

NEW RULE

538-X-3-.20ER

Special Procedures Relating to Certain Applications

The following special procedures shall apply to all license applications that both (1) were subject to an administrative stay issued by the Commission on August 31, 2023, or the Temporary Restraining Order as referenced in orders issued by the Montgomery County Circuit Court dated August 21, 2023, August 30, 2023, and September 11, 2023; and (2) are, or become, subject to an award of license by the Commission on or after the effective date of this Rule.

Notwithstanding any other provision of the Commission's Rules:

1. Applicants whose applications were deemed submitted by the Commission but, because of file size limitations in the application portal, were either (i) unable to submit all or portions of exhibits associated with such application; or (ii) required to submit exhibits that were compressed, truncated or otherwise distorted, shall be permitted to submit, within ten (10) business days after the date on which any such applicant becomes subject to an award of license by the Commission, a full copy (PDF via USB flash drive) of such exhibits to the Commission along with the following sworn statement:

STATE OF

COUNTY OF

CERTIFICATION

I hereby attest and certify that:

1. I am [insert name]. I am [insert position] of [insert applicant name] (hereafter the "Applicant") and am authorized to submit this certification on its behalf. I have knowledge of the facts set forth in this certification.

2. The Applicant attempted in good faith to submit the exhibits listed below on or before the application deadline of December 30, 2022 but, because of file size limitations in the application portal, was either (i) previously not submitted; or (ii) compressed, truncated or otherwise distorted:

[insert description of exhibits]

3. For each exhibit listed above, I have attached a true and correct copy of metadata confirming (a) the date and time of such exhibit's creation and modification, reflecting the existence of such exhibit as of the application deadline; and (b) that such exhibits have not been altered since such date.

SIGNED this the day of , 2023.

[insert name]

SWORN TO and subscribed before me on this the ____ day of _____, 2023.

NOTARY PUBLIC

My Commission Expires:

[SEAL]

2. After submission of full copies of any exhibits referenced in Paragraph 1 above, the Commission shall make available to the public copies of all application materials for each applicant. The application materials so disclosed shall be in unredacted form, except for (a) personally identifiable information and (b) trade secrets or competitively sensitive information. Information bearing on the financial ability of the applicant shall generally not be deemed competitively sensitive information for this purpose, however, nothing in this paragraph shall require disclosure of information obtained by the Commission from third parties and exempt from the Open Records Act under Ala. Code § 20-2A-55 (c) and (d). Applicants which have previously submitted a public copy of their application with redactions not permitted under this paragraph shall submit a new redacted copy (PDF via USB flash drive) to assist the agency staff with publication requirement within ten (10) business days after the date on which any applicant becomes subject to an award of license by the Commission, and the agency staff reserves the right to make further revisions to the redactions as required to meet the requirements of this paragraph. The Commission shall follow the procedure set forth in Ala. Code § 20-2A-56(a) regarding this information and the submission and receipt of public comment and shall permit additional public comments to be filed within thirty (30) days after the date on which any applicant becomes subject to an award of license by the Commission.

3. The Commission will provide notice to all applicants who are preliminarily determined to have failed one or more pass/fail items under Ala. Code § 20-2A-56(b) and Ala. Admin. Code § 538-x-3-.14, and any such applicant shall have ten (10) business days to show cause, through a written submission, as to why their application should not be rejected due to such pass/fail item(s).

4. Each Applicant will be given an opportunity, but not the obligation, to address their application and to answer questions from the Commissioners or the Commission staff, subject to the following time limitations:

License Category	Individual Time Limitation
Integrated Facility	45 Minutes
Cultivator	20 Minutes
Secure Transporter	20 Minutes
State Testing Laboratory	20 Minutes
Processor	20 Minutes
Dispensary	20 Minutes

The presentations will be scheduled by the Commission, to be conducted not earlier than thirty (30) days after the date on which any applicant becomes subject to an award of license by the Commission. The presentations shall be open to the public. Those participating in the presentations on behalf of the applicant must be physically present at the meeting site designated by the Commission, however, members of the Commission may observe and ask questions in person or by virtual means. As part of such presentation, and without extending the time limitation provided herein, Applicants may present video evidence or a written brief, not exceeding 20 pages, regarding the applicant's existing or proposed facilities, other matters identified in their application, or the appropriateness and application of the previous scoring results, which may include, but is not limited to, identification of instances where the applicant asserts that the scoring results were impacted by truncated, compressed, distorted or missing exhibits permitted to be submitted in full as provided in Paragraph 1 above. (Example: An applicant who is allowed 20 minutes for a presentation and who has submitted a 10-minute video will be permitted, at the presentation, to show the video and make a 10-minute live presentation.) Any such video evidence or written brief shall be submitted to the Commission at least five (5) business days in advance of the applicant's scheduled presentation. Applicants presenting a video must submit the video via USB flash drive. Applicants presenting a written brief must submit an original electronic version (PDF via USB flash drive) and twenty (20) hard copies. The presentation sessions shall be managed by the Commission's Chair or his or her designee, who may extend the time limitations as needed to accommodate questions from Commissioners. Each applicant making a presentation shall be responsible for the cost for the court reporter and preparation of a transcript of their presentation and question and answer session. Presentation sessions may be videotaped to be available for later review by Commissioners.

5. Regarding third-party scoring data and tabulations previously generated for applications:

a. Within ten (10) business days after the date on which any applicant becomes subject to an award of license by the Commission, the Commission will make available to all applicants:

(i) General scoring criteria utilized by the third-party scorers, along with information in the Commission's possession regarding each scorer's training and qualifications, excluding personal identifying information.

(ii) Notice of any instance where the same scorer was not used in scoring the same sections of applications within a license category.

b. In addition to the general disclosures identified in Subparagraph a. above, the Commission will, upon written request received by the Commission within thirty (30) days after the date on which any applicant becomes subject to an award of license by the Commission, provide any such requesting Applicant with the opportunity to inspect scoring sheets and any specific notes of third-party evaluators for such Applicant in the Commission's possession, subject to the prior redaction of personal identifying information of the evaluator or third parties other than the applicant. Fees for the compilation, redaction and copying of such material by the Commission shall be subject to the same payment(s) as permitted to be imposed by the Commission for public records requests.

c. As provided in Ala. Admin. Code § 538-X-3-.12, the Commission remains the primary decisionmaker with regard to licensing and each Commissioner retains full discretion to act independently of the previously generated third-party scoring and evaluations in applying the statutory and regulatory criteria.

6. As soon as practicable after the presentations are completed for an individual license category, the Commission will conduct a meeting to deliberate and award licenses in such license category. In order to determine the order in which Applicants should be considered, each Commissioner will be given an opportunity to submit, in an open meeting, a written form providing an overall preliminary rank, in descending order, of each of the Applicants in the license category, giving due consideration to all statutory and regulatory criteria. Such forms shall be tabulated and averaged by the Commission staff and used solely to determine the order in which individual Applicants are subsequently considered. In those instances where two or more applicants receive identical average rankings, the order shall be determined by a drawing. The Chair will call for a motion to approve or deny each application in the order established above. Following such motion, duly seconded, the Chair will provide an opportunity for further deliberations and a vote.

7. The Applicant has the sole responsibility to ensure proper and timely submission of any form, document, video, or other item submitted to the Commission pursuant to the provisions of this rule. Any form, document, video, or other item submitted to the Commission pursuant to the provisions of this rule shall be mailed or hand-delivered to the Commission at the address provided below.

Alabama Medical Cannabis Commission
RSA Dexter Avenue Building
445 Dexter Avenue, Suite 8040
Montgomery, AL 36104

8. If any provision of this Rule, as amended, or the application of such provision or amendment to any person or circumstance is invalidated by a Court, the remainder of this Rule, as amended, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

9. This emergency rule shall remain in effect for 120 days, or the adoption of a superseding permanent rule, whichever is less.

CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR

(Pursuant to Code of Alabama 1975 §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on the 12th day of July 2022 and filed with the agency secretary on the 12th day of July 2022.

AGENCY NAME: Alabama Department of Agriculture and Industries

 Amendment X New Repeal (Mark appropriate space)

Chapter No.: Chapter 80-14-1

(If amended rule, give specific paragraph, subparagraphs, etc., being amended) **Changes are noted in rules 80-14-1-.03, 80-14-1-.04 (subparagraph 5(c)), 18-14-1-.05, and 80-14-1-.08.**

Chapter Title: Medical Cannabis Cultivation.

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Chapter adopted with changes to address the majority of public comments.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XL
ISSUE NO. 8, DATED May 31, 2022.

Statutory Rulemaking Authority: Code of Ala., 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

(Date filed)
(For LRS Use Only)

REC'D & FILED

JUL 12 2022

LEGISLATIVE SVC AGENCY



Certifying Officer or his or her
Deputy

(NOTE: In accordance with §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.)

APA-7

TRANSMITTAL SHEET FOR
BUSINESS ECONOMIC IMPACT STATEMENT
(Section 41-22-5.1)

Control

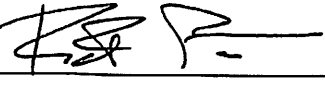
No. Department/Agency Alabama Department of Agriculture and Industries

Rule No. 80-14-1

Rule Title: Medical Cannabis Cultivation

 X New Amend Repeal Adopt by
Reference

Attached is a Business Economic Impact Statement filed pursuant to Section 41-22-5.1, Code of Alabama 1975.

Signature of Filing Officer 

Date 7-12-22

(DATE File)
(STAMP)

Business Economic Impact Statement for Ala. Admin Code Chapter 80-14-1- Medical Cannabis Cultivation

During the public comment period for new Ala. Admin Code Chapter 80-14-1 relating to Medical Cannabis Cultivation, the Alabama Department of Agriculture and Industries (ADAI) received various comments concerning the proposed rules. The vast majority of these comments were addressed by amendments to the proposed rules. The rules will only apply to the cultivation function of the 5 integrated facilities and 12 cultivators licensed by the Alabama Medical Cannabis Commission (AMCC). None of the rules in this chapter are the result of a federal requirement.

Comments requesting that ADAI not approve medical cannabis cultivars could not be accommodated because Ala. Code Section 20-2A-62 (d)(4) requires that cultivars, "... must be approved by the department prior to acquisition of plant material for cultivation." Similarly, comments discussing the potential for confusion or delay due to having multiple state agencies involved in the medical cannabis regulatory process cannot be addressed by administrative rule because Act 2021-450 created the structure wherein AMCC, ADAI, and other existing state agencies cooperate to implement the Act.

The reporting, recordkeeping, and other administrative costs of compliance with these rules will be minimal because most of the requirements will be in conjunction with the reporting, recordkeeping, and administrative costs required to comply with the rules proposed by the AMCC and the requirement of utilizing a seed-to-sale tracking system as required by Act 2021-450.

Alabama Department of Agriculture and Industries

**Food Safety
Administrative Code**

**Chapter 80-14-1
Medical Cannabis Cultivation**

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80-14-1-.01 Purpose.

To authorize the Alabama Department of Agriculture and Industries to regulate the cultivation of cannabis by licensed cultivators or licensed integrated facilities pursuant to Section 20-2A-1 et. seq., Code of Alabama 1975.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.02 Definitions.

For the purpose of this Chapter and to further implement and expand upon the definitions set out in § 20-2A-3, Code of Alabama 1975 (as amended), the following terms are defined as follows:

(1) Alabama Medical Cannabis Commission, Commission, or AMCC means the state agency created by Act # 2021-450 to regulate the medical cannabis industry in Alabama.

(2) Cultivation. The growing of cannabis until the time of harvest. Cultivation may occur on the premises of a licensed cultivator or a licensed integrated facility.

(3) Cultivator means an individual or entity licensed by the Alabama Medical Cannabis Commission to grow cannabis.

(4) Cultivation Facility. The enclosed structure, or portion of an enclosed structure, where cannabis is planted, grown, harvested, and stored to await transport or processing.

(5) Department means the Alabama Department of Agriculture and Industries.

(6) Enclosed Structure. A permanent structure to cultivate cannabis using artificial light exclusively or as a supplement to natural sunlight. The term may include a greenhouse or similar structure that protects plants from variable temperature, precipitation, wind, and other elements. The enclosed structure must meet the security requirements of 20-2A-1 et. seq., Code of Alabama 1975.

(7) Integrated Facility means an entity licensed by the Alabama Medical Cannabis Commission to grow, process, transport, and dispense cannabis.

(8) Operations Plan. The detailed plan that a Cultivator or Integrated Facility submits to the Department and the Commission, describing the operating standards the Cultivator or Integrated Facility will use to ensure the health, safety, and security of the public and the integrity of medical cannabis facility operations.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.03 Cultivator or Integrated Facility license required.

A medical cannabis cultivator or integrated facility must have applied to, be licensed by, and be in good standing with, the AMCC. If the AMCC revokes or suspends the license of a cultivator or integrated facility, the cultivator or integrated facility must stop growing cannabis and destroy any cannabis in its possession pursuant to §80-14-1-.11, Ala. Admin Code.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.04 Operations Plan Required

- (1) Prior to Cultivation and as part of the license application, each Cultivator and Integrated Facility must submit an Operations Plan to the Department and the AMCC.
- (2) Once the Operations Plan is approved by the Department and the AMCC as part of the licensing process, the Cultivator or Integrated Facility must operate consistently with the approved plan. Cultivators and Integrated Facilities may operate outside their originally approved Operations Plan only if they receive written permission from the Department and Commission, as applicable, for:
 - (a) a waiver, such that they may operate outside the Operations Plan for a specified period of time and for good cause shown, after which time operations in accordance with the Operations Plan will resume; or
 - (b) an amended Operations Plan, which will be in effect and must be followed from the time of the Department's and Commission's approval.
- (3) The Operations Plan must include a security plan to ensure cannabis and medical cannabis remain secure at all times, including but not limited to requiring that all cultivation facilities are (a) fully surrounded by perimeter barriers deterring unauthorized access to and limiting visibility of the cultivation facility; (b) housed in an enclosed structure as defined herein; (c) secured at all times by locks requiring keypad, card or similar coded interface to access; and (d) monitored by 24-hour video surveillance that shows with reasonable clarity the identity and activity of persons at all entry and exit points as well as in all growing areas.

- (4) The Operations Plan must include a grow plan that shall show the number of cannabis plants and methods of cultivation the Cultivator or Integrated Facility intends to utilize.
- (5) In addition to the foregoing, the Operations plan must, at a minimum, include protocols to address all the following requirements:
- (a) All cultivation facilities shall be protected by a 24-hour monitored security alarm system.
 - (b) All individuals entering and exiting cultivation facilities, including employees, shall be identified, logged in and out, and badged; in addition to the foregoing, all non-employees must report the purpose of their presence on the premises.
 - (c) Video monitoring inside the cultivation facility must cover all entry/exit points and all areas where cannabis is present. Monitoring cameras must be of such numbers, scope and clarity as to ~~allow for facial recognition~~ determine facial features of all persons in the camera's view at all times of day, such that the identity and activities of such persons being monitored is readily visible. Monitoring cameras at vehicle entry/exit points must be of such numbers, scope, and clarity to record the license plate information and description of all vehicles entering/exiting the facility.
 - (d) The Cultivator or Integrated Facility shall provide the Department and the AMCC with engineering plans and specifications of the entire cultivation facility. The plans and specifications shall include:
 - (1) A detailed plan and elevation drawings of all operational areas involved with the production of cannabis plants. This should include dimensions and elevation referenced to a single facility benchmark;
 - (2) Cross-sections that show the construction details and their dimensions to provide verification of construction materials, enhancement for security measures, and bio-security measures;
 - (3) Identification of all employee-accessible nonproduction areas;

- (4) The location, size, and capacity of all storage areas, ventilation systems, and equipment used for the production of cannabis;
 - (5) The location and door material specifications of all entrances and exits to the cultivation facility, as well as the physical makeup and specifications of all outer walls of the enclosed structure;
 - (6) The location and specifications of any windows, skylights and roof hatches;
 - (7) The location of all monitoring cameras and their field of view, verified to be operating 24 hours per day;
 - (8) The location of all alarm inputs (door contacts, motion detectors, duress/hold up devices) and alarm sirens;
 - (9) The location of the digital video recorder and alarm control panel;
 - (10) The location of all restricted, employee-accessible and public areas;
 - (11) The location where all plant inputs and application equipment are stored;
 - (12) The location of all enclosed, secure areas or loading/unloading docks out of public view for the loading/unloading of cannabis or medical cannabis into or out of any motor vehicle for secure transport.
 - (13) The location of any area used to store medical cannabis that has been returned to the cultivation facility from a processor or dispensary.
- (e) A detailed plan for the destruction and disposal of cannabis plants, including parts thereof, and any related materials that cannot or will not be processed, transported, or dispensed.
 - (f) A detailed plan to ensure chain of custody of cannabis and medical cannabis within the cultivation facility.
 - (g) A detailed plan to inventory and track cannabis and medical cannabis within the facility and to interface with the Statewide Seed-to-Sale Tracking system.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.05 Insurance Requirements for Cultivators

Cultivators and ~~ifs~~ Integrated Facilities are required to maintain a minimum of two million dollars (\$2,000,000) of liability and casualty insurance and shall establish and at all times maintain the minimum level of other financial guarantees, if appropriate and required by the Commission for all licensees. Liability insurance shall include, at a minimum, workers' compensation insurance as well as insurance against loss, damage or injury to any non-employee while on the premises; loss, damage or injury to the body or personal property of any third party as a proximate result of the acts of the Cultivator or Integrated Facility or its personnel; and loss, damage or injury to any foreseeable person as the result of any products derived from cannabis that had once been in the custody or control of the Cultivator or Integrated Facility. At a minimum the cultivator or integrated facility must be insured against, fire, flood, wind, or other acts of God.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-52, 20-2A-53, 2-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.06 Enclosed Structure & Cultivation Requirements

- (1) All cannabis must be cultivated in an enclosed structure; each cannabis plant or batch of cannabis plants must be cultivated in an individual receptacle containing soil or growing media, so as to foster portability, limit cross-contamination, and facilitate proper monitoring of each plant.
- (2) Containers may be for individual plants or for batches of plants as long as each plant is clearly identified and traceable.
- (3) No cultivation is allowed outdoors or directly in the ground.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.07 Cultivars must be approved by Department

(1) Cultivators and Integrated Facilities may only cultivate cannabis cultivars approved by the department prior to acquisition of plant material. Cultivars cannot be derived from hemp or industrial hemp as defined by Ala. Admin. Code Rule 80-10-21-.02 (19) but must be derived from cannabis plants that have a high likelihood of producing medical cannabis.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.08 Location and Visibility

~~(1) To deter cross pollination, cross contamination and erosion of the yield, Cultivators and Integrated Facilities shall not be located within 1 mile (5,280 feet) of any other cultivator or integrated facility, hemp grower licensed by the department, or any known stands of cannabis not licensed by the department or AMCC.~~

~~(2)~~ (1) Cultivators and Integrated Facilities should take steps to limit the visibility of cannabis, in any form, from outside the perimeter barrier of the cultivation facility.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.09 Background Checks

(1) Cultivators and Integrated Facilities must comply with the background check requirements mandated by the AMCC pursuant to Ala. Code Section 20-2A-59.

(2) Cultivators and Integrated Facilities must present evidence to the Department, upon request, that all employees comply with the requirements of §20-2A-62(d)(3), Code of Alabama 1975 (as amended), relating to crimes involving controlled substances.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.10 Inspections.

Cultivators and Integrated Facilities shall submit to all inspections required by §20-2A-52, Alabama Code 1975 (as amended). The Department will conduct inspections of cultivators and the cultivation facilities of integrated facilities at least twice per calendar year. Cultivators and Integrated Facilities must allow their cultivation facilities to be inspected by the Department at any time.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.11 Destruction and Disposal Procedures

Any cannabis material that is not used in medical cannabis must be destroyed in such a way as to render the material unusable and unrecognizable. Each Cultivator and Integrated Facility must include their destruction and disposal procedures in their operations plan. Cultivators and Integrated Facilities must enter destruction and disposal records into the Statewide Seed-To-Sale Tracking System.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-52, 20-2A-53, 2-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.12 Sales of Cannabis; Prohibited Activities

- (1) Cultivators and Integrated Facilities shall only sell or transfer cannabis to other licensees of the AMCC as provided by the Act, these rules, or rules adopted by the AMCC. Cultivators may not process, transport, or dispense cannabis in any form or for any reason.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.13 Pesticide Usage and Testing

- (1) Cultivators and Integrated Facilities shall fully comply with all laws and administrative rules relating to the usage of pesticides in the State of Alabama.

- (2) The Department may perform pesticide testing on a random basis or if the representatives of the Department have reason to believe that a pesticide may have been applied to cannabis in violation of the product label.
- (3) At least quarterly, Cultivators and Integrated Facilities shall, at their own cost, have their cannabis sampled by the State Testing Laboratory licensed by the AMCC pursuant to Ala. Code §20-2A-66 to ensure that no pesticides or other hazardous substances are present in the cannabis material. Cultivators and Integrated Facilities must maintain records of these tests for at least two years and provide the results to the department and AMCC, upon request. Nothing herein shall preclude a Cultivator or Integrated Facility from conducting or seeking, at its own cost, in-house or independent third-party testing of cannabis at any other time before, at, or after the time of harvest.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.14 Hazardous Waste and Chemical Waste

- (1) Cultivators and Integrated Facilities shall establish and maintain standards, procedures, and requirements for hazardous and chemical waste product storage and disposal, and chemical storage that comply with Chapters 27 and 30 of Title 22, Code of Alabama, 1975.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.15 Transportation of Cannabis and Medical Cannabis

- (1) A Cultivator may only transport cannabis or medical cannabis to another AMCC licensee by utilizing the services of a secure transporter licensed by the AMCC.

- (2) An Integrated Facility may only transport cannabis or medical cannabis to its own facilities or another AMCC licensee by utilizing its own vehicles as authorized by the AMCC or by using the services of a secure transporter licensed by the AMCC.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.16 Records and Video Retention:

- (1) All records related to the cultivation of cannabis, destruction and disposal of cannabis, and storage of medical cannabis in a cultivation facility shall be kept for at least 2 years and made available to the Department and AMCC upon request. This includes all records related to individuals entering and exiting the cultivation facility.

- (2) Cultivators and Integrated Facilities must preserve video from all cameras covering the cultivation facility for a minimum of 60 days.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.17 Statewide Seed-to-Sale Tracking System and Chain of Custody

- (1) Cultivators and Integrated Facilities must enter all transactions into the statewide seed-to-sale tracking system operated by the AMCC. At a minimum, these transactions must include the inventory of cannabis plants in the cultivation facility, the location of the cannabis when it leaves the cultivation facility, and the documentation showing any plants or cannabis material that were destroyed and disposed of at the cultivation facility.
- (2) Cultivators and Integrated Facilities must ensure that they can account for all cannabis plants and other materials that have ever been in the custody or control of the Cultivator or Integrated Facility, at all times from planting to disposal or from planting to such time as a medical cannabis product is dispensed through a dispensary or Integrated Facility dispensary site.

- (3) As part of its Operations Plan, a Cultivator or Integrated Facility must submit a plan to show a continuous chain of custody protocol for all cannabis plants and cannabis material. At a minimum, the chain of custody protocol must ensure that at any time, no fewer than two employees of the Cultivator or Integrated Facility are responsible for the location and security of all cannabis plants or related materials within the custody or control of the Cultivator or Integrated Facility. As with other operations protocols provided to and approved by the Commission and the Department, Cultivators and Integrated Facilities may not alter their chain-of-custody protocols, without first receiving written permission from the AMCC and the Department.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.18 Advertising and Signage

- (1) Cultivators and Integrated Facilities must comply with all provisions of Ala. Code Section 20-2A-61 and any rules of the AMCC related to advertising. Advertising or marketing materials, if any, must be appropriate to the subject matter and suitable for the target market to whom a Cultivator or Integrated Facility may sell.
- (2) Cultivators and Integrated Facilities shall not display any signage, logos, products, paraphernalia, or other identifying characteristics on the outside of buildings to alert the public that cannabis is being grown or stored at the cultivation facility.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.19 Medical Cannabis Storage

- (1) Cultivators and Integrated Facilities that store medical cannabis on-site after processing, must conform to the same security and storage rules required by the AMCC for processors and dispensaries.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.20 Violations

- (1) The Department shall report any violation of these rules to the AMCC. As with violations of any of the rules of this Chapter, violations of may result in oral or written reprimands, fines, suspension of licenses, or revocation of licenses by the AMCC.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

1 SB46
2 213029-6
3 By Senator Melson
4 RFD: Judiciary
5 First Read: 02-FEB-21
6 PFD: 01/14/2021

1 SB46

2
3
4 ENROLLED, An Act,

5 Relating to the medical use of cannabis; to add a
6 new Chapter 2A to Title 20, Code of Alabama 1975; to amend
7 Section 13A-7-2, Code of Alabama 1975; to create the Darren
8 Wesley 'Ato' Hall Compassion Act; to provide civil and
9 criminal protections to certain patients with a qualifying
10 medical condition who have a valid medical cannabis card for
11 the medical use of cannabis; to establish the Alabama Medical
12 Cannabis Commission and provide for its membership and duties;
13 to provide for certification of patients to authorize use of
14 medical cannabis; to license and regulate the cultivation,
15 processing, transporting, testing, and dispensing of medical
16 cannabis; to prohibit certain types of medical cannabis
17 products; to provide for patient registry and seed-to-sale
18 tracking; to impose taxes; to provide certain legal
19 protections for users of medical cannabis; to provide certain
20 legal protections for employers; to provide further for
21 workers' compensation benefits in certain circumstances where
22 an employee uses medical cannabis; to amend the crime of
23 trespass in the first degree; to establish the Medical
24 Cannabis Research Consortium to award research grants using
25 tax proceeds; and in connection therewith would have as its

1 purpose or effect the requirement of a new or increased
 2 expenditure of local funds within the meaning of Amendment 621
 3 of the Constitution of Alabama of 1901, now appearing as
 4 Section 111.05 of the Official ReCompilation of the
 5 Constitution of Alabama of 1901, as amended.

6 BE IT ENACTED BY THE LEGISLATURE OF ALABAMA:

7 Section 1. Chapter 2A, commencing with Section
 8 20-2A-1, is added to Title 20, Code of Alabama 1975, to read
 9 as follows:

10 Article 1. General Provisions.

11 §20-2A-1.

12 This chapter shall be known and may be cited as the
 13 Darren Wesley 'Ato' Hall Compassion Act.

14 §20-2A-2.

15 The Legislature finds all of the following:

16 (1) It is not the intent of this chapter to provide
 17 for or enable recreational use of marijuana in the State of
 18 Alabama.

19 (2) Medical research indicates that the
 20 administration of medical cannabis can successfully treat
 21 various medical conditions and alleviate the symptoms of
 22 various medical conditions.

23 (3) There are residents in Alabama suffering from a
 24 number of medical conditions whose symptoms could be
 25 alleviated by the administration of medical cannabis products

1 if used in a controlled setting under the supervision of a
2 physician licensed in this state.

3 (4) A majority of states have adopted a program
4 providing for the administration of cannabis or cannabis
5 derivatives for medical use for residents of their states.

6 (5) Establishing a program providing for the
7 administration of cannabis derivatives for medical use in this
8 state will not only benefit patients by providing relief to
9 pain and other debilitating symptoms, but also provide
10 opportunities for patients with these debilitating conditions
11 to function and have a better quality of life and provide
12 employment and business opportunities for farmers and other
13 residents of this state and revenue to state and local
14 governments.

15 (6) It is important to balance the needs of
16 employers to have a strong functioning workforce with the
17 needs of employees who will genuinely benefit from using
18 cannabis for a medical use in a manner that makes the employee
19 a productive employee.

20 (7) The State of Alabama, therefore, wishes to
21 create a health care market for medical cannabis.
22 Notwithstanding any medical benefit of cannabis or cannabis
23 derivatives, the recreational use of marijuana remains a
24 significant threat to public health and safety. Allowing the
25 cultivation, processing, dispensing, and use of cannabis for

1 medical use without appropriate safeguards to prevent unlawful
2 diversion for recreational use would pose a risk to public
3 health and safety.

4 (8) The power to regulate intrastate commerce
5 is vested in the several states under the Ninth and Tenth
6 Amendments to the United States Constitution.

7 (9) The Ninth Amendment to the United States
8 Constitution guarantees to the people rights not granted in
9 the United States Constitution and reserves to the people of
10 Alabama certain rights as they were understood at the time
11 Alabama was admitted into statehood in 1819, and the guarantee
12 of these rights is a matter of contract between the State
13 of Alabama and its people and the United States as of the time
14 that the compact with the United States was agreed upon and
15 adopted by Alabama and the United States in 1819.

16 (10) It is the intent of the Legislature to create
17 within Alabama a wholly intrastate system for the cultivation,
18 processing, and distribution of medical cannabis in the
19 interest of protecting its own residents from the danger that
20 recreational cannabis poses.

21 (11) Requiring licensees to prove a history of
22 residency within the state for a period of time is directly
23 related to avoiding an influx of companies engaged in the
24 recreational production of marijuana; the state has a

1 substantial interest in protecting its residents from the
2 dangers of recreational marijuana.

3 (12) Requiring that licensed cultivators,
4 processors, transporters, and dispensaries of cannabis for
5 medical use possess the requisite skill, expertise, resources,
6 and capital to conduct operations as proposed in their
7 business plans, and favoring those applicants who already
8 possess the requisite skill, expertise, resources, and
9 capital, promotes the goals of stability in licensing and
10 reduces the risks of unlawful diversion and misuse. A lengthy
11 base of agronomic experience will help achieve those goals, as
12 will past experience participating in an agronomic supply
13 chain.

14 (13) Ensuring that all cultivation, processing,
15 transportation, and dispensing operations remain intrastate in
16 nature reduces the risk of exposing licensees to the potential
17 penalties of federal law based on the activities of their
18 licensed operations.

19 (14) There is a pattern in states that have
20 legalized the use of medical cannabis or medical marijuana;
21 frequently, in the years following authorization of medical
22 use, recreational marijuana is subsequently authorized. It is
23 the intent of the Legislature to avoid a shift from medical
24 cannabis usage to recreational marijuana usage. Therefore,

1 safeguards to adequately protect the residents of this state
2 are essential.

3 §20-2A-3.

4 As used in this chapter, the following terms have
5 the following meanings:

6 (1) APPLICANT. The entity or individual seeking a
7 license under Article 4.

8 ~~(1)~~ (2) BOARD. The State Board of Medical Examiners.

9 ~~(2)~~ (3) CANNABIS. a. Except as provided in paragraph
10 b., all parts of any plant of the genus cannabis, whether
11 growing or not, including the seeds, extractions of any kind
12 from any part of the plant, and every compound, derivative,
13 mixture, product, or preparation of the plant.

14 b. The term does not include industrial hemp or hemp
15 regulated under Article 11 of Chapter 8 of Title 2.

16 ~~(3)~~ (4) COMMISSION. The Alabama Medical Cannabis
17 Commission created pursuant to Section 20-2A-20.

18 ~~(4)~~ (5) CULTIVATOR. An entity licensed by the
19 Department of Agriculture and Industries under Section
20 20-2A-62 authorized to grow cannabis pursuant to Article 4.

21 ~~(5)~~ (6) DAILY DOSAGE. The total amount of one or
22 more cannabis derivatives, including, but not limited to,
23 cannabidiol and tetrahydrocannabinol, which may be present in
24 a medical cannabis product that may be ingested by a

1 registered qualified patient during a 24-hour period, as
2 determined by a registered certifying physician.

3 ~~(6)~~ (7) DEPARTMENT. The Department of Agriculture
4 and Industries.

5 ~~(7)~~ (8) DISPENSARY. An entity licensed by the
6 commission under Section 20-2A-64 authorized to dispense and
7 sell medical cannabis at dispensing sites to registered
8 qualified patients and registered caregivers pursuant to
9 Article 4.

10 ~~(8)~~ (9) DISPENSING SITE. A site operated by an
11 dispensary licensee or an integrated facility licensee
12 pursuant to Article 4.

13 (10) ECONOMIC INTEREST. The rights to either the
14 capital or profit interests of an applicant or licensee or, if
15 the applicant or licensee is a corporation, the rights to some
16 portion of all classes of outstanding stock in the
17 corporation.

18 ~~(9)~~ (11) FACILITY or MEDICAL CANNABIS FACILITY. Any
19 facility, or land associated with a facility, of a licensee.

20 ~~(10)~~ (12) INTEGRATED FACILITY. An entity licensed
21 under Section 20-2A-67 authorized to perform the functions of
22 a cultivator, processor, secure transporter, and dispensary
23 pursuant to Article 4.

24 ~~(11)~~ (13) LICENSEE. A cultivator, processor, secure
25 transporter, state testing laboratory, dispensary, or

integrated facility licensed by the commission under Article
4.

~~(12)~~ (14) MEDICAL CANNABIS. a. A medical grade
product in the form of any of the following, as determined by
rule by the commission, that contains a derivative of cannabis
for medical use by a registered qualified patient pursuant to
this chapter:

1. Oral tablet, capsule, or tincture.
2. Non-sugarcoated gelatinous cube, gelatinous
rectangular cuboid, or lozenge in a cube or rectangular cuboid
shape.
3. Gel, oil, cream, or other topical preparation.
4. Suppository.
5. Transdermal patch.
6. Nebulizer.
7. Liquid or oil for administration using an
inhaler.

b. The term does not include any of the following:

1. Raw plant material.
2. Any product administered by smoking, combustion,
or vaping.
3. A food product that has medical cannabis baked,
mixed, or otherwise infused into the product, such as cookies
or candies.

1 ~~(13)~~ (15) MEDICAL CANNABIS CARD. A valid card issued
2 pursuant to Section 20-2A-35 or a temporary card issued
3 pursuant to Section 20-2A-36.

4 ~~(14)~~ (16) MEDICAL USE or USE OF MEDICAL CANNABIS or
5 USE MEDICAL CANNABIS. The acquisition, possession, use,
6 delivery, transfer, or administration of medical cannabis
7 authorized by this chapter. The term does not include
8 possession, use, or administration of cannabis that was not
9 purchased or acquired from a licensed dispensary.

10 ~~(15)~~ (17) PACKAGE. Any container that a processor
11 may use for enclosing and containing medical cannabis. The
12 term does not include any carry-out bag or other similar
13 container.

14 ~~(16)~~ (18) PATIENT REGISTRY. The Alabama Medical
15 Cannabis Patient Registry System that is an electronic
16 integrated system that tracks physician certifications,
17 patient registrations, medical cannabis cards, the daily
18 dosage and type of medical cannabis recommended to qualified
19 patients by registered certifying physicians, and the dates of
20 sale, amounts, and types of medical cannabis that were
21 purchased by registered qualified patients at licensed
22 dispensaries.

23 ~~(17)~~ (19) PHYSICIAN CERTIFICATION. A registered
24 certifying physician's authorization for a registered
25 qualified patient to use medical cannabis.

1 ~~(18)~~ (20) PROCESSOR. An entity licensed by the
2 commission under Section 20-2A-63 authorized to purchase
3 cannabis from a cultivator and extract derivatives from the
4 cannabis to produce a medical cannabis product or products for
5 sale and transfer in packaged and labeled form to a dispensing
6 site pursuant to Article 4.

7 ~~(19)~~ (21) QUALIFYING MEDICAL CONDITION. Any of the
8 following conditions or symptoms of conditions, but only after
9 documentation indicates that conventional medical treatment or
10 therapy has failed unless current medical treatment indicates
11 that use of medical cannabis is the standard of care:

- 12 a. Autism Spectrum Disorder (ASD).
- 13 b. Cancer-related cachexia, nausea or vomiting,
14 weight loss, or chronic pain.
- 15 c. Crohn's Disease.
- 16 d. Depression.
- 17 e. Epilepsy or a condition causing seizures.
- 18 f. HIV/AIDS-related nausea or weight loss.
- 19 g. Panic disorder.
- 20 h. Parkinson's disease.
- 21 i. Persistent nausea that is not significantly
22 responsive to traditional treatment, except for nausea related
23 to pregnancy, cannabis-induced cyclical vomiting syndrome, or
24 cannabinoid hyperemesis syndrome.
- 25 j. Post Traumatic Stress Disorder (PTSD).

k. Sickle Cell Anemia.

l. Spasticity associated with a motor neuron disease, including Amyotrophic Lateral Sclerosis.

m. Spasticity associated with Multiple Sclerosis or a spinal cord injury.

n. A terminal illness.

o. Tourette's Syndrome.

p. A condition causing chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or has proved ineffective.

~~(20)~~ (22) REGISTERED CAREGIVER. An individual who meets the requirements described in subsection (c) of Section 20-2A-30 and is authorized to acquire and possess medical cannabis and to assist one or more registered qualified patients with the use of medical cannabis pursuant to this chapter.

~~(21)~~ (23) REGISTERED CERTIFYING PHYSICIAN. A physician authorized by the State Board of Medical Examiners to certify patients for the use of medical cannabis under this article.

~~(22)~~ (24) REGISTERED QUALIFIED PATIENT. Either of the following:

a. An adult who meets the requirements described in subsection (a) of Section 20-2A-30 and is authorized to

1 acquire, possess, and use medical cannabis pursuant to this
2 chapter.

3 b. A minor who meets the requirements described in
4 subsection (b) of Section 20-2A-30 and is authorized to use
5 medical cannabis pursuant to this chapter with the assistance
6 of a registered caregiver.

7 ~~(23)~~ (25) SECURE TRANSPORTER. An entity licensed by
8 the commission under Section 20-2A-65 authorized to transport
9 cannabis or medical cannabis from one licensed facility or
10 site to another licensed facility or site.

11 ~~(24)~~ (26) STATE TESTING LABORATORY. An entity
12 licensed under Section 20-2A-66 authorized to test cannabis
13 and medical cannabis to ensure the product meets safety
14 qualifications required under this chapter.

15 ~~(25)~~ (27) STATEWIDE SEED-TO-SALE TRACKING SYSTEM.
16 The tracking system established pursuant to Section 20-2A-54
17 that tracks all cannabis and medical cannabis in the state.

18 ~~(26)~~ (28) UNIVERSAL STATE SYMBOL. The image
19 established by the commission pursuant to Section 20-2A-53
20 made available to processors which indicates the package
21 contains medical cannabis.

22 §20-2A-4.

23 This chapter supersedes state criminal and civil
24 laws pertaining to the recommending, acquisition, possession,
25 use, cultivation, manufacturing, processing, research and

1 development, and sale of medical cannabis. The acquisition,
2 possession, use, cultivation, manufacturing, processing,
3 research and development, transportation, testing, or sale of
4 cannabis or medical cannabis in compliance with this chapter
5 and rules of the commission does not constitute a violation of
6 Article 5 of Chapter 12 of Title 13A, or any other law to the
7 contrary.

8 §20-2A-5.

9 All data related to the implementation of this
10 chapter, including, but not limited to, application forms,
11 licensing information, physician certifications, registration
12 of qualified patients and designated caregivers, compliance,
13 and the status of cannabis research programs must be
14 maintained in a secure system developed or procured by the
15 commission. Data may not be sold, and patient information
16 shall remain confidential, except as otherwise permitted
17 pursuant to this chapter, and may not be transferred or sold.

18 §20-2A-6.

19 (a) This chapter does not do any of the following:

20 (1) Require an insurer, organization for managed
21 care, health benefit plan, or any individual or entity
22 providing coverage for a medical or health care service to pay
23 for or to reimburse any other individual or entity for costs
24 associated with the use of medical cannabis.

1 (2) Require any employer to permit, accommodate, or
2 allow the use of medical cannabis, or to modify any job or
3 working conditions of any employee who engages in the use of
4 medical cannabis or for any reason seeks to engage in the use
5 of medical cannabis.

6 (3) Prohibit any employer from refusing to hire,
7 discharging, disciplining, or otherwise taking an adverse
8 employment action against an individual with respect to
9 hiring, discharging, tenure, terms, conditions, or privileges
10 of employment as a result, in whole or in part, of that
11 individual's use of medical cannabis, regardless of the
12 individual's impairment or lack of impairment resulting from
13 the use of medical cannabis.

14 (4) Prohibit or limit the ability of any employer
15 from establishing or enforcing a drug testing policy,
16 including, but not limited to, a policy that prohibits the use
17 of medical cannabis in the workplace or from implementing a
18 drug-free workforce program established in accordance with
19 Article 13, commencing with Section 25-5-330, of Chapter 5 of
20 Title 25.

21 (5) Prohibit or limit any employer from adopting an
22 employment policy requiring its employees to notify the
23 employer if an employee possesses a medical cannabis card.

24 (6) Interfere with, impair, or impede, any federal
25 restrictions on employment, including, but not limited to,

1 regulations adopted by the United States Department of
2 Transportation in Title 49, Code of Federal Regulations.

3 (7) Permit, authorize, or establish any individual's
4 right to commence or undertake any legal action against an
5 employer for refusing to hire, discharging, disciplining, or
6 otherwise taking an adverse employment action against an
7 individual with respect to hiring, discharging, tenure, terms,
8 conditions, or privileges of employment due to the
9 individual's use of medical cannabis.

10 (8) Require a government medical assistance program,
11 employer, property and casualty insurer, or private health
12 insurer to reimburse an individual for costs associated with
13 the use of medical cannabis.

14 (9) Affect, alter, or otherwise impact the workers'
15 compensation premium discount available to employers who
16 establish a drug-free workplace policy certified by the
17 Department of Labor, Workers' Compensation Division, in
18 accordance with Article 13, commencing with Section 25-5-330,
19 of Chapter 5 of Title 25.

20 (10) Affect, alter, or otherwise impact an
21 employer's right to deny, or establish legal defenses to, the
22 payment of workers' compensation benefits to an employee on
23 the basis of a positive drug test or refusal to submit to or
24 cooperate with a drug test, as provided under Section 25-5-51.

1 (11) Affect, alter, or supersede any obligation or
2 condition imposed on a parolee, probationer, or an individual
3 participating in a pretrial diversion program or other
4 court-ordered substance abuse rehabilitation program.

5 (b) For the purpose of obtaining needed medical
6 care, including organ transplants, a registered qualified
7 patient's authorized use of medical cannabis in accordance
8 with this chapter is considered the equivalent of the
9 authorized use of any other medication used at the direction
10 of a licensed health care professional and may not constitute
11 the use of an illicit substance or otherwise disqualify a
12 registered qualified patient from such needed medical care.

13 (c) An individual who is discharged from employment
14 because of that individual's use of medical cannabis, or
15 refusal to submit to or cooperate with a drug test, shall be
16 legally conclusively presumed to have been discharged for
17 misconduct if the conditions of paragraph a. of subdivision
18 (3) of Section 25-4-78 are otherwise met.

19 (d) Nothing in this chapter shall prohibit the
20 Department of Human Resources from considering a parent or
21 caretaker's use of medical cannabis as a factor for
22 determining the welfare of a child in any of the following
23 circumstances:

24 (1) There is evidence of child abuse or neglect.

1 (2) The best interest of a child is determined for
2 custody purposes.

3 (3) A background check is performed for a
4 prospective foster, adoptive, or kinship caretaker.

