that exceeds 0.65 Aw and moisture content that is not between 5.0% and 13.0%; and

6. Foreign matter screening. A test will fail if it shows—

A. More than 5.0% of stems 3 mm or more in diameter; or

B. More than 2.0% of other foreign matter (mites, hair, dirt, etc.).

(5) Medical marijuana that fails mandatory testing shall not be retested and will be immediately placed on hold by the testing facility through the statewide track and trace system pending disposal or remediation.

(6) Testing facilities may acquire from cultivation, manufacturing, and dispensary facilities raw material, such as plant material, concentrates, extracts, and infused products, for testing method development.

(7) Testing facilities shall retain any portion of a sample that was not used in the testing process for, at a minimum, forty-five (45) business days after testing is complete.

(A) Excess sample material shall be securely stored in a manner that prohibits sample degradation, contamination, and tampering and available to the department upon request.

(B) When no longer subject to retention, sample material shall be disposed pursuant to 19 CSR 30-90.070(4)(E).

AUTHORITY: Sections 1.3.(1)(b), 1.3.(2), 1.3.(3), and 1.3.(4) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least five hundred thousand dollars ($500,000) in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.070 Testing
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
10	**Testing**	**$500,000 - $5,000,000 in the first year.**
Total =		**At least $500,000 in the first year.**

III. WORKSHEET

Testing Facility

Ten (10) testing facilities $50,000 - $500,000 for compliance with the regulations applicable to only this facility type in the first year = $500,000 - $5,000,000.

IV. ASSUMPTIONS

Each licensed entity will incur costs to comply with all of the regulations in this rule and all other rules in Chapter 95 related to this one. However, these costs are currently unknown. More specifically, because these rules establish an entirely new regulated industry unrelated to any existing industry in Missouri, the department does not know and can only speculate what any facility or any type of facility within this industry will need to expend to comply with these regulations. No two facilities will be the same in size or operations, and with no facilities existing yet, the department is unable to calculate an average of costs.

As noted in the private fiscal note for 19 CSR 30-95.040, which includes the bulk of the cost-causing regulation for each of the facility types in Chapter 95, the department has collected anecdotal reports from states with somewhat similar regulations to estimate

total cost of building and operating each type of facility. These cost estimates are not tied specifically to Missouri's regulations and are known to include costs that are unrelated to Missouri's regulations. However, as a starting point, the department assumes the costs in other states will be similar to the costs in Missouri. Since this rule represents only a fraction of the total regulatory costs to be incurred, a fraction (specifically, a tenth) of the total costs noted for 19 CSR 30-95.040 are assumed for this rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.080 Dispensary Facility

*PURPOSE: Under Article XIV, Section 1 of the **Missouri Constitution**, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply only to Dispensary Facilities.*

(1) Access to Dispensary Facility Licenses.

(A) The number of dispensary facility licenses will be limited to one hundred ninety-two (192) unless the department determines the limit must be increased in order to meet the demand for medical marijuana by qualifying patients.

(B) Dispensary facility licenses will be limited to twenty-four (24) in each of the eight (8) United States congressional districts in the state of Missouri as drawn and in effect on December 6, 2018. A map of the state of Missouri showing the applicable boundary lines of Missouri's congressional districts will be available on the department's website at http://medicalmarijuana.mo.gov.

(C) A facility license will be issued for a single facility in a single location. Combinations of licenses at the same location must be approved pursuant to 19 CSR 30-95.040(4)(C).

(2) Dispensary Facility Requirements. In addition to the requirements of 19 CSR 30-95.040, dispensary facilities shall also comply with the following:

(A) Dispensary facilities must ensure all facility employees are trained in at least the following:

1. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of marijuana;

2. Proper use of the statewide track and trace system;

3. Procedures for responding to an emergency, including severe weather, fire, natural disasters, and unauthorized intrusions;

4. Standards for maintaining the confidentiality of information related to the medical use of marijuana, including, but not limited to, compliance with the Health Insurance Portability and Accountability Act;

5. Procedures for verifying the identity and purchase limitations of qualifying patients and primary caregivers;

6. The differences in the purported effects and effectiveness of the strains of medical marijuana available for purchase at that dispensary and the methods of their use; and

7. Recognizing signs of medical marijuana abuse in patients;

(B) Dispensary facilities must make available to all customers patient education materials that include at least the following:

1. Local resources for concerns about addiction, as well as the phone number for the Substance Abuse and Mental Health Services Administration's National Helpline;

2. Information about the different strains of medical marijuana available at that dispensary and the purported effects of the different strains;

3. Information about the purported effectiveness of various methods, forms, and routes of administering medical marijuana;

4. Information about potential risks and possible side effects of medical marijuana use, including risk of poisoning and the phone number for the closest poison control center; and

5. The prohibition on consuming marijuana for medical use in a public place, including the definition of what constitutes a public place pursuant to this rule;

(C) Dispensary facilities must, for every transaction—

1. Receive the transaction order at the dispensary directly from the qualifying patient or primary caregiver in person, by phone, or via the internet, and not from a third party;