5 §20-2A-7.

6 (a) A registered qualified patient 19 years of age
7 or older or registered caregiver is not subject to arrest or
8 prosecution for unlawful possession of marijuana if he or she
9 possesses no more than 70 daily dosages of medical cannabis
10 and has a valid medical cannabis card.

11 (b) A registered certifying physician who acts in
12 good faith compliance with this chapter regarding the dosage
13 established under this chapter and the applicable
14 administrative rules established pursuant to this chapter
15 shall be immune from civil and criminal prosecution and is not
16 subject to arrest, prosecution, or penalty in any manner and
17 may not be denied any right or privilege, including, but not
18 limited to, protection from civil penalty for certifying
19 patients under Section 20-2A-33 or for otherwise stating that,
20 in the physician's professional opinion, a patient is likely
21 to receive therapeutic or palliative benefit from the medical
22 use of medical cannabis to treat or alleviate the patient's
23 qualifying medical condition or symptoms associated with the
24 qualifying medical condition, provided that nothing shall
25 prevent the board from disciplining a physician. Nothing in

1 this chapter shall modify, amend, repeal, or supersede any
2 provision of Section 6-5-333, the Alabama Medical Liability
3 Act of 1987, commencing with Section 6-5-540, or the Alabama
4 Medical Liability Act of 1996, commencing with Section
5 6-5-548, or any amendment to any of these laws or judicial
6 interpretation of these laws.

7 (c) A licensee or any employee of that licensee is
8 not subject to arrest or prosecution if the person is acting
9 pursuant to this chapter and within the scope of his or her
10 employment.

11 (d) A hospital, medical facility, assisted living
12 facility, or hospice program where a registered qualified
13 patient is receiving treatment in accordance with this chapter
14 is not subject to arrest, prosecution, or penalty in any
15 manner, or denied any right or privilege solely for providing
16 that treatment.

17 (e) Mere possession of, or application for, a
18 medical cannabis card does not constitute probable cause or
19 reasonable suspicion, nor shall it be used as the sole basis
20 to support the search of the person, property, or home of the
21 individual possessing or applying for the medical cannabis
22 card. The possession of, or application for, a medical
23 cannabis card does not preclude the existence of probable
24 cause if probable cause exists on other grounds.

1 (f) Nothing in this chapter shall preclude the
2 Alabama State Law Enforcement Agency or a local law
3 enforcement agency from searching a licensee where there is
4 probable cause to believe that a criminal law has been
5 violated and the search is conducted in conformity with
6 constitutional and state law.

7 §20-2A-8.

8 (a) (1) An individual may not distribute, possess,
9 manufacture, or use medical cannabis or a medical cannabis
10 product that has been diverted from a registered qualified
11 patient, a registered caregiver, or a licensed cultivator,
12 processor, secure transporter, dispensary, or a state testing
13 laboratory.

14 (2) An individual who violates this section is
15 guilty of a Class B felony.

16 (3) The penalty under this section is in addition to
17 any penalties that a person may be subject to for manufacture,
18 possession, or distribution of marijuana under Title 13A.

19 (b) This chapter does not permit any individual to
20 engage in, and does not prevent the imposition of any civil,
21 criminal, or other penalty for engaging in any of the
22 following conduct:

23 (1) Undertaking any task under the influence of
24 cannabis, when doing so would constitute negligence,

professional malpractice, or professional misconduct, or violation of law.

(2) Possessing or using medical cannabis on any property of a K-12 school or day care or child care facility, in any correctional facility, or in a vehicle unless the medical cannabis is in its original package and is sealed and reasonably inaccessible while the vehicle is moving.

§20-2A-9.

The commission shall provide annual written reports to the Legislature, with the first due no later than January 1, 2022, tracking implementation of this chapter. The report shall be made publicly available and posted on the commission's website. The report shall include all of the following:

(1) The number of patients applying for and receiving medical cannabis cards.

(2) The qualifying medical conditions identified to obtain the medical cannabis cards.

(3) Comments from physicians and other health care providers and from pharmacists.

(4) Revenues and expenses of card issuance and licensing of medical cannabis facilities.

(5) Relevant developments in other states' cannabis laws.

(6) Relevant scientific research.

1 (7) Applicable tax revenue.

2 (8) The commission's annual operating expenses and
3 revenues.

4 (9) The number of total applicants for each type of
5 license under Article 4 and the number of veterans,
6 minorities, and women who applied and the number of these
7 applicants who were denied a license.

8 (10) Any other information available to the
9 commission that would inform public officials of how this
10 chapter affects the public.

11 (11) Any suggested legislative changes to this
12 chapter or other state laws, including all of the following:

13 a. Any suggestions to ensure that veterans, women,
14 and minorities are not unfairly discriminated against in
15 obtaining licenses under Article 4.

16 b. Changes to reflect changes in federal law or
17 regulation.

18 c. Changes based on additional medical or scientific
19 research.

20 §20-2A-10.

21 (a) There is created a special account in the State
22 Treasury to be known as the Medical Cannabis Commission Fund.
23 Expenditures from the Medical Cannabis Commission Fund may be
24 made only by the commission to implement, administer, and

1 enforce this chapter. Specifically, the Medical Cannabis
2 Commission Fund includes all of the following:

3 (1) Tax proceeds collected pursuant to subsections
4 (a) and (b) of Section 2 of the act adding this language, less
5 an amount sufficient to cover the cost of administration of
6 the tax levies imposed under subsections (a) and (b) of
7 Section 2, which shall be retained by the Department of
8 Revenue.

9 (2) License fees, civil penalties, and other fees or
10 charges collected pursuant to Article 4 of the act adding this
11 language.

12 (3) Any monies appropriated by the Legislature for
13 the initial operation of the commission.

14 (b) Amounts in the Medical Cannabis Commission Fund
15 shall be budgeted and allotted in accordance with Section
16 41-4-80 through 41-4-96 and Sections 41-19-1 through 41-19-12,
17 but shall not be limited by the fiscal year appropriation cap.

18 (c) Beginning October 1, 2025, any funds in the
19 Medical Cannabis Commission Fund in excess of actual expenses
20 from the previous fiscal year shall be distributed, less 10
21 percent, as follows:

22 (1) 60 percent shall be transferred to the General
23 Fund.

(2) 30 percent shall be transferred to the Medical Cannabis Research Fund established pursuant to subsection (f) of Section 4.

§20-2A-11.

The possession of a medical cannabis card lawfully obtained pursuant to this chapter does not infringe on the cardholder's state or federal constitutional rights.

§20-2A-12.

The provisions of this chapter are severable. If any part of this chapter is declared invalid or unconstitutional, the declaration shall not affect the part that remains.

Article 2. Alabama Medical Cannabis Commission.

§20-2A-20.

(a) The Alabama Medical Cannabis Commission is established. The commission shall consist of the following members, with initial members appointed not later than July 1, 2021:

(1) Three members appointed by the Governor, one of whom is a physician licensed to practice medicine in this state; one of whom is a licensed pharmacist; and one of whom has experience in agricultural lending or banking. Initial terms shall be four, three, and two years, respectively.

(2) Three members appointed by the Lieutenant Governor, one of whom is a physician licensed to practice medicine in this state certified in the specialty of

1 pediatrics; one of whom is licensed to practice law in this
2 state who specializes in health law; and one of whom is a
3 biochemist. Initial terms shall be one, four, and three years,
4 respectively.

5 (3) Two members appointed by the President Pro
6 Tempore of the Senate, one of whom is a physician licensed to
7 practice medicine in this state certified in the specialty of
8 oncology; and one of whom has experience in multiple crop
9 development and agricultural practices. Initial terms shall be
10 two and one years, respectively.

11 (4) Two members appointed by the Speaker of the
12 House of Representative, one of whom has a background and
13 experience in mental health or substance abuse counselling and
14 treatment; and one of whom has professional experience in
15 agricultural systems management. Initial terms shall be four
16 and three years, respectively.

17 (5) One member appointed by the Commissioner of
18 Agriculture and Industries who is experienced in agricultural
19 production or agronomic or other horticultural practices. The
20 initial term shall be two years.

21 (6) One member appointed by the State Health
22 Officer. The initial term shall be four years.

23 (7) One member appointed by the Attorney General,
24 who shall be a nonvoting advisory member. The initial term
25 shall be three years.

1 (8) One member appointed by the Secretary of the
2 Alabama State Law Enforcement Agency, who shall be a nonvoting
3 advisory member. The initial term shall be one year.

4 (b) Each commission member appointed to the
5 commission is subject to confirmation by the Senate during the
6 legislative session in which the appointment is made or, if
7 the appointment is made when the Legislature is not in
8 session, during the next special or regular session. An
9 appointee may serve in the position pending confirmation by
10 the Senate. Each member of the committee shall serve after the
11 expiration of his or her term until his or her successor is
12 appointed.

13 (c) A member may not be an owner, shareholder,
14 director, board member, or otherwise have an economic interest
15 in an applicant or license issued under Article 4. Any current
16 public official, candidate for public office, current public
17 employee, or registered lobbyist may not serve as a member.

18 (d) Members must be at least 30 years of age and
19 residents of this state for at least five continuous years
20 immediately preceding their appointment. The appointing
21 officers shall coordinate their appointments so that diversity
22 of gender, race, and geographical areas is reflective of the
23 makeup of this state.

24 (e) After initial appointments, each member shall
25 serve a term of four years, but may be reappointed for one

1 additional term. If at any time there is a vacancy, a
2 successor member shall be appointed by the respective
3 appointing officer to serve for the remainder of the term.
4 Members may be removed for cause by the appointing authority.

5 (f) The commission shall elect from the membership
6 one member to serve as chair and one member to serve as
7 vice-chair.

8 (g) While serving on business of the commission,
9 members who are not public officials or public employees shall
10 be entitled to a per diem of five hundred dollars (\$500) per
11 day, as well as actual travel expenses incurred in the
12 performance of duties as a member, as other state employees
13 are paid, when approved by the chair.

14 (h) The commission shall meet at least six times per
15 year and hold other meetings for any period of time as may be
16 necessary for the commission to transact and perform its
17 official duties and functions. A majority of voting members of
18 the commission shall constitute a quorum for the transaction
19 of any business, or in the performance of any duty, power, or
20 function of the commission, and the concurrence of a majority
21 of those present and voting in any matter within its duties is
22 required for a determination of matters within its
23 jurisdiction. A special meeting may be called by the chair, or
24 upon the written request of two or more members. All members
25 shall be duly notified by the commission director of the time

1 and place of any regular or special meeting at least thirty
2 days in advance of any meeting. Members may participate by
3 telephone, video conference, or by similar communications
4 equipment so that all individuals participating in the meeting
5 may hear each other at the same time. Participating by such
6 means shall constitute presence in person at a meeting for all
7 purposes. The chair shall be responsible for setting and
8 keeping a meeting schedule that ensures the commission meets
9 the requirements of this chapter. A member who misses more
10 than two meetings in one calendar year shall be subject to
11 removal by his or her appointing authority.

12 (i) (1) The commission may employ a director to serve
13 at the pleasure of the commission. The director's salary shall
14 be fixed by the commission and shall not be subject to Section
15 36-6-6. The director shall be at least 30 years of age and
16 have been a citizen and resident of this state for at least
17 five years prior to employment. The director is the chief
18 administrative officer of the commission, and all personnel
19 employed by the commission shall be under the director's
20 direct supervision. The director shall be solely responsible
21 to the commission for the administration and enforcement of
22 this chapter and responsible for the performance of all duties
23 and functions delegated by the commission.

24 (2) The director shall maintain all records of the
25 commission and also serve as secretary of the commission. The

1 director shall prepare and keep the minutes of all meetings
2 held by the commission, including a record of all business
3 transacted and decisions rendered by the commission. A copy of
4 the record of the minutes and business transacted and
5 decisions rendered shall be kept on file at the commission's
6 main office and shall be available for public inspection.

7 (3) If the director is licensed to practice law in
8 this state, he or she shall act and serve as hearing officer
9 when designated by the commission and shall perform such
10 duties as the regular hearing officer.

11 (j) The commission may employ an assistant director
12 who shall perform all duties and functions which may be
13 assigned by the director or the commission. The assistant
14 director, if licensed to practice law in this state, may also
15 be designated by the commission to sit, act, and serve as a
16 hearing officer, and when designated as a hearing officer, the
17 assistant director may perform the same duties and functions
18 as the regular hearing officer.

19 (k) Each member of the commission shall be entitled
20 to the immunity provided by Section 36-1-12.

21 (l) In any action or suit brought against the
22 members of the commission in their official capacity in a
23 court of competent jurisdiction, to review any decision or
24 order issued by the commission, service of process issued
25 against the commission may be lawfully served or accepted by

1 the director on behalf of the commission as though the members
2 of the commission were personally served with process.

3 (m) The commission may employ additional officers,
4 including an inspection officer. The director, assistant
5 director, and any other officer or employee shall be
6 reimbursed for actual travel expenses as other state employees
7 are paid, when approved by the chair.

8 (n) The commission shall retain legal counsel
9 familiar with the requirements of this chapter and medical
10 cannabis licensing and best practices in other states in order
11 to assist the commission and staff with establishing a
12 functional program and achieving compliance with applicable
13 laws.

14 (o) All employees of the commission shall not be
15 subject to the state Merit System Act.

16 (p) The commission shall be subject to the Alabama
17 Administrative Procedure Act.

18 §20-2A-21.

19 (a) A member of the commission and any individual
20 employed by the commission may not be an owner, shareholder,
21 director, or board member of, or otherwise have any economic
22 interest in, a licensee. In addition, a member or employee of
23 the commission may not have any family member who is employed
24 by a licensee. A member or employee of the commission or his
25 or her family member may not have an interest of any kind in

1 any building, fixture, or premises occupied by any person
2 licensed under this chapter; and may not own any stock or have
3 any interest of any kind, direct or indirect, pecuniary or
4 otherwise, by a loan, mortgage, gift, or guarantee of payment
5 of a loan, in any licensee.

6 (b) A member or employee of the commission may not
7 accept any gift, favor, merchandise, donation, contribution,
8 or any article or thing of value, from any person licensed
9 under this chapter.

10 (c) Any individual violating this section shall be
11 terminated from employment or position, and as a consequence,
12 the individual shall forfeit any pay or compensation which
13 might be due.

14 (d) For purposes of this section, family member
15 includes a spouse, child, parent, or sibling, by blood or
16 marriage.

17 (e) A former member of the commission, for a period
18 of two years after leaving service as a member of the
19 commission, may not be an owner, shareholder, director, board
20 member, or otherwise have an economic interest in an applicant
21 or license issued under Article 4.

22 (f) In addition to any violation of Chapter 25 of
23 Title 36, a violation of this section is a Class C
24 misdemeanor.

25 §20-2A-22.

(a) The Alabama Medical Cannabis Commission shall implement this chapter by making medical cannabis derived from cannabis grown in Alabama available to registered qualified patients and by licensing facilities that process, transport, test, or dispense medical cannabis.

(b) The commission shall administer and enforce this chapter and all rules adopted pursuant to this chapter.

Article 3. Physician Certifications, Medical Cannabis Patient Registry, and Medical Cannabis Cards.

§20-2A-30.

(a)(1) A resident of this state who is 19 years of age or older is a registered qualified patient if he or she meets all of the following conditions:

a. Has been certified by a registered certifying physician as having a qualifying medical condition.

b. Is registered with the commission.

c. Has been issued a valid medical cannabis card by the commission.

(2) A registered qualified patient described in subdivision (1) may purchase, possess, or use medical cannabis, subject to subsection (d).

(b)(1) A resident of this state who is under the age of 19 is a registered qualified patient if he or she meets all of the following conditions:

1 a. Has been certified by a registered certifying
2 physician as having a qualifying medical condition.

3 b. Is registered with the commission.

4 c. Has a qualified designated caregiver who is the
5 patient's parent or legal guardian.

6 (2) A registered qualified patient described in
7 subdivision (1) may use medical cannabis but may not purchase
8 or possess medical cannabis.

9 ~~(c)(1) A resident of this state who is 19 years of~~
10 ~~age or older is a registered caregiver if he or she meets both~~

11 (c)(1) A resident of this state is a registered
12 caregiver if he or she meets all of the following conditions:

13 a. Is registered with the commission.

14 b. Has been issued a valid medical cannabis card by
15 the commission.

16 c. Is at least 21 years of age, unless he or she is
17 the parent or legal guardian of, and caregiver for, a
18 registered qualified patient.

19 d. Is the parent, legal guardian, grandparent,
20 spouse, or an individual with power of attorney for health
21 care of a registered qualified patient.

22 (2) A registered caregiver described in subdivision
23 (1) may purchase and possess medical cannabis, subject to
24 subsection (d), but may not use medical cannabis unless he or
25 she is also a registered qualified patient.

1 (3) The commission, by rule, may limit the number of
2 registered qualified patients a registered caregiver may have
3 under his or her care.

4 (4) A registered caregiver may receive compensation
5 for services provided to a registered qualified patient
6 pursuant to this chapter.

7 (d) Notwithstanding subdivision (2) of subsections
8 (a) and (c), a registered qualified patient or registered
9 caregiver may not purchase more than 60 daily dosages of
10 medical cannabis and may not renew the supply more than 10
11 days before the 60-day period expires. At no time may a
12 registered qualified patient or registered caregiver possess
13 more than 70 daily dosages of medical cannabis.

14 §20-2A-31.

15 (a) In order for a physician to qualify as a
16 registered certifying physician, he or she must meet the
17 following requirements:

18 (1) Hold an active license to practice medicine
19 under Chapter 24 of Title 34.

20 (2) Complete a four-hour course related to medical
21 cannabis and complete a subsequent examination, both of which
22 shall be offered by a multi-specialty statewide professional
23 organization of physicians in this state that is recognized to
24 accredit intrastate organizations to provide AMA PRA category
25 1 credits. The course must be administered at least annually

1 and may be offered in a distance learning format, including an
2 electronic online format upon request. The price of the course
3 may not exceed five hundred dollars (\$500). Every two years
4 thereafter, in order to requalify, a certifying physician must
5 complete a two-hour referresher course offered by an entity
6 described in this subdivision.

7 (3) Pay an initial registration fee established by
8 the board, not to exceed three hundred dollars (\$300).

9 (4) Meet any additional qualifications established
10 by rule by the board.

11 (b) Upon meeting the requirements of subsection (a),
12 the board shall issue a registration certificate and
13 registration number to each registered certifying physician.
14 The board shall maintain on its website an updated list of
15 registered certifying physicians.

16 (c) The board, by rule, may establish requirements
17 for registered certifying physicians to remain qualified,
18 grounds for revoking registration, and a process for renewing
19 registration of qualified certifying physicians, including
20 payment of an annual registration renewal fee, not to exceed
21 two hundred dollars (\$200).

22 §20-2A-32.

23 A registered certifying physician may not do any of
24 the following:

1 (1) Except for the limited purpose of performing a
2 medical cannabis-related study, accept, solicit, or offer any
3 form of remuneration from or to a qualified patient,
4 designated caregiver, or any licensee, including a principal
5 officer, board member, agent, or employee of the licensee, to
6 certify a patient, other than accepting payment from a patient
7 for the fee associated with the examination, medical
8 consultation, or other treatment, including, but not limited
9 to, any third party reimbursement for the same.

10 (2) Accept, solicit, or offer any form of
11 remuneration from or to a dispensary for the purpose of
12 referring a patient to a specific dispensary.

13 (3) Offer a discount of any other item of value to a
14 qualified patient who uses or agrees to designate a specific
15 caregiver or use a specific dispensary to obtain medical
16 cannabis.

17 (4) Hold a direct or indirect economic interest in a
18 licensee.

19 (5) Serve on the board of directors or as an
20 employee of a licensee.

21 (6) Refer qualified patients to a specific caregiver
22 or a specific dispensary.

23 (7) Advertise in a dispensary.

24 (8) Advertise on the physician's website, brochures,
25 or any other media that generally describe the scope of

1 practice of the physician, any statement that refers to the
2 physician as a "medical cannabis" or "medical marijuana"
3 physician or doctor, or otherwise advertises his or her status
4 as a registered certifying physician, other than the
5 following: "Dr. _____ is qualified by the State of Alabama
6 to certify patients for medical cannabis use under the Alabama
7 Compassion Act."

8 §20-2A-33.

9 (a) In order to certify a patient, a registered
10 certifying physician must diagnose the patient with at least
11 one qualifying medical condition or confirm that the patient
12 has been medically diagnosed with at least one qualifying
13 medical condition.

14 (b) Not later than December 1, 2021, the board shall
15 adopt rules for the issuance of physician certifications for
16 patients to use medical cannabis as recommended by a
17 registered certifying physician. The rules shall include, but
18 not be limited to, all of the following:

19 (1) Requirements for patient examination and the
20 establishment of a physician-patient relationship.

21 (2) Requirements for relevant information to be
22 included in the patient's medical record.

23 (3) Requirements for review of the patient's
24 controlled drug prescription history in the controlled

substance prescription database established under Article 10 of Chapter 2 of this title.

(4) Requirements for review of the patient registry.

(5) Requirements for obtaining the voluntary and informed written consent from the patient to use medical cannabis, or from the patient's designated caregiver to assist the patient with the use of medical cannabis, on a form created by the board and accessible at no charge on its website. The form shall include, but not be limited to, information relating to all of the following:

a. The federal and state classification of cannabis as a Schedule I controlled substance.

b. The approval and oversight status of cannabis by the Food and Drug Administration.

c. The current state of research on the efficacy of cannabis to treat the qualifying medical condition or conditions.

d. The potential for addiction.

e. The potential effect that cannabis may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require an individual to be alert or respond quickly.

f. The potential side effects of cannabis use.

1 g. The risks, benefits, and drug interactions of
2 cannabis.

3 h. A statement that the use of medical cannabis
4 could result in termination from employment without recourse
5 and that costs may not be covered by insurance or government
6 programs.

7 i. That the patient's de-identified health
8 information contained in the patient's medical record,
9 physician certification, and patient registry may be used for
10 research purposes or used to monitor compliance with this
11 chapter, as further provided in subsection (c) of Section
12 20-2A-34.

13 (6) Requirements for the issuance and reissuance of
14 physician certifications by certifying physicians, the
15 permissible length of duration of a physician certification,
16 and the process and circumstances under which a physician
17 certification may be deactivated, as well as stipulations for
18 timely updating of physician certifications on the patient
19 registry.

20 (c) At the time of physician certification, the
21 registered certifying physician shall enter electronically in
22 the patient registry, in a manner determined by rule by the
23 board, relevant information necessary to appropriately
24 identify the patient; the respective qualifying medical
25 condition or conditions of the patient; the daily dosage and

1 type of medical cannabis recommended for medical use; and any
2 other information the board, by rule, deems relevant.

3 (d) A physician certification does not constitute a
4 prescription for medical cannabis.

5 (e) A physician certification shall be valid for a
6 period of time as determined by the board, but in no event may
7 a physician certification exceed 12 months in duration.

8 (f) (1) The commission, by rule, shall specify, by
9 form and tetrahydrocannabinol content, a maximum daily dosage
10 of medical cannabis that may be recommended by a registered
11 certifying physician for a particular qualifying medical
12 condition, which may not exceed the limits set forth in
13 subdivision (2).

14 (2) The maximum daily dosage may not exceed 50 mg of
15 delta-9-tetrahydrocannabinol; provided, however, the maximum
16 daily dosage may be increased under either of the following
17 circumstances:

18 a. A registered certifying physician may increase a
19 patient's daily dosage if, after 90 days of continuous care
20 under the physician during which time the patient was using
21 medical cannabis, the physician determines that a higher daily
22 dosage is medically appropriate, provided the maximum daily
23 dosage under this paragraph may not exceed 75 mg of
24 delta-9-tetrahydrocannabinol.

1 b. A registered certifying physician may increase a
2 patient's daily dosage if the patient has been diagnosed with
3 a terminal illness, provided, if the recommended daily dosage
4 exceeds 75 mg of delta-9-tetrahydrocannabinol, the physician
5 shall notify the patient that the patient's driver's license
6 will be suspended.

7 (g) A registered certifying physician may not
8 lawfully recommend the use of medical cannabis with a potency
9 greater than three percent tetrahydrocannabinol to any minor
10 for any qualifying medical condition. A minor may not legally
11 use medical cannabis with a potency greater than three percent
12 tetrahydrocannabinol, whether or not the minor has a valid
13 medical cannabis card. A parent or legal guardian of a minor
14 who holds a medical cannabis card may not legally possess
15 medical cannabis with a potency greater than three percent
16 tetrahydrocannabinol, unless the parent or guardian holds a
17 valid medical cannabis card for his or her own qualifying
18 medical condition.

19 §20-2A-34.

20 (a) In order to commence, use, and maintain a
21 reliable system to track all aspects of patient and caregiver
22 qualification not later than September 1, 2022, the commission
23 shall do all of the following:

24 (1) Establish and administer an integrated,
25 electronic patient and caregiver registry, known as the

1 Alabama Medical Cannabis Patient Registry System, that does
2 all of the following:

3 a. Receives and records physician certifications.

4 b. Receives and tracks qualified patient
5 registration and issuance of medical cannabis cards.

6 c. Receives and tracks designated caregiver
7 registration and issuance of medical cannabis cards.

8 d. Includes in the patient registry database for
9 each qualified patient registrant the name of the qualified
10 patient and the patient's designated caregiver, if applicable,
11 the patient's registered certifying physician, the respective
12 qualifying medical condition or conditions, the recommended
13 daily dosage and type of medical cannabis, and any other
14 information the commission, by rule, deems relevant.

15 e. Verifies that a medical cannabis card is current
16 and valid and has not been suspended, revoked, or denied.

17 f. Tracks purchases of medical cannabis at
18 dispensaries by date, time, amount, and type.

19 g. Determines whether a particular sale of medical
20 cannabis transaction exceeds the permissible limit.

21 h. Tracks medical cannabis cards that are denied,
22 revoked, or suspended.

23 i. Interfaces as necessary with the statewide
24 seed-to-sale tracking system established under Article 4.

j. Provides access as further provided in subsection (b).

(b) The patient registry shall be accessible to the following:

(1) State and local law enforcement agencies, provided the database may only be accessed upon probable cause or reasonable suspicion of a violation of a controlled substance law or of driving under the influence, and access is strictly limited to information that is necessary to verify that an individual is registered and possesses a valid and current medical cannabis card and, if appropriate, to verify that the amount and type of product in the individual's possession complies with the daily dosage limit and type of medical cannabis recommended.

(2) Health care practitioners licensed to prescribe prescription drugs.

(3) Registered certifying physicians.

(4) Dispensaries.

(5) The State Board of Medical Examiners.

(6) Licensed pharmacists.

(c) The commission may monitor patient registrations in the patient registry for practices that could facilitate unlawful diversion or misuse of cannabis and shall recommend disciplinary action to the board as appropriate.

§20-2A-35.

1 (a) Once certified, a patient and, if applicable,
2 the patient's designated caregiver, shall register in the
3 patient registry. The commission shall develop the application
4 and renewal process for patient and designated caregiver
5 registration, that shall include, but not be limited to, an
6 application form, relevant information that must be included
7 on the form, any additional requirements for eligibility the
8 commission deems necessary, and an application fee not to
9 exceed sixty-five dollars (\$65).

10 (b) If the certified patient or designated caregiver
11 meets the criteria for registration, the commission shall
12 place the patient or caregiver on the patient registry and
13 issue the patient or designated caregiver a medical cannabis
14 card. The commission shall determine the criteria for revoking
15 or suspending a medical cannabis card. Medical cannabis cards
16 shall be resistant to counterfeiting and tampering and, at a
17 minimum, shall include all of the following:

18 (1) The name, address, and date of birth of the
19 qualified patient or caregiver, as applicable.

20 (2) A photograph of the qualified patient or
21 caregiver, as applicable.

22 (3) Identification of the cardholder as a qualified
23 patient or a caregiver.

24 (4) The expiration date, as determined by commission
25 rule.

1 (5) The following statement: "This card is only
2 valid in the State of Alabama".

3 (c) Once a patient or designated caregiver is
4 registered and issued a medical cannabis card, he or she is
5 qualified to acquire, possess, or use medical cannabis, as
6 applicable.

7 (d) If a registered qualified patient or registered
8 caregiver loses his or her medical cannabis card, he or she
9 shall notify the commission within 10 days of becoming aware
10 the card is lost or stolen. The commission, by rule, shall
11 determine the process and fee for replacing a lost or stolen
12 card, including a process for invalidating the lost or stolen
13 card.

14 (e) The commission shall adopt rules to implement
15 this section and may impose civil penalties for violations of
16 this section.

17 ~~§20-2A-36.~~

18 ~~(a) A nonresident patient or caregiver who holds a~~
19 ~~valid medical cannabis or medical marijuana card issued in~~
20 ~~another state may register on a temporary basis in the patient~~
21 ~~registry and be issued a temporary medical cannabis card that~~
22 ~~permits the temporary cardholder to access dispensaries in~~
23 ~~this state, as further provided in this section and pursuant~~
24 ~~to commission rules; provided, however, the commission may~~
25 ~~only register the nonresident patient or caregiver on a~~

1 ~~temporary basis and issue a temporary card if the commission~~
2 ~~can determine that a medical cannabis product comparable to~~
3 ~~the type of product the patient or caregiver is permitted to~~
4 ~~use in his or her home state is available and can be dispensed~~
5 ~~in this state.~~

6 ~~(b) A nonresident patient or caregiver shall~~
7 ~~complete an application, which shall be in a form~~
8 ~~substantially similar to the application required under~~
9 ~~Section 20-2A-35, along with proof, as determined by~~
10 ~~commission rule, that the applicant has lawful permission in~~
11 ~~his or her home state to purchase a medical cannabis or~~
12 ~~medical marijuana product that is comparable to a type of~~
13 ~~medical cannabis product dispensed in this state. An applicant~~
14 ~~shall pay a processing fee to cover the costs incurred by the~~
15 ~~commission to administer this section as determined by~~
16 ~~commission rule.~~

17 ~~(c) A temporary medical cannabis card shall be in a~~
18 ~~form substantially similar to medical cannabis cards issued~~
19 ~~under Section 20-2A-35.~~

20 ~~(d) A temporary medical cannabis card is valid for a~~
21 ~~period determined by the commission by rule, but in no event~~
22 ~~more than 60 days. A temporary medical cannabis card may not~~
23 ~~be renewed.~~

24 ~~(e) If requested by the regulatory agency of the~~
25 ~~nonresident's home state which issued the nonresident a valid~~

1 ~~medical cannabis or medical marijuana card, the commission~~
2 ~~shall notify that regulatory agency of the nonresident's~~
3 ~~purchase of medical cannabis pursuant to this section.~~

4 ~~(f) To the extent practicable, the commission shall~~
5 ~~coordinate with any other state that has a medical cannabis or~~
6 ~~medical marijuana program and may request notification by the~~
7 ~~regulatory agency of that other state when an Alabama resident~~
8 ~~with a medical cannabis card purchases medical cannabis~~
9 ~~through the reciprocal medical cannabis or medical marijuana~~
10 ~~program in that state. Notification shall include the dosage~~
11 ~~or amount and type of product the cardholder purchases.~~

12 Article 4. Cultivation, Processing, and Dispensing
13 of Medical Cannabis.

14 §20-2A-50.

15 (a) The state hereby preemptively regulates medical
16 cannabis from seed to sale and shall reasonably regulate and
17 control all aspects of the medical cannabis industry to meet
18 the intent of this chapter. All functions and activities
19 relating to the production of medical cannabis in the state
20 shall be licensed, and licenses shall be granted to integrated
21 facilities, as well as to independent entities in the
22 following categories: Cultivator, processor, dispensary,
23 secure transporter, and testing laboratory.

24 (b) The commission shall license and regulate all
25 aspects of medical cannabis under this article, excluding

1 cultivation. The Department of Agriculture and Industries
2 shall license and regulate the cultivation of cannabis. For
3 integrated facility licenses, the commission and the
4 department shall enter into a memorandum of understanding
5 relating to the sharing of regulatory and licensing and
6 enforcement authority over licensees with regard to the
7 cultivation function.

8 §20-2A-51.

9 (a) Where the commission is authorized under this
10 article to determine the number of licenses of a specific
11 license category the commission will grant, or increase the
12 number of licenses of a specific license category to grant,
13 the commission shall consider the population of the state, the
14 number of active registered qualified patients, market demand,
15 the unemployment rate, the need for agricultural and other
16 business opportunities in communities, access to health care,
17 infrastructure, and other factors the commission deems
18 relevant in providing the greatest benefits to the residents
19 of this state and taking into account the racial and economic
20 makeup of the state.

21 (b) The commission, and where applicable the
22 department, shall ensure that at least one-fourth of all
23 licenses, or in the case of Section 20-2A-67, one-fifth of all
24 licenses, are awarded to business entities at least 51 percent
25 of which are owned by members of a minority group or, in the

1 case of a corporation, at least 51 percent of the shares of
2 the corporation are owned by members of a minority group, and
3 are managed and controlled by members of a minority group in
4 its daily operations. For purposes of this subsection,
5 minority group means individuals of African American, Native
6 American, Asian, or Hispanic descent.

7 (c) (1) Notwithstanding any other provision of this
8 chapter to the contrary, the commission shall not permit a
9 dispensary to operate a dispensing site in any municipality or
10 unincorporated area of a county unless the municipality or
11 county has authorized the operation of dispensing sites within
12 its boundaries, as provided in subdivision (2).

13 (2) Any county commission, by resolution, may
14 authorize the operation of dispensing sites in the
15 unincorporated areas of the county, and the governing body of
16 any municipality, by ordinance, may authorize the operation of
17 dispensing sites within the corporate limits of the
18 municipality. The county commission or municipal governing
19 body shall notify the commission not more than seven calendar
20 days after adopting the resolution or ordinance.

21 (3) This subsection does not prohibit a municipality
22 from adopting zoning ordinances restricting the operation of
23 dispensing sites within its corporate limits.

24 §20-2A-52.

(a) The commission, and the department with regard to cultivation facilities, shall have all powers necessary and proper to fully and effectively oversee the operation of medical cannabis facilities licensed pursuant to this article, including the authority to do all of the following:

(1) Investigate applicants for licenses, determine the eligibility for licenses, and grant licenses to applicants in accordance with this article and the rules.

(2) Investigate all individuals employed by licensees.

(3) At any time, through its investigators, agents, or auditors, without a warrant and without notice to the licensee, enter the premises, offices, facilities, or other places of business of a licensee, if evidence of compliance or noncompliance with this article or rules is likely to be found and consistent with constitutional limitations, for the following purposes:

a. To inspect and examine all premises of licensees.

b. To inspect and examine relevant records of the licensee and, if the licensee fails to cooperate with an investigation, impound, seize, assume physical control of, or summarily remove from the premises all books, ledgers, documents, writings, photocopies, correspondence, records, and videotapes, including electronically stored records, money receptacles, or equipment in which the records are stored.

1 c. To inspect the person, and inspect or examine
2 personal effects of an individual who holds a license, while
3 that individual is present in a medical cannabis facility of
4 the licensee.

5 d. To investigate alleged violations of this
6 article.

7 (4) Investigate alleged violations of this article
8 or rules and take appropriate disciplinary action against a
9 licensee.

10 (5) Require all relevant records of licensees,
11 including financial or other statements, to be kept on the
12 premises authorized for operation of the licensee or in the
13 manner prescribed by the commission.

14 (6) Eject, or exclude or authorize the ejection or
15 exclusion of, an individual from the premises of a licensee if
16 the individual violates this article, rules, or final orders
17 of the commission; provided, however, the propriety of the
18 ejection or exclusion is subject to a subsequent hearing by
19 the commission.

20 (7) Conduct periodic audits of licensees.

21 (8) Take disciplinary action as the commission
22 considers appropriate to prevent practices that violate this
23 article and rules.

24 (9) Take any other reasonable or appropriate action
25 to enforce this article and rules.

1 (b) The commission and department shall adopt rules
2 addressing the frequency of conducting periodic inspections
3 and audits of respective licensees.

4 (c) The commission may enter into one or more
5 memoranda of understanding with law enforcement agencies to
6 assist with enforcement of this article.

7 (d) The commission and department may seek and shall
8 receive the cooperation and assistance of the Alabama State
9 Law Enforcement Agency in conducting criminal background
10 checks and in fulfilling its responsibilities under this
11 article. The Alabama State Law Enforcement Agency may recover
12 its costs of cooperation under this article.

13 (e) The commission and department shall assist any
14 prosecuting agency in the investigation or prosecution of a
15 violation of a controlled substances law.

16 (f) Nothing in this article shall affect the
17 authority of the Alabama Department of Environmental
18 Management to administer and enforce any existing law over
19 which the Alabama Department of Environmental Management has
20 jurisdiction.

21 §20-2A-53.

22 (a) The commission, and the department with regard
23 to cultivation, shall adopt rules as necessary to implement,
24 administer, and enforce this article in a timely manner that
25 allows persons to begin applying for a license by September 1,

1 2022. Rules must ensure safety, security, and integrity of the
2 operation of medical cannabis facilities, that do all of the
3 following for each category of license:

4 (1) Establish operating standards to ensure the
5 health, safety, and security of the public and the integrity
6 of medical cannabis facility operations.

7 (2) Require a minimum of two million dollars
8 (\$2,000,000) of liability and casualty insurance and establish
9 minimum levels of other financial guarantees, if appropriate,
10 that licensees must maintain.

11 (3) Establish qualifications and restrictions for
12 individuals participating in or involved with operating
13 medical cannabis facilities.

14 (4) Establish an on-site inspection process to be
15 conducted at each facility of an applicant prior to being
16 issued a license, as well as ongoing on-site inspections of
17 the facilities of a licensee.

18 (5) Establish standards or requirements to ensure
19 cannabis and medical cannabis remains secure at all times,
20 including, but not limited to, requirements that all
21 facilities of licensees remain securely enclosed and locked as
22 appropriate.

23 (6) Subject to Section 20-2A-66, establish testing
24 standards, procedures, and requirements for medical cannabis
25 sold at dispensaries.

1 (7) Provide for the levy and collection of fines for
2 a violation of this article or rules.

3 (8) Establish annual license fees for each type of
4 license, provided the fee shall be not less than ten thousand
5 dollars (\$10,000) and not more than fifty thousand dollars
6 (\$50,000), depending on the category of license.

7 (9) Establish quality control standards, procedures,
8 and requirements.

9 (10) Establish chain of custody standards,
10 procedures, and requirements.

11 (11) In compliance with Chapters 27 and 30 of Title
12 22, establish standards, procedures, and requirements for
13 waste product storage and disposal and chemical storage.

14 (12) Establish standards, procedures, and
15 requirements for securely and safely transporting medical
16 cannabis between facilities.

17 (13) Establish standards, procedures, and
18 requirements for the storage of cannabis and medical
19 cannabis.

20 (14) Subject to Section 20-2A-63, establish
21 packaging and labeling standards, procedures, and requirements
22 for medical cannabis sold at dispensaries.

23 (15) Establish marketing and advertising
24 restrictions for medical cannabis products and medical
25 cannabis facilities.

1 (16) Establish standards and procedures for the
2 renewal, revocation, suspension, and nonrenewal of licenses.

3 (b) The commission, by rule, shall design a
4 universal state symbol that is a color image and made
5 available to licensed processors to include on all packages of
6 medical cannabis, as required under Section 20-2A-63.

7 §20-2A-54.

8 (a) In order to ensure that all medical cannabis
9 sold in the state maintains product quality to protect the
10 health and welfare of state residents, the commission shall
11 establish a statewide seed-to-sale tracking system for use as
12 an integrated cannabis and medical cannabis tracking,
13 inventory, and verification system. The system must allow for
14 interface with third-party inventory and tracking systems as
15 described in Section 20-2A-60 to provide for access by this
16 state, licensees, and law enforcement personnel, to the extent
17 that they need and are authorized to receive or submit the
18 information, to comply with, enforce, or administer this
19 chapter.

20 (b) At a minimum, the system must be capable of
21 storing and providing access to information that, in
22 conjunction with the patient registry and with one or more
23 third-party inventory control and tracking systems under
24 Section 20-2A-60, allows all of the following:

(1) Retention of a record of the date, time, amount, and price of each sale or transfer of medical cannabis to a registered qualified patient or registered caregiver.

(2) Effective seed-to-sale tracking of cannabis and medical cannabis sales and transfers among licensees and with regard to integrated facility licensees, among facilities of the licensee.

(3) Receipt and integration of information from third-party inventory control and tracking systems under Section 20-2A-60.

(c) The commission shall seek bids to establish, operate, and maintain the statewide seed-to-sale tracking system under this section. The commission shall do all of the following:

(1) Evaluate bidders based on the cost of the service and the ability to meet all of the requirements of this chapter.

(2) Give strong consideration to the bidder's ability to prevent fraud, abuse, and other unlawful or prohibited activities associated with the commercial trade in cannabis and medical cannabis in this state, and the ability to provide additional tools for the administration and enforcement of this chapter.

(3) Institute procedures to ensure that the person awarded the contract does not disclose or use the information

1 in the system for any use or purpose except for the
2 enforcement, oversight, and implementation of this chapter.

3 (4) Require the person awarded the contract to
4 deliver the functioning system by 180 days after award of the
5 contract.

6 (d) The commission may terminate a contract with the
7 person awarded the contract for a violation of this chapter.

8 (e) The information in the statewide seed-to-sale
9 tracking system is confidential and is exempt from disclosure
10 under the Open Records Act, Article 3 of Chapter 12 of Title
11 36; provided, however, information in the system may be
12 disclosed for purposes of enforcing this chapter.

13 §20-2A-55.

14 (a) Beginning September 1, 2022, a person may apply
15 to the commission for a license for an integrated facility or
16 for a license in one of the following independent categories:
17 Cultivator, processor, secure transporter, state testing
18 laboratory, or dispensary. The application shall be made under
19 oath on a form provided by the commission and shall contain
20 information as prescribed by the commission, including, but
21 not limited to, all of the following:

22 (1) The name, business address, business telephone
23 number, and Social Security number or if applicable, federal
24 tax identification number, of the applicant.

1 ~~(2) The identity of every individual having any~~
2 ~~ownership interest in the applicant with respect to which the~~
3 ~~license is sought. If the disclosed entity is a trust, the~~

4 (2) With regard to each business entity that has any
5 ownership interest in the applicant, all of the following:

6 a. The identity of every individual having an
7 indirect or direct ownership interest in that business entity.
8 For purposes of this paragraph, if the business entity is a
9 trust, the application shall disclose the names and addresses
10 of all trustees and beneficiaries; if a privately held
11 corporation, the names and addresses of all shareholders,
12 officers, and directors; if a publicly held corporation, the
13 names and addresses of all shareholders holding a direct or
14 indirect interest of greater than five percent, officers, and
15 directors; if a partnership or limited liability partnership,
16 the names and addresses of all partners; if a limited
17 partnership or limited liability limited partnership, the
18 names of all partners, both general and limited; or if a
19 limited liability company, the names and addresses of all
20 members and managers.

21 ~~(3) An identification of any business that is~~
22 ~~directly or indirectly involved in the cultivation,~~
23 ~~processing, packaging, labeling, testing, transporting, or~~
24 ~~sale of cannabis, including, if applicable, the state of~~
25 ~~incorporation or registration, in which an applicant or, if~~

1 ~~the applicant is an individual, the applicant's spouse,~~
2 ~~parent, or child has any equity interest. If an applicant is a~~
3 ~~corporation, partnership, or other business entity, the~~
4 ~~applicant shall identify any other corporation, partnership,~~
5 ~~or other business entity that is directly or indirectly~~
6 ~~involved in the cultivation, processing, packaging, labeling,~~
7 ~~testing, transporting, or sale of cannabis in which it has any~~
8 ~~equity interest, including, if applicable, the state of~~
9 ~~incorporation or registration. An applicant may comply with~~
10 ~~this subdivision by filing a copy of the applicant's~~
11 ~~registration with the Securities and Exchange Commission if~~
12 ~~the registration contains the information required by this~~
13 ~~subdivision.~~

14 b.1. The identity of all of the following other
15 entities, if the other entities are directly or indirectly
16 involved in the cannabis industry, including, but not limited
17 to, the cultivation, processing, packaging, labeling, testing,
18 transporting, or sale of cannabis:

19 (i) Any subsidiary, affiliate, conglomerate, parent,
20 or other entity that shares common ownership, directly or
21 indirectly, with the business entity.

22 (ii) Any partnership of which the business entity is
23 a partner.

24 (iii) Any limited liability company of which the
25 business entity is a member or manager.

1 2. This paragraph shall be construed broadly to
2 ensure the broadest disclosure and greatest transparency
3 reasonably possible.

4 (3)a. With regard to each individual having any
5 ownership interest in the applicant, the identity of all of
6 the following entities, if the entities are directly or
7 indirectly involved in the cannabis industry, including, but
8 not limited to, the cultivation, processing, packaging,
9 labeling, testing, transporting, or sale of cannabis:

10 1. Any business entity of which the individual or
11 his or her spouse, parent, or child has any equity interest.

12 2. Any partnership of which the individual or his or
13 her spouse, parent, or child has any equity interest.

14 3. Any limited liability company of which the
15 individual or his or her spouse, parent, or child is a member
16 or manager.

17 b. This subdivision shall be construed broadly to
18 ensure the broadest disclosure and greatest transparency
19 reasonably possible.

20 (4) Whether an owner, director, board member, or
21 individual with a controlling interest in the applicant has
22 been indicted for, charged with, arrested for, or convicted
23 of, pled guilty or nolo contendere to, forfeited bail
24 concerning any criminal offense under the laws of any
25 jurisdiction, either felony or controlled substance-related

1 misdemeanor, not including traffic violations, regardless of
2 whether the offense has been reversed on appeal or otherwise,
3 including the date, the name and location of the court,
4 arresting agency, and prosecuting agency, the case caption,
5 the docket number, the offense, the disposition, and the
6 location and length of incarceration.

7 (5) Whether an applicant has ever applied for or has
8 been granted any commercial license or certificate issued by a
9 licensing board or commission in this state or any other
10 jurisdiction that has been denied, restricted, suspended,
11 revoked, or not renewed and a statement describing the facts
12 and circumstances concerning the application, denial,
13 restriction, suspension, revocation, or nonrenewal, including
14 the licensing board or commission, the date each action was
15 taken, and the reason for each action.

16 (6) Whether an applicant has filed, or been served
17 with, a complaint or other notice filed with any public body,
18 regarding the delinquency in the payment of, or a dispute over
19 the filings concerning the payment of, any tax required under
20 federal, state, or local law, including the amount, type of
21 tax, taxing agency, and time periods involved.

22 (7) A statement listing the names and titles of all
23 public officials of any unit of government, and the spouses,
24 parents, and children of those public officials, who, directly
25 or indirectly, own any financial interest in, have any

1 beneficial interest in, are the creditors of or hold any debt
2 instrument issued by, or hold or have any interest in any
3 contractual or service relationship with an applicant.

4 (8) The anticipated or actual number of employees;
5 and projected or actual gross receipts.

6 (9) Financial information in the manner and form
7 required by rule by the commission.

8 (10) Records indicating that a majority of ownership
9 is attributable to an individual or individuals with proof of
10 residence in this state for a continuous period of no less
11 than 15 years preceding the application date.

12 (11) For an applicant seeking an integrated facility
13 license or a cultivator license, records indicating that a
14 majority of ownership is attributable to an individual or
15 individuals, or an entity or entities, with cumulative
16 business experience in the field of commercial horticulture or
17 agronomic production for a period of at least 15 years.

18 ~~(b) An individual with a controlling interest in an~~
19 ~~applicant shall be subject to a state and national criminal~~
20 Each owner, shareholder, director, board member, and
21 individual with an economic interest in an applicant shall
22 submit to a state and national criminal background check. The
23 commission shall determine the manner in which fingerprints of
24 the individual shall be submitted to the Alabama State Law
25 Enforcement Agency along with a sufficient fee required to

1 perform the criminal history records check by the agency and
2 by the Federal Bureau of Investigation. The applicant shall
3 submit with its application the individual's written consent
4 to the criminal history records check.

5 (c) A false application is cause for the commission
6 to deny a license. The commission shall not consider an
7 incomplete application but, within a reasonable time, shall
8 return the application to the applicant with notification of
9 the deficiency and instructions for submitting a corrected
10 application. Information the commission obtains from the
11 background investigation is exempt from disclosure under the
12 Open Records Act, Article 3 of Chapter 12 of Title 36.

13 (d) An applicant shall provide written consent to
14 the inspections, examinations, searches, and seizures provided
15 for in subdivision (a)(3) of Section 20-2A-52 and to
16 disclosure to the commission and its agents of otherwise
17 confidential records, including tax records held by any
18 federal, state, or local agency, or credit bureau or financial
19 institution, while applying for or holding a license.
20 Information the commission receives under this subsection is
21 exempt from disclosure under the Open Records Act.

22 (e) An applicant shall certify that the applicant
23 does not have an economic interest in any other license under
24 this article.

1 (f) A nonrefundable application fee of two thousand
2 five hundred dollars (\$2,500) shall be paid at the time of
3 filing to defray the costs associated with the background
4 investigation conducted by the commission. If the costs of the
5 investigation and processing the application exceed the
6 application fee, the applicant shall pay the additional amount
7 to the commission. All information, records, interviews,
8 reports, statements, memoranda, or other data supplied to or
9 used by the commission in the course of its review or
10 investigation of an application for a license under this
11 article shall be disclosed only in accordance with this
12 article. The information, records, interviews, reports,
13 statements, memoranda, or other data are not admissible as
14 evidence or discoverable in any action of any kind in any
15 court or before any department, agency, board, commission, or
16 authority, except for any action considered necessary by the
17 commission, unless so ordered by a court of competent
18 jurisdiction according to the Rules of Civil Procedure.

19 (g) If the commission identifies a deficiency in an
20 application, the commission shall provide the applicant with a
21 reasonable period of time, as determined by the commission by
22 rule but not more than 60 days, to correct the deficiency.

23 §20-2A-56.

24 (a) Before issuing any license under this article,
25 the commission shall provide notice and a 30-day period during

1 which members of the public may submit written comments
2 regarding an applicant. The commission shall consider all
3 comments received during the 30-day period. The commission may
4 hold a public hearing as it deems necessary, at which the
5 applicant may present its business plan for the operation of
6 its facilities and allow further comments or questions from
7 the public. The hearing shall be conducted in a manner that
8 allows members of the public to participate remotely by
9 virtual means.

10 ~~(a)~~ (b) An applicant is ineligible to receive a
11 license if any of the following circumstances exist:

12 (1) An owner, director, board member, or individual
13 with a controlling interest in the applicant has been
14 convicted of or released from incarceration for a felony under
15 the laws of this state, any other state, or the United States
16 within the past 10 years or has been convicted of a controlled
17 substance-related felony within the past 10 years; provided,
18 however, the commission shall not consider any conviction
19 overturned on appeal or any charge that has been expunged
20 pursuant to Chapter 27 of Title 15.

21 (2) The applicant has knowingly submitted an
22 application for a license under this article that contains
23 false information.

1 (3) An owner, director, board member, or individual
2 with an economic interest in the applicant is a member of the
3 commission.

4 (4) The applicant fails to demonstrate the
5 applicant's ability to maintain adequate minimum levels of
6 liability and casualty insurance or other financial guarantees
7 for its proposed facility.

8 (5) The applicant cannot provide records described
9 in subdivision (a)(10) of Section 20-2A-55.

10 (6) For an applicant seeking an integrated facility
11 license or a cultivator license, the applicant cannot provide
12 records described in subdivision (a)(11) of Section 20-2A-55.

13 ~~(5)~~ (7) The applicant fails to meet other criteria
14 established by rule.

15 ~~(b)~~ (c) In determining whether to grant a license to
16 an applicant, the commission may consider all of the
17 following:

18 (1) The integrity, moral character, and reputation;
19 personal and business probity; financial ability and
20 experience; and responsibility or means to operate or maintain
21 a facility of the applicant and of any other individual that
22 meets either of the following:

23 a. Controls, directly or indirectly, the applicant.

1 b. Is controlled, directly or indirectly, by the
2 applicant or by a person who controls, directly or indirectly,
3 the applicant.

4 (2) The financial ability of the applicant to
5 maintain required financial guarantees.

6 (3) The sources and total amount of the applicant's
7 capitalization to operate and maintain the proposed facility.

8 (4) Whether an owner, director, board member, or
9 individual with a controlling interest in the applicant has
10 been indicted for, charged with, arrested for, or convicted
11 of, pled guilty or nolo contendere to, forfeited bail
12 concerning, or had expunged any relevant criminal offense
13 under the laws of any jurisdiction, either felony or
14 misdemeanor, not including traffic violations, regardless of
15 whether the offense has been expunged, pardoned, or reversed
16 on appeal or otherwise.

17 (5) Whether the applicant has filed, or had filed
18 against it, a proceeding for bankruptcy within the past seven
19 years.

20 (6) Whether the applicant has been served with a
21 complaint or other notice filed with any court or public
22 agency regarding payment of any tax required under federal,
23 state, or local law that has been delinquent for one or more
24 years.

(7) Whether the applicant has a history of noncompliance with any regulatory requirements in this state or any other jurisdiction.

(8) Whether at the time of application the applicant is a defendant in litigation involving its business practices.

(9) The applicant's ability to capitalize and conduct operations as proposed in its business plan, including business experience in related fields.

(10) The applicant's history of business activities as it applies to the specific license for which the applicant is seeking licensure.

(11) The proposed location of all proposed medical cannabis facilities as being suitable for all activities, not inconsistent with applicable zoning, and the applicant's ability to serve an identifiable geographic area.

(12) Whether the applicant meets other standards or requirements established under this article or by rules applicable to the license category.

(c) The commission shall review all applications for licenses and shall determine whether to grant or deny a license not more than 60 days after the date a license application was submitted, or if an applicant was notified of a deficiency under subsection (g) of Section 20-2A-55, the commission shall grant or deny a license not more than 60 days after the deficiency was corrected.

1 (d) After denial of a license, the commission, upon
2 request, shall provide a public investigative hearing at which
3 the applicant is given the opportunity to present testimony
4 and evidence to establish its suitability for a license. Other
5 testimony and evidence may be presented at the hearing, but
6 the commission's decision must be based on the whole record
7 before the commission and is not limited to testimony and
8 evidence submitted at the public investigative hearing.

9 (e) Before issuing a license, the applicant shall
10 pay the annual license fee, as established by the commission.

11 (f) A license shall be issued annually. Except as
12 otherwise provided in this article, the commission shall renew
13 a license if both of the following requirements are met:

14 (1) The licensee applies to the commission in a
15 timely manner on a renewal form provided by the commission
16 that requires information prescribed in rules and pays the
17 annual license fee.

18 (2) The licensee meets the requirements of this
19 article and any other renewal requirements set forth in the
20 rules.

21 (g) If a license renewal application is not
22 submitted by the license expiration date, the license may be
23 renewed within 60 days after its expiration date upon
24 application, payment of the annual license fee, and
25 satisfaction of any renewal requirement and late fee set forth

1 in rules. The licensee may continue to operate during the 60
2 days after the license expiration date if the license is
3 renewed by the end of the 60-day period.

4 (h) License expiration does not terminate the
5 commission's authority to impose sanctions on a licensee whose
6 license has expired.

7 (i) A licensee shall consent in writing to
8 inspections, examinations, searches, and seizures that are
9 permitted under this article.

10 (j) An applicant or licensee has a continuing duty
11 to provide information requested by the commission and to
12 cooperate in any investigation, inquiry, or hearing conducted
13 by the commission.

14 §20-2A-57.

15 (a) If any of the following occurs, the commission
16 may deny, suspend, revoke, or restrict a license:

17 (1) An applicant or licensee fails to comply with
18 this article or rules.

19 (2) A licensee no longer meets the eligibility
20 requirements for a license under this article.

21 (3) An applicant or licensee fails to provide
22 information the commission requests to assist in any
23 investigation, inquiry, or commission hearing.

24 (b) The commission may impose civil fines of up to
25 five thousand dollars (\$5,000) against an individual and up to

1 twenty-five thousand dollars (\$25,000) or an amount equal to
2 the daily gross receipts, whichever is greater, against a
3 licensee for each violation of this article, rules, or an
4 order of the commission. Assessment of a civil fine under this
5 subsection is not a bar to the investigation, arrest,
6 charging, or prosecution of an individual for any other
7 violation of this article and is not grounds to suppress
8 evidence in any criminal prosecution that arises under this
9 article or any other law of this state.

10 (c) The commission shall comply with the hearing
11 procedures of the Administrative Procedure Act when denying,
12 revoking, suspending, or restricting a license or imposing a
13 fine. The commission may suspend a license without notice or
14 hearing upon a determination that the safety or health of
15 registered qualified patients, registered caregivers, or
16 employees is jeopardized by continuing a facility's operation.
17 If the commission suspends a license under this subsection
18 without notice or hearing, a prompt post-suspension hearing
19 must be held to determine if the suspension should remain in
20 effect. The suspension may remain in effect until the
21 commission determines that the cause for suspension has been
22 abated. The commission may revoke the license or approve a
23 transfer or sale of the license upon a determination that the
24 licensee has not made satisfactory progress toward abating the
25 hazard.

1 (d) Any party aggrieved by an action of the
2 commission suspending, revoking, restricting, or refusing to
3 renew a license, or imposing a fine, shall be given a hearing
4 before the commission upon request. A request for a hearing
5 must be made to the commission in writing within 21 days after
6 service of notice of the action of the commission. Notice of
7 the action of the commission must be served either by personal
8 delivery or by certified mail, postage prepaid, to the
9 aggrieved party. Noticeservedby certified mail is considered
10 complete on the business day following the date of the
11 mailing.

12 (e) The commission may conduct investigative and
13 contested case hearings; issue subpoenas for the attendance of
14 witnesses; issue subpoenas duces tecum for the production of
15 books, ledgers, records, memoranda, electronically retrievable
16 data, and other pertinent documents; and administer oaths and
17 affirmations to witnesses as appropriate to exercise and
18 discharge the powers and duties of the commission under this
19 article.

20 (f) Any person aggrieved by an action of the
21 commission or the department under this article, within 30
22 days after receiving notice of the action, may appeal the
23 action to the circuit court in the county where the commission
24 or department is located.

25 §20-2A-58.

1 (a) Each license is exclusive to the licensee. A
2 license, and any interest in or rights under a license, and
3 any ownership interest or other beneficial interest in a
4 licensed entity, may not be sold, transferred, assigned,
5 conveyed, or otherwise disposed of in any manner, in whole or
6 in part, voluntarily or involuntarily, directly or indirectly,
7 except upon application to and approval of the commission.

8 (b) A nonrefundable application fee of two thousand
9 five hundred dollars (\$2,500) shall be paid to the commission
10 at the time of filing any transfer request under subsection
11 (a).

12 (c) The attempted transfer, sale, or other
13 conveyance of an interest or right in a license, or transfer
14 of an ownership interest or other beneficial interest in a
15 licensed entity, without the approval of the commission, shall
16 be grounds for suspension or revocation of the license or for
17 other sanction considered appropriate by the commission.

18 §20-2A-59.

19 ~~(a) Before hiring a prospective employee, a licensee~~
20 ~~shall conduct a background check of the prospective employee.~~
21 ~~If the background check indicates a pending charge or~~

22 (a) The commission, prior to appointment,
23 employment, or service for a licensee, shall require all
24 officers, employees, contractors, and other individuals
25 performing work of any character who would have access to

1 cannabis, a medical cannabis facility, or related equipment or
2 supplies, to submit to a state and national criminal
3 background check. The commission shall determine the manner in
4 which fingerprints of the individuals shall be submitted to
5 the Alabama State Law Enforcement Agency along with a
6 sufficient fee required to perform the criminal history
7 records check by the agency and the Federal Bureau of
8 Investigation. Notwithstanding any state law to the contrary,
9 all records related to any criminal background check conducted
10 pursuant to this subsection shall be accessible and made
11 available, upon request, by the commission.

12 (b) If the criminal background check of a
13 prospective officer, employee, or contractor indicates a
14 pending charge or conviction within the past five years for a
15 controlled substance-related felony or a controlled
16 substance-related misdemeanor, a licensee may not appoint,
17 hire, or contract with the prospective officer, employee, or
18 contractor without written permission of the commission;
19 provided, however, a licensee shall not consider any
20 conviction overturned on appeal or any charge that has been
21 expunged pursuant to Chapter 27 of Title 15.

22 ~~(b)~~ (c) Each licensee shall enter all transactions,
23 current inventory, and other information into the statewide
24 seed-to-sale tracking system in accordance with rules adopted

1 by the commission and the Department of Agriculture and
2 Industries.

3 §20-2A-60.

4 (a) Except as otherwise provided in subsection (b),
5 a licensee shall adopt and use a third-party inventory control
6 and tracking system that is capable of interfacing with the
7 statewide seed-to-sale tracking system to allow the licensee
8 to enter or access information in the statewide seed-to-sale
9 tracking system as required under this article and rules. The
10 third-party inventory control and tracking system must have
11 all of the following capabilities necessary for the licensee
12 to comply with the requirements applicable to the licensee's
13 license type:

14 (1) Tracking all cannabis plants, medical cannabis
15 products, patient and caregiver purchase totals, waste,
16 transfers, conversions, sales, and returns that are linked to
17 unique identification numbers.

18 (2) Tracking lot and batch information throughout
19 the entire chain of custody.

20 (3) Tracking all products, conversions, and
21 derivatives throughout the entire chain of custody.

22 (4) Tracking cannabis plant, batch, and product
23 destruction.

24 (5) Tracking transportation of product.

(6) Performing complete batch recall tracking that clearly identifies all of the following details relating to the specific batch subject to the recall:

- a. Sold product.
- b. Product inventory that is finished and available for sale.
- c. Product that is in the process of transfer.
- d. Product being processed into another form.
- e. Postharvest raw product, such as product that is in the drying, trimming, or curing process.

(7) Reporting and tracking loss, theft, or diversion of product containing cannabis.

(8) Reporting and tracking all inventory discrepancies.

(9) Reporting and tracking adverse patient responses or dose-related efficacy issues.

(10) Reporting and tracking all sales and refunds.

(11) Receiving testing results electronically from a state testing laboratory via a secured application program interface into the system and directly linking the testing results to each applicable source batch and sample.

(12) Identifying test results that may have been altered.

(13) Providing the licensee with access to information in the tracking system that is necessary to verify

1 that the licensee is carrying out all transactions authorized
2 under the licensee's license in accordance with this article.

3 (14) Providing information to cross-check that
4 product sales are made to a registered qualified patient, or a
5 registered caregiver on behalf of a registered qualified
6 patient, and that the product received the required testing.

7 (15) Providing the commission and state agencies
8 with access to information in the database that they are
9 authorized to access.

10 (16) Providing licensees with access only to the
11 information in the system that they are required to receive
12 before a sale, transfer, transport, or other activity
13 authorized under a license issued under this article.

14 (17) Securing the confidentiality of information in
15 the database by preventing access by a person who is not
16 authorized to access the statewide seed-to-sale tracking
17 system or is not authorized to access the particular
18 information.

19 (18) Providing analytics to the commission regarding
20 key performance indicators such as the following:

- 21 a. Total daily sales.
- 22 b. Total cannabis plants in production.
- 23 c. Total cannabis plants destroyed.
- 24 d. Total inventory adjustments.

1 (b) If the statewide seed-to-sale tracking system is
2 capable of allowing a licensee to access or enter information
3 into the statewide seed-to-sale tracking system without use of
4 a third-party inventory control and tracking system, a
5 licensee may access or enter information into the statewide
6 seed-to-sale tracking system directly and the licensee is not
7 required to adopt and use a third-party inventory control and
8 tracking system.

9 §20-2A-61.

10 (a) (1) With regard to any physical structure or
11 vehicle owned, leased, or otherwise used by a licensee, the
12 licensee may not do either of the following:

13 a. Advertise medical cannabis brand names or use
14 graphics related to cannabis or paraphernalia on the exterior
15 of the physical structure or vehicle.

16 b. Display medical cannabis products or
17 paraphernalia so as to be clearly visible from the exterior of
18 the physical structure or vehicle.

19 (2) Restrictions in this subsection shall apply to
20 any item located on real property on which a licensee's
21 physical structures are located

22 (b) Advertising for medical cannabis may not contain
23 any statements, illustrations, or other material that would be
24 appealing to minors.

(c) The commission shall adopt rules that establish restrictions and requirements for advertising, including signage, that may include limiting the media or forums where advertising may occur.

§20-2A-62.

(a) (1) A cultivator license authorizes all of the following:

a. The cultivation of cannabis.

b. The sale or transfer of cannabis to a processor.

c. If the cultivator contracts with a processor to process its cannabis into medical cannabis on the cultivator's behalf, the sale or transfer of medical cannabis to a dispensary.

(2) A cultivator license authorizes the cultivator to transfer cannabis only by means of a secure transporter.

(b) The commission shall consult with the Department of Agriculture and Industries when determining the number of cultivator licenses to issue, provided the commission shall issue no more than 12 cultivator licenses.

(c) An applicant for a license under this section shall meet all of the following requirements:

~~(2) Provide records indicating that majority ownership is attributable to an individual or individuals with proof of residency in this state for a continuous period of no less than eight years preceding the application date.~~

~~(3)~~ (1) Demonstrate the ability to secure and maintain cultivation facilities.

~~(4)~~ (2) Demonstrate the ability to obtain and use an inventory control and tracking system as required under Section 20-2A-60.

~~(5)~~ (3) Demonstrate the ability to commence cultivation of cannabis within 60 days of application approval notification.

~~(6)~~ (4) Demonstrate the ability to destroy unused or waste cannabis in accordance with rules adopted by the Department of Agriculture and Industries.

~~(7)~~ (5) Demonstrate the financial stability to provide proper testing of individual lots and batches.

(d) A licensed cultivator shall comply with all of the following, in accordance with rules adopted by the Department of Agriculture and Industries:

(1) All facilities shall be protected by a monitored security alarm system, be enclosed, and remain locked at all times.

(2) All individuals entering and exiting facilities shall be monitored by video surveillance and keypad or access card entry.

(3) All employees may not have any conviction within the past 10 years for a controlled substance-related felony or a controlled substance-related misdemeanor other than a

conviction that was overturned on appeal or a charge that was expunged pursuant to Chapter 27 of Title 15.

(4) Cultivars selected by a licensee must be approved by the department prior to acquisition of plant material for cultivation.

(e) A cultivator shall be subject to inspection by the Department of Agriculture and Industries.

(f) The cultivation of cannabis pursuant to this chapter shall be considered an agricultural purpose for purposes of Section 40-23-4.

(g) Nothing in this section shall be construed to prohibit the hydroponic growing of cannabis.

(h) The Department of Agriculture and Industries shall consult with the commission when adopting rules pursuant to this article.

§20-2A-63.

(a) (1) A processor license authorizes all of the following:

a. The purchase or transfer of cannabis from a cultivator.

b. The processing of cannabis into medical cannabis which shall include properly packaging and labeling medical cannabis products, in accordance with this section.

c. The sale or transfer of medical cannabis to a dispensary.

(2) A processor license authorizes the processor to transfer medical cannabis only by means of a secure transporter.

(b) The commission shall issue no more than four processor licenses.

(c) (1) All medical cannabis products must be medical grade product, manufactured using documented good quality practices, and meet Good Manufacturing Practices, such that the product is shown to meet intended levels of purity and be reliably free of toxins and contaminants. Medical cannabis products may not contain any additives other than pharmaceutical grade excipients.

(2) The Department of Agriculture and Industries shall be responsible for enforcing Good Manufacturing Practices.

(d) Medical cannabis products may not be processed into a form that is attractive to or targets children, including all of the following which are prohibited:

(1) Any product bearing any resemblance to a cartoon character, fictional character whose target audience is children or youth, or pop culture figure.

(2) Any product bearing a reasonable resemblance to a product available for consumption as a commercially available candy.

(3) Any product whose design resembles, by any means, another object commonly recognized as appealing to, or intended for use by, children.

(4) Any product whose shape bears the likeness or contains characteristics of a realistic or fictional human, animal, or fruit, including artistic, caricature, or cartoon rendering.

(e) All of the following shall apply to all packages and labels of medical cannabis products:

(1) Labels, packages, and containers shall not be attractive to minors and may not contain any content that reasonably appears to target children, including toys, cartoon characters, and similar images. Packages should be designed to minimize appeal to children and must contain a label that reads: "Keep out of reach of children."

(2) All medical cannabis products must be packaged in child-resistant, tamper-evident containers.

(3) All medical cannabis product labels shall contain, at a minimum, the following information:

a. Lot and batch numbers.

b. A license identification number for the cultivator and a license identification number for the processor.

c. Cannabinoids content and potency.

1 d. The universal state symbol printed in color at
2 least one-half inch by one-half inch in size.

3 (f) The commission shall establish one universal
4 flavor for all gelatinous cube, cuboid, and lozenge medical
5 cannabis products.

6 (g) The following statement shall be included on
7 each label, if space permits, or as an insert within the
8 package: "WARNING: This product may make you drowsy or dizzy.
9 Do not drink alcohol with this product. Use care when
10 operating a vehicle or other machinery. Taking this product
11 with medication may lead to harmful side effects or
12 complications. Consult your physician before taking this
13 product with any medication. Women who are breastfeeding,
14 pregnant, or plan to become pregnant should discuss medical
15 cannabis use with their physicians."

16 (h) Any advertisement and any package or label may
17 not contain any false statement or statement that advertises
18 health benefits or therapeutic benefits of medical cannabis.

19 (i) The commission may require the implementation of
20 a digital image such as a QRCode for purposes of tracking
21 medical cannabis products. The digital image must interface
22 with the statewide seed-to-sale tracking system.

23 (j) The commission shall determine what information
24 from the label shall be entered into the statewide
25 seed-to-sale tracking system.

1 §20-2A-64.

2 (a) (1) A dispensary license authorizes all of the
3 following:

4 a. The purchase or transfer of medical cannabis from
5 a processor.

6 b. If a cultivator contracted with a processor to
7 process its cannabis into medical cannabis on the cultivator's
8 behalf, the purchase or transfer of medical cannabis from the
9 cultivator.

10 c. The purchase or transfer of medical cannabis from
11 an integrated facility.

12 d. The dispensing and sale of medical cannabis only
13 to a registered qualified patient or registered caregiver.

14 (2) A dispensary license authorizes the dispensary
15 to transfer medical cannabis only by means of a secure
16 transporter, including transport between its dispensing sites.

17 (b) The commission shall issue no more than four
18 dispensary licenses.

19 (c) A dispensary license authorizes the dispensary to
20 transfer medical cannabis to or from a state testing
21 laboratory for testing by means of a secure transporter.

22 (d) A licensed dispensary shall comply with all of
23 the following:

1 (1) Each dispensing site must be located at least
2 one thousand feet from any school, day care, or child care
3 facility.

4 (2) Each dispensing site must be equipped with
5 surveillance cameras that are focused on each point of entry
6 and that operate on a continuous basis. The dispensary must
7 maintain surveillance records for a minimum of 60 days
8 following the date of recording.

9 (3) Sell and dispense medical cannabis at a
10 dispensing site to a registered qualified patient or
11 registered caregiver only after it has been tested and bears
12 the label required for retail sale.

13 (4) Enter all transactions, current inventory, and
14 other information into the statewide seed-to-sale tracking
15 system as required in Section 20-2A-54.

16 (5) Only allow dispensing of medical cannabis by
17 certified dispensers, as provided in subsection (e).

18 (6) Not allow the use of medical cannabis product on
19 the premises.

20 (7) Only allow registered qualified patients and
21 registered caregivers on the premises.

22 (e) (1) As used in this subsection, certified
23 dispenser means an employee of a dispensary who dispenses
24 medical cannabis to a registered qualified patient or

1 registered caregiver and who has been trained and certified by
2 the commission.

3 (2) The commission shall establish and administer a
4 training program for dispensers that addresses proper
5 dispensing procedures, including the requirements of this
6 subsection, and other topics relating to public health and
7 safety and preventing abuse and diversion of medical cannabis.
8 The commission shall certify trained dispensers and may
9 require, as a qualification to remain certified, periodic
10 training.

11 (3) A certified dispensary shall comply with all of
12 the following:

13 a. Before dispensing medical cannabis, inquire of
14 the patient registry to confirm that the patient or caregiver
15 holds a valid, current, unexpired, and unrevoked medical
16 cannabis card and that the dispensing of medical cannabis
17 conforms to the type and amount recommended in the physician
18 certification and will not exceed the 60-day daily dosage
19 purchasing limit.

20 b. Enter into the patient registry the date, time,
21 amount, and type of medical cannabis dispensed.

22 c. Comply with any additional requirements
23 established by the commission by rule.

24 (4) The commission shall adopt rules to implement
25 this subsection.

1 (f) A licensee may operate up to three dispensing
2 sites, each of which must be located in a different county
3 from any other dispensing site; provided, however, the
4 commission may authorize a licensee to operate a greater
5 number of dispensing sites if, at least one year after the
6 date when the maximum number of total dispensing sites
7 authorized under this section and Section 20-2A-67 are
8 operating, the commission determines that the patient pool has
9 reached a sufficient level to justify an additional dispensing
10 site in an underserved or unserved area of the state.

11 Notwithstanding the foregoing, a licensee may not
12 operate any dispensing site in the unincorporated area of a
13 county or in a municipality that has not adopted a resolution
14 or ordinance authorizing the operation of dispensing sites
15 under subsection (c) of Section 20-2A-51.

16 §20-2A-65.

17 (a) A secure transporter license authorizes the
18 licensee to store and transport cannabis and medical cannabis
19 for a fee upon request of a licensee. A license does not
20 authorize transport to a registered qualified patient or
21 registered caregiver.

22 (b) A secure transporter shall comply with all of
23 the following:

24 (1) Each employee who has custody of cannabis or
25 medical cannabis shall not have been convicted of or released

1 from incarceration for a felony under the laws of this state,
2 any other state, or the United States within the past five
3 years or have been convicted of a misdemeanor involving a
4 controlled substance within the past five years.

5 (2) A route plan and manifest shall be entered into
6 the statewide seed-to-sale tracking system, and a copy must be
7 carried in the transporting vehicle and presented to a law
8 enforcement officer upon request.

9 (3) The cannabis or medical cannabis shall be
10 transported in one or more sealed containers and not be
11 accessible while in transit.

12 (4) A secure transporting vehicle may not bear
13 markings or other indication that it is carrying cannabis or
14 medical cannabis.

15 (c) A secure transporter is subject to
16 administrative inspection by a law enforcement officer at any
17 point during the transportation of cannabis or medical
18 cannabis to determine compliance with this article.

19 §20-2A-66.

20 (a) A state testing laboratory license authorizes
21 the licensee to possess and test cannabis and medical cannabis
22 products cultivated or processed at licensed facilities.

23 (b) The commission, by rule, shall establish
24 protocols for product testing by a licensed state testing
25 laboratory, which shall be conducted during cultivation,

1 processing, and dispensing to ensure that all dispensed
2 medical cannabis is consistently high grade and maintains a
3 consistency with less than 0.5 percent variability among
4 batches of the same product. The protocols for testing shall
5 include the following, as well as a determination of
6 corresponding tolerance limits:

7 (1) Cannabinoid content and potency, including, but
8 not limited to, all of the following:

- 9 a. Total THC (THC+THCA).
10 b. Total CBD (CBD+CBDA).
11 c. THC/CBD ratio, if applicable.
12 d. Percent of THC relative to original plant
13 material (w/w).

14 (2) Terpene profiles.

15 (3) Heavy metals.

16 (4) Chemical contamination, such as residual
17 solvents remaining after extraction and concentration.

18 (5) Microbials, including pathogenic microbials.

19 (6) Mycotoxins.

20 (7) Residual insecticides, fungicides, herbicides,
21 and growth regulators used during cultivation.

22 (8) Residual solvents.

23 (c) A state testing laboratory license authorizes
24 the licensee to do all of the following without using a secure
25 transporter:

(1) Take cannabis or medical cannabis from, test cannabis or medical cannabis for, and return cannabis or medical cannabis to only a respective licensed facility.

(2) Collect a random sample of cannabis or medical cannabis at the premises of a cultivator, processor, or dispensary for testing.

(d) The licensee shall be accredited and shown to meet the requirements for a testing laboratory in international standard ISO/IEC 17025, with the licensee's scope of accreditation demonstrating testing capabilities in the categories of cannabinoids, pesticides, toxins, metals, and microbiological bacteria.

(e) To be eligible for a state testing laboratory license, the applicant and each investor with any interest in the applicant must not have an interest in any licensed cultivator, secure transporter, processor, or dispensary.

(f) The licensee shall comply with all of the following:

(1) Perform tests to certify that cannabis and medical cannabis is reasonably free of heavy metals, chemical contamination, residual pesticides and growth inhibitors, and residual solvents.

(2) Use validated test methods to determine delta-9-tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid levels.

1 (3) Perform tests that determine whether cannabis
2 and medical cannabis comply with the standards the commission
3 establishes for microbial and mycotoxin contents.

4 (4) Perform other tests necessary to determine
5 compliance with any other good manufacturing practices as
6 prescribed in rules.

7 (5) Have a secured laboratory space that cannot be
8 accessed by the general public.

9 (6) Retain and employ at least one staff member with
10 a relevant advanced degree in a medical or laboratory science.

11 §20-2A-67.

12 (a) An integrated facility license authorizes all of
13 the following:

14 (1) The cultivation of cannabis.

15 (2) The processing of cannabis into medical
16 cannabis, including proper packaging and labeling of medical
17 cannabis products.

18 (3) The dispensing and sale of medical cannabis only
19 to a registered qualified patient or registered caregiver.

20 (4) The transport of cannabis or medical cannabis
21 between its facilities.

22 (5) The sale or transfer of medical cannabis to a
23 dispensary.

24 (b) The commission may issue no more than five
25 ~~integrated facility licenses. The licenses must be awarded to~~

1 ~~entities whose majority ownership is attributable to an~~
2 ~~individual or individuals with proof of residency in this~~
3 ~~state for a continuous period of no less than eight years~~
4 ~~preceding the application date and who provide records~~
5 ~~indicating continuous, full-time business experience in the~~
6 ~~field of commercial horticulture or agronomic production for a~~
7 ~~period of at least eight years. integrated facility licenses.~~

8 (c) An integrated facility licensee shall have the
9 same authorizations granted to, and shall comply with all
10 requirements for, cultivators, processors, secure
11 transporters, and dispensaries, in addition to any other
12 authorizations or requirements under this section or as
13 established by rule by the commission.

14 (d) A applicant for an integrated facility license
15 shall provide all of the following:

16 (1) A letter of commitment or other acknowledgement,
17 as determined by commission rule, of the applicant's ability
18 to secure a performance bond issued by a surety insurance
19 company approved by the commission in the amount of two
20 million dollars (\$2,000,000).

21 (2) Proof of at least two hundred fifty thousand
22 dollars (\$250,000) in liquid assets.

23 (3) Proof that the applicant has the financial
24 ability to maintain operations for not less than two years
25 following the date of application.

1 (e) At the time a license is issued under this
2 section, the commission shall ensure that the licensee has
3 secured a performance bond as provided in subdivision (1) of
4 subsection (d).

5 (f) A licensee may operate up to five dispensing
6 sites, each of which must be located in a different county
7 from any other dispensing site that the licensee operates;
8 provided, however, the commission may authorize a licensee to
9 operate a greater number of dispensing sites if, at least one
10 year after the date when the maximum number of total
11 dispensing sites authorized under this section and Section
12 20-2A-64 are operating, the commission determines that the
13 patient pool has reached a sufficient level to justify an
14 additional dispensing site in an underserved or unserved area
15 of the state. Notwithstanding the foregoing, a licensee may
16 not operate any dispensing site in the unincorporated area of
17 county or in a municipality that has not adopted a resolution
18 or ordinance authorizing the operation of dispensing sites
19 under subsection (c) of Section 20-2A-51. This subsection
20 shall not be construed to limit wholesale distribution from
21 integrated facility licensees to dispensary licensees.

22 §20-2A-68.

23 A license issued under this article is a revocable
24 privilege granted by this state and is not a property right.
25 Granting a license does not create or vest any right, title,

1 franchise, or other property interest. A licensee or any other
2 person shall not lease, pledge, or borrow or loan money
3 against a license.

4 Section 2. (a) Commencing January 1, 2022, there is
5 levied, in addition to all other taxes of every kind now
6 imposed by law, and shall be collected and remitted in
7 accordance with Article 1, commencing with Section 40-23-1, of
8 Chapter 23 of Title 40, Code of Alabama 1975, a tax on the
9 gross proceeds of the sales of medical cannabis when sold at
10 retail in this state at the rate of nine percent of the gross
11 proceeds of the sales.

12 (b) (1) Commencing January 1, 2022, there is levied
13 an annual privilege tax on every person doing business under
14 Chapter 2A of Title 20, Code of Alabama 1975, in Alabama. The
15 tax shall accrue as of January 1 of every taxable year, or in
16 the case of a taxpayer licensed under Chapter 2A of Title 20,
17 Code of Alabama 1975, during the year, or doing business in
18 this state for the first time, as of the date the taxpayer is
19 licensed to do business under Chapter 2A of Title 20, Code of
20 Alabama 1975. The tax shall be levied upon the taxpayer's net
21 worth in Alabama for the taxable year. For purposes of this
22 subdivision, a taxpayer's net worth in Alabama shall be
23 determined by apportioning the taxpayer's net worth computed
24 under Section 40-14A-23, Code of Alabama 1975, in the same
25 manner as prescribed for apportioning income during the

1 determination period for purposes of the income tax levied by
2 Chapter 18 of Title 40, Code of Alabama 1975, or the manner in
3 which the income would be apportioned if the taxpayer were
4 subject to the income tax.

5 (2) The amount of tax due shall be computed in the
6 same manner and at the same rate of tax as prescribed in
7 Section 40-14A-22, Code of Alabama 1975, for purposes of
8 determining the annual privilege tax levied by Chapter 14A of
9 Title 40, Code of Alabama 1975.

10 (3) The annual return required by this subsection
11 shall be due no later than the corresponding federal income
12 tax return, as required to be filed under federal law. In the
13 case of a taxpayer's initial return, the annual return shall
14 be due no later than two and one-half months after the
15 taxpayer is licensed to do business, or commences business, in
16 Alabama.

17 (4) The Department of Revenue may grant a reasonable
18 extension of time for filing returns under rules adopted by
19 the Department of Revenue. No extension shall be for more than
20 six months.

21 (5) The annual medical cannabis privilege tax shall
22 be reported on forms and in the manner as prescribed by rule
23 by the Department of Revenue. The failure to receive a form
24 from the Department of Revenue shall not relieve a taxpayer
25 from liability for any tax, penalty, or interest otherwise

1 due. The tax due, as reported, shall constitute an admitted
2 liability for that amount. The Department of Revenue may
3 compute and assess additional tax, penalty, and interest
4 against a taxpayer as provided in Chapter 2A of Title 40, Code
5 of Alabama 1975.

6 (c) The Department of Revenue shall adopt rules to
7 implement this section.

8 Section 3. An employee who is injured or killed
9 under circumstances that might otherwise make the employee or
10 the employee's dependents eligible to receive worker's
11 compensation benefits under Chapter 5 of Title 25, Code of
12 Alabama 1975, is, along with the employee's dependents,
13 ineligible to receive compensation as defined in Section
14 25-5-1, Code of Alabama 1975, if the injury or death occurred
15 due to the employee's impairment by medical cannabis, which
16 shall be conclusively presumed in the event of a positive drug
17 test conducted and evaluated pursuant to standards adopted for
18 drug testing by the U.S. Department of Transportation in 49
19 C.F.R. Part 40, as provided under Section 25-5-51, Code of
20 Alabama 1975, or if the employee refuses to submit to or
21 cooperate with a blood or urine test, as provided by that
22 section.

23 Section 4. (a) As used in this section, cannabis,
24 medical cannabis, and use of medical cannabis shall have the
25 same meanings as defined in Section 20-2A-3.

1 (b) There is established the Consortium for Medical
2 Cannabis Research for the purpose of awarding grants to
3 entities for research relating to cannabis and medical
4 cannabis. The initial member institutions shall consist of the
5 HudsonAlpha Institute for Biotechnology, the Southern Research
6 Institute, and public and private four-year colleges and
7 universities within the state designated not later than
8 January 1, 2022, by the Alabama Commission on Higher
9 Education. Membership in the consortium may be increased or
10 decreased by rules established by the board of directors of
11 the consortium.

12 (c) The management of the consortium shall be vested
13 in a board of directors, composed of the President of
14 HudsonAlpha Institute for Biotechnology, the Chief Executive
15 Officer of the Southern Research Institute, and the presidents
16 of each member college and university. The board of directors
17 shall determine the overall program and general policies of
18 the consortium in conformance with the purposes set forth in
19 subsection (d). The board may elect or appoint officers as it
20 deems desirable, who may or may not be members of the board,
21 to have responsibilities and to exercise authority as the
22 board may prescribe.

23 (d) The purposes of the consortium are as follows:

24 (1) Award grants to public or private entities to
25 conduct rigorous research relating to cannabis, the cannabis

1 industry, medical cannabis, and the use of medical cannabis
2 and its impact.

3 (2) Monitor research conducted pursuant to grant
4 awards and require accountability by entities awarded grants.

5 (3) Encourage dialog among interested entities.

6 (4) Effectively disseminate research findings and
7 outcomes.

8 (e) By February 15 of each year, the board of
9 directors shall issue a report to the Governor, the President
10 Pro Tempore of the Senate, the Speaker of the House of
11 Representatives, and the Attorney General on research
12 projects, research findings, community outreach initiatives,
13 and future plans for the consortium.