2. At the time of sale, verify through the statewide track and trace system that the qualifying patient or primary caregiver is currently authorized to purchase the amount of medical marijuana requested and, in the case of a seed purchase, that the patient or primary caregiver is currently authorized to cultivate medical marijuana;

3. In the case of a delivery order, receive payment before the medical marijuana leaves the dispensary, subject to refund if the delivery cannot be completed; and

4. At the time of sale or delivery, require production of a qualifying patient or primary caregiver identification card, a government-issued photo ID, and in the case of medical marijuana seed purchases, a patient cultivation identification card;

(D) Dispensary facilities must report any incident of theft or attempted theft of medical marijuana to the department within twenty-four (24) hours of the incident;

(E) Dispensary facilities must design their facility and staffing in such a way as to accomplish the following:

1. The general public, qualifying patients, and primary caregivers may only enter the facility through one (1) access point into an area where facility agents shall screen individuals for qualifying patient or primary caregiver status. No medical marijuana may be accessible in this area;

2. Only qualifying patients, primary caregivers, and, if requested by a qualifying patient, up to two (2) additional persons to support the qualifying patient, may enter any areas beyond the facility's access point area; and

3. In any limited access area where medical marijuana is accessible, the facility shall only allow access at any given time for a number of qualifying patients and/or primary caregivers equal to the number of staff available to serve those individuals at that time;

(F) Dispensary facilities shall not sell medical marijuana until the medical marijuana has been tested by a testing facility, according to the provisions of 19 CSR 30-95.070, and been verified as passing all required testing;

(G) Dispensary facilities may only transport medical marijuana—

1. To qualifying patients, primary caregivers, testing, manufacturing, and other dispensary facilities; and

2. If the facility complies with the requirements of 19 CSR 30-95.100(2);

(H) Dispensary facilities that sell ingestible medical marijuana-infused products shall comply with the applicable food safety standards set forth in 19 CSR 20-1.025;

(I) Dispensary facilities shall store all medical marijuana—

1. At the approved location of the facility; or

2. In offsite warehouses that comply with the security requirements of 19 CSR 30-95.040(4)(H), the location requirements of 19 CSR 30-95.040(4)(B), and that have been approved pursuant to 19 CSR 30-95.040(3)(C);

(J) Dispensary facilities shall only sell medical marijuana seeds acquired from cultivation facilities;

(K) Dispensary facilities shall not sell medical marijuana to a qualifying patient or primary caregiver in amounts greater than what that individual is currently authorized to purchase per the statewide track and trace system;

(L) Dispensary facilities shall not sell medical marijuana seeds to a qualifying patient or primary caregiver who is not currently authorized to cultivate medical marijuana;

(M) Dispensary facilities may accept returns and issue refunds or credits as needed except that medical marijuana that has been removed from the packaging in which it arrived at the dispensary, whether removed before sale by the dispensary or after sale by a patient or caregiver, may not be accepted as a return;

(N) Dispensary facilities shall not disburse medical marijuana as part of a promotional event. If a facility disburses medical marijuana free of charge for any other reason, the facility shall record that

disbursement of product in its seed-to-sale system with all relevant entries, including the qualifying patient or primary caregiver information and the amount of medical marijuana disbursed to that qualifying patient or primary caregiver;

(O) Dispensary facilities shall not allow consumption of medical marijuana on their licensed premises; and

(P) Dispensary facilities shall not allow physicians to meet with individuals on the dispensary's premises for the purpose of certifying them as qualifying patients.

AUTHORITY: Sections 1.3.(1)(b) and 1.3.(2) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $9,600,000 in the aggregate.

NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.080 Dispensary
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
192	**Dispensary**	**$9,600,000 – $96,000,000 in the first year.**
Total =		**At least $9,600,000 in the first year.**

III. WORKSHEET

Dispensary Facility

One hundred ninety-two (192) dispensary x $50,000 - $500,000 for compliance with the regulations applicable to only this facility type in the first year – $9,600,000 – $96,000,000.

IV. ASSUMPTIONS

Each licensed entity will incur costs to comply with all of the regulations in this rule and all other rules in Chapter 95 related to this one. However, these costs are currently unknown. More specifically, because these rules establish an entirely new regulated industry unrelated to any existing industry in Missouri, the department does not know and can only speculate what any facility or any type of facility within this industry will need to expend to comply with these regulations. No two facilities will be the same in size or operations, and with no facilities existing yet, the department is unable to calculate an average of costs.

As noted in the private fiscal note for 19 CSR 30-95.040, which includes the bulk of the cost-causing regulation for each of the facility types in Chapter 95, the department has

collected anecdotal reports from states with somewhat similar regulations to estimate total cost of building and operating each type of facility. These cost estimates are not tied specifically to Missouri's regulations and are known to include costs that are unrelated to Missouri's regulations. However, as a starting point, the department assumes the costs in other states will be similar to the costs in Missouri. Since this rule represents only a fraction of the total regulatory costs to be incurred, a fraction (specifically, a tenth) of the total costs noted for 19 CSR 30-95.040 are assumed for this rule.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.090 Seed-to-Sale Tracking

*PURPOSE: Under Article XIV, Section 1 of the **Missouri Constitution**, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply to certification of seed-to-sale tracking systems.*

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

(A) The department will not limit the number of certifications available for seed-to-sale tracking system entities.

(B) The department will begin accepting applications for review on August 3, 2019. All complete applications received by the department that are submitted on or after that date will be approved or denied within one hundred fifty (150) days of that application's submission. An application will be considered complete if it includes all information required for applications by this rule. The department will notify an applicant if an application is incomplete and will specify in that notification what information is missing. Applicants will be given seven (7) days to provide missing information. Failure to provide missing information may result in denial of the application.

(C) The department shall charge an application fee for a seed-to-sale certification and also an annual fee once a certification is granted. 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. The department shall publish the current fees, including any adjustments, on its website at http://medicalmarijuana.mo.gov. The amount of fees due will be the amount that is effective as of the due date for the fee.

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

(A) Name and address of the applicant;

(B) Legal name of the entity, including any fictitious business names, and a certificate of good standing from the Missouri Office of the Secretary of State;

(C) 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

(D) All applicable fees or proof that all applicable fees have already been paid.

(3) Seed-to-Sale Tracking System Requirements. All seed-to-sale tracking systems used by cultivation, manufacturing, dispensary, testing, and transportation facilities shall be capable of—

(A) Interfacing with the statewide track and trace system such that a licensed or certificated facility may enter and access information in the statewide track and trace system as required for inventory control and tracking by 19 CSR 30-95.040(4)(G) and for purchase limitations by 19 CSR 30-95.080(2)(D);

(B) Providing the department with access to all information stored in the system's database;

(C) Maintaining the confidentiality of all patient 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

(D) Producing analytical reports to the department regarding—

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

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

3. Total inventory or sales record adjustments at the facility.

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

(A) Before beginning operations, all certified seed-to-sale tracking system entities shall sign the department's Medical Marijuana Application Programming Interface User Agreement.

(B) No seed-to-sale tracking system entity may sell seed-to-sale tracking services or services related to compliance with seed-to-sale tracking regulations to a licensed or certified facility if it is owned by or affiliated with an entity that currently holds a contract with the state of Missouri for any product or service related to the department's medical marijuana program.

(5) Failure to comply with this rule and failure to abide by the department's Medical Marijuana Application Programming Interface User Agreement may result in revocation of certification.

AUTHORITY: Sections 1.3.(1)(b) and 1.3.(2) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule has an estimated cost to state agencies or political subdivisions of three hundred sixty-two thousand twenty-one dollars ($362,021) in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $17,085,000 in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PUBLIC COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.090 Seed to Sale
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Affected Agency or Political Subdivision	Estimated Cost of Compliance in the Aggregate
Department of Health & Senior Services' costs =	**$362,021 for the first three year period and $119,120 annually thereafter for personnel costs; the cost of the contract is unknown.**
Total =	**$362,021 for the first three year period and $119,120 annually thereafter for personnel costs; the cost of the contract is unknown.**

III. WORKSHEET

Operations Manager

One (1.0) FTE with an annual salary of $60,000 and with estimated fringe benefits of $30,894.

First Year expense (computer, office, furniture etc.) for one FTE listed above - $4,661

On-going expenses (including travel, office supplies, network, printing, etc.) for one FTE - $28,226

$60,000 (salary) + $30,894 (fringe benefits) + $28,226 (on-going expenses) X three (3) =$357,360 + $4,661 (one-time first year expense) = $362,021 for the first three year period.

$60,000 (salary) + $30,894 (fringe benefits) + $28,226 (on-going expenses) = $119,120 annually thereafter.

Facility Licensing System Contract

Estimated contract cost is unknown.

IV. ASSUMPTIONS

In order to process applications for certification as a seed-to-sale system, the department will need an Operations Manager, who will also perform other duties not covered by this proposed rule.

In order to receive, process, and maintain records related to seed to sale certifications, the department will need a Seed to Sale application processing component within a Facility Licensing System, which is an IT solution specifically designed for medical marijuana program functions. The cost for adding a Seed to Sale application processing component to a Facility Licensing System is currently unknown

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.090 Seed to Sale Tracking
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
67	**Seed-to-Sale companies**	**$335,000 in the first year and $670,000 for two additional years in total.**
67	**Seed-to-Sale companies**	**$16,750,000 - $33,500,000 in the first year.**
Total =		**At least $17,085,000 in the first year.**

III. WORKSHEET

Seed-to-Sale companies

Sixty-seven (67) seed-to-sale companies x five thousand (5,000) dollars for application fee in year one = $335,000.

Sixty-seven (67) seed-to-sale companies x five thousand (5,000) dollars for annual fee in years two and three = $335,000.