14 (f) There is created a special account in the State
15 Treasury to be known as the Medical Cannabis Research Fund.
16 Expenditures from the Medical Cannabis Research Fund shall be
17 made to fund grants awarded by the consortium in accordance
18 with this section and to otherwise implement and administer
19 this section. Amounts in the Medical Cannabis Research Fund
20 shall be budgeted and allotted in accordance with Sections
21 41-4-80 through 41-4-96 and Sections 41-19-1 through 41-19-12,
22 Code of Alabama 1975.

23 Section 5. Section 13A-7-2, Code of Alabama 1975, is
24 amended to read as follows:

25 "§13A-7-2.

1 "(a) A person is guilty of criminal trespass in the
2 first degree if he knowingly enters or remains unlawfully in a
3 dwelling or on the premises of any cultivator or processor, as
4 those terms are defined in Section 20-2A-3, or on the premises
5 of any cultivation or processing operation that is part of an
6 integrated facility, as defined in Section 20-2A-3.

7 "(b) Criminal trespass in the first degree is a
8 Class A misdemeanor."

9 Section 6. Any person who is recommended a daily
10 dosage of medical cannabis that exceeds 75 mg of
11 delta-9-tetrahydrocannabinol under paragraph (f)(2)b. of
12 Section 20-2A-33, Code of Alabama 1975, shall automatically
13 have his or her driver's license suspended, regardless of
14 whether he or she holds a valid medical cannabis card under
15 Chapter 2A of Title 20, Code of Alabama 1975.

16 Section 7. Although this bill would have as its
17 purpose or effect the requirement of a new or increased
18 expenditure of local funds, the bill is excluded from further
19 requirements and application under Amendment 621, now
20 appearing as Section 111.05 of the Official Recompile of
21 the Constitution of Alabama of 1901, as amended, because the
22 bill defines a new crime or amends the definition of an
23 existing crime.

1 Section 8. This act shall become effective
2 immediately following its passage and approval by the
3 Governor, or its otherwise becoming law.

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President and Presiding Officer of the Senate

Speaker of the House of Representatives

SB46

Senate 24-FEB-21

I hereby certify that the within Act originated in and passed
the Senate, as amended.

Patrick Harris,
Secretary.

House of Representatives
Amended and passed 06-MAY-21

Senate concurred in House amendment 06-MAY-21

By: Senator Melson

**Alabama Medical Cannabis Commission
Rules and Regulations**

**Chapter 1
General Provisions, Scope and Construction of Rules**

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538-x-1-.01 Scope.

These rules, in accordance with the Darren Wesley “Ato” Hall Compassion Act (§ 20-2A-1, et seq., Ala. Code 1975 (as amended)) (“the Act”), govern the production, transportation, dispensation, testing and use of medical cannabis, as well as the procedures for patient registration, industry licensing, and general regulation of medical cannabis within the State of Alabama. Authority for these rules, as promulgated and amended from time to time by the Alabama Medical Cannabis Commission (“the Commission”), is derived from the Act.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.02 Construction.

These rules shall be construed and administered to provide registered qualified patients the maximum benefit of medical cannabis with minimum diversion, in accordance with, and giving reasonable effect to, the Act.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.03 Time.

In computing any period of time prescribed or allowed by these rules, by order of the Commission, or by the Act, the day of the act, event or default from which the designated period of time begins to run shall not be included, unless it is a Saturday, a Sunday, or a legal holiday, in which event

the period runs until the end of the next day which is not a Saturday, a Sunday, or a legal holiday, or, when the act to be done is the filing of a document with the Commission, a day on which weather or other conditions have caused the Commission's offices to be inaccessible or to close upon the orders of the Governor, in which event the period runs until the end of the next day that is not one of the aforementioned days. Except as otherwise provided in these Rules or by order of the Commission, when the period of time prescribed or allowed is less than seven (7) days, intermediate Saturdays, Sundays, and legal holidays shall be excluded in the computation. As used in this rule, "legal holiday" includes New Year's Day, Birthday of Martin Luther King, Jr., Presidents' Day, Memorial Day, Independence Day, Labor Day, Columbus Day, Veterans Day, Thanksgiving Day, Christmas Day and any other day appointed as a holiday by the President or the Congress of the United States, or as prescribed in § 1-3-8, Code of Alabama 1975 (as amended).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.04 Definitions.

As used in these Rules, the following terms have the following meanings:

1. "Act." The Darren Wesley "Ato" Hall Compassion Act, § 20-2A-1, et seq., Code of Alabama 1975 (as amended).
2. "Affiliate" or "Affiliated with." An entity is an "affiliate" of, or "affiliated with", another entity if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with or by, such other entity. The term shall include sister entities (i.e., entities owned, directly or indirectly through one or more intermediaries, by the same parent entity).
3. "Applicant." An entity or individual seeking a license under Article 4 of the Act.
4. "Approved Solvent." Solvent-based medical cannabis products may be manufactured using only the following solvents: butane, propane, CO2, ethanol, isopropanol, acetone, heptane, and pentane. The use of any other solvent is expressly prohibited unless and until approved by the Commission.
5. "Batch."
 - a. "With regard to cannabis, i.e., a "harvest batch":
 - (1) A homogenous, identified quantity of cannabis;
 - (2) That has been cultivated and harvested together;
 - (3) That has received identical propagation and cultivation treatment, including, but not limited to: growing media, ambient conditions, watering and light regimes and agricultural or hydroponic inputs; and
 - (4) That has been assigned the same cultivation batch number for entry in the Statewide Seed-to-Sale Tracking System.
 - b. With regard to medical cannabis, i.e., a "production batch":
 - (1) A quantity of medical cannabis that is uniform and derived from one or more identifiable cannabis harvest batches;
 - (2) That has been or is intended to be processed under the same processing protocol, using the same methods, equipment and ingredients;

- (3) That is intended to meet the same specifications for identity, strength and composition;
 - (4) That has been assigned the same production batch number for entry in the Statewide Seed-to Sale Tracking System; and
 - (5) That is to be packaged and labeled during the same specified period of time according to a single packaging and labeling protocol.
- 6. "Board." The State Board of Medical Examiners.
- 7. "Cannabis." All parts of any plant of the genus cannabis, whether growing or not, including the seeds, extractions of any kind from any part of the plant, and every compound, derivative, mixture, product, or preparation of the plant; but excluding industrial hemp or hemp regulated under § 2-8-11, Code of Alabama 1975 (as amended) and also excluding cannabis that is cultivated, processed, transported, stored, possessed, or used outside the Statewide Seed-to-Sale Tracking System (i.e., illicit cannabis), including but not limited to cannabis that once was included within and/or intended for placement on the Statewide Seed-to-Sale Tracking System (i.e., diverted cannabis).
- 8. "CBD." Cannabidiol, a nonintoxicating cannabinoid found in cannabis and hemp.
- 9. "Commission." The Alabama Medical Cannabis Commission, also sometimes referred to as "AMCC," created pursuant to § 20-2A-20, Code of Alabama 1975 (as amended).
- 10. "Confidential." Not to be shared, except within and among the parties who own or are responsible for the information, and the Commission, AMCC staff, or their agents, except upon judicial or administrative order or with respect to de-identified information used exclusively for educational or research purposes.
- 11. "Controlling Interest." An ownership interest held by an individual or group with respect to a business, particularly a corporation, that is sufficient to permit the exercise of control over the business, i.e., greater than 50% of the interest in the business.
- 12. "Conventional Medical Treatment or Therapy Has Failed." Within the term "Qualifying Medical Condition" as used and defined in these Rules, the determination as to whether conventional medical treatment or therapy has failed shall be within the sole discretion of the registered certifying physician acting in compliance with § 20-2A-7(b), Code of Alabama 1975 (as amended); the term "failed" (like the term "proved ineffective" in § 20-2A-3(21)p.) need not entail exhaustion of conventional medicine or therapies, if the registered certifying physician is reasonably satisfied that other approaches are contraindicated and/or would be futile to attempt or not reasonably likely to succeed, and that the patient may benefit from the use of medical cannabis.
- 13. "Court of Competent Jurisdiction." A court having authority to act as to a particular party or subject matter; with respect to the Commission, its members and representatives, courts of competent jurisdiction are the Circuit Courts of Montgomery County, Alabama and coordinate appellate courts, and the United States District Court for the Middle District of Alabama and coordinate appellate courts.
- 14. "Cultivator." An entity licensed by the Commission (or, as applicable, the Department of Agriculture and Industries) under § 20-2A-62, Code of Alabama 1975 (as amended), to grow cannabis pursuant to Article 4 of the Act.
- 15. "Daily Dosage" and "Maximum Daily Dosage." The total amount of one or more cannabis derivatives, including, but not limited to, cannabidiol ("CBD") and tetrahydrocannabinol

(“THC”) which may be present in a medical cannabis product that may be ingested by a registered qualified patient during a 24-hour period, as determined by a registered certified physician. “Maximum Daily Dosage” means the maximum total amount of one or more cannabis derivatives that may be ingested during a 24-hour period by a registered qualified patient, as determined by a registered certified physician, without a follow-up appointment and/or requiring compliance with § 20-2A-33(f), Code of Alabama 1975 (as amended).

16. “Department.” The Department of Agriculture and Industries.
17. “Dispensary.” An entity licensed by the commission under § 20-2A-64, Code of Alabama 1975 (as amended), authorized to dispense and sell medical cannabis at dispensing sites to registered qualified patients and registered caregivers pursuant to Article 4 of the Act.
18. “Dispense.” To distribute or provide medical cannabis, per the certification and recommendation of a registered certified physician, to a registered qualified patient or, if applicable, a registered caregiver.
19. “Dispensing Site.” A site operated by a dispensary licensee or an integrated facility licensee pursuant to Article 4 of the Act.
20. “Economic Interest.” The rights to either the capital or profit interests of an applicant or licensee or, if the applicant or licensee is a corporation, the rights to some portion of all classes of outstanding stock in the corporation. Particularly with respect to applicants and licensees, having a financial interest in, or relationship to, an applicant’s or licensee’s investments, employment, contracts, purchases, leases, sales, or other pecuniary interest in the applicant’s or licensee’s business, or the applicant’s income or anticipated income, by which to obtain a return of capital. For purposes of these Rules, economic interest does not include interest in a publicly traded corporation unless such interest is greater than 5% of the publicly traded corporation.
21. “Enclosure” or “Enclosed Facility.” A fully floored, walled, roofed, locked and secured building, room, greenhouse, or warehouse facility, for cultivating, storing, processing, or dispensing cannabis or medical cannabis, at which security is maintained and that is accessible only to persons who are employed or contracted by a licensee, or who have been given permission to come onto the premises and have provided state or federally issued photo identification.
22. “Extraordinary Circumstances.” Circumstances that are unforeseen, unusual, and unlikely to be repeated.
23. “Facility” or “Medical Cannabis Facility.” Any facility or land associated with a facility, of a licensee.
24. “Food Product.” An edible offered for sale or provided for consumption as such.
25. “Good Manufacturing Practices.” Manufacturing Practices meeting the minimum standards for the methods, facilities, and controls used in manufacturing, processing, and packing of medical cannabis, to assure the product’s safety, integrity, intended strength, and expected shelf-life. See 21 CFR Part 210.
26. “Ingested.” Eaten, chewed, swallowed, or consumed by mouth in any other manner; inhaled, sniffed, snorted, sprayed, or introduced into the breathing passages in any other manner; injected or otherwise introduced into the body in any manner, including through the skin or other membrane.

27. "Injury." Any wrong or harm done by a licensee or to the body, rights, reputation or property of an individual or entity.
28. "Integrated Facility." An entity licensed under § 20-2A-67, Code of Alabama 1975 (as amended).
29. "Leaders" or "Leadership." In an Applicant's or Licensee's business, the individuals who hold a position of interest, power or responsibility for the day-to-day operations of the business, including but not limited to the owners, shareholders, board members, officers, directors, executives, or managers of the business.
30. "License." Authorization by the Commission (or as applicable, the Department) in accordance with the Act and these Rules to operate as a cultivator, processor, secure transporter, dispensary, integrated facility, or state testing laboratory.
31. "Licensee." A cultivator, processor, secure transporter, state testing laboratory, dispensary, or integrated facility licensed by the Commission under Article 4 of the Act.
32. "Loss." Economic, physical or extreme emotional damage sustained by an individual or entity, including but not limited to such damages resulting from loss of product, loss of income, loss of production, and loss of reputation.
33. "Material Breach." A substantial violation in the performance of, or a failure to perform an obligation, created by a promise, duty, or law; as to licensees, a significant difference between circumstances as affirmed to the Commission and current reality, often including a risk of danger or harm to individuals or property.
34. "Medical Cannabis." A medical grade product grown and processed within the State of Alabama, in one of the approved forms set forth in § 20-2A-3(14), Code of Alabama 1975 (as amended), that contains a derivative of cannabis for medical use by a registered qualified patient pursuant to the Act and these Rules.
35. "Medical Cannabis Card." A valid card, which may be tangible or virtual, issued by the Commission to a registered qualified patient or a registered qualified caregiver pursuant to §§ 20-2A-35 and -36, Code of Alabama 1975 (as amended).
36. "Medical Grade." Manufactured in accordance with Good Manufacturing Practices (GMP) and tested and approved by a State Testing Laboratory or audited by a third-party auditor, to meet or exceed the same standards applicable within the United States for products manufactured for medical use.
37. "Medical use" or "use of medical cannabis" or "use medical cannabis." The acquisition, possession, use, delivery, transfer, or administration of medical cannabis authorized by the Act and these Rules, but not including possession, use, or administration of cannabis that was not purchased from a dispensing site as defined by the Act and this Chapter.
38. "Minor." An individual who has not yet reached nineteen years of age.
39. "Minority Group." Individuals of African American, Native American, Asian or Hispanic descent.
40. "Package" or "Packaging." A closed and sealed container in which a processor or integrated facility may provide medical cannabis, in accordance with the Act and these Rules; the term does not include any carry-out bag or other similar container.
41. "Patient Registry." The Alabama Medical Cannabis Patient Registry System that is an electronic integrated system that tracks physician certifications, patient and caregiver registrations, medical cannabis cards, the daily dosage and type of medical cannabis

recommended to qualified patients by registered certifying physicians, and the dates of sale, amounts, and types of medical cannabis that were purchased by registered qualified patients at licensed dispensing sites.

42. "Pharmaceutical Grade." Manufactured to meet or exceed the same standard or grade as any active or inactive drug, biologic, reagent, or other pharmaceutical, in accordance with Good Manufacturing Practices ("GMP"), as tested and approved by (A) the Food and Drug Administration (FDA) in the case of clinically available pharmaceutical grade excipients under these Rules; or otherwise by (B) a State Testing Laboratory or an independent third-party auditor performing tests or audits in accordance with the same FDA standards and protocols as required for pharmaceuticals available in the United States.
43. "Physician Certification." A registered certifying physician's authorization for a registered qualified patient to use medical cannabis in a recommended daily dosage that shall include a recommended maximum daily dosage.
44. "Processor." One who is licensed by the Commission under § 20-2A-63, Code of Alabama 1975 (as amended), authorized pursuant to Article 4 of the Act and these Rules to purchase cannabis from a cultivator and extract derivatives from the cannabis to produce a medical cannabis product or products for sale and transfer in packaged and labeled form back to the contracting cultivator, if applicable, or to a dispensary or integrated facility where the packaged and labeled product may be offered for sale at a dispensary site to holders of a valid, unrevoked and unexpired Medical Cannabis Card.
45. "Qualifying Medical Condition." One of the various conditions or symptoms of conditions provided in § 20-2A-3(21), Code of Alabama 1975 (as amended), but only after documentation indicates that conventional medical treatment or therapy has failed, unless current medical treatment indicates that use of medical cannabis is the standard of care.
46. "Registered Caregiver." An individual who meets the requirements described in § 20-2A-30(c), Code of Alabama 1975 (as amended), and is authorized to acquire and possess medical cannabis and to assist one or more registered qualified patients with the use of medical cannabis pursuant to the Act and these Rules.
47. "Registered Certifying Physician." A licensed physician who is authorized by the State Board of Medical Examiners to certify patients for the use of medical cannabis under the Act and these Rules.
48. "Registered Qualified Patient." Either an adult who meets the requirements of § 20-2A-30(a), Code of Alabama 1975 (as amended), and is authorized to acquire, possess, and use medical cannabis pursuant to the Act and these Rules, or a minor who meets the requirements described in § 20-2A-30(b), Code of Alabama 1975 (as amended), and is authorized to use medical cannabis pursuant to these Rules with the assistance of a registered caregiver.
49. "Remediation." One of various methods whereby cannabis or medical cannabis that has failed an official test by a State Testing Laboratory may be subjected to further processing to remove dangerous substances or other contaminants or otherwise bring the cannabis or medical cannabis within appropriate testing ranges. For purposes of these Rules, remediation may include processes conducted by, and at the facility of, the licensee whose cannabis or medical cannabis failed the test or another licensee acting at the

- request of such licensee; such processes shall include those that change the form or chemical makeup of the regulated cannabis or medical cannabis (i.e., formal remediation), or not (i.e., decontamination). Nothing in this definition shall preclude a licensee that is subject to official testing from performing its own tests and implementing processes in an effort to bring non-compliant cannabis or medical cannabis within proper testing parameters at any time prior to official testing by a State Testing Laboratory.
50. “Representative.” Employee, leader, contracted agent or other designated person authorized to act or speak on behalf of another.
51. “Resident” or “Non-Resident.” – For purposes of the Act and these Rules, a Resident or Non-Resident is:
- a. As to individuals, a resident is domiciled in the State of Alabama or has otherwise established residency in Alabama within the requirements of § 40-18-2, Code of Alabama 1975 (as amended); a non-resident is one who is not domiciled in Alabama and has not otherwise established residency in Alabama within the requirements of § 40-18-2, Code of Alabama 1975 (as amended).
 - b. As to business entities, a resident is an entity that is registered with the Secretary of State of Alabama to do business in Alabama and that has its principal place of business in Alabama; a non-resident is an entity that is not registered with the Secretary of State of Alabama to do business in Alabama or does not have its principal place of business in Alabama.
52. “Secure Transporter.” An entity licensed by the Commission under § 20-2A-65, Code of Alabama 1975 (as amended), authorized to transport cannabis or medical cannabis from one licensed facility or site to another licensed facility or site.
53. “Self-Reporting.” A licensee’s report to the Commission as the result of a reported incident or condition involving an injury, loss (including, but not limited to loss of product, loss of production, or loss of reputation) or material breach that has occurred at its facilities or involving one or more of its representatives.
54. “State Testing Laboratory.” – An entity licensed under § 20-2A-66, Code of Alabama 1975 (as amended), authorized to test cannabis and medical cannabis to ensure the product meets safety qualifications and efficacy requirements as provided in the Act and these Rules.
55. “Statewide Seed-to-Sale Tracking System.” The tracking system established pursuant to § 20-2A-54, Code of Alabama 1975 (as amended), that tracks all medical cannabis and cannabis destined for processing as medical cannabis in the state of Alabama.
56. “THC.” Tetrahydrocannabinol; either of two physiologically active isomers $C_{21}H_{30}O_2$ from cannabis plant resin, including, especially, delta-9 THC, the chief intoxicant in cannabis.
57. “These Rules.” The Rules and Regulations of the Alabama Medical Cannabis Commission.
58. “This Chapter.” Within the specified portion or the same portion of the Rules and Regulations of the Alabama Medical Cannabis Commission.
59. “Transfer.” An exchange of titular, possessory or custodial interest, usually, but not always involving physical movement. As used in these Rules, the authority to “transfer” products does not necessarily include the authority to “transport” such products.
60. “Transit.” The phase of transportation during which cannabis or medical cannabis is physically moved from one facility to another.

61. "Transport." The process of loading or unloading and physically moving harvested and prepared cannabis or medical cannabis from one facility to another, usually but not always coinciding with "transfer" of cannabis or medical cannabis.
62. "Universal State Symbol." The image to be established by the Commission pursuant to Section § 20-2A-53, Code of Alabama 1975 (as amended), made available to processors, which indicates the package contains medical cannabis.
63. "Verification," "Verified" and "Verifying." As to a document or statement, the act or condition of having the document or statement be affirmed in writing to be accurate and bearing the printed name and signature of the individual making such affirmation, and date provided.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.05 Administration and Enforcement of Rules.

The Commission shall have authority to administer and enforce these Rules in accordance with § 20-2A-22(b), Code of Alabama 1975 (as amended).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.06 Fees.

The Commission shall levy and collect fees as provided in the Act and as it shall hereafter establish; a schedule of fees payable under the Act and these Rules shall be maintained on the AMCC website at www.AMCC.Alabama.gov.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.07 Fines and Penalties.

The Commission shall impose fines and penalties as provided in the Act and as it shall hereafter establish; a schedule of fines and penalties that may be imposed under the Act and these Rules shall be maintained on the AMCC website at www.AMCC.Alabama.gov.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.08 Request for Variance of Rules.

A requested variance of these Rules may be either temporary or permanent.

1. *Temporary Variance.* A patient, caregiver, applicant or licensee may request a temporary variance to relax or suspend these Rules when, in the opinion of the requesting party, circumstances dictate that the requesting party must be out of compliance with these Rules for a period of time specified by the requesting party, not longer than six months. The Commission cannot grant a variance of any type in conflict with the Act; a temporary variance may not issue to excuse the requesting party from the mandates of the Act. Unless otherwise directed, a requesting party may operate consistently with its requested temporary variance pending its final disposition by the Commission. On motion of the requesting party and for good cause shown, the Commission after inquiry, may vote to renew a temporary variance for an additional term not exceeding six months. Circumstances warranting a temporary variance must be unusual, unforeseen to the requesting party, unavoidable (i.e., incapable of being addressed other than through special dispensation to have the Rule not apply), and for the prevention of undue hardship. A motion for temporary variance must be filed electronically through the AMCC website and shall be reviewed and initially decided by AMCC staff. All unchallenged decisions by AMCC staff may be ratified, as appropriate, by a majority vote of the Commission upon due inquiry into the request at the next duly called meeting more than fourteen (14) days from the AMCC staff's decision. Within fourteen (14) days of the AMCC staff's denial of a motion for temporary variance, the aggrieved requesting party may file an electronically submitted notice of appeal, which shall be heard and decided by the majority vote of the Commission at the next duly called meeting more than fourteen (14) days from the date of filing the notice of appeal. Temporary Variances are not otherwise subject to appeal.
2. *Permanent Variance.* A patient, caregiver, applicant or licensee may file a motion for a permanent variance from these Rules when, in the opinion of the requesting party, circumstances dictate that the requesting party must be permanently out of compliance with these Rules (the Commission cannot grant a variance of any type in conflict with the Act; a permanent variance may not issue to excuse the requesting party from the mandates of the Act.). Circumstances warranting a permanent variance must be extraordinary (e.g., that the permanent noncompliance requested by the requesting party is superior to compliance with the Rules in terms of economics, expedience, justice and overall benefit to the requesting party as well as any family members, employees, agents, or other members of the public). A motion for permanent variance must be filed electronically through the AMCC website and shall be reviewed and decided by a majority vote of the Commission at a the next duly called meeting of the Commission more than fourteen (14) days from the date of the motion's filing. A party aggrieved by the initial decision of the Commission may seek review by electronically filing an application for rehearing within fourteen (14) days from the date of the Commission's initial decision. The rehearing shall occur at the next duly called meeting of the Commission more than fourteen (14) days from the date of its filing. An application for rehearing should contain any argument (not to exceed 10 pages) and written materials (not to exceed 25 pages) that the aggrieved party wishes the Commission to consider; the requesting party may be asked to be present at the meeting to provide further information regarding its application and any extraordinary circumstances attending the request. Permanent

variances are not otherwise subject to review. In the event a permanent variance is granted, the Commission should consider whether the Rules should be amended to allow others similarly situated the same opportunity as has been granted for the requesting party.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.09 Notification of Proceedings.

Except as otherwise provided in these Rules, or in extraordinary circumstances as may be determined by the Commission, the Commission shall notify any interested party of proceedings before it not less than fourteen (14) days before the proceeding is to occur.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.10 Hearings.

Except as otherwise noted in the Notification Order issued by the Commission pursuant to r. 538-x-1-.09, or as specifically provided by these Rules, hearings before the Commission shall take place not less than twenty-one (21) days from the date of the order setting the hearing at the Offices of the Commission at 445 Dexter Avenue, Montgomery, AL 36104.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-1-.11 Appeals.

Appeals authorized by these Rules from any final determination of the Commission shall be governed by the Alabama Administrative Procedure Act (AAPA), § 41-22-20, et seq., Code of Alabama 1975 (as amended).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

**Alabama Medical Cannabis Commission
Rules and Regulations**

**Chapter 3
APPLICATIONS AND LICENSING REQUIREMENTS – GENERALLY**

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538-x-3-.01 Purpose.

Chapter 3 of these Rules sets forth the general requirements for Applicants seeking licensure by the Commission. Specific rules applicable to each category of Applicant may be found in the rules pertaining to each category.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.02 Definitions.

1. “Amended Application.” An Applicant’s filing, after an original application, by which the Applicant may correct any errors identified by the Applicant, to more accurately reflect facts relating to the proposed business, to generally revise and improve the quality of its previously filed application to the Commission, or for any other valid purpose. An Amended Application may be filed at any time during the window for filing an original

application. After the window closes for filing an original application, an Amended Application may be filed only upon a showing of extenuating circumstances.

2. "Applicant Questions Portal." A platform on the AMCC website designed to allow Applicants, Licensees, and others at the Commission's discretion to ask questions, make requests or share information with the Commission, particularly during the Application Process.
3. "Application Process." The time from the date of the Offering Announcement to the Commission's issuance of all licenses in the same offering. Notwithstanding the foregoing, for the initial offering period, the Application Process shall begin on September 1, 2022.
4. "Begin Applying for a License." The Applicant's submission of a request for application to the Commission. As to the initial offering, the window to submit such a request opens on September 1, 2022.
5. "Commencement of Operations." The date on which the Applicant expects to begin doing business as a licensee in the cannabis or medical cannabis industry, assuming the Applicant is ultimately issued a license.
6. "Contact Person." A knowledgeable individual designated by the Applicant to be the liaison between the Applicant and the Commission during the application process.
7. "Correction." or "Deemed Corrected." The Commission's act of accepting a proposed change offered by an Applicant in response to a deficiency identified by the Commission. The application is "deemed corrected" when the proposed change is approved by the Commission.
8. "Deficiency." An error in an application identified by the Commission for which a Notice of Deficiency is communicated in writing to the Applicant. As used herein, a deficiency shall include but is not limited to: corrupted or illegible file materials, incomplete applications (i.e., missing required documentation), improperly formatted or labeled materials, and typographical or formatting errors preventing reasonable understanding of one or more of the Applicant's statements.
9. "Extenuating Circumstances." Reasons offered by the Applicant for needing to amend its application after the window for filing original Applications has closed, to be explained by the Applicant in a Petition to Amend Application Based on Extenuating Circumstances. An Amended Application sought in connection with such a Petition, which may be approved, or not, by the Commission, may be referred to as an "Extenuating Circumstances Amended Application."
10. "Extraordinary Circumstances." Reasons offered by the Applicant for needing additional time to file proposed corrections in response to a Notice of Deficiency issued by the Commission, to be explained by the Applicant in a Petition to Extend Time for Filing Proposed Corrections Due to Extraordinary Circumstances. An Applicant's Proposed Corrections in connection with such a Petition, which may be approved, or not, by the Commission, may be referred to as an "Extraordinary Circumstances Application."
11. "License Awarded." The Commission's decision to grant a license to a particular Applicant, after which the Applicant has an obligation to pay the license fee.
12. "License Issued." The Commission's delivery of a license to a particular Applicant, after the license fee has been paid and all obstacles to the Applicant's assuming the role of a

Licensee have been removed. An Applicant becomes a Licensee upon receipt of the Commission's issuance of the license.

13. "Offering," The licenses at stake, as to which the Commission may consider awarding and issuing, during a particular application process. For purposes of this Chapter, the "Initial Offering" is the licenses at stake during the first application process, which begins with the Applicants' Request for Application, the window for which opens September 1, 2022. For purposes of this Chapter, "Subsequent Offerings" shall refer to the licenses that are at stake during future application processes, after the initial offering.
14. "Offering Announcement." The Commission's public announcement of an offering, to occur prior to (normally 15-45 days before) the opening of the window during which Requests for Application may be submitted.
15. "Responsible Person." A person other than the contact person who holds substantial ownership or is employed by Applicant and has authority to speak and act on behalf of the Applicant.
16. "Submitted" or "Deemed Submitted." With respect to applications filed by Applicants pursuant to an offering, the time when all proposed corrections have been accepted and approved by a vote of the Commission and all properly filed applications (both original and amended) have been formally accepted and approved by a vote of the Commission, thereby opening the 60-day window in which the Commission must decide which Applicants shall be awarded licenses.
17. "Sufficient Capital." Unless otherwise ordered by the Commission, the total of the Applicant's or Licensee's annual budgets or projected annual budgets during the first three full years after the license is issued to the Applicant.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.03 Licensing and Regulation of Medical Cannabis; Exceptions.

1. *License Required.* In each of the following categories a license to operate is required: integrated facility, cultivator, processor, secure transporter, dispensary, and state testing laboratory. To obtain a license, a person, including a business entity, must have applied to the Commission and been issued a license in accordance with the Act and this Chapter. No person or entity may apply for more than one category of license at a time; an applicant who withdraws an application may reapply, so long as the application is timely, in accordance with Rule 538-x-3-.05 of this Chapter.
2. *Number of Licenses to be issued by the Commission.* The Commission will limit the number of licenses per category listed in paragraph 1. of this Rule to the extent directed by the Act. Nothing in the Act or this Chapter shall prevent the Commission from issuing less than the maximum number of licenses per category. The Commission may, in its discretion, determine not to issue a license in any or all categories listed in paragraph 1.; the Commission shall not issue the maximum number of licenses to the extent it

determines that an insufficient number of the available Applicants in a category are properly qualified to hold a license in the category applied for.

3. *Hemp Act Exception.* Licenses under this Chapter do not apply with respect to hemp or hemp-related products regulated by the Alabama Industrial Hemp Act, § 2-8-380, et seq., Code of Alabama 1975 (as amended).
4. *Illegal Cannabis Exception.* Licenses under this Chapter do not apply with respect to cannabis or cannabis-related products:
 - a. grown, manufactured, transported, tested, or dispensed outside the state of Alabama;
 - b. grown, manufactured, transported, tested, dispensed or used within the State of Alabama other than for medical use as defined under the Act and these Rules; or
 - c. diverted from cannabis or cannabis-related products grown or produced for medical use under the Act and these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.04 Applications and Applications Processing Generally.

1. *Application Fees.* Applicants for a license under the Act and this Chapter shall pay a nonrefundable Application Fee in accordance with the most recent Application Fee Schedule approved by the Commission and then in effect, as applicable to the particular license sought. The current Application Fee Schedule may be found at www.AMCC.Alabama.gov (hereinafter, “the AMCC website”).
2. *License Does not Convey Rights; Burden on Applicant.* The license granted and issued by the Commission is deemed to be a revocable privilege (§ 20-2A-68, Code of Alabama 1975 (as amended)), and no person or legal entity holding such a license is deemed to have acquired any vested rights therein. An Applicant for a license authorized by the Act or this Chapter is seeking the granting of a privilege rather than a right, and the burden of proving qualification and suitability to receive the license is, at all times, on the Applicant. Responsibility for the continued use of the license is, at all times, on the licensee; licenses are non-delegable and non-transferable except with the express permission of the Commission, as provided in Chapter 4 of these Rules.
3. *Limited Communication – Generally; Exceptions.* The integrity of the application and licensing process is of paramount importance to the Commission and will not be compromised. Throughout the Application Process, Applicants (including all employees, agents and representatives of Applicants and any other individual acting on an Applicant’s behalf) must not initiate communication with any member of the Commission or any AMCC staff, officials, or representatives regarding the application, except as follows:
 - a. through the “Applicant Questions” portal as provided at the AMCC website;
 - b. by written notification to the Commission of a change in the Applicant’s Summary Sheet information;
 - c. to file an Amended Application, request additional time for filing proposed corrections to a deficiency noted by the Commission, to request additional opportunity to amend the application based on extenuating circumstances, or to

request an investigative hearing before the Commission in the event the applicant's license was denied.

To the extent oral communication is deemed to be helpful to resolving any issue or answering any question, AMCC staff will initiate the oral communication, and the result of the oral communication will be memorialized in writing.

4. *Limited Communication – Response to questions and requests for information initiated by AMCC.* An applicant shall, as directed, answer questions from, and provide information to, the Commission or its staff, officials, agents, and representatives, including to propose corrections to deficiencies noted; however, unsolicited communications from the Applicant other than through the “Applicant Questions” portal are strictly prohibited. Any unauthorized contact with the Commission or its staff, officials, or representatives during the course of the Application Process may disqualify the Applicant from further consideration.
5. *Limited Communication -- Applicant Questions; Question Clearinghouse.* Questions or requests for assistance regarding the Request for Application, the Application, or the selection process, will be considered only when submitted through the “Applicant Questions” portal at the AMCC website. As the Commission may deem helpful, questions submitted by Applicants to the AMCC website, along with AMCC's response, may be made public for the benefit of other Applicants as part of a Question Clearinghouse database accessible through the AMCC website. Direct communication with Commission members during the application process is strictly prohibited. *Ex parte* communications by individual Commission members to Applicants (or their representatives) during the application process are unofficial and improper.
6. *Limited Communication -- Writing Required.* Communications to Commission staff in response to any question, whether through the “Applicant Questions” portal or if initiated by the AMCC Staff or other Commission representatives, must be in writing. Any oral communications will be considered unofficial and shall not be binding upon the Commission.
7. *Procedures for Filing Applications – Request for Application Form – Initial Offering.* As to the initial offering of licenses under the Act and this Chapter, a prospective licensee in any category may “begin applying for a license” as stated in § 20-2A-53, Code of Alabama 1975 (as amended) (see also § 20-2A-55, Code of Alabama 1975 (as amended): “Beginning September 1, 2022....”) by electronically submitting to the Commission at the AMCC website a Request for Application Form as to one of the various categories of licenses beginning at the window opening time of 10:00 a.m., CDT, on Thursday, September 1, 2022 (For a helpful timetable applicable to the initial offering, see Appendix A to this Chapter). As to the initial offering, the window for submitting a Request for Application Form shall close as of 4:00 p.m., CDT on October 17, 2022, or at 4 p.m. Central Time on the date these Rules become effective, whichever is later.
8. *Procedures for Filing Applications – Subsequent Offerings – Offering Announcement.* As to subsequent offerings, approximately 15-45 days prior to opening a window in one or more categories, the Commission shall issue an Offering Announcement on its website, providing public notice of its intention to offer one or more licenses in one or more categories. In addition to specifying the license or licenses to be offered in a category or

categories, the Offering Announcement shall provide Requests for Application Forms, the window of time during which the Request for Application Forms shall be made available, and the time by which Application Forms will be supplied to those who make a timely, properly filled out and properly submitted Request for Application. As to Subsequent Offerings, the Offering Announcement shall include the timetable for the Commission's issuance of licenses to be offered, but such timetables may be amended by the Commission at its discretion.

9. *Procedures for Filing Applications – Request for Application Form – Generally.* The Commission will respond to properly filled out, properly submitted and timely Requests for Application Forms per category, by electronically supplying the appropriate Application Form. The Request for Application Form shall contain the following information: the category of license being applied for, the Applicant's name, business address, business email address, business telephone number, Social Security Number or Federal Tax Identification Number; as well as the name, business address, email address, and direct dial telephone number of the contact person who will be responsible for fielding and responding to additional requests by the Commission. The Request for Application form shall also contain a verification that the contact person has authority to act on behalf of the applicant and that the Applicant, by filing the Request for Application, voluntarily submits to the Act, these Rules, and the jurisdiction, authority and discretion of the Commission.

10. *Procedures for Application Forms – Disqualification from Application Process.* Requests for Application Forms will not be considered if they are:
 - a. untimely,
 - b. improperly filled out, or
 - c. submitted or attempted to be submitted by any means other than electronically as provided herein.

Request for Application Forms that are untimely (i.e., submitted before the window opens or after the window closes), improperly filled out, or improperly submitted, will not receive an application form and therefore will not be considered for licensure in the offering. The Commission or its representatives may, in their discretion, contact an Applicant to seek clarification of information provided on the Request for Application Form, but the absence of contact from the Commission to an Applicant, or the Commission's not providing an Application Form when that form was untimely requested, not properly filled out, or improperly submitted, shall not constitute a breach of due process or permit the Applicant a right of appeal under the Act, these Rules or any provision of the Alabama Administrative Procedure Act, § 41-22-1, et seq., Code of Alabama 1975 (as amended) ("AAPA").

11. *Procedures for Filing Applications – Issuance of Application Forms – Timing.* As to the initial offering, properly requested Application forms shall issue on Monday, October 24, 2022, or at 4:00 p.m. Central Time on the seventh day from the closing of the window for requesting applications, whichever is later. For subsequent offerings, issuance of application forms shall occur on the date provided in the Offering Announcement.
12. *Procedure for Filing Applications – Form of Application.* Applications for licenses under the Act and this Chapter shall be filed with the Commission electronically at the AMCC

website and shall be in accordance with the instructions accompanying the electronic application form. The Commission shall not consider any Application, or any part thereof, that has not been filed as provided in this paragraph or that fails to follow the format prescribed by the electronic application form. Notwithstanding anything herein to the contrary, the “filing” of an application as described in these Rules shall not mean that the application is “submitted” pursuant to § 20-2A-56(d), Code of Alabama 1975 (as amended); as provided in Rule 538-x-3-.07, an application is “submitted” such that the 60 days for determining whether to award a license begins to run only when the Commission accepts and approves the application for submission (including any amended applications, proposed corrections or extraordinary circumstances corrections), along with applications filed by other Applicants of a particular category in the same offering.

13. *Procedure for Filing Application – Time for Filing Application.* After receiving an Application Form from the Commission, an Applicant may continue the application process by filing an application in the form specified in Rule 538-3-.05, within the window for filing provided in the Application Form provided to the Applicant. For the initial offering, the window for filing an Application shall begin at 10:00 a.m., CDT, October 31, 2022, or on the seventh day following the Commission’s issuance of application forms, whichever is later. The window for filing an original application shall remain open for no less than 30 days. With respect to the initial offering, all original applications (including all exhibits to be attached thereto) must be filed on or before 4:00 p.m., CST, on December 30, 2022, or sixty days from the date the window opens to file applications, whichever is later.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.05 Contents of Application.

The Application filed with the Commission shall include the following, in the order stated:

1. Cover Sheet – as provided with the Application Form.
2. Summary Sheet – as provided with the Application Form based on information provided in the Applicant’s Request for Application:
 - a. the category of license being applied for;
 - b. the Applicant’s name, business address, business email address, and business telephone number;
 - c. the Applicant’s Social Security Number or Federal Tax Identification Number;
 - d. the name, business address, business email address, and direct dial telephone number of the contact person who will be responsible for fielding and responding to additional requests by the Commission.

Throughout the Application Process, any changes to the foregoing information must be brought to the immediate attention of the AMCC through the website, and such information changes do not constitute an “Amendment” as provided under this chapter. Notwithstanding the foregoing, changes with respect to the category of license being applied for may not be made after the window closes for requesting an application form

(for the initial offering, 4:00 p.m., CDT on October 17, 2022, or at 4:00 p.m. Central Time on the date these rules become effective, whichever is later.

3. Application Information – Responses to the Application Form, in the order provided on the Application, to the following, all of which shall be construed broadly to ensure the broadest disclosure and greatest transparency reasonably possible based on the best available information at the time of the application is submitted or amended:
 - a. With regard to each ownership entity that has any ownership interest in the applicant (“ownership entity”), the applicant shall verify all of the following:
 - (1) The identity of every individual having an indirect or direct ownership interest in the ownership entity. For purposes of this paragraph, if the business entity is a trust, the application shall disclose the names and addresses of all trustees and beneficiaries; if a privately held corporation, the names and addresses of all shareholders, officers, and directors; if a publicly held corporation, the names and addresses of all shareholders holding a direct or indirect interest of greater than five percent, officers, and directors; if a partnership or limited liability partnership, the names and addresses of all partners; if a limited partnership or limited liability limited partnership, the names of all partners, both general and limited; or if a limited liability company, the names and addresses of all members and managers.
 - (2) The identity of all of the following other entities, if the other entities are directly or indirectly involved in the cannabis industry, including, but not limited to, the cultivation, processing, packaging, labeling, testing, transporting, or sale of cannabis.
 - (a) Any subsidiary, affiliate, conglomerate, parent, or other entity that shares common ownership, directly or indirectly, with the ownership entity.
 - (b) Any partnership or limited liability partnership of which the ownership entity is a partner.
 - (c) Any limited liability company of which the ownership entity is a member or manager.
 - b. Verification with regard to each individual having any ownership interest in the applicant (greater than 5% with respect to publicly traded corporations), the identity, street address and responsible person of all entities with which the individual is connected, to the extent the entity is directly or indirectly involved in the cannabis industry, including, but not limited to, the cultivation, processing, packaging, labeling, testing, transporting, or sale of cannabis or medical cannabis, either in Alabama or any other jurisdiction:
 - (1) Any business, including any partnership, limited liability partnership, sole proprietorship, limited liability company or other incorporated or unincorporated business entity or venture, of which the individual or his or her spouse, parent, or child has any equity interest.
 - (2) Any business, including any partnership, sole proprietorship, limited liability company, or other incorporated or unincorporated business entity or venture of which the individual or his or her spouse, parent, or child is a member or manager.

- c. Verification as to whether an owner, director, board member, or individual with a controlling interest in the applicant has been indicted for, charged with, arrested for, convicted of, pled guilty or nolo contendere to, or forfeited bail concerning any felony or controlled substance-related misdemeanor, not including traffic violations, regardless of whether the offense has been reversed on appeal or otherwise, including the date, the name and location of the court, arresting agency, and prosecuting agency, the case caption, the docket number, the offense, the disposition, and the location and length of incarceration.
- d. Verification as to whether the applicant or any entity affiliated with the applicant has ever applied for or has been granted any commercial license or certificate issued by a licensing board or commission in this state or any other jurisdiction that has been denied, restricted, suspended, revoked, or not renewed and a statement describing the facts and circumstances concerning the application, denial, restriction, suspension, revocation, or nonrenewal, including the licensing board or commission, the date each action was taken, and the reason for each action.
- e. Verification as to whether the applicant or any entity affiliated with the applicant is or has been authorized in any other jurisdiction to participate in the cannabis or medical cannabis industry or has been licensed (i.e., a “licensee” as defined in Chapter 1 of these Rules) or provided similar status in any other jurisdiction; if so, the applicant must provide a list of any disciplinary measures (including but not limited to formal written reprimands, citations, fines, violations, suspensions, non-renewals, or license terminations/revocations) received by any of its affiliate entities during the last five (5) years, including the jurisdiction, date, reason for the discipline, steps taken in compliance, and the outcome of such disciplinary measures, if any.
- f. Verification whether the applicant or any affiliate has within the last ten (10) years filed or been served with, a complaint or other notice by any governmental body, regarding a delinquency in the payment of, or a dispute over the filings concerning the payment of, any tax required under federal, state, or local law, including the amount, type of tax, taxing agency, time periods involved, and the resolution, if any, of the matter.
- g. A statement listing the names and titles of all public officials of any unit of government, and the spouses, parents, and children of those public officials, who, directly or indirectly, own any financial interest in, have any beneficial interest in, are the creditors of or hold any debt instrument issued by, or hold or have any interest in any contractual or service relationship with an applicant.
- h. The anticipated or actual number of employees at prospective commencement of operations and during the first five calendar years thereafter.
- i. The number of days, if awarded a license, within which the Applicant reasonably projects it will commence operations as to each facility identified in the application, and the number of days within which the Applicant reasonably projects it will reach full capacity as to the operations contemplated with regard to each facility identified in the Application.