Sixty-seven (67) seed-to-sale companies x $250,000 - $500,000 for compliance with all regulations applicable to seed-to-sale entities in the first year = $16,750,000 - $33,500,000.

IV. ASSUMPTIONS

Each facility that applies for and receives a seed-to-sale certification from the department will incur application fees and annual fees. The department does not know how many seed-to-sale entities will apply for or receive certifications. However, the department

assumes there will be a similar number of such entities willing and able to be operate in Missouri as there are in Michigan, which is a state with similar requirements for integration with the same statewide track and trace system as will be used in Missouri.

Additionally, every entity that applies for a certification that does not receive one will incur a non-refundable application fee. It is unknown how many of these entities will submit applications.

Finally, each licensed entity will incur costs to comply with all of the regulations in this rule and all other rules in Chapter 95 related to this one. However, these costs are currently unknown. More specifically, because these rules establish an entirely new regulated industry unrelated to any existing industry in Missouri, the department does not know and can only speculate what any facility or any type of facility within this industry will need to expend to comply with these regulations. No two facilities will be the same in size or operations, and with no facilities existing yet, the department is unable to calculate an average of costs.

For purposes of this rule, the department has used anecdotal reports from states with somewhat similar regulations to estimate total costs of building and operating a seed-to-sale business. However, these cost estimates are not tied specifically to Missouri's regulations and are known to include costs that are unrelated to Missouri's regulations.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.100 Transportation Facility

*PURPOSE: Under Article XIV, Section 1 of the **Missouri Constitution**, the Department of Health and Senior Services has the authority to regulate and control Medical Marijuana Facilities. This rule explains what regulations apply only to Transportation Facilities.*

(1) Access to Transportation Facility Certifications.

(A) The department will certify all transportation facilities that can demonstrate they meet minimum standards as described in 19 CSR 30-95.025(4)(A).

(B) A facility license will be issued for a single facility with a single, primary place of business. Combinations of licenses at the same location must be approved pursuant to 19 CSR 30-95.040(4)(C).

(2) Transportation Facility Requirements. In addition to the requirements for transportation facilities in 19 CSR 30-95.040, transportation facilities shall also comply with the provisions of this section.

(A) Transportation facilities must ensure all facility employees are trained in at least the following:

1. The use of security measures and controls that have been adopted by the facility for the prevention of diversion, inversion, theft, or loss of medical marijuana;

2. Proper use of the statewide track and trace system;

3. Procedures for responding to an emergency, including severe weather, fire, natural disasters, and unauthorized intrusions; and

4. Standards for maintaining the confidentiality of information related to the medical use of marijuana, including, but not limited to, compliance with the Health Insurance Portability and Accountability Act of 1996.

(B) Transportation facilities shall transport all medical marijuana from an originating facility to a destination facility within twenty-four (24) hours. When extenuating circumstances necessitate holding medical marijuana longer than twenty-four (24) hours, the transportation facility shall notify the department of the circumstances and the location of the medical marijuana.

(C) Unless allowed by the local government, a transportation facility's primary place of business shall not be sited, at the time of application for certification or for local zoning approval, whichever is earlier, within one thousand feet (1,000') of any then-existing elementary or secondary school, daycare, or church.

1. In the case of a freestanding facility, the distance between the facility and the school, daycare, or church shall be measured from the property line of the facility to the closest point of the property line of the school, daycare, or church.

2. In the case of a facility that is part of a larger structure, such as an office building or strip mall, the distance between the facility and the school, daycare, or church shall be measured from the property line of the school, daycare, or church to the facility's entrance or exit closest in proximity to the school, daycare, or church.

3. Measurements shall be made along the shortest path between the demarcation points that can be traveled by foot.

(D) A transportation facility's primary place of business shall meet the security requirements of 19 CSR 30-95.040(4)(H). In addition to those requirements, transportation facilities shall also comply with the following:

1. All vehicles used to transport medical marijuana shall not be marked in any way that indicates medical marijuana is being transported by that vehicle and shall be equipped with at least—

A. A secure lockbox or locking cargo area made of smooth, hard surfaces that are easily cleaned for storing medical marijuana during transit;

B. A secure lockbox for storing payments and video monitoring recording equipment during transit;

C. Video monitoring of the driver and passenger compartment in the vehicle and of any space where medical marijuana is stored during transit; and

D. GPS tracking;

2. Facility agents transporting medical marijuana shall—

A. Prior to transporting medical marijuana, print an inventory manifest for the trip generated from the statewide track and trace system and create a trip plan, which shall be provided to the facility from which the medical marijuana is transported, and which shall include:

(I) The name of the facility agent(s) transporting the medical marijuana;

(II) The date and start time of transportation;

(III) The anticipated delivery time; and

(IV) The anticipated route of transportation;

B. During transport—

(I) Have facility agent identification card(s) accessible at all times;

(II) Keep a copy of the applicable inventory manifest and trip plan in the transportation vehicle, which shall be placed under the driver's seat or in a compartment beside the driver's seat for the duration of the trip;

(III) Have a means of communication accessible at all times;

(IV) Immediately report to law enforcement any vehicle accidents in which the transportation vehicle is involved; and

(V) Immediately report any loss or theft of medical marijuana to a person designated by the transportation facility for this purpose; and

C. After transport, revise the trip plan to reflect the actual route taken and the end time of transportation and deliver the revised trip plan to a person designated by the transportation facility for this purpose;

3. Any incident of theft or attempted theft of medical marijuana shall be reported to the department within twenty-four (24) hours of the incident; and

4. All trip plans and revised trip plans shall be maintained by the transportation facility for at least five (5) years.

AUTHORITY: Sections 1.3.(1)(b) and 1.3.(2) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule will 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 Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.100 Transportation
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
unknown	**Transportation**	**At least $500 in the first year**
Total =		**At least $500 in the first year**

III. WORKSHEET

Transportation Facility

Unknown number of transportation facilities x unknown cost = unknown cost.

IV. ASSUMPTIONS

Each licensed entity will incur costs to comply with all of the regulations in this rule and all other rules in Chapter 95 related to this one. However, these costs are currently unknown. More specifically, because these rules establish an entirely new regulated industry unrelated to any existing industry in Missouri, the department does not know and can only speculate what any facility or any type of facility within this industry will need to expend to comply with these regulations. No two facilities will be the same in size or operations, and with no facilities existing yet, the department is unable to calculate an average of costs. Finally, the department has been unable to identify another state with requirements similar enough to Missouri's on which to base a reasonable comparison. The department assumes the cost to private entities will be well over $500 in the aggregate.

Title 19—DEPARTMENT OF HEALTH AND SENIOR SERVICES
Division 30—Division of Regulation and Licensure
Chapter 95—Medical Marijuana

PROPOSED RULE

19 CSR 30-95.110 Physicians

*PURPOSE: Under Article XIV, Section 1 of the **Missouri Constitution**, patients with qualifying medical conditions have the right to discuss freely with their physicians the possible benefits of medical marijuana use, and physicians have the right to provide professional advice concerning the same. This rule explains how the department will implement provisions of Article XIV, Section 1 related to Physicians.*

(1) Physician Certification. Physicians will submit certifications electronically through a department-provided, web-based system. In the event of system unavailability, the department will arrange to accept physician certifications in an alternative, department-provided format and will notify the public of those arrangements through its website at http://medicalmarijuana.mo.gov.

(A) Physician certifications must be issued no earlier than thirty (30) days before the date the patient will apply for a patient identification card or renewal of a patient identification card.

(B) Physician certifications must include at least the following information:

1. The physician's name, as it appears in the records of the Missouri Division of Professional Registration;
2. The physician's licensee number;
3. Whether the physician is licensed to practice medicine or osteopathy;
4. The physician's business address, telephone number, and email address;
5. The qualifying patient's name, date of birth, and Social Security number;
6. The qualifying patient's qualifying condition;
7. The physician's recommendation for the amount of medical marijuana the qualifying patient should be allowed to purchase in a thirty- (30-) day period if the recommended amount is more than four (4) ounces of dried, unprocessed marijuana or its equivalent;
8. Statements confirming the following:

A. In the case of a non-emancipated qualifying patient under the age of eighteen (18), before certifying the qualifying patient for use of medical marijuana, the physician received the written consent of a parent or legal guardian who asserts he or she will serve as a primary caregiver for the qualifying patient;

B. The physician met with and examined the qualifying patient, reviewed the qualifying patient's medical records or medical history, reviewed the qualifying patient's current medications and allergies to medications, discussed the qualifying patient's current symptoms, and created a medical record for the qualifying patient regarding the meeting;

C. In the opinion of the physician, the qualifying patient suffers from the qualifying condition; and

D. The physician discussed with the qualifying patient risks associated with medical marijuana, including known contraindications applicable to the patient, risks of medical marijuana use to fetuses, and risks of medical marijuana use to breastfeeding infants; and

9. The signature of the physician and date on which the physician signed.

AUTHORITY: Sections 1.3.(1)(b) and 1.3.(2) of Article XIV, Mo. Const. Emergency rule filed May 24, 2019, effective June 3, 2019, expires Feb. 27, 2020. Original rule filed May 24, 2019.

PUBLIC COST: This proposed rule will cost state agencies or political subdivisions less than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed rule has an estimated cost to private entities of at least $1,956,200 in the aggregate.

*NOTICE TO SUBMIT COMMENTS: Anyone may file a statement in support of or in opposition to this proposed rule with Lyndall Fraker, PO Box 570, Jefferson City, MO 65102 or via email at 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.*

FISCAL NOTE
PRIVATE COST

I. Department Title: Department of Health and Senior Services
Division Title: Division of Regulation and Licensure
Chapter Title: Medical Marijuana

Rule Number and Title:	19 CSR 30-95.110 Physicians
Type of Rulemaking:	Proposed

II. SUMMARY OF FISCAL IMPACT

Estimate of the number of entities by class which would likely be affected by the adoption of the rule:	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:
unknown	**Physicians**	**$1,956,200 for first year**
Total =		**$1,956,200 for first year**

III. WORKSHEET

Physicians

Unknown number of physicians x $97.81/hr x 1 hr x twenty thousand (20,000) patients = $1,956,200 for the first year.