- j. The Applicant's consent as required by § 20-2A-55(d), Code of Alabama 1975 (as amended) to the inspections, examinations, searches and seizures contemplated by § 20-2A-52(a)(3), Code of Alabama 1975 (as amended).
- k. Verification that the Applicant's proposed facility or facilities will be in a permissible location, if applicable, and will maintain compliance with all State and local laws, resolutions, and ordinances.
- l. Verification that the Applicant and its leadership have no economic interest in any other license or Applicant for license under the Act or this Chapter (See § 20-2A-55(e), Code of Alabama 1975 (as amended)).
- m. Exhibits to the Application Information, separately formatted and labeled, in the following order:
 - (1) The *résumé* or *curriculum vitae* of each individual listed in response to subparagraph 3.(a)(1) of this Rule, showing, at a minimum, all institutions of higher education attended, including the date, location and type of any degree received; all residential addresses in the last 15 years; and the name, business address and telephone number of all employers in the last 15 years, including a contact person at each.
 - (2) A demonstration of sufficient capital (as defined in this Chapter) available to the Applicant, as well as the source thereof, and verification of the same by a responsible person designated by the Applicant, the Applicant's contact person, and an independent certified public accountant.
 - (3) Certified copies of the Applicant's business formation documents, to the extent applicable.
 - (4) Records indicating that a majority of ownership in the Applicant is attributable to an individual or individuals with proof of residence in this state for a continuous period of no less than 15 years preceding the application date.
 - (5) For an applicant seeking an integrated facility license or a cultivator license, records indicating that a majority of ownership in the Applicant is attributable to an individual or individuals, or an entity or entities, with cumulative business experience in the field of commercial horticulture or agronomic production for a period of at least 15 years.
 - (6) Verified Written Consent from all individuals identified by § 20-2A-55(b), Code of Alabama 1975 (as amended), to a state (SBI Form 46) and national (FBI Background Request Form) criminal background check, which shall be conducted, at the Applicant's expense, by ALEA and/or another state agency or qualified third party specializing in obtaining such background checks, as chosen by the Commission.
 - (7) If applicable, certified copies of the applicant's business license and resolution or ordinance by local authorities (County or Municipality, as appropriate) approving the facility's business presence in the local jurisdiction.
 - (8) A current financial statement or pro forma containing the following, with year-end projections as to each over the first three (3) calendar years (i.e., the year of commencement plus three more) following commencement of operations:

- (a) Balance sheet report, providing a snapshot of the value of assets, liabilities and equity at commencement, or for projections, as of December 31 of each year.
 - (b) Profit and loss report, summarizing any income, expenses and net profit from the applicant's inception to date of commencement and as projected over each calendar year thereafter, including the year of commencement.
 - (c) Statement of cash flow, examining the cash flowing into and out of the applicant's business from inception to commencement and during each calendar year thereafter, including the year of commencement.
- (9) The Applicant's verified tax plan demonstrating understanding of, and plans for compliance with, all applicable tax laws, including but not limited to providing all information required for purposes of the taxes levied by Chapter 2A of Title 20, and payment of the same.
- (10) The Applicant's proposed Employee Handbook, if available, including but not limited to safety policies, including personnel safety and crime prevention techniques; the Applicant shall provide a verified current copy of same.
- (11) The Applicant's proposed Policies and Procedures Manual, if available; the applicant shall provide a verified copy of same.
- (12) A statement of the following, regarding each facility the Applicant proposes to operate, as of the commencement of operations and within two (2) years thereafter:
- (a) The physical address and GPS coordinates of the facility.
 - (b) An aerial photograph of the facility, including clearly identified site boundaries.
 - (c) Proof of authorization for the Applicant to occupy the property where each facility is proposed to be located.
 - (d) Proof of local zoning and other approvals necessary to operate the business in the local jurisdiction where the business is located, including but not limited to the local jurisdiction's ordinance or resolution approving the operation of medical cannabis facilities there.
 - (e) A professionally rendered blueprint (or, if not available, a professionally rendered floorplan or schematic) of each facility the Applicant proposes to operate, showing clearly drawn and labeled interiors of such facilities, including but not limited to the general function of each area of the structure, for ease in identification of operations and processes by the Commission during future inspections.
 - (f) A timetable for completion and commencement of operations as to each facility.
 - (g) A statement whether such facility shall be open to the public and if so the anticipated hours of business operation.
 - (h) The hours of operation during which the facility will be occupied by Applicant's employees; if not continuous, the after-hours contact information for management.

- (13) A complete site map of any website owned or operated by the Applicant, and the web address of any webpage, social media page or other online site owned or operated by the Applicant.
- (14) A roster of all personnel (all leaders and employees) affiliated with the company, including names, street addresses, contact telephone numbers, email addresses and social security numbers, current to within the last thirty (30) days. Applicant must verify that all employees are registered to the AMCC website and have undergone or are scheduled to undergo appropriate pre-employment background checks.
- (15) The Applicant's Verified Business Plan, to include, at a minimum, the following:
- (a) A clearly defined business structure and plan for adherence to applicable corporate conventions.
 - (b) Clearly defined business goals, including a three (3)-year and a five (5)-year plan.
 - (c) An Organizational Chart – a diagram that visually conveys the Applicant's internal structure by detailing the roles, responsibilities, and relationships between individuals within an entity.
 - (d) Job descriptions of all managerial positions, showing clear delineation of authority, qualifications, and duties.
 - (e) Job descriptions of all non-managerial employee positions, showing clear delineation of qualifications and duties.
 - (f) An executive summary, including mission statement, leadership background and qualifications, business style and philosophy, key personnel, identification of facilities' location and function.
 - (g) A description of products and/or services to be cultivated, processed, transported, dispensed, or tested at each facility, as applicable, including actual (or projected) pricing data, if applicable; actual (or projected) product lifespan, if applicable; projected benefits to consumers; patents, if any; and proprietary technology, if any.
 - (h) An advertising/marketing analysis and strategy, if any.
 - (i) A Community Engagement Plan describing all efforts that have been or will be made to foster the applicant's relationship with, involvement in, and commitment to any community (including municipality or county) in which the applicant intends to locate a facility within the next three years.
 - (j) An Environmental Impact Statement outlining the anticipated impact of each of the applicant's proposed operations, per facility, on the local environment; the applicant's efforts or plans, if any, to build a relationship to foster cooperation and compliance with federal, state and local agencies providing environmental oversight; and any steps the applicant has taken or will take to reduce or eliminate its carbon footprint and/or to achieve and maintain a positive environmental profile in each community where the applicant intends to locate and operate a facility within the next three years.

- (k) An insurance plan, including declarations pages and letters of intent, if any, from an A-rated insurer as to, at a minimum, casualty, workers' compensation, liability, and (as applicable) auto or fleet policy.
- (16) The Applicant's Standard Operating Plan and Procedures, verified by Applicant. Applicants must demonstrate and maintain standard operating procedures regarding the following subjects in such a way that they can be readily accessed from the physical site of operations upon the request of inspectors, the Commission, or Commission staff, including, at a minimum, the following:
- (a) IT plan for ensuring accurate recordkeeping, compliance with inventory protocols, and coordination of information and systems with vendors, customers and others, as applicable, through the Alabama Medical Cannabis Patient Registry System (§ 20-2A-35, Code of Alabama 1975 (as amended)); the Statewide Seed-to-Sale Tracking System (§ 20-2A-54, Code of Alabama 1975 (as amended)), access to and coordination of which shall be paid for and maintained by the licensee; and, as applicable, a third-party inventory control and tracking system (§ 20-2A-60, Code of Alabama 1975 (as amended)), also to be paid for and maintained by the licensee.
 - (b) Plan for maintenance and storage of cannabis and medical cannabis at all times while in possession and control of licensee, including the limitation of access to cannabis and medical cannabis to essential personnel by position.
 - (c) Quality Control/Quality Assurance plan. Applicants shall have a plan for performing, at their own expense after licensure, quality control and testing of a qualified sampling (as defined in 538-x-10-.01 et seq. of these Rules) of medical cannabis in their control, regardless of whether said medical cannabis has been packaged, labeled and sealed. Such testing shall be conducted by the State Testing Laboratory (as detailed in 538-x-10-.01, et seq. of these Rules). Nothing herein shall prohibit a licensee from conducting, at the licensee's own expense, separate in-house testing or testing by an independent third party at any point during the licensee's possession and control of cannabis or medical cannabis.
 - (d) Contamination and recall plan. Applicants must, during the application process, provide to the Commission, and, upon licensing, must maintain and review at least annually thereafter, a clear written contamination and recall plan, detailing the steps to be undertaken in the event of discovery of contamination of cannabis or medical cannabis within the possession and control of the licensee. The plan must account for the safety of employees and others on the premises, notification of proper authorities, proper disposal of contaminated cannabis and medical cannabis, steps to be taken for the preservation of cannabis or medical cannabis, and the reasonable efforts to maintain access to medical cannabis by those who depend on it.
 - (e) Criminal activity plan. Applicants must, during the application process, provide to the Commission, and, upon licensing, must maintain and review at least annually thereafter, a clear written criminal activity plan, detailing the steps to be undertaken in the event of discovery of criminal activity related

to cannabis or medical cannabis within the possession and control of the licensee. The plan must account for the safety of employees and others on the premises, reporting the criminal activity to proper authorities, steps to be taken for the preservation of cannabis or medical cannabis, and the reasonable efforts to maintain access to medical cannabis by those who depend on it.

- (f) Emergency procedures/disaster plan. Applicants must, during the application process, provide to the Commission, and, upon licensing, must maintain and review at least annually thereafter, a clear written Emergency Procedures and Disaster Plan, detailing the steps the Applicant will take to ensure the safety of employees and others on the premises, the preservation of cannabis or medical cannabis, and the reasonable efforts to maintain access to medical cannabis by those who depend on it, in the event of any reasonably foreseeable emergency, or natural disaster that may affect the licensee, its facilities, personnel, products or customers.
- (g) Alcohol, smoke, and drug-free workplace policies. Applicants must, during the application process, provide to the Commission, and, upon licensing, must maintain and review at least annually thereafter, a clear written Alcohol, Smoke and Drug Free Workplace Policy, which shall be included in the Employee Handbook and/or the Policies and Procedures Manual.
- (h) Employee Safety Plan in compliance with parallel OSHA standards applicable in similar types of workplaces.
- (i) Confidential Information and Cybersecurity Plan. The Applicant's plan for maintaining confidential information and any records required to be confidentially maintained.
- (j) A plan for tracking and proper disposal of waste cannabis or medical cannabis, as necessary.
- (k) A verified Security Plan as to each of the Applicant's proposed facilities, addressing each of the following aspects of security and meeting the following minimum thresholds:
 - i. Alarm systems must be installed in all facilities where cannabis or medical cannabis is maintained or stored. Such alarms shall be provided and installed by experts in industry-standard commercial-grade alarm systems. Alarm systems must be fully operational securing all entry points and perimeter windows, be equipped with motion detectors and pressure switches covering all areas where cannabis or medical cannabis is grown, handled, stored, prepared, transported, tested, or dispensed.
 - ii. Reception areas and personnel adjacent to ingress and egress points shall have ready access to duress panic and hold-up alarms that may be activated in the event of access by unauthorized personnel or intruders.
 - iii. Licensee facilities shall maintain an audio/video surveillance system that shall be in continuous operation 24 hours per day. Recording devices shall be fixed in place covering both the interior and exterior of the facility, in such quantity and at such resolution as shall allow for the clear

identification of individuals and activities in all reasonably accessible areas of the premises, including but not limited to all point-of-sale areas, entrances, exits, parking lots, and any area where cannabis or medical cannabis is grown, handled, stored, prepared, transported, tested, or dispensed. Audio recordings shall clearly and accurately capture sound within camera range at a level of 20 decibels or greater. Audio/video surveillance recordings must clearly and accurately display the time and date.

- iv. The facility's perimeter and any outdoor premises must be surrounded by a sufficient fence or barrier to prevent access by unauthorized persons and must have sufficient lighting to allow for the proper functioning of video surveillance equipment, at all times between dusk and dawn, or at any other time when ambient lighting requires enhancement to permit identification of individuals or activities upon or immediately adjacent to the premises. Indoor premises must likewise be sufficiently lit to allow for the identification of individuals and activities.
- v. Exterior doors of each facility must be designed or reinforced to withstand unlawful forcible entry; exterior doors shall, at all times, remain locked against outside intruders, while allowing free egress by the facility's occupants in the event of an emergency; doors must permit ingress to employees and other appropriate persons only by means of a keycard or other similar electronic access device.
- vi. Exterior walls of each facility must be reinforced to withstand unlawful forcible entry. Windows, likewise, must be reinforced to prevent breakage by outside intruders.
- vii. Applicants must provide and maintain a plan for sufficient staffing of security guards at each facility where cannabis and medical cannabis is present to reasonably ensure the safety of the products stored therein; however, the applicant's plan must provide, at a minimum, one (1) security guard per facility during the facility's business/operating hours.
- viii. Strict access controls shall protect areas where cannabis or medical cannabis is handled or stored – in a secured, locked room or vault.
- ix. Records, whether electronic or manual, must be kept, at all times, of all persons on the premises at a facility, including employees, vendors, transporters, medical cannabis patients and caregivers, and all others, recording the individuals' name, date, time of ingress and egress, and (as to non-employees) the reason for their presence; such records shall be kept for a minimum of two years.
- x. Audio/Video surveillance records must be kept for at least 60 days, and longer upon the request of the Commission, its inspectors, or any law enforcement personnel. Audio/Video recordings potentially reflecting an incident of actual or attempted diversion must be kept for the longer of a period of two years, or until resolution of the incident and

- apprehension and discipline or prosecution of the individuals involved in the actual or attempted diversion.
- xi. Employees, while on duty, shall wear identification badges that clearly identify them as employees.
 - xii. Visitors, including Commission members, inspection personnel, or other representatives, shall wear a “visitor pass” or “AMCC Official” pass, as applicable, at all times while on the premises.
 - xiii. Applicants, and upon licensure, Licensees, shall maintain, review and update policies to report theft, diversion or other loss of cannabis or medical cannabis to the Commission and to law enforcement within 24 hours of the event or its discovery.
 - xiv. The Applicant, and upon licensure, the Licensee, upon request, shall make available to the Commission or its inspectors all information relating to security alarm systems, monitoring, alarm activity, maps of camera locations and camera coverage, surveillance equipment maintenance logs, authorized use lists, operation instructions, and any other security-related information deemed relevant by the Commission or its inspectors.
- n. To the extent that an applicant seeks status as a licensee that is at least 51% owned by, and is managed and controlled in its daily operations by, members of a minority group as defined in § 20-2A-51(b) of the Code of Alabama 1975 (as amended), the applicant must provide a verified statement that it is applying for such status as well as documentation demonstrating the basis for seeking such status, including but not limited to a showing that at least 51% of the owners are (or, in the case of a corporation, 51% of the shares belong to) members of a minority group, and that the applicant is managed and controlled by members of a minority group in its daily operations. To the extent that the applicant has entered into contracts with any members of a minority group to assist the applicant in attaining such status, the applicant must provide verified copies of such contracts.
 - o. Any information and/or documents specific to the category of Applicant (Cultivator, Processor, Secure Transporter, Dispensary, State Testing Laboratory, Integrated Facility) as identified separately in these Rules.
 - p. Affidavit of the Applicant (or, if an entity, the responsible party thereof AND the contact person) that the information provided in the Application is true and correct, to the best of the Affiants’ knowledge upon a diligent investigation thereof.
 - q. Application Fee as provided in § 20-2A-55(f), Code of Alabama 1975 (as amended). The Applicant’s nonrefundable Application Fee, in the designated amount, must be submitted electronically per instructions accompanying the Application Form.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.06 Amended Applications.

1. Not more than once during an offering period, absent extenuating circumstances, an applicant having previously filed an application may, acting on its own and not as the result of incompleteness or other concerns relating to the Application as pointed out by the Commission (i.e., a notice of deficiency and proposed corrections filed by the Applicant), file an amended application, paying an amended application fee equal to one-half of the applicable application fee paid at the time of the Applicant's original filing.
2. An amended application may be filed to correct any errors identified by the applicant, to more accurately reflect facts relating to the Applicant's proposed business, to generally revise and improve the quality of the Applicant's previously filed application to the Commission, or for any other valid purpose.
3. An amended application may not attempt to alter the category of business for which the applicant seeks to be licensed.
4. Changes to information contained on the summary sheet are not considered an amendment to the application, but such changes can (and should) be made at any time during the application process and as soon as possible once the information contained on the summary sheet is no longer correct.
5. The filing, or not, of an Amended Application shall have no bearing on whether an application may receive a notice of deficiency and warrant proposed corrections, nor whether a deficient application as to which corrections have been proposed, may also be amended.
6. Filing an amended application replaces all information provided in the original application filing, and the Commission or its personnel shall not consider any information contained in the original filing upon receipt of an amended application or the acceptance of an extenuating-circumstances amended application. However, filing an amended application does not preclude an applicant from responding to a notice of deficiency provided by the Commission and proposing corrections for approval by the Commission.
7. The form of the Amended Application, whether filed pursuant to paragraph 1 or 10 of this Rule, must follow the form for filing an original application set forth in this Chapter. An amended application requires a full refiling of all required parts of the original application (whether or not modified) and may not incorporate by reference or adopt any portion of the original filing. In addition to providing all information and exhibits as required in an original application, the Applicant filing an amended application or proposed amended application shall include as an exhibit a redline version of the original application, showing what changes were made and an explanation of the reasons the change was necessary.
8. An applicant who has filed an original application may file an amended application only once during the window of time for filing amended applications. Except as provided in paragraph 11 of this Rule, an amended application will not be accepted more than once from the same applicant, and an amended application may not be accepted in any event outside the window for filing amended Applications.
9. The window for filing an Amended Application shall close on the date the window for filing original applications closes. For the initial offering, the window for filing an amended application shall open on November 1, 2022, at 10:00 a.m., CDT, or eight days from the date application forms are issued, whichever is later; the window for filing Amended

Applications shall close at 4:00 p.m., CST, on December 30, 2022, or at the time the window for filing initial applications closes, if that date is later than December 30, 2022.

10. In the event of extenuating circumstances, an Applicant may seek permission to extend the time for filing an amendment to its application by means of a written petition to the Commission. The petition for permission to file an amended application based on extenuating circumstances must show in detail the changes being requested and the alleged extenuating circumstances that have prevented the Applicant from including the information in the original application or in a timely amendment thereto. At the time of filing the petition, the Applicant must pay a nonrefundable amended application fee equal to the Application fee paid at the time of the Applicant's original application. The burden is upon the Applicant to demonstrate that the application should be allowed to be amended.
11. Notwithstanding the provisions of paragraph 8 of this Rule, permission to file an amended application under extenuating circumstances will not be withheld based on the Applicant's already having filed an amended application. However, permission to file a proposed amendment under this paragraph will not be granted more than once for the same Applicant, and an amended application based on extenuating circumstances will not be considered if permission is not requested on a timely basis or, if permission is granted, the amended application proposed under this paragraph is not filed on or before the date specified in the Application Form. As to the Initial Offering, the date for seeking permission to file an amended application under extenuating circumstances is the later of March 3, 2023, at 4:00 p.m. CST, or at 4:00 p.m., 63 days from the deadline for filing an original application. The date for filing a proposed amended application requested under this paragraph shall be no more than 21 days from the deadline for seeking permission to file an amended application under extenuating circumstances; as to the initial offering, that date is the later of 4:00 p.m. CDT, March 24, 2023, or at 4:00 p.m. 21 days from the deadline for seeking permission to file an amended application under extenuating circumstances.
12. The Commission's decision to grant or deny a petition to file an amended application under paragraph 10, and the Commission's acceptance or not of the Applicant's proposed amended application, shall be made at the next meeting of the Commission not less than 15 days from the deadline for filing the proposed amended application under paragraph 10. If the petition is denied or the Applicant fails to amend its application after filing a petition under paragraph 10, the Commission shall consider the Applicant's original application (as amended, if applicable). For the initial offering, the decision to grant or deny a petition to file an amended application under extenuating circumstances shall be made at the meeting of the Commission on April 13, 2023, or at the next Commission meeting not less than 15 days after the deadline for filing the proposed amended application under paragraph 10, whichever is later. Notice of the decision shall issue to the Applicant no later than 4:00 p.m. Central Time the following business day.
13. Notwithstanding anything herein to the contrary, the "filing" of an amended application as described in these Rules shall not mean that the application, as amended is "submitted" pursuant to § 20-2A-56(d), Code of Alabama 1975 (as amended); as provided in Rule 538-x-3-.07, an application, including an amended application, is "submitted" such

that the 60 days for determining whether to award a license begins to run only when the Commission accepts and approves all applications for submission (along with any original applications, or applications filed in response to a Notice of Deficiency with proposed corrections or extraordinary circumstances corrections), filed by other Applicants of a particular category in the same offering.

14. The Applicant's failure to timely and properly file an amendment filed based on a request for an extension of time due to extenuating circumstances, and the Commission's rejection and refusal to consider applications as to which the proposed amendment were not filed, untimely filed, improperly filled out, or improperly formatted, shall not constitute a breach of due process nor permit the Applicant a right of appeal under the Act, this Chapter or any provision of the AAPA.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.07 Withdrawal of Application.

Applicants may withdraw a filed Application or Amended Application at any time; however, an Applicant who has withdrawn an application may refile (and pay a new application fee) only once, and then only if the window for original Application filing remains open. Withdrawal of an Application does not exempt the applicant from the jurisdiction and authority of the Commission to issue sanctions, as appropriate to address any improper conduct by the applicant during the application process.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.08 Application Deficiencies; Proposed Corrections.

1. Not more than 45 days after the window closes for original application filing, the Commission shall issue a Notice of Deficiency, notifying any Applicant whose original or amended application filing is deficient and specifying the date by which the deficiency must be corrected, not more than eighteen (18) days after issuing the notice of deficiency. As to the initial offering, the issuance of Notices of Deficiency shall be 4:00 p.m., CST, February 13, 2023, or at 4:00 p.m. 45 days after the window closes for original application filing, whichever is later.
2. Deficiencies, as provided herein, shall include but are not limited to: corrupted or illegible file materials, incomplete applications (i.e., missing required documentation), improperly formatted or labeled materials, typographical errors preventing reasonable understanding of one or more of the Applicant's statements.
3. The Notice of Deficiency shall specify in what way or ways the Application has been deemed deficient and shall point out, to the extent possible, the portions of the application that were affected by the deficiency or deficiencies.
4. Upon receiving the Notice of Deficiency, the Applicant shall have not more than 18 days to propose corrections and refile the application in full, with the proposed corrections

shown as required and a redline version of the original Application filed therewith as an exhibit. At that time, the Applicant shall pay a nonrefundable corrections processing fee equal to one-half the application fee paid at the time of the Applicant's original filing. For the initial offering, proposed corrections shall be due, barring extraordinary circumstances, as provided in paragraphs 5 and 6, at or before 4:00 p.m., CST, on March 3, 2023, or 18 days from the date of the Notice of Deficiency, whichever is later. The deadline for proposing corrections based on a deficiency shall be as noted by the Commission on the Application Form.

5. The Commission, in its discretion, may allow additional time based on extraordinary circumstances, up to 60 days from the date the deficiencies were identified to the Applicant, to correct and refile the application. The Applicant's petition for additional time based on extraordinary circumstances shall be in made in writing, explaining in detail the need for additional time to make the required corrections, but the presumption shall be against allowing such additional time.
6. With regard to the initial offering, a petition for additional time based on extraordinary circumstances must be made on or before 4:00 p.m. CST on March 3, 2023, or by 4:00 p.m., Central time 63 days after the window closes for filing an original application, whichever is later, and, if granted, would extend the time for providing proposed corrections from March 3, 2023, to March 24, 2023 at 4:00 p.m., CDT, or at 4:00 p.m., Central Time, 21 days from the initial deadline for filing corrections to deficiencies, whichever is later. At that time, the Applicant shall pay a nonrefundable corrections processing fee equal to the application fee paid by the Applicant at the time of its original filing.
7. Deficient applications are not deemed "corrected" as set forth in §§ 20-2A-55(g) and 20-2A-56(d), Code of Alabama 1975 (as amended) until an Applicant's proposed corrections are formally approved by the Commission. For the initial offering, such approval shall be granted or denied at the meeting of the Commission on April 13, 2023 (60 days from the date of the Notices of Deficiency), or at the next Commission meeting not less than 15 days after the deadline for filing the proposed extraordinary-time corrections under paragraph 6, whichever is later. Notice of the Commission's decision shall issue to the Applicant no later than 4:00 p.m. CDT the following business day.
8. The Commission's decision to grant or deny a petition for additional time to make corrections due to extraordinary circumstances, and the Commission's approval or not of the Applicant's proposed corrections shall be made at the next meeting of the Commission not less than 15 days from the deadline for filing the proposed extraordinary-time corrections under paragraph 6 of this Rule. For the initial offering, the decision shall be made at the meeting of the Commission on April 13, 2023, or at the next Commission meeting not less than 15 days after the deadline for filing the proposed extraordinary-time corrections under paragraph 6, whichever is later. Notice of the decision shall issue to the Applicant no later than 4:00 p.m. Central Time, the following business day.
9. Filing a corrected version of the application in response to a Notice of Deficiencies issued by the Commission replaces all information provided in the original application filing, and the Commission or its personnel shall not consider any information contained in the original filing upon the acceptance and approval of proposed corrections to an original

application or an extraordinary-circumstances application. However, filing an amended application does not preclude an applicant from responding to a notice of deficiency provided by the Commission and proposing corrections for approval by the Commission.

10. Notwithstanding anything herein to the contrary, the “filing” of proposed corrections to an application or amended application as described in these Rules shall not mean that the application has been “submitted” or “corrected” pursuant to § 20-2A-56(d), Code of Alabama 1975 (as amended); as provided in paragraph 7 and in Rule 538-x-3-.07, an application, including an amended application and any application as to which proposed corrections have been made, is “corrected” and “submitted,” such that the 60 days for determining whether to award a license begins to run, only when the Commission accepts and approves the proposed corrections and all accepts and approves all applications for submission (along with any original applications or amended applications) filed by other Applicants of a particular category in the same offering.
11. The Applicant’s failure to timely and properly file suitable proposed corrections, and the Commission’s rejection and refusal to consider applications as to which proposed corrections were not filed, untimely filed, improperly filled out, improperly formatted, or which were unsuitable to correct the deficiencies noted, shall not constitute a breach of due process nor permit the Applicant a right of appeal under the Act, this Chapter or any provision of the AAPA.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.09 Applications Deemed “Submitted.”

Particularly with respect to offerings potentially involving multiple available licenses, but otherwise at the discretion of the Commission based on a timeline to be set forth in the Offering Announcement or included on the Application Form, no Application by any Applicant may be deemed “submitted” pursuant to § 20-2A-56(d), Code of Alabama 1975 (as amended), until the Commission decides to accept and approve or reject proposed corrections and extraordinary-time proposed corrections with respect to all other deficient applications, regardless of whether the applicant’s own application was deemed deficient and required proposed corrections. In such instances, the date applications are deemed “submitted” shall also be the date the Commission decides whether to accept and approve an Amended Application under extenuating circumstances or proposed corrections filed in respect to a Notice of Deficiency or an Extraordinary Circumstances Application. With respect to the initial offering period, the Commission shall, by vote, deem all properly filed and, as necessary, corrected applications “submitted” at or before its meeting on April 13, 2023, or 60 days from the date Notices of Deficiency were issued based on deficient applications, whichever is later. The time for the Commission to determine whether a license should issue to an Applicant does not begin until all applications are deemed “submitted” as set forth in this rule, and the 60 days to grant or deny a license does not begin to run until that date. Notice of the Commission’s decision shall issue to the Applicant no later than 4:00 p.m. Central Time the following business day.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.10 Processing and Evaluation of Applications.

1. *Review.* The Commission, one or more independent consultants selected by the Commission, or a combination of the two, shall review submitted applications (either original, amended or as corrected) as described in this Chapter and the instructions accompanying the application form. At least a portion of the review shall be conducted under “blind” conditions, where the reviewers scoring, averaging, or ranking the applications are not made aware of the identity of the applicant or any of the individuals or other entities associated therewith. Any independent consultants selected by the Commission will provide recommendations for the Commission to consider, but the Commission shall not be bound by the recommendation and the decision as to final approval or rejection of licensees shall remain the province of the Commission at all times. Review and evaluation of applications as provided in this Rule may occur at any time during the offering period, from the date of filing requests for application through the date all licenses in the offering have been issued.
2. *Scoring, Averaging and Ranking.* Applicants shall be scored, averaged, and ranked using an impartial numerical process in accordance with the requirements of the Act and the Criteria for Awarding Licenses set forth in r. 538-x-3-.11.
3. *Communication during the application process.* The Commission, or as applicable, the Department, may engage in communications with an Applicant or others at any time to gather information that may be useful in determining the applicant’s suitability as a licensee in a particular category. Applicants and their representatives shall not initiate communications with the Commission or its representatives except as provided in paragraph 3 of 538-x-3-.03 of this Chapter.
4. *Public Records and Applicants’ Confidential or Proprietary Information.* In general, information contained in applications filed by Applicants are public records. Applicants may, through a process to be outlined on the AMCC website at or before the time for filing applications, redact portions of the Application to protect from public view in order to protect confidential or proprietary information. Failure to include a redacted version of the application at the time of filing will result in the entire application being made public.
5. *Investigation of Applicant and Owners; Criminal Background Checks.* As part of the selection process, the Commission and its representatives shall investigate the Applicant and its owners, either directly or through a third party with expertise in performing such investigations and/or conducting background checks.
6. *Pre-licensure Inspections of Applicants’ Facilities.* Prior to issuing a license, the Commission may, in its discretion, either directly or through one or more independent consultants selected by the Commission, or both, conduct a Pre-Licensure Inspection to verify the information received in the Application and to provide further insights to assist in the license determination process. The Commission’s decision to conduct a Pre-

Licensure Inspection, or not, should not be interpreted as an indication that the Commission ultimately will or will not issue a license to the Applicant.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.11 Criteria for Awarding Licenses -- Standards, Procedures and Requirements.

1. The number of licenses awarded as to each category of Applicant shall be in accordance with provisions of the Act, to the extent licenses regarding any particular category are limited. In no event shall the Commission award a license, as to any category, in excess of any limitation provided in the Act.
2. In every instance, the primary consideration of the Commission in awarding any license shall be the merits of the application submitted, including, but not limited to the Applicant's solvency, stability, suitability, capability, projected efficiency, and experience, both in relation to any baseline set by the Commission as well as in comparison with other Applicants.
3. The Commission's criteria for granting licenses, or increasing the number of a specific category of license to grant, shall include, but shall not necessarily be limited to, the following factors:
 - a. The population of the state,
 - b. The number of active or anticipated registered qualified patients,
 - c. Market demand for medical cannabis,
 - d. The unemployment rate of the state,
 - e. The need for agricultural and other business opportunities in communities,
 - f. Access to health care,
 - g. Infrastructure,
 - h. The extent to which an Applicant, if awarded a license, anticipates fully utilizing its license authorization and/or the number of its permitted facilities,
 - i. The anticipated time within which an Applicant projects being able to commence operations and/or reach full capacity as to its operations,
 - j. The measures, if any, an Applicant is willing to take in seeking to minimize costs to patients,
 - k. The existing or projected distribution of licenses in a category across the State,
 - l. Providing the greatest benefits to the residents of Alabama, and
 - m. The racial and economic makeup of Alabama.
 - n. Providing variety within licensees' business models, so as to foster a diversity of approaches to doing business, engage creative or innovative ways of achieving business goals and serving the citizens of Alabama, and increase choice to patients and caregivers.
4. The weight to be given to any particular factor, in determining whether to award a license, is discretionary with the Commission, and the Commission need not weigh any particular factor more or less than others considered. In accordance with § 20-2A-51(b), Code of Alabama 1975 (as amended), the Commission shall ensure that at least one fifth of all integrated facility licenses in Alabama, and at least one fourth of licenses in all other

categories, are awarded to business entities at least 51% of which are owned by members of a minority group, or, in the case of corporations, at least 51% of the shares of the corporation are owned by members of a minority group, and are managed and controlled by members of a minority group in its daily operations. In the event that death, resignation, attrition, dissolution, bankruptcy or any other eventuality should cause the number of 51% minority-owned integrated facilities to fall below one fifth of the total number of such integrated facilities, or as to all other categories, one fourth of the total number of such licensees, the Commission shall, at the next opportunity to award a license, prioritize awarding a license to a qualified company that fulfills the 51% minority-owned goal set forth in the Act. The foregoing goal of the Act does not pretermitt the requirement that the applicant must demonstrate compliance with all applicable rules, regulations, criteria and statutory guidelines as set forth herein.

5. In addition to the foregoing considerations, in determining whether to award a license, the Commission may consider the following factors:
 - a. The integrity, moral character, and reputation; personal and business ethics; financial ability and experience; and responsibility or means to operate or maintain a facility of the Applicant and of any other individual that meets either of the following:
 - (1) Controls, directly or indirectly, the Applicant;
 - (2) Is controlled, directly or indirectly, by the Applicant or by a person who controls, directly or indirectly, the Applicant.
 - b. The financial ability of the Applicant to maintain required financial guarantees.
 - c. The nature, quality, and tenor of the Applicant's interactions with the Commission and AMCC personnel during the current or in any previous application process.
 - d. The sources and total amount of the Applicant's capitalization to operate and maintain the proposed facility.
 - e. Whether an owner, director, board member, or individual with a controlling interest in the Applicant has been indicted for, charged with, arrested for, convicted of, pled guilty or *nolo contendere* to, or forfeited bail concerning, or had expunged any relevant criminal offense under the laws of any jurisdiction, either felony or misdemeanor, not including traffic violations, regardless of whether the offense has been expunged, pardoned, or reversed on appeal or otherwise. See 538-x-3-.05-3.c.
 - f. Whether the Applicant has filed, or had filed against it, a proceeding for bankruptcy within the past seven years.
 - g. Whether the Applicant has been served with a complaint or other notice filed with any court or public agency regarding payment of any tax required under federal, state, or local law that has been delinquent for one or more years.
 - h. Whether the Applicant has a history of noncompliance with any regulatory requirements in this state or any other jurisdiction.
 - i. Whether at the time of application the Applicant is, or in the past 10 years has been, a defendant in litigation involving its business practices.
 - j. The Applicant's ability to capitalize and conduct operations as proposed in its business plan, including business experience in related fields.
 - k. The Applicant's history of business activities as it applies to the specific license for which the applicant is seeking licensure.

- l. The Applicant's history of business activities as it applies to licenses applied for or awarded in other jurisdictions.
 - m. The proposed location of all proposed medical cannabis facilities as being suitable for all activities, not inconsistent with applicable zoning, and the Applicant's ability to serve an identifiable geographic area.
 - n. Whether the Applicant meets other standards or requirements established under the Act or these Rules. (See § 20-2A-56(c) (1)-(12), Code of Alabama 1975 (as amended))
6. In the absence of other determinative factors set forth herein, where two or more Applicants at the threshold for being awarded a license or not have earned average scores (as set forth in paragraph 2 of 538-x-3-.08) within one percentile point of each other, the Commission may, in its discretion, utilize a lottery or tie-breaking system among affected Applicants, to select which one or ones of such affected Applicants should be awarded a license.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.12 Third-Party Evaluation and Recommendation.

In the event the Commission opts to act through third-party "agents" (as provided in § 20-2A-55(d), Code of Alabama 1975 (as amended)) or representatives of a State Agency, to perform inspections, examinations, evaluations, and recommendations as to licenses, the Commission remains the primary decisionmaker with regard to licensing and has authority to act independently of any third-party evaluation and recommendation. This means that the Commission has discretion to act consistently with such evaluation and recommendations, to differently weigh the factors contained within such evaluation and recommendations, or to apply different factors and issue licenses based on reasons not considered by the third party, but upon such other factors as the Commission, in its discretion, may deem appropriate. The Commission, AMCC Staff, and any entities or individuals contracting with the Commission or its agents, must keep confidential (as defined in 538-x-1-.02) all information and any documents obtained from any inspection, examination or evaluation of any applicant, licensee or individual in connection herewith.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.13 Public Notice and Comment Period; Public Hearing.

A 30-day public comment period in compliance with § 20-2A-56(a), Code of Alabama 1975 (as amended) shall begin on the next business day after applications are deemed "submitted" as provided in Rule 538-x-3-.07. As to the initial offering period, applications are deemed submitted as to all original applications, amended applications and applications as to which corrections have been proposed, accepted and approved, upon a vote of the Commission to be taken at its meeting at 1:00 p.m., CDT, April 13, 2023, or the next meeting of the Commission not less than 15 days after the deadline to propose extraordinary-time corrections or to propose amendments to be

filed under extenuating circumstances, whichever is later. On the next business day after such date, the Commission shall issue a public notice on the AMCC website, identifying by category of license sought all individuals or entities whose applications have been submitted and who are being considered for license under the Act and this Chapter and providing links to the applications (redacted versions, if provided) supplied by the applicants. Public comments in favor or opposed to granting a license to a particular applicant must be made electronically through the AMCC website, in accordance with the instructions to be provided at that time. The Commission, in its discretion, but in any event during the public notice period and upon at least 7 days' notice, may choose to hold a public hearing as to one or more of the prospective licensees. As to the initial offering, the public notice period expires at 4:00 p.m. CST on Sunday, May 14, 2023, or at 4:00 p.m., Central Time, 30 days after the date public comment is opened, whichever is later.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.14 Ineligibility for License.

In addition to the provisions of § 20-2A-56(b), Code of Alabama 1975 (as amended), setting forth the conditions under which an applicant shall be ineligible for license, the Commission also shall deem an applicant ineligible to receive a license for the following reasons:

1. An owner, director, board member, or individual with a controlling interest in the Applicant has pled guilty to, been convicted of, or released from incarceration either in Alabama or in any other jurisdiction for, a felony, or other crime that would constitute a felony under the laws of Alabama within the past 10 years, or has in any jurisdiction pled guilty to or been convicted of a controlled substance-related misdemeanor (or other crime that would constitute a controlled substance-related misdemeanor under the laws of Alabama) within the past 10 years; provided, however, the Commission shall not consider any conviction overturned on appeal or any charge that has been expunged pursuant to Chapter 27 of Title 15 of the Code of Alabama, 1975 (as amended).
2. The Applicant has knowingly filed an application for a license under the Act and this Chapter that contains false information.
3. An owner, director, board member, employee, agent, or other individual with an economic interest in the Applicant is a member of the Commission.
4. The Applicant fails to demonstrate the ability to maintain adequate minimum levels of liability and casualty insurance or other financial guarantees for its proposed facility.
5. The Applicant cannot provide records as described in § 20-2A-55(a)(10), Code of Alabama 1975 (as amended), indicating that a majority of the ownership of any Applicant is attributable to an individual or individuals with proof of residence in this state for a continuous period of no less than 15 years preceding the application date.
6. For an Applicant seeking an integrated facility license or cultivator license, the Applicant cannot provide records described in § 20-2A-55(a)(11), Code of Alabama 1975 (as amended), indicating that a majority of ownership is attributable to an individual or individuals, or an entity or entities, with cumulative business experience in the field of commercial horticulture or agronomic production for a period of at least 15 years.

7. The Applicant has failed to follow the instructions of the Commission in respect to filing its application or otherwise relating to the Act and this Chapter.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.15 Issuance of License Notices of Award and Notices of Denial.

Within 60 days of the date the Applicant's application (either as originally filed or as amended) is deemed submitted in accordance with Rule 538-x-3-.07 (which also shall be within 60 days of the date the Commission accepts and approves proposed corrections by an Applicant whose application had been deemed deficient), the Commission shall issue notices of award and notices of denial, as appropriate, to all Applicants under consideration for licenses in accordance with the Act and this Chapter. As to the initial offering by the Commission, the date such notices shall issue is noon, CDT, June 12, 2023, or at noon, Central Time, sixty days from the date the applications are deemed submitted, whichever is later.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.16 Payment of License Fee.

Licensees having received a notice of award granting a license shall have 14 days (as to the initial offering, until 4:00 p.m., CDT, June 26, 2023, or within 14 days of the issuance of the notice of award) to submit the appropriate license fee. The Amount of the license fee for each Applicant which has been awarded a license shall be in accordance with the annual license fee established by the Commission, which shall be as set forth in the schedule of fees, and payable electronically via the payment portal, both of which shall be contained on the AMCC website. Licensees shall be responsible for any and all transaction fees that may be assessed for their use of the payment portal.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-3-.17 Issuance of Licenses.

Unless the Commission or other court of competent jurisdiction enters a stay against the issuance of some or all licenses, licenses shall issue to all Applicants who have been awarded licenses upon processing of the appropriate license fees, not later than 14 days after the deadline for payment of the appropriate fee; for the initial offering, issuance of licenses shall occur on the later of noon, CDT, July 10, 2023, or 28 days from the date licenses are awarded, or within three (3) business days after the lifting of any stay on the issuance of licenses.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: **New Rule: Published August 31, 2022; Effective October 15, 2022.**

538-x-3-.18 Denial of application; Request for Hearing from Application Denial.

In accordance with § 20-2A-56(e), Code of Alabama 1975 (as amended), any Applicant who has been denied a license by the Commission may seek an investigative hearing before the Commission to seek reconsideration of said denial. Request for hearing must be filed electronically on or before 4 p.m., CDT, 14 days from the date of the denial. At the time of the hearing request, the disappointed Applicant shall submit funds equal to the amount of the license fee for which it otherwise would have been responsible. The funds paid by the disappointed Applicant are nonrefundable; if the Applicant is successful in challenging the award, the Applicant's payment shall be used to pay the Applicant's license fee, but if the applicant is unsuccessful, the funds shall be used to defray the costs, expenses and attorney fees of the Commission in defending its decision. The decision of the Commission on such hearing is considered a final action; thereafter, a disappointed Applicant may appeal, as provided in the Act (§ 20-2A-57(f), Code of Alabama 1975 (as amended)). Despite the Commission's announcement of the award of licenses, due to the pendency of hearings or appeals on some or all licenses in a particular offering, some or all licenses may not issue, in the discretion of the Commission, but may be stayed until the time for appeal has lapsed or all appeals from the Commission's decision have resolved, whichever is later. Any deadlines or obligations imposed on licensees based on licensure under these Rules or the Act shall not begin to run until such time as licenses are issued.