IV. ASSUMPTIONS

Each physician who wants to certify a patient for the medical use of marijuana must meet with the patient and conduct certain administrative functions in connection with that meeting, such as creating a medical record and logging in to the state's Patient Registry system to fill out and submit a certification form. Recent anecdotal and media reports indicate physicians in Missouri are scheduling certification appointments with patients in thirty- (30-) minute increments. The appointments are required by this rule in order for a physician to certify a patient. The department assumes the additional administrative functions related to these appointments that are required by this rule will take approximately thirty (30) minutes per patient. According to the Missouri Economic Research and Information Center, the mean hourly wage for Physician and Surgeons, All Other is $97.81.

The University of Missouri conducted a market analysis to try to predict, among other things, how many patients would apply for medical marijuana access in the first year the program is functioning. The analysis concluded Missouri can expect approximately twenty thousand patients in the first year. It is unknown how many physicians will participate in certifying patients.

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2010—Missouri State Board of Accountancy
Chapter 4—Continuing Education Requirements

PROPOSED AMENDMENT

20 CSR 2010-4.010 Effective Dates and Basic Requirements. The board is amending the purpose and section (1).

PURPOSE: This amendment updates the continuing professional education requirements and adds a grace period.

PURPOSE: This rule sets forth the continuing ***professional*** *education requirements for [renewal of]* ***a*** *license to practice.*

(1) The following requirements of continuing professional education **(CPE)** apply to *[the renewal of licenses pursuant to section 326.286, RSMo:]* **all applicants and active individual licensees who hold a license for an entire calendar year—**

(A) *[An]* **Prior to January 1, 2020, an** applicant seeking renewal of a license shall have completed no less than one hundred twenty (120) hours of *[continuing professional education]* **CPE**, complying with these rules during the three- (3-) year period preceding renewal**, ending December 31, 2019**. Commencing on January 1, 2004 **(and through December 31, 2019)**, a minimum of twenty (20) hours of *[continuing professional education]* **CPE** is required in each calendar year. Commencing on January 1, 2012 **(and through December 31, 2019)**, a minimum of six (6) hours of the required one hundred twenty (120) hours of CPE in a three- (3-) year period preceding renewal shall be in the area of ethics. An applicant seeking renewal of a license shall demonstrate participation in a program of learning meeting the standards set forth in the Statement on Standards for Continuing Professional Education (CPE) Programs jointly approved by National Association of State Boards of Accountancy (NASBA) and American Institute of Certified Public Accountants (AICPA) as provided in 20 CSR 2010-4.020, or such other standards acceptable to the board*[;]***.**

(B) *[An applicant seeking reinstatement of their license, and who has not been practicing public accounting, shall submit evidence to the board that he or she has completed forty (40) hours of continuing professional education (CPE) during the twelve (12) months previous to making application for reinstatement of the license; or;]* **Beginning January 1, 2020, a licensee shall complete and maintain documentation of no less than forty (40) hours of qualifying CPE each calendar year a licensee holds a license. A minimum of two (2) hours of the required forty (40) hours of CPE shall be in the area of ethics.**

(C) *[The applicant agrees to obtain forty (40) hours of continuing professional education within sixty (60) days of applying for reinstatement]* **Beginning January 1, 2021, licensees in good standing will be granted a thirty-one (31) day grace period ending January 31 after each calendar year to cure a CPE shortage for the preceding calendar year. Licensees requesting to use this grace period shall submit a written application to the board on a form prescribed by the board.**

(D) *[A nonresident licensee seeking renewal of a license in this state shall be determined]* **The board may deem a nonresident applicant or licensee** to have met the CPE requirements of this *[rule]* **chapter** by meeting the CPE requirements *[for renewal of a license]* in the state in which the **licensee resides or where the** licensee's principal office is located*[;]*. **Nonresidents may request approval by submitting written application to the board.**

[(E) Nonresident applicants for renewal shall demonstrate compliance with the CPE renewal requirements of the state in which the licensee's principal office is located by attesting on an application provided by the board;

(F) If a nonresident licensee's principal office state has no CPE requirements for renewal of a license, the nonresident licensee must comply with all CPE requirements for renewal of a license in this state.]