Author: **William H. Webster**

Statutory Authority: **§20-2A-22, Code of Alabama 1975 (as amended).**

History: **New Rule: Published August 31, 2022; Effective October 15, 2022.**

538-x-3-.19 Penalties for False Information or Fraud.

Any Applicant, including any responsible party or contact person of any applicant, who knowingly submits false information or otherwise attempts to commit fraud in connection with the application and licensing process under this Chapter, in addition to having its application ruled ineligible, may be subject to penalties and fines and, potentially, criminal charges. Penalties and fines to be levied upon Applicants under this Rule shall be established by the Commission and set forth in the schedule of fines on the AMCC website.

Author: **William H. Webster**

Statutory Authority: **§20-2A-22, Code of Alabama 1975 (as amended).**

History: **New Rule: Published August 31, 2022; Effective October 15, 2022.**

**APPENDIX A TO CHAPTER 3
TIMELINE FOR APPLICATIONS AND LICENSING
(ASSUMING RULES BECOME EFFECTIVE OCT. 17, 2022)**

TH September 1, 2022, 10:00 a.m. CDT	Window opens for Request for License Application Forms
MO October 17, 2022, 10:00 a.m., CDT	Deadline for Request for License Application Forms
MO October 24, 2022, 4:00 p.m., CDT	License Application Forms go out to Requestors
MO October 31, 2022, 10:00 a.m., CDT	Window opens to begin accepting License Applications
TU November 1, 2022, 10:00 a.m., CDT	Window opens to begin accepting Amended Applications
FR December 30, 2022, 4:00 p.m., CST	Deadline for original application filings Deadline for amending previously submitted Applications, barring extenuating circumstances
MO February 13, 2023, 4:00 p.m., CST	Deficiency Notices go out re: all deficient Applications
FR March 3, 2023, 4:00 p.m., CST	Deadline to propose corrections (without extension) re: deficient application. Deadline to request extension of time for proposed corrections based on extraordinary circumstances Deadline to seek permission to amend an Application due to extenuating circumstances
FR March 24, 2023, 4:00 p.m., CDT	Deadline to propose deficiency corrections under extraordinary circumstances Deadline to submit a proposed Amended Application based on extenuating circumstances
TH April 13, 2023, 1:00 p.m., CDT (at Meeting)	By vote of Commission, proposed deficiency corrections formally accepted as submitted By vote of Commission, extraordinary time deficiency correction requests formally granted or denied By vote of Commission, submitted deficiencies formally deemed “corrected” or not By vote of the Commission, Petition to Amend Application due to extenuating circumstances

	shall be granted or denied and proposed amendments accepted or not
	By vote of the Commission, all properly filed and corrected Applications accepted as final and deemed “submitted” as of this date
	60 days begins to determine whether license may be issued
FR April 14, 2023, 4:00 p.m., CDT	Public notice as to all Applicants, 30-day public comment begins
TU April 25, 2023, 4:00 p.m., CDT	Public hearing date announced, if necessary
TH May 11, 2023, 10:00 a.m., CDT (at Meeting)	Public hearing date to hear comments on pending Applications
SU May 14, 2023, 4:00 p.m., CDT	Public comment period closes
MO June 12, 2023, NOON, CDT April 13, 2023)	Initial Licenses Granted or Denied (60 days from
	Window opens to pay license fee (if not stayed)
MO June 26, 2023, NOON, CDT	Deadline to request public hearing after denial of license
	Window closes to pay license fee (if not stayed)
MO June 26, 2023, 2:00 p.m., CDT	Issue Stay and Set Hearing Dates (if necessary due to appeal)
MO July 10, 2023, NOON, CDT	Licenses Issued (unless appeals are ongoing)

**Alabama Medical Cannabis Commission
Rules and Regulations**

**Chapter 4
LICENSEE REQUIREMENTS – GENERALLY.**

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538-x-4-.01 Purpose.

Chapter 4 of these Rules regulates licensees’ conduct and details general procedures applicable after a license has been issued.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.02 Post-Licensing Inspection of Facilities

1. *Generally.* Inspections of licensees (except cultivators, who shall be inspected under procedures set forth in Rule 80-14-1-.10, promulgated by the Department) shall be carried out by the

Commission in accordance with § 20-2A-52(a)(3), Code of Alabama 1975 (as amended). Immediately prior to commencing operations and, thereafter, no less often than annually (and more often, depending on the type of license provided), a licensee shall undergo at least one announced inspection by the Commission or its representatives; the licensee may also be subject to one or more unannounced inspections.

2. *Announced Inspections.*

- a. Pre-Commencement Inspection. When a licensee is set to commence operations at any facility, the licensee shall contact the Commission to set a date for inspection under the procedures for an announced inspection set forth in this Chapter, except that the Pre-Commencement Inspection may be set at any mutually acceptable time. No licensee's operations may commence at any facility until the facility has passed a pre-commencement inspection with no critical violations and all minor infractions having been corrected. Reinspection following a failed pre-commencement inspection shall occur within 30 days, after which, if the licensee passes the inspection it may commence operations; a licensee having failed a second pre-commencement inspection must petition the Commission for permission for a further pre-commencement inspection; if the Commission denies a third pre-commencement inspection or the licensee fails the third inspection, the licensee is precluded from commencing operations and its license shall be revoked.
- b. Announced Inspections Generally.
 - (1) Timing. Not less than 14 days prior to any announced inspection, the Commission, acting by and through its representative, will notify the licensee of its intention to conduct an announced inspection of the licensee's facilities, operations, and documentation, advising the licensee of a specific date and time for the inspector's anticipated arrival as well as the individuals who are anticipated to be part of the inspection team.
 - (2) Scope. At the time of the announced inspection, licensees shall make their facilities, personnel, operations, and documentation available for review and auditing at the request of the inspector. Areas of inspection shall include, but are not limited to: all areas of all facilities that have been in operation at any time since the last announced inspection; all facilities not in operation that the licensee is planning to put in operation at any time during the next two years; proper credentialling, licensing, qualifications, education, suitability and experience, as applicable, for all personnel, including owners, officers, administrators, managers, employees (full-time or part-time) and volunteers; all operations and processes being conducted by the licensee, including but not limited to, all machinery, equipment and supplies; all security monitoring and video surveillance files and log book data maintained by the licensee; all IT files maintained by the licensee, including but not limited to the licensee's test results, any third-party inventory control and tracking systems, and the Statewide Seed-to-Sale Tracking System; background check certificates and/or personnel files of all owners, officers, administrators, managers, employees (full-time or part-time), and volunteers; and all documents provided to the Commission at the time of licensing, including all updates to such documents made at any time since the last announced inspection, with or without the permission of the Commission. (See 538-x-4-.07 of this Chapter.)
 - (3) Compliance liaison. Throughout the announced inspection, the licensee shall have a designated compliance liaison who is knowledgeable about the licensee's facilities,

personnel, operations, and documentation, and who will be on hand to answer questions or coordinate with additional persons to provide answers or information in response to questions by the inspection team.

- (4) Duty of Cooperation. The licensee is expected to comply with all inspections with the highest level of integrity and transparency. Failure to cooperate with an inspection by the Commission may lead to sanctions, within the Commission's discretion, up to and including revocation of license.

c. Unannounced Inspections.

- (1) Timing. Unannounced Inspections may be conducted without prior notice at any time, without respect to whether the licensee has or has not undergone an announced inspection.
- (2) Scope. An unannounced inspection may cover any and all areas described above with respect to announced inspections.
- (3) Procedures. The licensee shall, at the time of licensing, receive confidential instructions relating to procedures that will be implemented immediately before the unannounced inspection begins. The licensee shall follow these instructions and can therefore be secure in the knowledge that the inspection is authentic and is being carried out at the instance of the Commission and not otherwise.
- (4) Point of Contact. At the time of any unannounced inspection, the licensee shall identify to the inspectors an acceptable point-of-contact for the inspection, usually one of the leaders of the company then on duty, who will fill the role of compliance liaison (as set forth in subparagraph 2.b.(3) of this rule) in all respects possible for the unannounced inspection.
- (5) Duty of Cooperation. To the extent the Commission follows the confidential procedures set forth at the time of licensing, the licensee, during an unannounced inspection, has the same obligations of cooperation as with an announced inspection, and the same consequences for failing to cooperate.

3. *Use of Third-Party Inspectors.* The Commission may, in its discretion, utilize qualified independent third parties and may cooperate with State and Local Agencies in conducting inspections, both announced and unannounced.

4. *Inspection Report.*

As a result of all inspections, the Commission, acting by and through its inspectors, shall issue a written report within 14 days, covering all areas inspected, addressing any noted infractions and, in addition to the notation described below, any critical violations.

a. Noted Infractions

- (1) Definition. An infraction is a minor violation of the Act or these Rules, or a benign difference between the documentation previously provided to the Commission and the reality of the licensee's operations. Those infractions which cannot be corrected to the satisfaction of the inspector immediately or, in any event, prior to the inspector's report, or which represent a repeated issue the licensee has been orally warned of previously, shall be noted on the report and then constitute a "noted infraction."
- (2) Remediation. Noted Infractions must be set forth in the written report and addressed to the satisfaction of the Commission within 30 days and either demonstrated as compliant by the licensee or re-inspected and deemed compliant. A licensee's remediation of a

noted infraction within 30 days is usually, but not always, sufficient for the licensee to avoid sanctions. A licensee's failure to address and correct a noted infraction to the Commission's satisfaction within 30 days, or any repeat noncompliance of the same noted infraction within a period of five (5) years, shall be deemed sanctionable conduct by the licensee.

b. Critical violations.

- (1) Definition. A critical violation is an intentional or substantial violation of the Act or these Rules, or a material difference between the documentation previously provided to the Commission and the reality of the licensee's operations, when that difference poses a clear and present danger to the safety of the licensee's employees, patients, caregivers, or the public.
- (2) Notice. In addition to being included in the report filed by the inspector, critical violations shall be noted in writing to the licensee and the Commission at the time of the inspection and in no event more than 48 hours after the inspection in which the critical violation was noted.
- (3) Shutdown. A critical violation may warrant an immediate shutdown of the facility in question, pending remediation of the violation by the licensee; a shutdown is considered a matter of health and safety and does not comprise a sanction, which may also be warranted and may result in license suspension, revocation, or non-renewal.
- (4) Correction. A licensee must address and remedy a critical violation immediately and in no event, more than the time allowed for re-inspection of a critical violation pursuant to this rule.
- (5) Consequences. A critical violation shall result in sanctions as may be imposed by the Commission, and failure to address a critical violation or a repeat of the same critical violation within five (5) years, or more than three critical violations within five (5) years, may result in an escalation of sanctions imposed as a result of the original critical violation. In determining the sanction to be imposed on the licensee for a critical violation, the Commission may consider whether the conduct that gave rise to the sanction was knowing, willful, reckless or negligent, the prior conduct of the licensee, the licensee's compliance history, and the swiftness with which the licensee addressed and remedied the critical violation.
- (6) Re-inspection. If necessary, a re-inspection may be performed to determine whether a noted infraction or critical violation has been properly corrected or remedied. Re-inspections shall be performed no less than 30 and no more than 45 days from the date of the notice, or, alternatively, at a mutually agreeable time and date after the licensee announces ready.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.03 Investigation of Licensees.

During the term of any license issued under these Rules, the Commission, in accordance with § 20-2A-52(a), Code of Alabama 1975 (as amended), acting on information received or for other reasonable cause

or suspicion, may investigate any alleged violation by the licensee of the Act or these Rules, as well the licensee's owners, officers, directors, interest holders, administration, management, or employees. Investigations may be conducted by the Commission through its employees, or through an independent third party, a state agency, or any combination thereof. Such investigations shall ensure license eligibility, compliance with the Act and these Rules, and consistency with representations made to the Commission in the documents submitted by the licensee. The fact of an investigation pursuant to this rule may or may not be disclosed to the licensee while the investigation is ongoing. Results of any investigation, to the extent revelatory of any issue of concern to the Commission, shall be made known to the licensee, who shall be given an opportunity to respond, to the extent it did not have the opportunity to do so previously.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.04 Training and Continuing Education Requirements.

1. *For Licensees' Owners, Officers, Administrators, and Managers.* A licensee's owners, board members, officers, administrators, managers, and any other salaried employees (as those positions and/or individuals were identified in the Business Plan provided by the licensee during the application process or as modified at any time thereafter), require training and continuing education as follows:
 - a. A medical cannabis foundations training program as shall be provided by the Commission on the AMCC website at or before the issuance of licenses, to be completed prior to the licensee's commencing operations (or at the time of hiring, if after the commencement of operations).
 - b. No less than twenty (20) hours of continuing education to be completed during every full calendar year after receiving the foundations training; appropriate courses must be as provided by or preapproved by the Commission, including any specific courses that are required by the Commission. For any of the foregoing individuals who, as part of their duties, have direct contact with cannabis or medical cannabis, no less than five (5) of the required continuing education hours must be from courses regarding safety of cannabis and medical cannabis.
2. *Medical Cannabis Education and Safety Training Requirements for Licensees' Employees.* Licensees' hourly or non-salaried employees must complete the following:
 - a. A medical cannabis foundations training program as shall be provided by the Commission on the AMCC website at or before the issuance of licenses, to be completed prior to the licensee's commencing operations (or at the time of hiring, if after the commencement of operations); and
 - b. No less than ten (10) hours of continuing education of medical cannabis education and no less than five (5) hours of safety training, both of which may be conducted by the licensee or a third party, shall be completed during every full calendar year after receiving the foundations training; appropriate courses must be as provided by or preapproved by the Commission, including any specific courses that are required by the Commission.
3. *Certificates of Completion.* Certificates of completion from all training and continuing education courses must be signed by the individual who has completed the course and a Human Resources Director or other person tasked with oversight of the licensee's continuing education compliance, and the same shall be kept on file for review at the time of inspection. Copies of all certificates

must be maintained for at least three (3) years and must be provided electronically at any time upon the Commission's request.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.05 Maintenance of Proper Technology.

1. Licensees shall, at all times, maintain technology (whether proprietary, provided through a third party, or if applicable, through the Statewide Seed-to-Sale Tracking System), and through such technology shall track information, sufficient to comply with the requirements of § 20-2A-60, Code of Alabama 1975 (as amended), and any other requirements of the Commission. Tracking information contained in any databases created or maintained by such licensees shall be updated no less often than daily (during the next business day after the incident is discovered or new information has been received) and maintained for a minimum of six years or longer at the request of the Commission, law enforcement personnel, or any court having jurisdiction of a matter arising out of or relating to the information so tracked.
2. Licensees' network security shall, at a minimum, comply with cybersecurity standards set by the International Society of Automation (ISA) and the International Electrotechnical Commission (IEC) standard ISA/IEC 62443 applicable to industrial facilities operated by manufacturers of medical or pharmaceutical businesses.
3. Licensees shall bear the cost of technology sufficient to comply with the requirements of § 20-2A-60. The Commission will not pay for licensees' systems or upgrades, RFIDs, barcodes, and/or hardware. Licensees' costs are outside the scope of the Commission's responsibility to maintain or procure; such responsibility, at all times, remains upon each licensee to procure the necessary technology for itself.
4. Consistent with the requirements of § 20-2A-54, Code of Alabama 1975 (as amended), licensees shall support, participate in, and contribute to the Statewide Seed-to-Sale Tracking System. The licensee shall ensure that its third-party inventory and tracking systems, if any, shall properly interface with the Statewide Seed-to-Sale Tracking System and, as appropriate, with the patient registry. Licensees' technology and uploads to the Statewide Seed-to-Sale Tracking System shall be sufficient to allow access to said system by the Commission, and, to the extent necessary and appropriate, patients and caregivers, qualified certifying physicians, other state agencies, other licensees, and law enforcement personnel, for all purposes set forth in said section.
5. Notwithstanding any other requirements for training or continuing education, all individuals who as part of their duties to licensees must interact with the patient registry, the AMCC website, or the Statewide Seed-to-Sale Tracking System, shall undergo pre-employment (or, for new licensees, pre-commencement) IT certification for each database with which they must interact, demonstrating their proficiency in respect to those databases. IT certification as set forth herein shall be administered by the third-party IT provider, or another, as the Commission may designate.
6. Licensees shall identify to the Commission an individual, by name and position within the licensee's business, who shall be the designated liaison with the Commission for purposes of

coordinating, monitoring, and updating the Licensee's input to the Statewide Seed-to-Sale-Tracking System.

7. Licensees shall take all necessary steps to ensure the confidentiality of the information received, maintained, and uploaded to any of the above databases.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.06 Annual Licensing Fees; Schedule.

Licensees shall be responsible for paying a renewal license fee, which shall be due annually on the date of issuance of the licensee's original license. Renewal license fees shall be in accordance with the Commission's approved schedule in effect on the date of issuance of the license renewal. All such fees shall be reflected on the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.07 Duty to Meet and Maintain Standards, Policies, Procedures and Operations Per Application.

A licensee has an ongoing duty to meet and maintain the standards, policies, procedures, and operations as it affirmed to the Commission at the time of licensing, as such standards, policies, procedures, and operations may have been amended by the licensee from time to time in accordance with Rules 538-x-4-.08 and 538-x-4-.19. Specifically, at the time of the licensee's pre-commencement inspection and at each inspection thereafter, a licensee must meet and/or maintain the following, in the manner previously provided at the time of licensing, as updated (i.e., current to within 30 days, unless otherwise required):

1. With regard to each business entity that has any ownership interest in the licensee, the licensee shall verify all of the following:
 - a. The name and street address of every individual having an indirect or direct ownership interest in that business entity. For purposes of this paragraph, if the business entity is a trust, the verification shall disclose the names and street addresses of all trustees and beneficiaries; if a privately held corporation, the names and street addresses of all shareholders, officers, and directors; if a publicly held corporation, the names and addresses of all officers, directors, and shareholders holding a direct or indirect interest of greater than five percent; if a partnership or limited liability partnership, the names and street addresses of all partners; if a limited partnership or limited liability limited partnership, the names of all partners, both general and limited; or if a limited liability company, the names and street addresses of all members and managers.
 - b. The name and street address of all of the following other entities, if the other entities are directly or indirectly involved in the cannabis industry, including, but not limited to, the cultivation, processing, packaging, labeling, testing, transporting, or sale of cannabis or medical cannabis.
 - (1) The name and street address of any subsidiary, affiliate, conglomerate, parent, or other entity that shares common ownership, directly or indirectly, with the business entity.

- (2) The name and street address of any partnership or limited liability partnership of which the business entity is a partner.
 - (3) The name and street address of any limited liability company of which the business entity is a member or manager.
- 2. With regard to each individual having any ownership interest in the licensee, the licensee shall verify the name and street address of all of the following entities, if the entities are directly or indirectly involved in the cannabis industry, including, but not limited to, the cultivation, processing, packaging, labeling, testing, transporting, or sale of cannabis or medical cannabis:
 - a. Any business, including any partnership, limited liability partnership, sole proprietorship, limited liability company or other incorporated or unincorporated business entity or venture, of which the individual or his or her spouse, parent, or child has any equity interest, and the identity and relationship of such person having such interest.
 - b. Any business, including any partnership, sole proprietorship, limited liability company, or other incorporated or unincorporated business entity or venture of which the individual or his or her spouse, parent, or child is a member or manager, and the identity and relationship of such person who is a member or manager.
- 3. Verification that no owner, director, board member, or individual with a controlling interest in the licensee has been indicted for, charged with, arrested for, convicted of, pled guilty or nolo contendere to, or forfeited bail concerning any criminal offense under the laws of any jurisdiction, either a felony or controlled substance-related misdemeanor, not including traffic violations, regardless of whether the offense has been reversed on appeal or otherwise; if for any reason verification cannot be given, the licensee must include the name of the person, the date, the name and location of the court, arresting agency, prosecuting agency, the case caption, the docket number, the offense, the disposition, the location and length of incarceration, and any explanation as to why such person remains affiliated with the company.
- 4. Verification that neither the licensee nor any of its affiliates, subsidiaries, parent corporations, owners, board members, officers, shareholders, members or interest holders has ever applied for or has been granted any commercial license or certificate issued by a licensing board or commission in this state or any other jurisdiction that has been:
 - a. denied,
 - b. restricted,
 - c. suspended,
 - d. surrendered,
 - e. revoked, or
 - f. non-renewed, either voluntarily or involuntarily.

The licensee must also provide a statement describing the facts and circumstances concerning the application denial, restriction, suspension, surrender, revocation, or nonrenewal, including the licensing board or commission, the date each action was taken, the reason for each action, and the outcome.

- 5. Verification that neither the licensee nor any of its affiliates, subsidiaries, parent corporations, owners, board members, officers, shareholders, members or interest holders has filed, or been served with, a complaint or other notice filed with any public body, regarding the delinquency in the payment of, or a dispute over the filings concerning the payment of, any tax required under federal, state, or local law, including the amount, type of tax, taxing agency, and time periods

involved. If for any reason verification cannot be given, the licensee must include the name of the person or entity, the date, the name and location of the court and/or prosecuting agency, the case caption and number, the disposition, and any explanation as to why such person or entity remains affiliated with the company.

6. A statement listing the names and titles of all public officials of any unit of government, and the spouses, parents, and children of those public officials, who, directly or indirectly, own any financial interest in, have any beneficial interest in, are the creditors of or hold any debt instrument issued by, or hold or have any interest in any contractual or service relationship with the licensee.
7. A graph showing the current number of employees of the licensee, the number of employees during the past five calendar years, if available, and the projected number of employees for the next five calendar years.
8. A verified statement of the number of days:
 - a. within which the licensee reasonably projects it will commence operations as to any incomplete or projected facility previously identified to the Commission, and
 - b. within which the licensee reasonably projects it will reach full capacity as to the operations contemplated with regard to each facility previously identified to the Commission.
9. The licensee's current consent to the inspections, examinations, searches and seizures attending the annual inspections as required herein.
10. Verification and proof that the licensee's facility or facilities have been sited in a permissible location, without prohibition by (and as necessary, with the approval of) applicable local authorities, and in compliance with all State and local laws, resolutions, and ordinances.
11. Verification that the licensee and its leadership have no economic interest in any other licensee or applicant for license under the Act or these Rules (See § 20-2A-55(e), Code of Alabama 1975 (as amended)).
12. The following documents, labeled, and in the following order:
 - a. The résumé or *curriculum vitae* of each individual listed in response to subparagraph 1.a. of this Rule, showing, at a minimum, all institutions of higher education attended, including the date, location and type of any degrees received; all residential addresses in the last (15) years; and the name, business address and telephone number of all employers in the last 15 years, including a contact person at each.
 - b. A demonstration of sufficient capital (as defined in Chapter 3 of these Rules) available to the licensee, including verification of same by a responsible person designated by the licensee, the licensee's contact person, and an independent Certified Public Accountant.
 - c. Certified copies of the licensee's business formation documents.
 - d. Records indicating that a majority of the licensee's ownership is attributable to an individual or individuals with proof of residence in this state for a continuous period of no less than the previous 15 years.
 - e. For an integrated facility licensee or a cultivator licensee, records indicating that a majority of ownership is attributable to an individual or individuals, or an entity or entities, with cumulative business experience in the field of commercial horticulture or agronomic production for a period of at least 15 years.
 - f. At the licensee's expense, each owner, shareholder, director, board member, and individual with an economic interest in the licensee must provide written consent and submit to, and

- the licensee shall provide the Commission with the results of, a state and national criminal background check conducted by ALEA and/or by a third party specializing in obtaining such background checks. Results of each background check shall be obtained and forwarded to the Commission prior to the licensee's commencement of operations and once every three years thereafter.
- g. Certified copies of the licensee's business license, if required by local authorities, and, as applicable, resolution or ordinance by local authorities (County or Municipality, as appropriate) approving the licensee's business presence in the local jurisdiction.
 - h. A verified current financial statement or pro forma covering the following items: year-end financial statements as to the same items over the last five (5) calendar years, as applicable; and year-end projections of the same items for each of the next five (5) calendar years:
 - (1) Balance sheet report, providing a snapshot of the value of assets, liabilities and equity at commencement, or for projections, as of December 31 of each year.
 - (2) Profit and loss report, summarizing any income, expenses and net profit from the licensee's inception to date of commencement and as projected over each calendar year thereafter, including the year of commencement.
 - (3) Statement of cash flow, examining the cash flowing into and out of the licensee's business from inception to commencement and during each calendar year thereafter, including the year of commencement.
 - i. Demonstrated compliance with (or plan for compliance with) all applicable tax laws; and the licensee's verified tax plan.
 - j. The licensee must provide a verified current copy of the following items, which, at a minimum, must include all items contained in the Standard Operations and Procedures Plan set forth at subparagraph 12.o.(1)-(11) below:
 - (1) Employee Handbook, including but not limited to safety policies, including personnel safety and crime prevention techniques.
 - (2) Policies and Procedures Manual.
 - k. A statement of the following, regarding each facility the licensee operates or proposes to operate as of the commencement of operations and within no less than two (2) years of the date of inspection, to the extent available:
 - (1) The physical address and GPS coordinates of the facility.
 - (2) An aerial photograph of the facility, including clearly identified site boundaries.
 - (3) Proof of authorization to occupy the property where each facility is proposed to be located.
 - (4) Proof of local zoning and other approvals necessary to operate the business in the community, including but not limited to, as necessary, any local ordinance or resolution approving the operation of medical cannabis facilities there.
 - (5) A professionally rendered blueprint certified by a nationally accredited architect or nationally accredited engineer of each facility the licensee operates or proposes to operate within the next three years, showing clearly drawn and labeled interiors of such facilities, including but not limited to the general function of each area of the structure, for ease in identification of operations and processes by the Commission during future inspections.
 - (6) A timetable for completion and commencement of operations as to each facility.

- (7) A statement whether such facility shall be open to the public and, if so, the anticipated hours of business operation.
- (8) The hours of operation during which the facility will be occupied by the licensee's employees and, if not continuous, the after-hours contact information for management.
- (9) As to each facility, a description of any and all products that are or will be cultivated, processed, transported, dispensed, or tested; and any and all services that are or will be provided.
- l. A complete site map of any website owned or operated by the licensee, and the web address of any webpage, social media page or other online site owned or operated by the licensee.
- m. A roster of all leaders and employees affiliated with the licensee, including names, street addresses, contact telephone numbers, email addresses and social security numbers, current to within the last thirty (30) days. Applicant must verify that all employees are registered to the AMCC website and have undergone or are scheduled to undergo appropriate pre-employment background checks.
- n. The licensee's verified Business Plan, to include, at a minimum, the following:
 - (1) A clearly defined business structure and plan for adherence to applicable corporate conventions.
 - (2) Clearly defined business goals, including a 3-year and a 5-year plan.
 - (3) An Organizational Chart – a diagram that visually conveys the licensee's internal structure by detailing the roles, responsibilities, and relationships between individuals within the entity.
 - (4) Job descriptions of all managerial positions, showing clear delineation of authority, qualifications, and duties.
 - (5) Job descriptions of all non-managerial employee positions, showing clear delineation of qualifications and duties.
 - (6) An executive summary, including mission statement, leadership background and qualifications, business style and philosophy, key personnel, and identification of facilities' location and function.
 - (7) A description of any and all products that are or will be cultivated, processed, transported, dispensed, or tested; and any and all services that are or will be provided. The licensee shall include in the descriptions its actual (or projected) pricing data; the actual (or projected) lifespan of each product, as applicable; the projected benefits to the public; patents, if any; and proprietary technology, if any.
 - (8) An advertising/marketing analysis and strategy, if any.
 - (9) An insurance plan, including declarations pages and letters of intent, from an A-rated insurer as to, at a minimum, casualty, workers' compensation, liability, and (as applicable) auto or fleet policy.
 - (10) A Community Engagement Plan describing all efforts that have been or will be made to foster the licensee's relationship with, involvement in, and commitment to any community (including municipality or county) in which the applicant intends to locate a facility within the next three years.
 - (11) An Environmental Impact Statement outlining the anticipated impact of the licensee's operations, per facility, on the local environment over the next three to five years; the licensee's efforts or plans, if any, to build a relationship to foster cooperation and

compliance with federal, state and local agencies providing environmental oversight; and any steps the licensee has taken or will take to reduce or eliminate its carbon footprint and/or to achieve and maintain a positive environmental profile in each community where the licensee intends to locate and operate a facility within the next three years.

- o. The licensee's verified Standard Operating Plan and Procedures. The licensees must demonstrate and maintain standard operating procedures regarding the following subjects in such a way that they can be readily accessed from the physical site of operations upon the request of inspectors, the Commission, or Commission staff, including, at a minimum, the following:
 - (1) An IT Plan. Licensees must maintain at all times and review annually, a plan for ensuring accurate recordkeeping, compliance with inventory protocols, and coordination of information and systems with vendors, customers and others, as applicable. Said plan must include not only a plan for obtaining, installing and maintaining the Licensee's own internal operating systems, if applicable, through a third-party inventory control and tracking system (§ 20-2A-60, Code of Alabama 1975 (as amended)), but also the licensee's plan for interactivity with, as applicable, the Alabama Medical Cannabis Patient Registry System (§ 20-2A-35, Code of Alabama 1975 (as amended)); the Statewide Seed-to-Sale Tracking System (§ 20-2A-54, Code of Alabama 1975 (as amended)); and the AMCC website. Licensees must demonstrate proof of purchasing and accessing the foregoing platforms, and the plan should demonstrate how interaction with the platforms will be successfully maintained and properly updated.
 - (2) A Cannabis/Medical Cannabis Storage and Maintenance Plan. Licensees must maintain at all times and review at least annually a plan for maintenance and storage of cannabis and medical cannabis in the possession and control of licensee. Such plan shall include, at a minimum, maintaining cannabis and medical cannabis in a moisture- and temperature-controlled environment free of pests; keeping stored items secure, properly separated and labeled; and limiting access to cannabis and medical cannabis to essential personnel by position.
 - (3) A Quality Assurance Plan. Licensees (except secure transporters) shall perform, at the licensee's own expense, quality control and testing of a qualified sampling (as defined in 538-x-10-.01 et seq. of these Rules) of cannabis or medical cannabis in their control at each stage of production, including cultivation, processing and dispensing of cannabis or medical cannabis, regardless of whether packaged, labeled and/or sealed, per the following requirements:
 - (a) Required testing shall be conducted by a State Testing Laboratory (as detailed in 538-x-10-.01, et seq. of these Rules).
 - (b) A sample of cannabis for testing must be derived from a single batch and must comprise at least ten (10) grams and no more than thirty (30) grams; a sample of medical cannabis must be derived from a single batch and must be the lesser of one percent (1%) of the total product weight of the production run or ten (10) units of product. All samples must be homogenized before testing.
 - (c) Under no circumstances shall the licensee which provided the sample sell or transfer the cannabis or medical cannabis to another licensee, patient, or caregiver, unless

and until the State Testing Laboratory clears the licensee to do so based on the written results of successfully completed testing.

- (d) Nothing herein shall prohibit a licensee from conducting, at the licensee's own expense, separate in-house testing or designated unofficial testing by the State Testing Laboratory, at any point during the licensee's possession and control of cannabis or medical cannabis, but the results of such testing shall be unofficial and designated as such no later than the time of collection, and non-dispositive without approval from the Commission upon the written request of the licensee.
- (4) Contamination and Recall Plan. Licensees must maintain at all times and review at least annually a clear written contamination and recall plan, detailing the steps to be undertaken in the event of discovery of contamination of cannabis or medical cannabis within the possession and control of the licensee. The plan must account for the safety of employees and others on the premises, notification of proper authorities, exploring the possibility of retesting or remediation, proper disposal of contaminated cannabis and medical cannabis, steps to be taken for the preservation of cannabis or medical cannabis, and the reasonable efforts to maintain access to medical cannabis by those who depend on it.
- (5) A Criminal Activity Plan. Licensees must maintain at all times and review at least annually a clear written criminal activity plan, detailing the steps to be undertaken in the event of discovery of criminal activity related to cannabis or medical cannabis within the possession and control of the licensee. The plan must account for the safety of employees and others on the premises, reporting the criminal activity to proper authorities, steps to be taken for the preservation of cannabis or medical cannabis, and the reasonable efforts to maintain access to medical cannabis by those who depend on it.
- (6) An Emergency Procedures/Disaster Plan. Licensees must maintain at all times, and review at least annually, a clear written Emergency Procedures and Disaster Plan, detailing the steps the licensee will take to ensure the safety of employees and others on the premises, the preservation of cannabis or medical cannabis, and the reasonable efforts to maintain access to medical cannabis by those who depend on it, in the event of any reasonably foreseeable emergency, or natural disaster that may affect the licensee, its facilities, personnel, products or customers.
- (7) An Alcohol, Smoke, and Drug-Free Workplace and Non-Discrimination Policies. Licensees must maintain at all times and review at least annually at a clear written Alcohol, Smoke and Drug Free Workplace Policy and a clear written Non-Discrimination Policy, which shall be included in the licensee's Employee Handbook and/or the Policies and Procedures Manual.
- (8) An Employee Safety Plan. Licensees must maintain at all times and review at least annually, an employee safety plan that must comply with parallel OSHA standards applicable to similar types of businesses, to the extent such standards can be extrapolated to fit the licensee's workplace.
- (9) A Confidential Information and Cybersecurity Plan. The licensee must maintain at all times and review at least annually, a plan for securing and maintaining confidentiality as to any and all sensitive information and any records required to be confidentially maintained,

including, at a minimum, information and records communicated interpersonally, kept physically, or stored virtually.

- (10) A Cannabis/Medical Cannabis Waste and Disposal Plan. Licensees must maintain at all times and review at least annually, a plan for tracking and proper disposal of waste cannabis or medical cannabis, including all parts thereof, as applicable. Such plan must, at a minimum, leave no part of the disposed or waste cannabis or medical cannabis either useable or recognizable as such.
- (11) A Security Plan as to each of the licensee's facilities, addressing all of the following aspects of security and meeting the following minimum thresholds:
- (a) Alarm systems must be installed in all facilities where cannabis or medical cannabis is maintained or stored. Such alarms shall be provided and installed by experts in industry-standard commercial-grade alarm systems. Alarm systems must be fully operational securing all entry points and perimeter windows, be equipped with motion detectors and pressure switches covering all areas where cannabis or medical cannabis is grown, handled, stored, prepared, transported, tested, or dispensed.
 - (b) Reception areas and personnel adjacent to ingress and egress points shall have ready access to duress panic and hold-up alarms that may be activated in the event of access by unauthorized personnel or intruders.
 - (c) Licensee facilities shall maintain an audio/video surveillance system that shall be in continuous operation 24 hours per day. Recording devices shall be fixed in place covering both the interior and exterior of the facility, in such quantity and at such resolution as shall allow for the clear identification of individuals and activities in all reasonably accessible areas of the premises, including but not limited to all point-of-sale areas, entrances, exits, parking lots, and any area where cannabis or medical cannabis is grown, handled, stored, prepared, transported, processed, packaged, labeled tested, or dispensed. Audio recordings shall clearly and accurately capture sound within camera range at a level of 20 decibels or greater. Audio/video surveillance recordings must clearly and accurately display the time and date.
 - (d) The facility's perimeter and any outdoor premises must be surrounded by a sufficient fence or barrier to prevent access by unauthorized persons and must have sufficient lighting to allow for the proper functioning of video surveillance equipment at all times between dusk and dawn or at any other time when ambient lighting requires enhancement to permit identification of individuals or activities upon or immediately adjacent to the premises. Indoor premises must likewise be sufficiently lit to allow for the identification of individuals and activities.
 - (e) Exterior doors of each facility must be designed or reinforced to withstand unlawful forcible entry; exterior doors shall remain locked against outside intruders at all times, while allowing free egress by the facility's occupants in the event of an emergency; doors must permit ingress to employees and other appropriate persons only by means of a keycard or other similar electronic access device.
 - (f) Exterior walls of each facility must be reinforced to withstand unlawful forcible entry. Windows, likewise, must be reinforced to prevent breakage by outside intruders.
 - (g) Licensees must maintain sufficient staffing of security guards at each facility where cannabis and medical cannabis is present to reasonably ensure the safety of the

products stored therein; however, licensees must maintain, at a minimum, one (1) security guard per facility during the facility's business/operating hours.

- (h) Strict access controls shall protect areas where cannabis or medical cannabis is handled or stored – in a secured, locked room or vault.
- (i) Records, whether electronic or manual, must be kept of all persons on the premises at a facility at all times, including employees, vendors, transporters, medical cannabis patients and caregivers, and all others, recording the individuals' name, date, time of ingress and egress, and (as to non-employees) the reason for their presence; such records shall be kept for a minimum of two years.
- (j) Audio/Video surveillance records must be kept for at least 60 days, and longer upon the request of the Commission, its inspectors, or any law enforcement personnel. Audio/Video recordings potentially reflecting an incident of actual or attempted diversion must be kept for the longer of a period of two years, or until resolution of the incident and apprehension and discipline or prosecution of the individuals involved in the actual or attempted diversion.
- (k) Employees shall wear identification badges that clearly identify them as employees while on duty.
- (l) Visitors, including Commission members, inspection personnel, or other representatives, shall wear a "visitor pass" or "AMCC Official" pass, as applicable, at all times while on the premises.
- (m) Licensees shall maintain, review and update policies to report theft, diversion or other loss of cannabis or medical cannabis to the Commission and to law enforcement within 24 hours of the event or its discovery.
- (n) The Licensee, upon request, shall make available to the Commission or its inspectors all information relating to security alarm systems, monitoring, alarm activity, maps of camera locations and camera coverage, surveillance equipment maintenance logs, authorized use lists, operation instructions, and any other security-related information deemed relevant by the Commission or its inspectors.

13. Any information and/or documents specific to the category of licensee (Cultivator, Processor, Secure Transporter, Dispensary, Integrated Facility, State Testing Laboratory,) as identified separately in these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.08 Duty to Notify or Seek Permission Regarding Material Change in Licensing Information.

1. *Generally.* A licensee has an ongoing duty to notify the Commission or to seek the Commission's permission regarding any "material change" (as defined at Rule 538-x-4-.19) in licensing information, particularly where such change will or could pose a risk to employees, patients, caregivers, or members of the public.
2. *Procedure for Reporting Material Change.* Licensees shall notify the Commission within 30 days of any material change in the information provided at the time of its application for license, in accordance with the procedures and documentation for doing so set forth in Chapter 3 of these Rules. A "material change" is one that in any way affects or relates to (a) the licensee's eligibility

or suitability to maintain a license; (b) the licensee's personnel, ownership, management, or facilities; (c) the licensee's role in the cultivation, processing, packaging, transportation, dispensing or testing of cannabis; or (d) which was or could have been a consideration of the Commission in the decision to award the licensee a license. Guidance as to whether a particular change is "material" so as to warrant notification may be provided through the AMCC website.

3. *Self-Reporting*. A licensee's duty to report is mandatory in the event of "injury," "loss," or a "material breach" of the licensee's policies and procedures as affirmed to the Commission in the application or any amendment thereto; reports should be made promptly to the Commission, and, as applicable, law enforcement, in no event more than 24 hours after its occurrence or discovery, to allow for swift investigation and remediation.
4. *Waivers*. The licensee may request a waiver to excuse it from noncompliance with its verified plans as previously communicated to the Commission (as opposed to noncompliance with the Rules, warranting a variance (see below)) where the requested change is needed only for a temporary period due to an identifiable reason, after which the licensee expects to return to operations as set forth in its previously provided documentation, the licensee may seek a waiver, identifying the reason for the difference and a specific period of time (no longer than six (6) months, renewable once for good cause shown for an additional six (6) months) during which operations must return to compliance with documentation previously provided. The Commission shall rule on a requested waiver within 14 days of its submission.
5. *Amendment*. The licensee may request an Amendment to previously provided documentation where the identified change is expected to be permanent; if not in contravention of the Act or these Rules, Amendments should be quickly and routinely granted.
6. *Temporary Variance*. A licensee may request a temporary variance pursuant to the procedures of 538-x-1-.08-1. When seeking a temporary variance under these Rules, Licensees should also, when applicable, notify the Commission of a material change in circumstances as defined herein.
7. *Permanent Variance*. A licensee may request a permanent variance pursuant to the procedures of 538-x-1-.08-2. When seeking a permanent variance under these Rules, Licensees should also, when applicable, notify the Commission of a material change in circumstances as defined herein.
8. *Consequences*. Except in the case of self-reporting as delineated above, a licensee's timely discharge of this duty, by filing amended documentation, seeking a waiver or variance, should not result in sanctions:
 - a. in the absence of clear and convincing evidence that the licensee's request was fraudulent, frivolous or a subterfuge for willful non-compliance, or
 - b. where the circumstances necessitating the self-report or giving rise to a material change were accompanied by a substantial risk of harm to individuals or property and occurred due to the negligent, reckless, willful or deliberate conduct (whether an act or omission) of the licensee or its representatives.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.09 Term of Licenses.

The term of licenses for Cultivators, Processors, Secure Transporters, Dispensaries, Integrated Facilities and State Testing Laboratories is one year from the date of issuance. Except as expressly provided herein, licensees may not operate without a valid license under the Act and these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.10 Application for Renewal.

Licenses may be renewed by filing an Application for Renewal of License (forms available on the Commission's website) and paying the appropriate application fee as set forth in the Commission's schedule of fees. The application fee must be paid at the time the Application for Renewal is filed, or the Commission will not process the application. Applications for Renewal of License must be filed not more than 60 days before the date of the license expiration to ensure timely renewal of license and are delinquent if not filed on or before the date of license expiration.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.11 Notification to Apply for Renewal.

The Commission will notify licensees electronically of the need to file an Application for Renewal not more than 60 days prior to the date of license expiration.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.12 Expiration of Licenses; Delinquent License Renewal; Failure to Apply for Renewal.

1. Licenses under the Act and these Rules expire one year from the date of issuance.
2. A licensee who fails to file an Application for Renewal of License on or before the date of expiration (delinquent) may continue to operate for a period of not more than sixty (60) days. A licensee filing an untimely application for renewal during the sixty days after the expiration date shall be assessed an application fee, a renewal license fee, and a per-day penalty equal to 10 times the daily cost of the license fee.
3. Although the Commission will make effort to expedite a late-filed Application for Renewal, a licensee is prohibited from operating without a valid license and must cease operations pending renewal of its license in the event the license is not renewed on or before sixty days after the license expiration date, and the Commission is not responsible for any loss suffered by a licensee for inability to operate beyond sixty (60) days after the license expiration date based on an untimely Application for Renewal.
4. A licensee that fails to file an Application for Renewal of License until after expiration of the license must cease operations if the license is not renewed within sixty (60) days after the license expiration date. If the license is renewed after the sixtieth day from the date of expiration, the licensee may then resume operations.

5. Filing an untimely license renewal application does not change the expiration date of the licensee's license for the subsequent year. The licensee is responsible for filing a license renewal application and paying all appropriate fees one year from the date the previous year's license expired.
6. If a licensee fails to file an Application for Renewal of License on or before the sixtieth day after the date of its license expiration, its license is revoked, and the licensee shall pay a per-day penalty equal to 10 times the daily cost of the license fee for each day in which the licensee continued to operate. To be reinstated, the former licensee must reapply to the Commission, subject itself to the rigors of the application process, and compete for licensing in the same way as other prospective licensees.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.13 License Renewal Process and Procedures; Use of Independent Third-Party Consultants.

The license renewal process is not meant to be onerous, but it provides a checkpoint to ensure that licensees are continuing to operate in accordance with the Act, these Rules, and the licensee's representations to the Commission in the License Application, as amended. License renewal may be overseen by the Commission, one or more independent third-party consultants, or both.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.14 License Renewal Fee.

License Renewal Fees shall be assessed as set forth in the Commission's Schedule of Fees applicable to the category of license being renewed at the time of filing the Application for Renewal. License Renewal fees are due and may be paid at the time of filing the Application for Renewal, but such fees must be paid within sixty (60) days after the license expiration date, or the renewed license will not be issued.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538 x-4-.15 Non-renewal of Licenses.

1. Voluntary Non-Renewal

- a. A licensee may choose not to renew its license by filing a Notification of Voluntary Nonrenewal with the Commission on or before the date of license expiration.
- b. A licensee who fails to file a Notification of Voluntary Nonrenewal by the date of license expiration may continue to operate for a period of not more than sixty (60) days. A licensee who files an untimely Notification of Voluntary Nonrenewal, or who fails to file such notice during the sixty days after the date of license expiration, shall be assessed a per-day penalty, equal to 10 times the daily cost of the license fee, for each day after the date of license expiration in which the Notification of Nonrenewal is not filed.

- c. A licensee, upon filing a Notification of Voluntary Nonrenewal, shall cease its operations. The Commission shall, within 30 days of receipt of a Notification of Voluntary Nonrenewal, issue the licensee a notification of non-renewal.
2. *Involuntary Non-Renewal*

A licensee may be notified by the Commission that its license is being non-renewed if the licensee is no longer eligible to hold a license or if the Commission, in its discretion, determines that the licensee's performance over the term of its license period and any previous license period warrants non-renewal, considering the licensee's inspection record, application submissions and representations, compliance and cooperativeness with the Commission, growth or lack thereof, fulfillment of its purpose, and its overall benefit to patients and the citizens of Alabama. A notification of nonrenewal may be conditional, such that the licensee may take steps to correct the issue that led to the notification. A notification of non-renewal will be issued electronically not less than 30 days prior to license expiration. A licensee wishing to challenge the nonrenewal may seek a hearing before the Commission not less than 21 days after the date of the nonrenewal notification date, in accordance with the procedures set forth in § 20-2A-57(d), Code of Alabama 1975 (as amended).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.16 Transfer of Licenses; Change of Ownership.

1. A license under the Act and these Rules is a privilege and not a right. A license under these Rules is a representation of the Commission's trust in the licensee's commitment to participate in the provision of medical cannabis for the benefit of the citizens of this state; the license issued is therefore exclusive and unique to each licensee and is not a commodity to be freely traded nor the property of the licensee to be freely sold, purchased, or otherwise transferred for monetary or other gain without the express permission of the Commission, regardless of any scheme, device or artifice that may be employed in an attempt to legitimize the licensee's or transferee's efforts to do so. (See § 20-2A-58(a), Code of Alabama 1975 (as amended)).
2. Assumption by the would-be successor of the licensee's real or personal property, equipment and supplies, responsibility for personnel, or operations, in no way constitutes a valid transfer that will exempt the would-be successor from an obligation to seek the permission of the Commission and/or to obtain its own license.
3. Except upon the express written permission of the Commission in response to a written application (including nonrefundable application fee) by the licensee given with no less than 60 days' notice prior to the proposed date, a licensee shall not attempt to, nor shall it:
 - a. transfer, sell, lease, assign, merge, cede, gift, delegate, convert, or otherwise turn over its license, to another individual, group of individuals, entity, or group of entities; or
 - b. within any 36-month period, effect or allow its owners to transfer, sell, lease, assign, merge, cede, gift, delegate, convert, or otherwise turn over more than 35% of its stock (voting, nonvoting, or both), ownership or controlling interest to another individual, group of individuals, entity, or group of entities; or
 - c. assume the business or any part of the operations of a licensee or former licensee.

4. Any attempt by any licensee or would-be successor licensee to avoid the approval of the Commission with respect to this Rule and § 20-2A-58, Code of Alabama 1975 (as amended), shall be grounds for peremptory suspension or revocation of the license or for other sanction as the Commission may deem appropriate.
5. The Commission, in its discretion, upon review of the licensee's written request, may require the licensee seeking such transfer or change of ownership to resubmit its application for license, including the submission of an additional application fee. If approved and prior to issuance of the transfer license, the transferee shall pay a transfer license fee equal to one year's license fee.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.17 Marketing and Advertising.

1. For purposes of this rule, "advertisement" means any written or verbal statement, illustration, or depiction created to induce sales through the use of or a combination of letters, pictures, objects, sounds, lighting effects, illustrations, or other similar means. An "advertisement" includes but is not limited to brochures, promotional and other marketing materials. Any advertisement likely to reach or appeal to minors is prohibited.
2. The state of Alabama has a compelling interest in ensuring that any advertising or marketing campaign related to or involving medical cannabis does not encourage, promote, or otherwise create any impression that cannabis is legal, therapeutic, or beneficial, except as specifically authorized by the Act and these Rules.
3. A licensee shall not use a name, logo, sign, advertisement, or other marketing campaign or program unless the same, including all related materials, have been submitted to the Commission. Materials that must be submitted to the Commission shall include, but are not limited to, the following:
 - a. To the extent possible, the name, logo, sign, advertisement or other marketing campaign or program proposed for use;
 - b. A brief description of the format, medium, and length of the distribution;
 - c. A verification that an actual patient is not being used on the advertisement;
 - d. Verification that an official translation of a foreign language advertisement is accurate; and
 - e. A final copy of the advertisement, including a video where applicable, in a format acceptable to the Commission.
4. Review by Commission
 - a. The Commission shall have 14 days to review materials submitted under paragraph 3 of this Rule.
 - b. After the Commission has reviewed the proposed advertisement submitted in accordance with paragraph 3 of this Rule, the Commission may, in its discretion, do any of the following:
 - (1) Require a specific disclosure be made in the advertisement in a clear and conspicuous manner if the advertisement would be false or misleading without such disclosure;
 - (2) Require changes as necessary to protect the public health, safety, and welfare; or
 - (3) Prohibit the use of the advertisement.
 - c. The initial decision as to the acceptability of a proposed name, logo, sign, advertisement or other marketing campaign or program, as well as any requirements that may be imposed,

shall be made by AMCC staff. If a licensee aggrieved by the initial decision submits through the AMCC website a notice of appeal electronically in writing, the Commission as a whole shall hear and decide the appeal by majority vote at the next duly called meeting more than fifteen (15) days after the initial decision. The appealing licensee may be requested to appear and give information and oral argument. The Commission's decision on the appeal shall be final and is not subject to further review.

- d. If the Commission does not complete one of the actions permitted under subparagraph 4.b. of this rule within the applicable review period, the submitted materials may be used in accordance with these Rules. However, failure by the Commission to act within the applicable review period does not constitute a waiver of its authority to undertake any of the actions permitted by the Act and these Rules, if it is subsequently determined that the submitted material violates any provision of the Act or these Rules.
5. No licensee shall place or maintain, or cause to be placed or maintained, an advertisement of medical cannabis or any related product, in any of the following ways:
 - a. Within 500 feet of the perimeter of a prohibited facility or any business or organization where, in the opinion of the Commission, the placement of the advertisement targets or is attractive to minors;
 - b. On a billboard;
 - c. On a radio or television broadcast, including a system for transmitting visual images and sound that are reproduced on screens, and includes broadcast, cable, on-demand, satellite, cinema, social media, or another internet-based platform;
 - d. On any handheld or other portable sign;
 - e. With respect to public places, on a brochure, handbill, pamphlet, leaflet, or flyer directly handed, deposited, fastened, thrown, scattered, cast, or otherwise distributed to any person;
 - f. Left upon any private property without the consent of the property owners;
 - g. On or in a vehicle, public transit vehicle, or public transit shelter; or
 - h. On or in a publicly-owned or operated property.
6. Any name, logo, sign, advertisement, or other marketing campaign or program of or on behalf of a licensee, regardless of the medium, must not:
 - a. Include reference to, or be accompanied by, any image bearing a resemblance to a cartoon character or of any individual (actual or fictional) more than fifteen percent (15%) of whose audience is, or should be reasonably anticipated to be, composed of minors;
 - b. Market, distribute, offer, sell, license, or cause to be marketed, distributed, offered, sold, or licensed, any apparel or other merchandise related to the sale of medical cannabis;
 - c. Suggest, by direct or indirect reference, a relationship to edibles (including candy, cookies, brownies, cakes, and the like) or beverages;
 - d. Include designs or other presentational effects that are commonly used to target minors;
 - e. Suggest or otherwise indicate that the product or entity in the advertisement has been approved or endorsed by the Commission, the State of Alabama or any person, entity or agency associated with the State of Alabama;
 - f. Advertise in a manner that is inconsistent with the medicinal and approved use of medical cannabis;
 - g. Encourage the use of medical cannabis for a condition other than a qualifying medical condition;

- h. Contain any statement, design, representation, picture, or illustration that contains or communicates:
 - (1) False or misleading statements;
 - (2) Names other than the registered name of the licensee's registered business name or an approved d/b/a, or the registered name of medical cannabis or related products;
 - (3) A depiction of cannabis plants or any part thereof, except with respect to:
 - (a) signs, displays and marketing material provided inside a dispensing site, including but not limited to brochures or other written materials provided directly to patients and caregivers within the sales area of a dispensing site, or
 - (b) on a website maintained by the licensee for the exclusive use of patients and caregivers.
 - (4) Slang terms and similar references, including words or depictions directly or indirectly referring to, unlicensed uses of cannabis;
 - (5) Disparagement of a competitor's products;
 - (6) Obscene, indecent, or profane statements or depictions; or
 - (7) Statements as to the health benefits or therapeutic benefits of cannabis or medical cannabis, and statements as to the safety or efficacy of cannabis or medical cannabis unless supported by substantial clinical data.
- 7. A licensee may develop a website or otherwise establish a web presence advertising the name, business address, contact information, and services provided by the licensee. A licensee's website shall require each user's affirmation that the user is not a minor before access to the website is granted. A licensee that establishes any type of web presence shall not:
 - a. Allow for direct engagement between or among consumers or consumer-generated content including but not limited to consumer reviews or testimonials; notwithstanding the foregoing, licensees are not prohibited from seeking or obtaining direct patient feedback or sharing actual unsolicited statements made by consumers to the licensee, so long as the content of the statement does not otherwise violate any prohibitions contained in this Rule.
 - b. Provide a medium for website users to transmit website content to minors;
 - c. Target a consumer group with a high likelihood of reaching or appealing to minors;
 - d. Display or otherwise post content that has not been submitted to the Commission under paragraph 4 of this Rule, if such content has been created or produced within Alabama or is specifically targeted to or available only to Alabama residents;
 - e. Transact business or otherwise facilitate a sales transaction to consumers or businesses; or
 - f. Maintain a web presence that would otherwise violate the Act or these Rules.
- 8. Licensees shall not do any of the following:
 - a. Display external signage larger than sixteen inches in height by eighteen inches in width that is not attached to the entity's permanent structure or vehicle;
 - b. Illuminate a sign advertising a medical cannabis product or strain at any time;
 - c. Sell or otherwise distribute clothing, apparel, or wearable accessories, unless such sale or distribution is to an employee for purposes of identification while at the licensed facility;
 - d. Advertise medical cannabis brand names or utilize graphics related to medical marijuana on the exterior of any building or vehicle operated by the licensee; and
 - e. Display medical marijuana, medical marijuana products, or medical marijuana paraphernalia that is visible from the exterior of the facility.

9. This Rule, as it pertains to advertisements, does not apply to noncommercial messages, i.e., the content of which is primarily for charitable, educational, or public service purposes and does not overtly seek profit or promote the licensee or its products.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.18 Relocation of Licensee Facilities.

Relocation of a licensee's facility, in all instances, requires the express permission of the Commission, and except in extraordinary circumstances in the discretion of the Commission, requires 60 days' notice to the Commission. A request to relocate a facility must provide the address of the facility requested for transfer as well as the site where the facility is proposed for relocation; photographs from all sides, including aerial and a street view; the reasons for the proposed relocation; verification that the relocated site will be in compliance with all local laws, the Act and these Rules; and a detailed explanation of the expected impact on patients, the community and the general public.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.19 Material Change in Information.

Licensees shall notify the Commission within 30 days of any material change in the information provided at the time of its application for license, in accordance with the procedures and documentation for doing so set forth in Chapter 3 of these Rules. A "material change" is one that in any way affects or relates to (a) the licensee's eligibility or suitability to maintain a license; (b) the licensee's personnel, ownership, management, or facilities; (c) the licensee's role in the cultivation, processing, packaging, transportation, dispensing or testing of cannabis; or (d) which was or could have been a consideration of the Commission in the decision to award the licensee a license. Guidance as to whether a particular change is "material" so as to warrant notification may be provided through the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.20 Temporary Licenses.

Except in extraordinary circumstances upon written request and at the discretion of the Commission, there shall be no temporary licenses issued to any applicant or prospective licensee. All prospective licensees must undergo the same scrutiny as other licensees.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.21 Surrender of License.

1. At any time after the issuance of license, a Licensee may voluntarily surrender its license and cease operations. If not subject to sanctions under these Rules, a licensee must give 60 days' notice of the intent to surrender and cease operations, otherwise, the licensee must seek written permission from the Commission to surrender and cease operations, based on a demonstration of extraordinary circumstances. Failure to provide such notice will subject the licensee to a per-day penalty for noncompliance in accordance with the provisions of these Rules. Surrender of license does not excuse the licensee from sanctions or other disciplinary action under these Rules.
2. Notwithstanding the provisions of paragraph 1. of this rule, any licensee who intends to cease operations within 60 days prior to the date of license expiration shall comply with the voluntary non-renewal provisions of Rule 538-x-4-.15.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.22 Disciplinary Action.

Disciplinary measures available to the Commission are as follows:

1. Oral Warning – For the lightest infractions or inadvertences warranting that a matter be brought to the licensee's attention and immediately corrected (either while the inspector is present or prior to the inspector's submission of the report, with proof of correction by the licensee), the Commission, acting through its inspector or other representatives, may communicate an oral warning to the licensee. An oral warning is not included on any permanent record by which the licensee will be judged.
2. Written Warning. – A written warning is provided in instances where an oral warning has been issued or would not be warranted, but a written reprimand is not appropriate. A written warning is not included in any permanent records by which the licensee will be judged, but it will be maintained by the Commission for a period of one year after its issuance and may be considered in conjunction with other similar violations in determining any discipline that may be appropriate under such other violations during that time.
3. Reprimand. – A reprimand is a writing from the Commission issued where an oral or written warning has been imposed previously or is not warranted due to the circumstances. Depending on the conduct warranting discipline, a written reprimand may be the least stringent discipline imposed; for willful, reckless, or intentional misconduct, a reprimand is the lowest level of discipline that may be considered. The reprimand shall detail the date, the name of the licensee, the reasons for its issuance and shall be maintained on the records of the licensee for a period not to exceed 10 years and during that time may be considered by the Commission in determining whether renewal of license is appropriate and whether stronger sanctions may be appropriate in the future based on any instances of similar conduct. A reprimand shall accompany any administrative penalty or fine, and any suspension or revocation of license imposed on the licensee.
4. Administrative Penalties and Fines. – An administrative penalty or fine is appropriate where less stringent discipline has been imposed previously or is not warranted; this level of discipline is particularly appropriate to provide restitution for the licensee's misconduct, to defray the costs of administrative intervention by the Commission, or to emphasize a need to correct misconduct,

including willful, reckless, repeated, or intentional misconduct. Administrative penalties and fines must not be imposed arbitrarily, capriciously, or in excessive amounts, but should be imposed justly and fairly to fit the level of the licensee's misconduct. An administrative penalty or fine is the threshold level discipline for a critical violation as defined at subparagraph 4.(b) of Rule 538-x-4-.02-4, above. A written reprimand must accompany any administrative penalty or fine.

5. Probation. – Probation, in addition to a reprimand and any administrative penalty or fine, is appropriate when a licensee's conduct warrants that the licensee be placed on notice that any further misconduct warranting a reprimand will result in the nonrenewal, suspension or revocation of the licensee's license. The imposition of probation will be noted on the reprimand and may be imposed for a period not to exceed three years, and it will be accompanied by an appropriate penalty or fine.
6. Suspension of License. – A suspension of license, involving a temporary restriction on a licensee's ability to lawfully operate its business, is imposed when, for an anticipated period of time, a licensee is or will be ineligible to operate under its license or when, due to the licensee's misconduct (as opposed to a shutdown, which may occur due to events beyond a licensee's control and is not imposed for disciplinary reasons), operation of the business poses a risk to the safety and wellbeing of patients, caregivers, employees or the general public. A notice of suspension may be issued peremptorily, prior to a full investigation, in situations where the Commission has reason to believe that the ongoing operation of the licensee poses such a risk; however, a full investigation and determination should follow as soon as practicable and not more than 30 days from the peremptory notice of suspension. Following the Commission's determination on full investigation, the decision of the Commission shall be deemed a final action, entitling an aggrieved licensee to the rights set forth in § 20-2A-57(d), Code of Alabama 1975 (as amended). A suspension may not be issued for a period longer than one year. A suspension, upon finalization, will be noted on the reprimand issued to the licensee in connection with the misconduct that required the suspension. In most cases, the suspension will include a penalty or fine, and it may involve a period of probation following the suspension.
7. Revocation of License – The Commission's revocation of license is the most serious disciplinary measure that the Commission, acting on its own, may impose. Revocation should not be imposed arbitrarily or capriciously, but only for grave misconduct by the licensee in contradiction of § 20-2A-57(a), Code of Alabama 1975 (as amended), and usually only upon repeated instances of serious misconduct; or posing a serious risk of loss to property, injury, or death; or involving overtly intentional disregard of the authority of the Commission, the Act, or these Rules. In most instances, revocation will not be imposed until other forms of discipline have been unsuccessful, after the licensee has been provided a fair opportunity to correct its misconduct, and/or a clear pattern of misconduct has become apparent.
8. Civil Penalties, Restitution and Damages – As warranted, in addition to the disciplinary measures above, the Commission may notify appropriate civil authorities regarding the licensee's misconduct and shall cooperate fully in any civil or administrative proceeding or judgment that may lead to the imposition of civil penalties or exact civil restitution or other damages from the offending licensee or any associated individual or entity.
9. Criminal Penalties – As warranted, in addition to the disciplinary measures listed above, the Commission may notify appropriate authorities regarding the licensee's misconduct and shall

cooperate fully in any criminal investigation that may lead to the imposition of charges and penalties against the licensee or any associated entity or individual.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-4-.23 Licensee Appeals from Adverse Decisions.

Within 21 days after the Commission's decision under the Act or these Rules to suspend or revoke a license, impose a fine or penalty, deny a license renewal, reject the proposed transfer of a license, or prohibit relocation of one or more facilities, the licensee may challenge the adverse decision by electronically filing a request for an evidentiary hearing before the Commission. Notice of the Commission's action will be in accordance with the provisions of § 20-2A-57(d), Code of Alabama 1975 (as amended), and may also be provided electronically. The requested hearing may be conducted in accordance with the provisions of § 20-2A-57(e), Alabama Code 1975 (as amended), and such hearing shall be held not less than 14 nor more than 45 days after the licensee files its request.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

**Alabama Medical Cannabis Commission
Rules and Regulations of Medical Cannabis**

**Chapter 5
REGULATION OF CULTIVATORS.**

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538-x-5-.01 Scope.

Chapter 5 of these Rules applies to Cultivators as defined under the Act, and shall be read in conjunction with the Rules and Regulations pertaining to Cultivators promulgated by the Alabama Department of Agriculture and Industry (“the Department”) at Ala. Admin. r. 80-14-1, et seq.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-5-.02 Construction.

These Rules shall be construed and administered to regulate cultivators and the cultivation functions of integrated facilities, to the extent these Rules apply to all licensees rather than matters specifically regulated by the Department at Ala. Admin. r. 80-14-1, et seq.; such construction shall be in accordance with, and giving reasonable effect to, the Act. Specifically, cultivation under these rules requires reference to and compliance with these Rules, including but not limited to Chapters 1, 3, and 4, of these Rules, as well as this Chapter.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-5-.03 Application Fee.

The cultivator applicant must provide the appropriate application fee as required by § 20-2A-55(f) Code of Alabama 1975 (as amended). The application fee is nonrefundable and must be submitted electronically per instructions in the Application Form received in response to the applicant’s Request for Application.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-5-.04 License Fees and Renewal License Fees.

Cultivators' duty regarding annual license fees and renewal license fees shall be as set forth in Rule 538-x-4-.06 of Chapter 4 of these Rules, and the schedule therefor shall be contained on the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

**Alabama Medical Cannabis Commission
Rules and Regulations**

**Chapter 7
Regulation of Secure Transporters**

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538-x-7-.01 Scope.

Secure Transporters authorized pursuant to § 20-2A-65, Code of Alabama 1975 (as amended), shall operate in accordance with the provisions of the Act and this Chapter. Except as specifically provided in this Chapter, Secure Transporters shall be governed by the General Rules for Licensee Applications (Chapter 3 of these Rules) and the General Rules for Licensee Conduct (Chapter 4 of these Rules).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.02 Licensing and Regulation of Medical Cannabis as to Secure Transporters.

1. *License Required.* Secure Transporters are required to be licensed as set forth in Rule 3 of Chapter 3 of these Rules.
2. *Number of Licenses to be issued by the Commission.* The number of licenses to be issued to Secure Transporters is within the discretion of the Commission, which will award licenses to Secure Transporters based on merit, need, and other factors identified generally and specifically by the Act and this Chapter. (See 20-2A-51, Code of Alabama 1975 (as amended)).
3. *Duties.* It shall be the duty of a Secure Transporter:
 - a. To transport cannabis and medical cannabis, in a safe, efficient and professional manner from and to licensees' facilities, pursuant to such contracts as the Secure Transporter may negotiate between itself and one or more licensees.
 - b. To log details regarding the product and the transport in the Statewide Seed-To-Sale Tracking System and/or the manifest relating to said transport.
 - c. During transit, to maintain cannabis and medical cannabis:
 - (1) in accordance with an approved security plan

- (2) in a moisture- and temperature-controlled environment acceptable to the contracting licensee, to avoid deterioration or loss of efficacy of the cargo.
- 4. A Secure Transporter must not:
 - a. Cultivate, process or dispense cannabis.
 - b. Perform the functions of a State Testing Laboratory.
 - c. Make home delivery of cannabis or medical cannabis to anyone.
 - d. Transport patients or caregivers to or from dispensing sites or any other licensees' facilities.
 - e. Transport any cargo except cannabis, medical cannabis and associated products, materials, packages or containers.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.03 Applications and Applications Processing as to Secure Transporters Generally.

- 1. *Generally.* Applicants for a license to operate as a Secure Transporter under the Act and this Chapter shall be governed by Rule 3 of Chapter 3 of these Rules, except as specifically modified below.
- 2. *Procedure for Filing Application – Contents of Application Specific to Secure Transporters.* A Secure Transporter's Application filed with the Commission shall conform to the general application requirements for all licensees set forth in Rule 3 of Chapter 3 of these Rules, except as noted below:
 - a. Cover Sheet – as provided in Rule 3 of Chapter 3 of these Rules.
 - b. Summary Sheet – as provided in Rule 3 of Chapter 3 of these Rules.
 - c. Application Information – as provided in Rule 3 of Chapter 3 of these Rules, except that:
 - (1) Verified Written Consent to a state and national criminal background check shall also be obtained for each of the Secure Transporter Applicant's proposed drivers; upon request, all Secure Transporter Applicants and their employees must submit an ALEA Application to Review Alabama Criminal History Record Information (SBI Form 46).
 - (2) Verification that the leaders of all Secure Transporter Applicants and all secure transport drivers and secure transport passengers shall not have received a criminal conviction within the last eight years for:
 - (a) Any indictable offense.
 - (b) Any offense involving stolen property or vehicles; fraud relating to any business the driver has owned, in whole or part, or in which the driver has been employed; stolen property; or other offense of similar nature.
 - (c) Operation of a motor vehicle while under the influence of a controlled substance, or offense of similar nature.
 - (d) Any offense involving possession, distribution or trafficking in, any illegal substance.A license shall not be awarded to any Secure Transporter Applicant not in compliance with this provision.
 - (3) Verification of compliance with Alabama Public Service Commission requirements for motor carriers; a license shall not be awarded to any Secure Transporter Applicant who fails to comply with this provision.
 - (4) License Plate and DOT numbers, if available, for all secure transport vehicles.

- (5) Driver's License and Social Security Number, if available, of each secure transport driver.
- (6) Verification that all Secure Transport drivers are at least 21 years of age and have a minimum of three years of driving experience; a license shall not be awarded to any Secure Transporter Applicant who fails to comply with this provision.
- (7) The Applicant's consent, as required by § 20-2A-55(d), Code of Alabama 1975 (as amended), to the inspections, examinations, searches and seizures contemplated by § 20-2A-52(a)(3), Code of Alabama 1975 (as amended), shall specifically extend to all secure transport vehicles; a license shall not be awarded to any Secure Transporter Applicant who fails to provide the requisite consent.
- (8) Other information or documentation as the Commission may require of Secure Transporters, as contained on the application.
 - (a) The Secure Transporter Applicant's Verification regarding all proposed facilities shall conform with Rule 3 of Chapter 3 of these Rules.
 - (b) The Secure Transporter Applicant's Verification that it has no economic interest in any other license or Applicant for license under the Act or this Chapter shall conform with Rule 3 of Chapter 3 of these Rules.
 - (c) Exhibits to the Secure Transporter Applicant's application Information shall be as provided in Rule 3 of Chapter 3 of these Rules, except as follows:
 - i. Secure Transporters also must provide, as available, title, lease or other documentation demonstrating possessory interest in all vehicles to be used for secure transportation of cannabis or medical cannabis.
 - ii. Secure Transporters also must provide, as available, copies of declarations pages of insurance policies applicable to all vehicles to be owned and operated by the company, particularly those proposed for the secure transport of cannabis or medical cannabis.
 - iii. Secure Transporters must also provide copies of all contracts, contingent contracts or memoranda of understanding (or, if not available, exemplars) between the Secure Transport Applicant and any other licensee or applicant under the Act and these Rules.
 - iv. Secure Transporters must include a list of any motor vehicle citations, fines or violations received by its drivers, identified to each individual, in the last three years.
 - v. To the extent that a Secure Transporter intends to operate a vehicle that requires a Commercial Drivers' License, documentation demonstrating that proposed drivers are properly trained and licensed. Secure Transporters must verify that all vehicles and drivers have the requisite training and shall maintain compliance with all federal, state and local laws applicable to them at all times while employed as a driver.
 - vi. Secure Transporters also must provide a Fleet Summary showing the make, model, VIN Number, license plate number and specifications of all vehicles proposed for the secure transport of cannabis or medical cannabis including but not limited to the design and specification of all areas in which cannabis or medical cannabis is to be stored.

- vii. The Employee Handbook provided by Secure Transporters shall include or be accompanied by a Drivers' Manual detailing qualifications, standards, and procedures to be met and followed by prospective drivers.
 - viii. In addition to the contents of the Policies and Procedures Manual common to all applicants, the Policies and Procedures Manual and/or the Drivers' Manual of Applicants for a Secure Transporter's license shall specifically address protocols for the care and maintenance of all vehicles proposed for secure transport of cannabis or medical cannabis.
- (d) Exemplar or, if available, proposed, if not copies of actual route plans for all proposed secure transport vehicles, for inclusion in the Statewide Seed-to-Sale Tracking System.
- (e) The Secure Transporter's Security Plan must also include a verified plan for security during transport of medical cannabis, including but not limited to the following:
- i. Variable route plans and GPS tracking systems must be monitored from the secure transporter's security center using Wi-Fi or hardline network technology.
 - ii. Locks and Alarm systems must be installed on all vehicles proposed for the secure transport of medical cannabis, including but not limited to the storage area within each vehicle where the product is to be kept while in transit.
 - iii. Vehicle dashboard and storage area audio/video recording devices (self-recording and, at all times possible, viewable from and saved directly to the secure transporter's security center) must be installed and operational at all times while the vehicle is in transit, and shall include lighting and resolution sufficient to readily identify individuals and activities depicted in the same way as required of audio/video recordings inside licensees' facilities, and kept for the same time and under the same conditions as for such audio/video recordings. See paragraph 3.m.(16)(k) of Rule 538-x-3-.03.
 - iv. Secure transport vehicles must be free of markings:
 - (a) indicating that they are carrying cannabis or medical cannabis, or
 - (b) bearing the name or logo of any other licensee.
 - v. Cannabis and/or medical cannabis shall be kept in sealed tamper-evident containers that are not accessible to transport personnel during transit but are equipped with tracking devices that can be monitored remotely by the secure transporter at all times during transit.
 - vi. Cannabis, medical cannabis and containers holding the same must not be visible or recognizable outside the secure transport vehicle.
 - vii. Secure Transport drivers shall have ready access to duress panic and/or hold-up alarms that may be activated in the event of an attempted diversion by unauthorized personnel, hijackers, terrorists, or other improper intervenors. Each employee in a secure transport vehicle must have communication access to the Secure Transporter's security center and be able to contact 911 at all times while the secure transport vehicle contains cannabis or medical cannabis.
 - viii. If an emergency requires stopping the vehicle, employees must notify the secure transporter's security center (or ALEA) of the nature of the emergency and complete an incident report form provided by the Commission.

- ix. Under no circumstances may any person other than a designated secure transporter employee have actual physical control of the motor vehicle transporting cannabis or medical cannabis.
- x. Secure Transport drivers shall be trained in, and have ready access to, secure procedures for undergoing administrative inspection by law enforcement pursuant to § 20-2A-65(c), Code of Alabama 1975 (as amended). A Secure Transport employee must carry an employee ID card at all times when transporting or delivering cannabis or medical cannabis; upon request, the ID card must be presented to the Commission or law enforcement officer acting in the course of official duties.
- xi. Individual batches of cannabis or medical cannabis prepared for storage or transport must be appropriately labeled and inserted in containers prior to transport. Batches shall be bar-coded, QR coded, or otherwise digitally coded to identify the following:
 - (a) The batch number(s) or plant tag number(s),
 - (b) The contracting licensee,
 - (c) Facility of origin,
 - (d) The type of product,
 - (e) The date of harvest and/or processing and packaging, as applicable, and
 - (f) The date of the last State Testing Laboratory approval.
- xii. Secure Transport vehicles shall have no fewer than two personnel (a driver and one other) in the vehicle at all times when the vehicle is carrying cannabis or medical cannabis and is (A) making more than a single stop on the route and/or (B) traveling more than ten (10) miles while carrying cannabis or medical cannabis. Notwithstanding the foregoing, a single employee may transport cannabis or medical cannabis to or from a State Testing Laboratory. Secure Transport vehicles may not be left unattended at any time when containing cannabis or medical cannabis; at least one employee must remain with the vehicle at all times when the vehicle contains cannabis or medical cannabis. Only designated personnel shall occupy a secure transport vehicle during transport of cannabis or medical cannabis; non-employee passengers of any kind are prohibited.
- xiii. Secure Transport vehicles carrying cannabis or medical cannabis must adhere to the designated route at all times. If an alternate route is necessary, the driver must contact the security office and note the change on the route plan. Secure transporters shall document all stops in transit for refueling or otherwise, including the reason for the stop, the duration of the stop, the location of the stop, and all activities of employees exiting the vehicle.
- xiv. Secure transport vehicles must be equipped with GPS tracking and monitored throughout transit by the Secure Transporter's security center through Wi-Fi or hardwire networking technology.
- xv. Route plans, manifests, transport logs, freight bills, bills of lading and any free-on-board ("FOB") terms of sale documents, maintenance and repair records, and insurance documentation must be kept (either manually or electronically,

including, but not limited to, as part of the Statewide Seed-to-Sale Tracking System), as to all vehicles in the secure transporter's fleet, for a period of not less than two (2) years, and longer upon the request of the Commission or law enforcement. Such documents shall be made available to the Commission or its representatives (including inspectors) during inspections and other official visits.

- xvi. Upon request, a secure transporter shall make available to the Commission or its inspectors all information relating to the security plan.
- (f) The Secure Transporter Applicant must provide an affidavit signed by the responsible individual and designated contact person (or, if the Secure Transporter is an entity, the duly authorized officer, owner or interest holder and the designated contact person) that the information provided in the Application is true and correct, to the best of the Affiants' knowledge upon a diligent investigation thereof.
- (g) The Secure Transporter Applicant must provide an Application Fee pursuant to § 20-2A-55(f), Code of Alabama 1975 (as amended). The Applicant's nonrefundable Application Fee must be submitted electronically per instructions in the Application Form received in response to the applicant's Request for Application.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.04 Post-Licensing Inspection of Secure Transporter Facilities and Vehicles

1. Generally. In addition to the general inspections for licensee facilities to be carried out by the Commission in accordance with § 20-2A-52(a)(3), Code of Alabama 1975 (as amended), a secure transporter licensee shall be subject to inspection of all secure transport vehicles, under the same terms and on the same basis as for licensees' facilities generally.
 - a. Pre-Commencement Inspection. When a licensee is set to commence operations at any facility, the licensee shall contact the Commission to set a date for inspection of all facilities and secure transport vehicles under the procedures for a pre-commencement inspection set forth under the procedures outlined in Chapter 4, including that the pre-commencement inspection may be set at any mutually acceptable time. No Secure Transporter's operations may commence at any facility or with respect to any secure transport vehicle until the facility and all secure transport vehicles have passed a pre-commencement inspection with no critical violations and all minor infractions having been corrected. Reinspection following a failed pre-commencement inspection shall occur within 30 days, after which, if the Secure Transporter passes the inspection, it may commence operations. A Secure Transporter which has failed a second pre-commencement inspection must petition the Commission for permission for a further pre-commencement inspection; if the Commission denies a third pre-commencement inspection or the Secure Transporter fails the third inspection, the Secure Transporter is precluded from commencing operations and its license shall be revoked.
2. Announced Inspections of Secure Transporter Facilities and Vehicles. Not less than 14 days prior to any announced inspection, the Commission, acting by and through its representative, will notify the secure transporter licensee of its intention to conduct an announced inspection of the licensee's facilities, vehicles, operations, and documentation, advising the licensee of a specific date and time for the inspector's anticipated arrival as well as the individuals who are anticipated

to be part of the inspection team. At the time of the announced inspection, secure transporter licensees shall make their facilities, vehicles, personnel, operations, and documentation available for review and auditing at the request of the inspector. In addition to the aspects of inspection listed in Chapter 4 of these Rules, aspects of the inspection of secure transporters shall include, but are not limited to: maintenance and repair logs, transport documentation, PSC licensing and compliance, and insurance records of all vehicles that have been in operation at any time since the last announced inspection; all vehicles not yet acquired or placed into operation that the secured transporter is planning to obtain and/or place in operation at any time during the next two years; motor vehicle citations, penalties, and violations in the last three (3) years; all operations and transports being conducted by the secured transporter, including but not limited to, all machinery, vehicles, equipment and supplies; all security monitoring records, records of route plans, and incident reports related to any vehicle, transport or driver; background check certificates and/or personnel files of all owners, officers, administrators, managers, transport personnel or other employees (full-time or part-time), and volunteers.

3. Unannounced Inspections of Secure Transporter Facilities and Vehicles. Unannounced Inspections may be conducted without prior notice at any time, without respect to whether the secure transporter has or has not undergone an announced inspection, on the same basis as licensees generally, in accordance with the provisions for such inspections contained in Part IV. Unannounced inspections for secure transporters include, but are not limited to, the category of “administrative inspection” that may be conducted by law enforcement on a secure transporter’s vehicle at any time. At the time of licensing, Secure Transporters shall receive information regarding specific procedures that shall be employed to ensure the safety of transport personnel and their cargo when law enforcement officers, acting upon the request of the Commission or otherwise, seek to perform an administrative inspection of a secure transport vehicle.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.05 Medical Cannabis Education and Safety Training Requirements for Employees.

In addition to the medical cannabis education and safety training applicable to all employees of licensees generally, transport personnel (i.e., drivers and any other employees whose job is to accompany drivers) employed by a secured transporter shall annually complete and receive certification for no less than five (5) hours of training specifically tailored to driver safety and procedures related to the proper procedures to be followed when transporting cannabis and medical cannabis.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.06 Maintenance of Proper Technology.

In addition to the technology requirements for all licensees generally, Secure Transporters must also do the following:

1. Prior to transport, Secure Transporters must enter into the Statewide Seed-to-Sale Tracking System the route plans and manifests (containing information as set forth in Rule 538-x-7-.07) of any vehicle transporting cannabis or medical cannabis.
2. Secure Transporters must maintain GPS tracking technology to monitor and record transportation of cannabis and medical cannabis by its vehicles using Wi-Fi or hardline networking technology.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.07 Manifests and Transport of Cannabis and Medical Cannabis.

1. As used herein, a “manifest” is a document listing the cargo and crew of a vehicle, for the review and use of state officials and licensee personnel.
2. Before transporting cannabis or medical cannabis, a Secure Transporter must:
 - a. Complete a manifest on a form approved by the Commission, and
 - b. Input the manifest to the Statewide Seed-to-Sale Tracking System.
3. At a minimum, manifests as used in this Chapter shall contain each of the following:
 - a. The names of the driver, crewmember, and any other individuals onboard.
 - b. The name and address of the destination.
 - c. The weight and description of each individual package that is part of the shipment, and the total number of individual packages.
 - d. The date and time the medical cannabis shipment is placed into the transport vehicle.
 - e. The date and time the shipment is accepted at the delivery destination.
 - f. The identity of the employee having custody of the cannabis or medical cannabis, and the circumstances, duration, and disposition of any other person who had custody or control of the shipment.
 - g. Any handling or storage instructions.
4. The manifest must be signed by:
 - a. An authorized employee of the facility from which the cannabis or medical cannabis is being transported; and
 - b. The Secure Transporter’s driver; and
 - c. An authorized employee of the receiving facility.
5. Prior to transport, the Secure Transporter must verify the following:
 - a. That individual batches of cannabis or medical cannabis have been tagged or otherwise identified and inserted in containers.
 - b. That batches and containers are QR coded or otherwise digitally coded, identifying at a minimum the licensee and facility of origin, the licensee and facility of destination, and the date of the State Testing Laboratory’s last testing and approval.
 - c. That cannabis and medical cannabis is accompanied by a manifest and any other appropriate documentation, and that the information thereon is accurate and has been duly executed by the transporting licensee and the driver.
 - d. That all information from the QR code relating to the cannabis or medical cannabis, as well as the date and time of shipment, has been logged into the Statewide-Seed-to-Sale Tracking System.
6. Upon delivery, the Secure Transporter must coordinate with the receiving licensee to:

- a. Verify and document the type and quantity of the transported medical cannabis against the manifest.
- b. Input the updated manifest to the Statewide Seed-to-Sale Tracking System.
- c. Sign the manifest and other documents demonstrating that delivery has been accomplished.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.08 Advertising and Marketing Specific to Secure Transporters.

Regulations for advertising and marketing by Secure Transporters shall be the same as for licensees generally. Specifically in addition thereto, Secure Transporters' vehicles may bear the logo or name of the Secure Transporter, but they must not bear markings or other indication that they carry cannabis or medical cannabis.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.09 Application Fee for Secure Transporters.

At the time of submitting its application, the Secure Transporter applicant must provide the appropriate application fee as required by § 20-2A-55(f), Code of Alabama 1975 (as amended). The application fee is nonrefundable and must be submitted electronically per instructions in the Application Form received in response to the applicant's Request for Application.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-7-.10 License Fees and Renewal License Fees for Secure Transporters.

Secure Transporters' duty regarding annual license fees and renewal license fees shall be as set forth in Rule 538-x-4-.06 of Chapter 4 of these Rules, and the schedule therefor shall be contained on the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

**Alabama Medical Cannabis Commission
Rules and Regulations**

**Chapter 8
REGULATION OF DISPENSARIES**

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538-x-8-.01 Scope.

Dispensaries authorized pursuant to § 20-2A-64, Code of Alabama 1975 (as amended), shall operate in accordance with the provisions of the Act and this Chapter. Except as specifically provided in this Chapter, Dispensaries shall be governed by the General Rules for Licensee Applications (Chapter 3 of these Rules), the General Rules for Licensee Conduct (Chapter 4 of these Rules)

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.02 Licensing and Regulation of Medical Cannabis as to Dispensaries.