AUTHORITY: section 326.271, RSMo [Supp. 2012] ***2016****. This rule originally filed as 4 CSR 10- 4.010. Original rule filed Nov. 5, 1984, effective Feb. 11, 1985. Amended: Filed Aug. 3, 1988, effective Nov. 24, 1988. Amended: Filed April 18, 1989, effective July 27, 1989. For intervening history, please consult the* ***Code of State Regulations****. Amended: Filed May 20, 2019.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment 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 amendment with the Board of Accountancy, PO Box 613, Jefferson City, MO 65102, by facsimile at 573-751-0012, or via email at mosba@pr.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.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2010—Missouri State Board of Accountancy
Chapter 4—Continuing Education Requirements

PROPOSED AMENDMENT

20 CSR 2010-4.020 Qualifying Programs. The board is amending section (1).

PURPOSE: This amendment clarifies qualifying requirements a Continuing Professional Education (CPE) course needs to meet to be accepted by the board.

(1) Programs Qualifying for Continuing Professional Education **(CPE)** Credit.

(A) Standards. *[Effective January 1, 2003 a]***A** program qualifies as acceptable *[continuing professional education for purposes of section 326.286, RSMo and these rules if it is a program of learning that contributes to the growth in the professional knowledge and professional competence of a licensee. The]* **CPE if the** program *[must]* meet**s or exceeds** the minimum standards of quality of development, presentation, measurement, and reporting of credits set forth in the Statement on Standards for Continuing Professional Education **(CPE)** Programs jointly approved by the National Association of State Boards of Accountancy (NASBA) and the American Institute of Certified Public Accountants (AICPA) or such other standards acceptable to the board.

(B) The Statement on Standards for Continuing Professional Education (CPE) Programs, revised August 2016 and effective September 1, 2016, published by the NASBA and AICPA are incorporated in this rule by reference. A copy of the Statement on Standards for Continuing Professional Education (CPE) Programs may be obtained online at www.nasbaregistry.org, or by contacting NASBA, 150 Fourth Avenue N., Suite 700, Nashville, TN, 37219 or AICPA, 1211 Avenue of the Americas, New York, NY 10036 This rule does not incorporate any later amendments or additions to the standards.

*[(B)]***(C)** Subject Areas. The board will accept programs meeting the standards set forth in the Statement on Standards for Continuing Professional Education (CPE) Programs *[jointly approved by the NASBA and the AICPA or standards deemed by the board to be comparable thereto]* **(September 1, 2016) and as set forth in this rule**. **The board will accept the following sources of CPE as defined in the Statement on Standards:**

1. Group programs;

2. Self-study programs;

3. Blended learning programs;

4. Nano-learning programs;

5. Instructor/developer of CPE programs;

6. Technical reviewer of CPE programs or work on technical committees;

7. Independent study;

8. College or university courses in accounting or accounting-related field of study; except basic or introductory accounting courses or CPA exam preparation/review courses; and

9. Authorship of published articles, books, and other publications relevant to maintaining or improving professional competence. Authorship hours claimed for CPE shall not exceed two (2) hours in any calendar year.

*AUTHORITY: section 326.271, RSMo [Supp. 2003] **2016**. This rule originally filed as 4 CSR 10-4.020. Original rule filed Nov. 5, 1984, effective Feb. 11, 1985. Amended: Filed June 4, 1990, effective Nov. 30, 1990. Rescinded and readopted: Filed April 5, 2004, effective July 30, 2004. Moved to 20 CSR 2010-4.020, effective Aug. 28, 2006. Amended: Filed May 20, 2019.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment 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 amendment with the Board of Accountancy, PO Box 613, Jefferson City, MO 65102, by facsimile at 573-751-0012, or via email at mosba@pr.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.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2010—Missouri State Board of Accountancy
Chapter 4—Continuing Education Requirements

PROPOSED AMENDMENT

20 CSR 2010-4.031 Continuing Professional Education (CPE) Documentation. The board is amending section (1).

PURPOSE: This amendment clarifies the requirements for documenting CPE and adds a thirty (30) day grace period.

(1) Continuing Professional Education **(CPE)** Records.

(A) *[Applicants for renewal of a license shall attest on an application provided by the board that they have met the requirements for participation in a program of continuous learning as set forth by the board or contained]* **All licensees must maintain documentation demonstrating compliance in meeting their CPE requirements.**

(B) Acceptable documentation requirements are set forth in the Statement on Standards for Continuing Professional Education (CPE) Programs *[jointly approved by the National Association of State Boards of Accountancy (NASBA) and the American Institute of Certified Public Accountants (AICPA)]* **in rule 20 CSR 2010-4.020**.

(C) Responsibility for documenting the acceptability of the program and the validity of the credits rests with the applicant **or license holder** who should retain such documentation for a period of five (5) **calendar** years *[following completion of each learning activity]*.

*[(B)]***(D)** The board may verify *[information submitted]* **the CPE reported** by applicants for licensure **and licensees**. In cases where the board determines that the requirement is not met, the board may grant an additional period of time in which the deficiencies *[can]* **may** be cured.

(E) Beginning January 1, 2021, a licensee in good standing may cure their CPE deficiencies due to a disallowance of courses or hours by the board as follows:

1. A licensee shall have thirty (30) days from the date of notice of the board's assertion of a licensee's failure to comply with the annual qualifying CPE requirements to obtain qualifying CPE hours.

2. Licensees requesting to use the above cure period shall submit a written application to the board on a form provided by the board no later than thirty (30) days from the date of the board's notice.

(F) Failure to comply with CPE requirements and/or fraudulent reporting of CPE is a basis for disciplinary action.

*AUTHORITY: section[s] 326.271**, RSMo 2016,** and **section** 326.310, RSMo Supp. [2009] **2017**. This rule originally filed as 4 CSR 10-4.031. Original rule filed April 5, 2004, effective July 30, 2004. Moved to 20 CSR 2010-4.031, effective Aug. 28, 2006. Amended: Filed Feb. 23, 2010, effective Aug. 30, 2010. Amended: Filed May 20, 2019.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment 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 amendment with the Board of Accountancy, PO Box 613, Jefferson City, MO 65102, by facsimile at 573-751-0012 or via email at mosba@pr.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.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2010—Missouri State Board of Accountancy
Chapter 4—Continuing Education Requirements

PROPOSED AMENDMENT

20 CSR 2010-4.035 Inactive Licenses. The board is amending section (1), adding sections (2)-(5), renumbering, and amending section (6).

PURPOSE: This amendment updates the requirements and restrictions for an inactive license.

(1) *[Inactive License.]* A licensee *[who received a license after*

August 28, 2001, and] who is not practicing public accounting**, as defined in section 326.256.1(18), RSMo,** in any setting may be granted an inactive license. An inactive licensee *[shall place]* **may use the CPA designation only with** the word "inactive," "retired," or "ret." *[in association with their certified public accountant title. The inactive licensee shall not perform or offer to perform for the public any public accounting services or professional services, including attest, review, or compilation services or any management advisory, financial advisory, or consulting services or the preparation of tax returns, the furnishing of advice on tax, or any other accounting matters.]*

(2) Licensees seeking an inactive license shall apply in writing on the form provided by the board and must submit biennial renewal applications in order to maintain inactive status.

(3) Licensees applying for inactive status shall pay an inactive application fee and a biennial renewal fee as set forth by rule.

(4) Individuals who hold a CPA certificate, and are not practicing public accounting in any form, are not required to hold an inactive license in order to continue to use the CPA designation as set forth in section 326.292, RSMo.

(5) Licensees may allow their license to expire in lieu of an inactive license status. An individual not applying for renewal continues to hold an expired license and may apply for late renewal until the license period ends. At the end of the license period, the individual is deemed to hold a lapsed license. Licensees who hold an expired or lapsed license shall not practice public accounting nor use the CPA designation in any form, as provided by section 326.292, RSMo.

*[(2)]***(6)** *[The]* **Individuals who hold a lapsed or** inactive *[licensee]* **license** may return to active status by applying for reinstatement of license as defined in 20 CSR 2010-2.075.

*AUTHORITY: sections 326.262 and 326.286.6, RSMo Supp. [2009] **2017**. Original rule filed Feb. 23, 2010, effective Aug. 30, 2010. Amended: Filed May 20, 2019.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment 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 amendment with the Board of Accountancy, PO Box 613, Jefferson City, MO 65102, by facsimile at 573-751-0012, or via email at mosba@pr.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.*

Title 20—DEPARTMENT OF INSURANCE, FINANCIAL INSTITUTIONS AND PROFESSIONAL REGISTRATION
Division 2010—Missouri State Board of Accountancy
Chapter 4—Continuing Education Requirements

PROPOSED AMENDMENT

20 CSR 2010-4.041 Continuing Professional Education (CPE) Exceptions and Waivers. The board is amending section (1).

PURPOSE: This amendment clarifies the exceptions and waivers of CPE.

(1) Exceptions.

(A) A licensee who *[received a license after August 28, 2001, and who]* is not practicing public accounting in any setting may be granted an inactive license at the discretion of the board and be exempted from the continuing professional education (CPE) requirements by the board.

(B) The board may *[in particular cases]* make exceptions to the requirements *[set out in 20 CSR 2010-4.010]* **for CPE** for reasons of individual hardship including health, military service, foreign residence, or other good cause.

(C) Applicants **or licensees** requesting a waiver of CPE requirements shall do so in writing and shall provide documentation supporting the request if required by the board.

*AUTHORITY: section 326.271, RSMo [Supp. 2009] **2016**. This rule originally filed as 4 CSR 10-4.041. Original rule filed April 5, 2004, effective July 30, 2004. Moved to 20 CSR 2010-4.041, effective Aug. 28, 2006. Amended: Filed Feb. 23, 2010, effective Aug. 30, 2010. Amended: Filed May 20, 2019.*

PUBLIC COST: This proposed amendment will not cost state agencies or political subdivisions more than five hundred dollars ($500) in the aggregate.

PRIVATE COST: This proposed amendment 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 amendment with the Board of Accountancy, PO Box 613, Jefferson City, MO 65102, by facsimile at 573-751-0012 or via email at mosba@pr.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.*