1. *Generally.* Dispensaries are required to be licensed by the Commission. Dispensaries shall be licensed in accordance with the provisions of this Chapter, § 20-2A-64, Code of Alabama 1975 (as amended), and other applicable sections of the Act. Dispensary Licenses shall be awarded only to qualified applicants.
2. *Limits on Number of Dispensary Licenses.* In accordance with § 20-2A-64, the Commission shall grant no more than four dispensary licenses.
3. *Limits on Dispensing Sites per Licensee.* Each dispensary licensee may operate no more than three dispensing sites, provided that each dispensing site shall be located in a separate county from other dispensing sites operated by the same dispensary licensee. If the criteria for seeking additional dispensing sites as provided in § 20-2A-64(f), Code of Alabama 1975 (as amended), has been met, a dispensary licensee may petition the Commission to allow it to provide an additional dispensing site in an unserved or underserved area of the state based on demand for medical cannabis as reflected by numbers in the patient pool. Notwithstanding the foregoing, a dispensary licensee is not prohibited from dispensing approved medical cannabis products from a dispensing site within the same county as another dispensing site operated by a competing dispensary licensee or integrated facility licensee.
4. *Authority.* A dispensary license authorizes the following:
 - a. The purchase and transfer of medical cannabis from a processor.
 - b. If a cultivator contracts with a processor to process its cannabis into medical cannabis on the cultivator's behalf, the purchase or transfer of medical cannabis from the cultivator.
 - c. The purchase and transfer of medical cannabis from an integrated facility.
 - d. The dispensing and sale of medical cannabis only to a registered qualified patient or registered caregiver holding a valid, unexpired, and unrevoked medical cannabis card, and only within the sales area of the dispensing site.
 - e. The transfer of medical cannabis, including between the dispensary's own dispensing sites, only by means of a secure transporter.
5. *Restrictions.* A dispensary license does not permit a dispensary, including its subsidiaries, affiliates, parent entities, board members, officers, managers or employees, individually or collectively, to engage in any of the following:
 - a. Dispense cannabis prior to its processing into medical cannabis.
 - b. Purchase cannabis from a cultivator prior to its processing by a processor or Integrated Facility.
 - c. Dispense medical cannabis to non-residents of Alabama, including patients or caregivers registered or eligible for medical cannabis or the equivalent under the laws of another

- jurisdiction, or residents of Alabama who are not qualified registered patients or registered caregivers, including but not limited to registered certifying physicians.
- d. Cultivate, process or transport cannabis or medical cannabis, or perform the functions of an Integrated Facility or State Testing Laboratory.
 - e. Deliver medical cannabis to anyone, including a registered qualified patient or registered caregiver.
 - f. Hold a license as or possess stock or ownership interest in a licensed cultivator, licensed processor, licensed secure transporter, or licensed integrated facility as those terms are defined in Chapter 1 of these Rules.
 - g. Permit the sale of any products except to qualified registered patients and qualified registered caregivers, and then, only to the extent that such patients and caregivers can produce a valid medical cannabis card.
 - h. Permit sale of any products to any other person, including but not limited to individuals who are qualified registered patients or qualified registered caregivers under the laws of another state.
 - i. Except under extraordinary circumstances at the discretion of the Commission, sell medical cannabis grown or processed by entities other than the dispensary's contracting processor, cultivator, or integrated facility (See § 20-2A-64(a)(1), Code of Alabama 1975 (as amended)).
 - j. Offer for sale items other than medical cannabis obtained through contract with a licensed processor, cultivator or integrated facility, or approved medical-cannabis related equipment and supplies (see AMCC website for approved list).
 - k. Licensed Dispensaries may not perform dispensing operations at any site or facility other than those specifically approved by the Commission.
6. *Duties and Requirements.* A licensed dispensary must comply with the following:
- a. Sell or dispense only tested medical cannabis, properly packaged, bearing the universal State symbol, and properly labeled for retail sale to a registered qualified patient or registered caregiver.
 - b. Enter all transactions, account for all inventory, monitor patient usage, and log other relevant information as may be necessary or appropriate to the dispensary's business, into the Statewide Seed-to-Sale Tracking System, pursuant to § 20-2A-54, Code of Alabama 1975 (as amended).
 - c. Dispense medical cannabis only under the supervision of a certified dispenser as provided in Rule 583-x-8-.03, below.
 - d. Dispense only medical cannabis provided through valid contracts with other (non-dispensary) licensees and related products associated with medical cannabis, e.g., inhalers or other administration aids.
 - e. Prohibit medical cannabis use on its premises.
 - f. Restrict access to the premises of dispensing sites to registered qualified patients and registered caregivers, except for other authorized individuals as provided in paragraph 3.j. of Rule 583-x-8-.04.
 - g. Equip dispensing sites with surveillance cameras or other recording devices as provided in a cohesive security plan, maintaining footage captured thereon for a period of no less than sixty (60) days following the date of recording, in accordance with 20-2A-64(d)(2), Code of Alabama 1975 (as amended) and paragraph 3.j. of Rule 583-x-8-.04.

- h. Dispense medical cannabis to patients and caregivers holding a valid, unexpired and and unrevoked medical cannabis card, only in accordance with product and dosing instructions provided by the registered certifying physician and the provisions of 538-x-2-.07 of Chapter 2 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

583-x-8-.03 Certified Dispensers.

Medical cannabis may only be dispensed under the supervision of a certified dispenser, in accordance with the following Rules:

1. *Definition.* For purposes of this Chapter, a certified dispenser is a managing employee of a dispensary who has undergone training and certification as required by the Commission to oversee the dispensing of medical cannabis to a registered qualified patient or registered caregiver at a dispensing site.
2. A certified dispenser must be on duty at all times while the dispensing site is open for business; a certified dispenser must oversee and sign off on all sales of medical cannabis as the dispensary employee ultimately responsible for each transaction.
3. A certified dispenser must have, at a minimum, two years of education or experience in the fields of biology, biochemistry, chemistry, physiology, pharmacology, medicine, medical cannabis, nursing, pharmaceuticals, or a similar field.
4. *Training and Continuing Education of Certified Dispensers.*
 - a. Prior to the dispensary's commencing operations or prior to beginning work, a certified dispenser must take and pass a medical cannabis foundations training course as required by the Commission.
 - b. Annually, in addition to the Commission's continuing education requirement for all employees a certified dispenser must undergo not fewer than ten (10) hours of continuing education approved by the Commission, to address proper dispensing procedures, including the requirements of the Act and this Chapter, prevention of abuse and diversion of medical cannabis, and other topics related to public health, safety and good business practices relating to cannabis, medical cannabis and the dispensing thereof.
5. Prior to dispensing medical cannabis, the dispensary, acting through a certified dispenser or employee supervised by a certified dispenser, shall confirm that the patient or caregiver holds a valid, current, unexpired, and unrevoked medical cannabis card, and that the dispensing of medical cannabis conforms to the type and amount recommended in the physician certification, and that the amount recommended will not exceed the 60-day daily dosage purchasing limit.
6. At the time of dispensing medical cannabis, the certified dispenser, or another dispensary employee under the supervision of the certified dispenser, shall enter into the patient registry and the Statewide Seed-to-Sale Tracking System, and shall attach to the package containing the medical cannabis the following patient-specific information:
 - a. The name and medical cannabis card number of the patient;
 - b. The name and medical cannabis card number of the caregiver, if applicable;
 - c. The name and contact information of the registered certifying physician;
 - d. The amount and type of medical cannabis being dispensed;

- e. The physician's dosing comments and maximum daily dosage recommendation; and
 - f. The date and time the medical cannabis was dispensed.
7. A certified dispenser may, at the request of the patient or caregiver, provide instructions on the proper administration of medical cannabis, education regarding potential side effects, potential drug interactions, or other aspects of medical cannabis. Notwithstanding the foregoing, a certified dispenser may not offer advice regarding the safety or effectiveness of medical cannabis, the recommended daily dosage, or type of medical cannabis recommended by the registered certifying physician, except that a certified dispenser may direct the patient or caregiver back to the registered certifying physician to address questions or provide advice that the certified dispenser cannot.
 8. At the time required by law, the certified dispenser or another dispensary employee acting under the supervision of the certified dispenser, must allocate the appropriate sum for satisfaction of taxes as may be levied against the sale.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

583-x-8-.04 Requirements and Limitations as to Dispensing Sites.

Dispensing sites must comply with the following:

1. *Premises.* A "dispensing site" as defined in Chapter 1 of these Rules may consist of a stand-alone building or occupy dedicated exclusive space within a multi-use structure, strip mall or other such retail facility, except that a dispensing site may not occupy space within the same multi-use structure, strip mall or other such retail facility as a certifying physician or another licensee. To the extent that the dispensing site occupies space within a multi-use structure, strip mall or other retail facility, the licensee must provide a verified plan demonstrating that the space is reasonably secure from outside intrusion and that the safety and privacy of patients and caregivers is fully supported and monitored at all times during their visits to the dispensary (including in the parking area outside the dispensing site, see 538-x-8-.04-2). Other facilities owned or leased and operated by a dispensary, such as a business office and a warehouse, shall not be deemed a dispensing site, provided that no medical cannabis products are offered for sale at such facilities.
2. *Parking Lot.* To the extent that a dispensing site is housed in a stand-alone building, a dispensary must maintain a parking area adjacent to its structure that shall be for the exclusive use of patients and caregivers seeking to purchase medical cannabis and related equipment and supplies; the parking area must be designed to provide reasonable privacy to those individuals in their ingress and egress from the dispensing site. Alternatively, if an exclusive parking area is not feasible for the stand-alone dispensary site, the dispensary must maintain for the exclusive use of patients and caregivers a designated portion of the parking area that is situated conveniently to the dispensing site, and which may be monitored and supported for the reasonable safety and security of customer patients and caregivers. To the extent that a dispensing site is housed in a multi-use structure, strip mall or other such retail facility, the dispensary must maintain for the exclusive use of patients and caregivers a designated portion of the parking area that is situated conveniently to the dispensing site, and which may be monitored and supported for the reasonable safety and security of customer patients and caregivers.

3. *Restricted Proximity to School, Daycare or Childcare Facility.*
 - a. The location of any dispensing site must be at least 1000 feet from any school, day care, or childcare facility.
 - b. For purposes of paragraph 3.a. of this Rule, the following terms have the following meanings:
 - (1) “At Least One Thousand Feet” shall mean at least one thousand feet in a straight line from the property line of the dispensing site premises to the property line of the school, daycare or childcare facility, measured at the nearest possible point between the two.
 - (2) “School, Daycare or Childcare Facility” shall mean the real property on which a public or private school for students in any grade K-12 (not including a residence in which school-age children are being home-schooled) has actively operated within the last six months, or the real property on which a licensed daycare or childcare facility has actively operated within the last six months.
 - (3) “Premises” shall mean a stand-alone structure housing a dispensing site, all portions of the real property where a dispensing site operates, including but not limited to the parking lot and any peripheral space outside the structure housing the dispensing site.
4. *Dispensing Site Prohibited in the Absence of Authorizing Local Resolution or Ordinance.* A dispensing site may not operate in the unincorporated area of a county or in a municipality that has not adopted a resolution or ordinance authorizing the operation of dispensing sites under § 20-2A-51, Code of Alabama 1975 (as amended).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-08-.05 Applications and Licensing Procedures as to Dispensaries Generally.

1. *Generally.* Applicants for a license to operate as a Dispensary under the Act and these Rules shall be governed by the Rules for filing applications and seeking a license contained in Chapters 3 (538-x-3-.01, et seq.) and 4 (538-x-4-.01, et seq.) of these Rules, except as specifically modified below.
2. *Procedure for Filing Application – Contents of Application Specific to Dispensaries.* A Dispensary’s application filed with the Commission shall conform to the following requirements for all licensees set forth in 538-x-3-.05 of Chapter 3 of these Rules, except as noted below:
 - a. Cover Sheet – as provided in 538-x-3-.05 of Chapter 3 of these Rules.
 - b. Summary Sheet – as provided in 538-x-3-.05 of Chapter 3 of these Rules.
 - c. Application Information – as provided in 538-x-3-.05 of Chapter 3 of these Rules, except as provided otherwise below:
 - (1) The Dispensary Applicant’s verification regarding each business entity that has any ownership interest in the applicant shall conform with paragraph 3.a. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (2) The Dispensary Applicant’s verification regarding individuals having any ownership interest in the applicant, as to the identity, street address and responsible person of all entities with which the individual is connected, to the extent the entity is directly or indirectly involved in the cannabis industry, shall conform with paragraph 3.b. of Rule 538-x-3-.05 of Chapter 3 of these Rules.

- (3) The Dispensary Applicant's verification regarding any criminal history as to any owner, director, board member, or individual with a controlling interest in the applicant shall conform with paragraph 3.c. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (4) The Dispensary Applicant's verified licensing history, cannabis industry history, and tax history regarding itself or any affiliate shall conform with paragraphs 3.d., 3.e. , and 3.f. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (5) The Dispensary Applicant's verification regarding any public officials having any interest in the applicant shall conform with paragraph 3.g. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (6) The Dispensary Applicant's statement of the anticipated or actual number of employees shall conform with paragraph 3.h. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (7) The Dispensary Applicant's statement of the number of days, if awarded a license, within which it will commence operations and reach full capacity shall conform with paragraph 3.i. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (8) The Dispensary Applicant's consent to the inspections, examinations, searches and seizures contemplated by § 20-2A-52(a)(3), Code of Alabama 1975 (as amended) shall conform with paragraph 3.j. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (9) The Dispensary Applicant's verification of the permissibility of its facilities' locations and compliance with all State and local laws shall conform with paragraph 3.k. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (10)The Dispensary Applicant's Verification that it and its leadership have no economic interest in any other license or Applicant for license under the Act or this Chapter shall conform with paragraph 3.l. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (11)Self-Reporting. In the Event of an Incident Involving Injury, Loss, or Material Breach of Policies and Procedures. As provided in Chapter 3 of these Rules, any "injury," "loss," or a "material breach" of the licensee's policies and procedures shall be promptly reported to the Commission, and, as applicable, law enforcement, and in no event more than 24 hours after its occurrence or discovery, to allow for swift investigation and, as necessary, remediation.
 - (12)Background Checks. As provided in Chapter 3 of these Rules, all board members, officers, management, staff and volunteers of prospective dispensaries shall undergo a pre-engagement background check, to be renewed no less often than during every third year following the date of each individual's commencement of service on behalf of the dispensary.
3. *Procedure for Filing Application – Exhibits to Dispensary's Application.* Exhibits to the Dispensary Applicant's application information shall include all those as provided in subparagraphs 3.m.(1) through 3.m.(16) of Rule 538-x-3-.05 of Chapter 3 of these Rules, unless specifically provided otherwise as follows:
- a. Dispensary applicants must provide a quality control and quality assurance plan for each of their facilities, including all dispensing sites, identifying:
 - (1) An overview of the steps to be taken in the dispensing process to provide high quality products and/or to ensure the safety, potency, stability, lifespan, and consistency among batches of the same product, whether as required by law or otherwise.

- (2) What tests will be conducted, if any, and at what point or points during the dispensing process.
 - (3) Whether each test to be conducted will be performed in-house, through unofficial private testing performed by a State Testing Laboratory, or through an official test by a State Testing Laboratory.
 - (4) A plan for return and remediation or destruction of any failed test samples, including entry of the event on the Statewide Seed-to-Sale Tracking System.
- b. Dispensary applicants must provide:
 - (1) A *curriculum vitae* for the business, demonstrating the education, experience, and other credentials of the certified dispenser(s), and any other science- or engineering-based employees or employees with a business background (i.e., accounting, finance, managing, marketing, advertising, public relations, etc.) among its leadership and/or employed at each facility, including but not limited to all dispensing sites.
 - (2) A detailed explanation of the role each leader, certified dispenser, scientist, businessperson, or engineer is to have in the operation of the dispensary at each facility.
 - (3) A 5-year hiring plan for its employees, identifying the types, positions, required education, required experience, and expected roles of such personnel.
 - c. Dispensary Applicants must provide a plan for receiving and coordinating information and certifications from registered certifying physicians recommending medical cannabis products for patient and caregiver customers.
 - d. Dispensary Applicants must provide a plan for point-of-sale education, consultation, provision of information, responses to patient and caregiver questions, and instructions for use regarding all medical cannabis products, to be conducted by the certified dispenser.
 - e. Dispensary applicants must create and maintain at all times a plan pursuant to 538-x-3-.05-3.m.(16)(i) and 538-x-4-.07-12.o.(9), for maintaining confidential information and providing cybersecurity for sensitive information with respect to patients and caregivers, but the dispensary shall include within that plan a set of protocols for maintaining the confidentiality of patient information in accordance with HIPAA arising from or related to the dispensary's access to the Patient Registry and/or from any other source.
 - f. Dispensary applicants must provide a Community Engagement Plan describing all efforts that have been or will be made to foster the dispensary's relationship with, involvement in, and commitment to any community (including municipality or county) in which the dispensary intends to locate a facility within the next three years.
 - g. Dispensary applicants must provide an Environmental Impact Statement outlining the anticipated impact of each of the dispensary's proposed operations, per facility, on the local environment; the applicant's efforts or plans, if any, to build a relationship to foster cooperation and compliance with federal, state and local agencies providing environmental oversight; and any steps the applicant has taken or will take to reduce or eliminate its carbon footprint and/or to achieve and maintain a positive environmental profile in each community where the applicant intends to locate and operate a facility within the next three years.
 - h. Dispensary applicants must provide a detailed plan for handling money and allocating and remitting taxes as required by any local, state or federal agency.

- i. Dispensary applicants must provide copies of all contracts, contingent contracts, memoranda of understanding (or, if none of the foregoing are available, exemplars) between themselves and:
 - (1) Any Cultivator or prospective Cultivator.
 - (2) Any Secure Transporter or prospective Secure Transporter.
 - (3) Any State Testing Laboratory or prospective State Testing Laboratory.
 - (4) Any Processor or prospective Processor.
 - (5) Any Integrated Facility or prospective Integrated Facility.
- j. Dispensary applicants must create a receiving and shipping plan that, at a minimum, ensures the following, in coordination with the contracted Secure Transporter or State Testing Laboratory, as applicable:
 - (1) Individual batches of medical cannabis being received for storage and/or dispensing were appropriately prepared, packaged, and labeled at the time of receipt, having been QR coded or otherwise digitally coded to identify, at a minimum, the Processor or Integrated Facility, the facility of origin, date of processing, packaging, and labeling, and the date of the Processor's or Integrated Facility's State Laboratory testing approval.
 - (2) Incoming medical cannabis is accompanied by the Secure Transporter's manifest and other appropriate documentation; the information thereon is accurate, and the manifest has been duly executed by all appropriate parties.
 - (3) All information from the QR code relating to the incoming medical cannabis, as well as the date and time of arrival, has been logged into the Statewide-Seed-to-Sale Tracking System.
 - (4) Medical cannabis products being received by the Dispensary by means of a Secure Transporter must be appropriately packaged, labeled, and inserted in containers prior to transport.
 - (5) Batches and containers being shipped by the Dispensary to or from another licensee's facility or to or from another of the Dispensary's own facilities must be QR coded or otherwise digitally coded to identify, at a minimum, the Cultivator, Processor or Integrated Facility from which the medical cannabis was sourced, the facility or facilities of origin, type of product, date of processing and packaging, expiration date (or, if no expiration date, a notation that the expiration date does not apply), the date of the Processor's State Laboratory testing approval, and the Alabama Poison Control contact information as provided on the AMCC website.
 - (6) Outgoing medical cannabis being sent for testing is accompanied by the Secure Transporter's or State Testing Laboratory's manifest and other appropriate documentation; the information thereon is accurate and has been duly executed by all appropriate parties.
 - (7) All information from the QR code relating to the outgoing medical cannabis, as well as the date and time of shipment, has been logged into the Statewide-Seed-to-Sale Tracking System.
- k. Dispensary applicants must provide a marketing and advertising plan, if any, including:
 - (1) Any proposed logos, branding, messaging, or other marketing or advertising communications, either in-house (e.g., in displays or on video monitors installed in the dispensing site) or providing exemplars of any specific advertisements.

- (2) Any specific media outlets or platforms where the marketing or advertising campaigns or programs will be utilized.
- (3) The identity of any media outlet, social media platform, or third-party individual or entity which is projected to play any role in the Dispensary's marketing or advertising efforts, and copies of all contracts or contract forms proposed for use, if any, between itself and such media outlet or third-party individual or entity.
- l. Dispensary applicants must provide a detailed recall plan that will be followed in the event one or more of the products offered for sale at its dispensing sites, including any lots or batches thereof, is determined to require recall. The plan must include, but is not limited to, the following:
 - (1) Provisions for notifying the originating Processor or Integrated Facility and any other licensee in the chain of custody of an adverse event;
 - (2) Factors about an adverse event that would likely necessitate a recall, and any potential for retesting or remediation;
 - (3) Responsible individuals or positions within the Dispensary's organization who will oversee the recall process;
 - (4) Notification protocols to other licensees and the Commission through the Statewide Seed-to-Sale Tracking System;
 - (5) Processes to ensure that the recalled product is returned, remediated (and ultimately approved as safe), or destroyed; processes to report to the Commission and any other appropriate regulatory body regarding crisis response and steps taken to mitigate or avoid danger to the public;
 - (6) Steps to be taken to avoid further contamination, to preserve and protect uncontaminated cannabis or medical cannabis products, and to ensure access to said products by those who depend on it; and
 - (7) Investigation and analysis of the factors that led to the unsafe condition requiring the recall, and any adjustments to internal protocols and processes to avoid recurrence.
- m. The Dispensary Applicant's Security Plan must include a plan for security at each facility, including but not limited to the following:
 - (1) Twenty-four-hour alarm systems must be installed in all facilities where cannabis or medical cannabis products are present. Such alarms shall be provided and installed by experts in industry-standard commercial-grade alarm systems. Alarm systems must be fully operational, securing all entry points and perimeter windows, be equipped with motion detectors and pressure switches, and must cover all areas where cannabis or medical cannabis products are delivered, received, handled, stored, prepared, dispensed or sold.
 - (2) Reception areas and personnel adjacent to ingress and egress points shall have ready access to duress panic and hold-up alarms that may be activated in the event of access by unauthorized personnel or intruders.
 - (3) Broadcast communication devices (cell phones, intercom equipment or the like) must be:
 - (a) Carried by each employee or installed in all areas of each Dispensary's facility designed for regular access by humans.
 - (b) Accessible for communication by all personnel at all times, and particularly at perimeter ingress/egress stations, facility reception areas, and the security office.

- (c) Capable of providing information with sufficient clarity to be heard and understood by all personnel and visitors within earshot of the employee receiving the communication.
- (4) Dispensary's facilities shall maintain an audio/video surveillance system that shall be in continuous operation 24 hours per day. Cameras shall be fixed in place covering both the interior and exterior of the Dispensary's facility, in such quantity, with such lighting, and at such resolution as shall allow for the clear identification of individuals and activities in all reasonably accessible areas of the premises, including but not limited to all entrances, exits, parking lots, and any area where cannabis or medical cannabis is delivered, received, handled, stored, prepared, dispensed, or sold. Audio/Video surveillance recordings must clearly and accurately display the time and date. Audio recordings shall clearly and accurately capture sound within camera range at a level of 20 decibels or greater.
- (5) As to any facility owned by a dispensary at which medical cannabis is maintained, except a dispensary site, the dispensary must surround the perimeter of such facility with a sufficient fence or barrier to prevent access by unauthorized persons and must have sufficient lighting to allow for the proper functioning of video surveillance equipment at all times between dusk and dawn or at any other time when ambient lighting requires enhancement to permit identification of individuals and activities upon or immediately adjacent to the premises. Indoor premises must likewise be sufficiently lit to allow for the identification of individuals and activities.
- (6) Exterior doors of each facility operated by a Dispensary must be designed or reinforced to withstand unlawful forcible entry; exterior doors shall remain locked against outside intruders at all times, while allowing free egress by the facility's occupants in the event of an emergency; doors must permit ingress to employees and other appropriate persons (other than Patients and Caregivers) only by means of a keycard or other similar electronic access device. Patients and caregivers may be granted access by Dispensary personnel only upon showing a valid, unexpired and unrevoked medical cannabis card.
- (7) A dispensary site must be housed (A) in a stand-alone building or (B) within a multi-use structure, strip mall or other such retail facility; the area occupied by the dispensary site is not to be accessible to or used by neighboring businesses, other tenants or others not employed by the dispensary. To the extent that the dispensary site is housed within a multi-use structure, strip mall or other such retail facility, the dispensary site must be self-contained, or at a minimum, segregated from other businesses and activities being conducted in the multi-use structure, strip mall or other such retail facility by separate points of ingress and egress or, at a minimum, separately keyed and electronically protected entryways accessible only to employees of the dispensary; patients and caregivers; AMCC representatives and their guests; representatives of other licensees; vendors, cleaning crew personnel, and repair workers carrying out business-related functions on the premises; representatives of the lessor during routine inspections or similar circumstances warranting a physical visit to the premises; or other appropriate individuals.
- (8) Dispensary Facilities must maintain sufficient staffing of security guards at each facility where cannabis and medical cannabis is present to reasonably ensure the safety of the

- products stored therein; however, the dispensary must provide, at a minimum, one (1) security guard per facility during the facility's business/operating hours.
- (9) Strict access controls shall protect areas where cannabis or medical cannabis and daily monetary receipts are handled or stored – in a secured, locked room or vault.
 - (10) Protocols for beginning-of-day and end-of-day movement of medical cannabis and cash between secure areas and sales areas, as well as a plan for maintaining security of daily cash on hand at all times.
 - (11) Members of the public, other than patients and caregivers holding a valid, unexpired, unrevoked medical cannabis card, are not allowed inside a dispensing site. Records, whether electronic or manual, must be kept of all persons on the premises at a facility at all times, including employees, vendors, transporters or other licensees, and all official visitors, recording the individuals' name, date, time of ingress and egress, and (as to non-employees) the reason for their presence; such records shall be kept for a minimum of two years, and longer at the request of the Commission or law enforcement.
 - (12) Audio/Video surveillance records must be kept for at least 60 days, and longer upon the request of the Commission, its inspectors, or any law enforcement personnel. Audio/Video recordings potentially reflecting an incident of actual or attempted diversion must be kept for the longer of a period of two years, or until resolution of the incident and apprehension and discipline or prosecution of the individuals involved in the actual or attempted diversion.
 - (13) Employees, while on duty, shall wear identification badges that clearly identify them as employees.
 - (14) Visitors, including vendors, other licensees, Commission members, inspection personnel, or other representatives must wear a "visitor pass" or "AMCC Official" pass, as applicable, at all times while on the premises.
 - (15) Dispensaries shall maintain, review and update policies to report theft, diversion, or other loss of cannabis products to the Commission and to law enforcement as early as practicable and not more than 24 hours from the event or its discovery.
 - (16) Upon request, a Dispensary shall make available to the Commission or its inspectors all information relating to security alarm systems, monitoring, alarm activity, maps of camera locations and camera coverage, audio/video footage, surveillance equipment maintenance logs, authorized use lists, operation instructions, and any other security-related information deemed relevant by the Commission or its inspectors.
 - (17) Upon request, a Dispensary shall make available to the Commission or its inspectors all information relating to the Dispensary's security plan.
 - (18) Signage. The dispensary shall prominently display at each entrance point to a dispensing site and in at least one location in the sales area of the dispensing site signs stating as follows:

"WARNING: This facility is monitored at all times using audio and video surveillance. Entry to this business and purchases within are strictly prohibited except as to registered patients and caregivers presenting valid identification as required by law."
- n. The number of patients, caregivers and others on the premises at a dispensing site at any given time may not be more than can be reasonably monitored by the employees present in

- the retail area, and in no event shall the total number of individuals on the premises exceed that permitted by the applicable fire code.
- o. The Dispensary Applicant must provide an affidavit signed by the responsible individual and designated contact person (or, if the Dispensary is an entity, the duly authorized officer, owner or interest holder and the designated contact person) that the information provided in the Application is true and correct, to the best of the Affiants' knowledge upon a diligent investigation thereof.
 - p. The Dispensary Applicant must provide the application fee required by § 20-2A-55(f), Code of Alabama 1975 (as amended). The application fee is nonrefundable and must be submitted electronically per instructions in the Application Form received in response to the applicant's Request for Application.
4. In all other respects except as expressly stated otherwise in this Rule, Dispensary Applicants shall be governed by the rules for applications (Chapter 3 of these Rules) and licensing (Chapter 4 of these Rules) generally pertaining to all applicants.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.06 Post-Licensing Inspection of Dispensary Facilities.

Post-Licensing Inspection of Dispensary facilities under the Act and these Rules shall be governed by Rule 538-x-4-.02 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.07 Investigation of Dispensary Licensees.

Investigation of Dispensary licensees under the Act and these Rules shall be governed by Rule 538-x-4-.03 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.08 Training and Continuing Education Requirements for Dispensaries.

Training and Continuing education requirements for Dispensaries' owners, officers, administrators, managers, and employees shall be as set forth in Rule 538-x-4-.04 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.09 Dispensaries' Maintenance of Proper Technology.

Dispensaries' duty to maintain proper technology shall be governed by Rule 538-x-4-.05 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.10 Dispensaries' Annual Licensing Fees; Schedule.

Dispensaries' duty regarding annual license fees, shall be as set forth in Rule 538-x-4-.06 of Chapter 4 of these Rules, and the schedule therefor shall be contained on the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.11 Dispensaries' Duty to Meet and Maintain Standards, Policies, Procedures and Operations Per Application.

A Dispensary licensee has an ongoing duty to meet and maintain the standards, policies, procedures, and operations, both at the pre-commencement inspection and at all times thereafter, as it affirmed to the Commission at the time of licensing, as such standards, policies, procedures, and operations may have been amended and updated by the licensee from time to time in accordance with Rules 538-x-4-.08 and 538-x-4-.19., as provided in Rule 538-x-4-.07 of Chapter 4 of these Rules and as modified by Rule 538-x-8-.04 of this Chapter.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.12 Dispensaries' Duty to Notify or Seek Permission Regarding Material Change in Licensing Information.

Dispensaries' duty to notify or seek the Commission's permission regarding any material change in licensing information shall be governed by Rule 538-x-4-.08 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.13 Dispensaries' Term of Licenses.

The term of Dispensaries' licenses shall be governed by Rule 538-x-4-.09 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.14 Dispensaries' Applications for Renewal of License.

Dispensaries' applications for renewal of license shall be governed by Rule 538-x-4-.10 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.15 Dispensaries' Notifications to Apply for Renewal.

Dispensaries' notifications to apply for renewal shall be governed by Rule 538-x-4-.11 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.16 Expiration of Dispensaries' Licenses; Delinquent License Renewal; Failure to Apply for Renewal.

The expiration of Dispensaries' licenses, renewal of delinquent licenses and consequences for failing to apply for renewal shall be governed by Rule 538-x-4-.12 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.17 Dispensaries' License Renewal Process and Procedures; Use of Independent Third-Party Consultants.

Dispensaries' renewal process and procedures, and the Commission's use of independent third-party consultants as to Dispensaries, shall be governed by Rule 538-x-4-.13 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.18 Dispensaries' License Renewal Fees.

License renewal fees for Dispensaries shall be governed by Rule 538-x-4-.14 of Chapter 4 of these Rules. License renewal fees shall be set forth on the schedule of fees maintained by the Commission on the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.19 Non-renewal of Dispensaries' Licenses.

Non-renewal of Dispensaries' licenses shall be governed by Rule 538-x-4-.15 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.20 Dispensaries' Transfer of Licenses; Change of Ownership.

Dispensaries' transfer of licenses and change of ownership shall be governed by Rule 538-x-4-.16 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.21 Marketing and Advertising by Dispensaries.

Dispensaries' duties with respect to Advertising, except as specifically modified within these Rules, shall be governed by Rule 538-x-4-.17 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.22 Relocation of Dispensaries' Facilities.

Relocation of Dispensaries' facilities shall be governed by Rule 538-x-4-.18 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.23 Material Change in Dispensaries' Information.

Rules regarding a material change in a Dispensaries' Information previously provided to the Commission shall be governed by Rule 538-x-4-.19 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.24 Temporary Licenses for Dispensaries.

Rules regarding temporary licenses for Dispensaries shall be governed by Rule 538-x-4-.20 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.25 Dispensaries' Surrender of License; Cessation of Operations.

A Dispensary's surrender of license and/or cessation of operations shall be governed by Rule 538-x-4-.21 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.26 Disciplinary Actions Against Dispensaries.

Disciplinary Actions against Dispensaries shall be governed by Rule 538-x-4-.22 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-8-.27 Dispensaries' Appeals from Adverse Decisions by the Commission.

Dispensaries' appeals from adverse decisions by the Commission shall be governed by Rule 538-x-4-.23 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

**Alabama Medical Cannabis Commission
Rules and Regulations**

**Chapter 9
REGULATION OF INTEGRATED FACILITIES**

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538-x-9-.01 Licensing Applications and Oversight of Integrated Facilities.

Integrated Facilities authorized pursuant to § 20-2A-67, Code of Alabama 1975 (as amended), shall operate in accordance with the provisions of the Act and this Chapter. Except as specifically provided in this Chapter, Integrated Facilities shall be governed by the General Rules for Licensee Applications (Chapter 3 of these Rules), the General Rules for Licensee Conduct (Chapter 4 of these Rules) and, as applicable to the cultivation aspect of an Integrated Facility's business, Rules 80-14-1-.01, et seq., adopted by the Department of Agriculture and Industry.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.02 Licensing and Regulation of Medical Cannabis as to Integrated Facilities.

1. *License Required.* Integrated Facilities are required to be licensed as set forth in Rule 538-x-3-.03 of Chapter 3 of these Rules.
2. *Number of Licenses to Be Issued by the Commission.* In accordance with § 20-2A-67(b), Code of Alabama 1975 (as amended), the Commission shall issue no more than five Integrated Facility licenses, which will be awarded based on merit, need, and other factors identified generally and specifically by the Act and these Rules. (See § 20-2A-51, Code of Alabama 1975 (as amended)).
3. *Number of Dispensing Sites That May Be Operated by Integrated Facility Licensee.*
 - a. An Integrated Facility licensee may operate up to five dispensing sites, each of which must be located in a different county from any other dispensing site operated by the same licensee.
 - b. Notwithstanding the foregoing, if at least one year has passed after the date in which the maximum number of dispensing sites allowable by this Chapter are operating, the Commission may authorize an Integrated Facility licensee to operate a greater number of dispensing sites if the patient pool has reached a sufficient level to justify an additional dispensing site in an underserved or unserved area of the state.
 - c. This paragraph shall not be construed to limit the wholesale distribution of medical cannabis from an integrated facility licensee to dispensary licensees.
4. *Authority and Duties.* A license to operate as an Integrated Facility authorizes the following:
 - a. The cultivation of cannabis.
 - b. The processing of cannabis into medical cannabis, which shall include properly packaging and labeling medical cannabis products, in accordance with § 20-2A-63(d), Code of Alabama 1975 (as amended), Rule 538-x-6-.05 of Chapter 6 of these Rules, and this Chapter.
 - c. The dispensing and sale of medical cannabis only to a registered qualified patient or registered caregiver.
 - d. The transport of cannabis or medical cannabis between its facilities.
 - e. The sale or transfer of medical cannabis to a dispensary.
 - f. Pursuant to § 20-2A-67(c), Code of Alabama 1975 (as amended), an Integrated Facility licensee shall have the same authorizations granted to, and shall comply with all requirements for, cultivators, processors, secure transporters, and dispensaries, in addition to any other authorizations or requirements under the Act or as established by rule by the Commission. This includes:
 - (1) Licensees generally under Chapters 3 and 4 of these Rules.
 - (2) Cultivators under the Rules for Medical Cannabis Cultivation provided by the Department at Administrative Code 80-14-1-.01, et seq. (and, to the extent applicable, these Rules).
 - (3) Processors under Chapter 6 of these Rules.
 - (4) Secure Transporters under Chapter 7 of these Rules.
 - (5) Dispensaries under Chapter 8 of these Rules.
5. *Restrictions.*
 - a. A license to operate as an Integrated Facility does not authorize the Integrated Facility to:

- (1) Transport cannabis or medical cannabis on behalf of a secure transporter, to or from another licensee facility, or to a patient or caregiver.
 - (2) Cultivate or Process cannabis on behalf of another Integrated Facility.
 - (3) Dispense or sell medical cannabis on behalf of a Dispensary Licensee or another Integrated Facility.
- b. An Integrated Facility may not perform the functions of a State Testing Laboratory as defined in the Act and these Rules.
 - c. Under no circumstances may an Integrated Facility operate a dispensing site in the unincorporated area of a county or in a municipality that has not adopted a resolution or ordinance authorizing the operation of dispensing sites under § 20-2A-51(c), Code of Alabama 1975 (as amended).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.03 Applications and Applications Processing as to Integrated Facilities.

1. *Generally.* Applicants for a license to operate as an Integrated Facility under the Act and these Rules shall be governed by the Rules for filing applications and seeking a license contained in Chapter 3 (538-x-3-.01, et seq.), except as specifically modified below.
2. *Procedure for Filing Application – Contents of Application Specific to Integrated Facilities.* An Integrated Facility's application filed with the Commission shall conform to the following requirements common to all licensees set forth in 538-x-3-.05 of Chapter 3 of these Rules, as well as any rules regarding information to be provided at the time of application applicable to Cultivators promulgated by the Department at Administrative Code 80-14-1-.01, et seq., except as noted below:
 - a. Cover Sheet – as provided in 538-x-3-.05 of Chapter 3 of these Rules.
 - b. Summary Sheet – as provided in 538-x-3-.05 of Chapter 3 of these Rules.
 - c. Application Information – as provided in 538-x-3-.05 of Chapter 3 of these Rules, except as provided otherwise below:
 - (1) The Integrated Facility Applicant's Verification regarding each business entity that has any ownership interest in the applicant shall conform with paragraph 3.a. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (2) The Integrated Facility Applicant's Verification regarding individuals having any ownership interest in the applicant, as to the identity, street address and responsible person of all entities with which the individual is connected, to the extent the entity is directly or indirectly involved in the cannabis industry, shall conform with paragraph 3.b. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (3) The Integrated Facility Applicant's Verification regarding any criminal history as to any owner, director, board member, or individual with a controlling interest in the applicant shall conform with paragraph 3.c. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (4) The Integrated Facility Applicant's verified licensing history, cannabis industry history, and tax history regarding itself or any affiliate shall conform with paragraphs 3.d., 3.e., and 3.f. of Rule 538-x-3-.05 of Chapter 3 of these Rules.

- (5) The Integrated Facility Applicant's Verification regarding any public officials having any interest in the applicant shall conform with paragraph 3.g. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (6) The Integrated Facility Applicant's statement of the anticipated or actual number of employees shall conform with paragraph 3.h. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (7) The Integrated Facility Applicant's statement of the number of days, if awarded a license, within which it will commence operations and reach full capacity shall conform with paragraph 3.i. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (8) The Integrated Facility Applicant's consent to the inspections, examinations, searches and seizures contemplated by § 20-2A-52(a)(3), Code of Alabama 1975 (as amended) shall conform with paragraph 3.j. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (9) The Integrated Facility Applicant's verification of the permissibility of its facilities' locations and compliance with all State and local laws shall conform with paragraph 3.k. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (10) The Integrated Facility Applicant's Verification that it and its leadership have no economic interest in any other license or Applicant for license under the Act or these Rules shall conform with paragraph 3.l. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
3. *Procedure for Filing Application – Exhibits to an Integrated Facility Application.* Exhibits to the Integrated Facility Applicant's application information shall include all those as provided in subparagraphs 3.m.(1) through 3.m.(16) 538-x-3-.05 of Chapter 3 of these Rules, as well as any rules regarding documentation or exhibits to be filed at the time of application applicable to Cultivators promulgated by the Department at Administrative Code 80-14-1-.01, et seq., and shall also provide the following, unless specifically provided otherwise as follows:
- a. Minimum Performance Bond Requirements.
 - (1) At the time of application, an Integrated Facility Applicant must provide a letter of commitment or other form of acknowledgement approved by the Commission (i.e., executed bond documents, proof of capital in the required amount, or other similar verifying documentation), of the ability to secure a performance bond issued by a surety insurance company acceptable to the Commission, possessing at minimum an A rating, in the amount of at least two million dollars (\$2,000,000).
 - (2) Said performance bond must have been secured by the Integrated Licensee at the time a license is issued.
 - b. Minimum Liquid Assets Requirement. Proof of at least two hundred fifty thousand dollars (\$250,000) in liquid assets, available at the time the license is issued.
 - c. Minimum Operating Capital Requirement. Proof that the applicant has the financial ability to maintain operations for not less than two years following the date the application is accepted by the Commission.
 - d. Plan for Segregation of Processes Within and Transportation Between Facilities. An Integrated Facility applicant must provide a plan for keeping strictly separated all aspects of production, including cultivation of cannabis, the processing of medical cannabis, the dispensing of medical cannabis, and the secure transport of medical cannabis to and from its facilities.
 - e. Integrated Facility applicants must provide, as available, sales contracts and receipts, lease agreements or other documentation demonstrating possessory interest in all machinery and

- equipment to be used in the processing of medical cannabis, as well as specifications and operations manuals of such machinery.
- f. Integrated Facility applicants must:
 - (1) identify which of the approved types of medical cannabis will be produced at each facility where cannabis is to be processed,
 - (2) provide a summary of the manufacturing processes and methods to be utilized to produce each product, including the machinery, equipment, materials, and personnel necessary to produce each product,
 - (3) provide a professionally-rendered blueprint (or if not available, professionally rendered floorplans or schematics) showing which portions of each of its facilities are ascribed to a particular phase or department of integrated production – cultivation, processing, transporting, and dispensing (or, as applicable, none of the foregoing).
 - (4) identify specific plans to ensure safety of personnel and facilities based on the types of processes proposed to be utilized, and
 - (5) provide a detailed list of formulae and ingredients for each medical cannabis product, including a list of all excipients to be utilized in the manufacture of each product, and the purpose served by each.
 - g. Integrated Facility applicants must provide a quality control and quality assurance plan for each of their proposed medical cannabis products identifying:
 - (1) An overview of the steps to be taken in the manufacturing process to provide high quality products and/or to ensure the safety, potency, stability, lifespan, and consistency among batches of the same product, whether as required by law or otherwise.
 - (2) What tests will be conducted, if any, at each stage or stages of production.
 - (3) Whether the testing at each stage will be in house, unofficially by private testing through a State Testing Laboratory, or solely by official testing through a State Testing Laboratory.
 - (4) A plan for return and remediation or destruction of any failed test samples, including entry of the event on the Statewide Seed-to-Sale Tracking System.
 - h. Integrated Facility applicants must provide:
 - (1) A curriculum vitae for the business, demonstrating the education, experience, and other credentials of its leadership, including but not limited to all scientists and engineers employed at each facility.
 - (2) A detailed explanation of the role each leader, scientist or engineer is to have in the processing of medical cannabis at each facility.
 - (3) A 5-year hiring plan for its leaders, scientists, and engineers, identifying the types, positions, required education, required experience, and expected roles of such personnel.
 - i. Integrated Facility applicants must provide copies of all contracts, contingent contracts, memoranda of understanding (or, if none of the foregoing are available, exemplars) between themselves and:
 - (1) Any Cultivator or prospective Cultivator.
 - (2) Any Secure Transporter or prospective Secure Transporter.
 - (3) Any State Testing Laboratory or prospective State Testing Laboratory.
 - (4) Any Dispensary or prospective Dispensary.
 - (5) Any Processor or prospective Processor.
 - (6) Any other Integrated Facility or prospective Integrated Facility.

- j. Integrated Facility applicants must create a receiving and shipping plan that, at a minimum, ensures the following, in coordination with the contracted Secure Transporter or State Testing Laboratory, as applicable:
 - (1) Individual batches of cannabis being received for storage and/or processing were appropriately prepared, tagged or otherwise identified, and inserted in containers at the time of receipt.
 - (2) Batches and containers arriving from the cultivator have been QR coded or otherwise digitally coded to identify, at a minimum, the Cultivator, facility, plant tag identification number, date of harvest, and the date of the cultivator's State Laboratory testing approval.
 - (3) Incoming cannabis is accompanied by the Secure Transporter's manifest and other appropriate documentation; the information thereon is accurate and has been duly executed by all appropriate parties.
 - (4) All information from the QR code relating to the incoming cannabis, as well as the date and time of arrival, has been logged into the Statewide-Seed-to-Sale Tracking System.
 - (5) Individual batches of medical cannabis products being shipped from a facility operated by an Integrated Facility to a Dispensary or Cultivator by means of a Secure Transporter must be appropriately packaged, labeled, and inserted in containers prior to transport.
 - (6) Batches and containers being shipped from the Integrated Facility's facility must be QR coded or otherwise digitally coded to identify, at a minimum, the Integrated Facility, facility, type of product, date of processing and packaging, and the date of the Integrated Facility's State Laboratory testing approval(s).
 - (7) Outgoing medical cannabis is accompanied by the Secure Transporter's manifest and other appropriate documentation; the information thereon is accurate and has been duly executed by all appropriate parties.
 - (8) All information from the QR code relating to the outgoing medical cannabis, as well as the date and time of shipment, has been logged into the Statewide-Seed-to-Sale Tracking System.
- k. Integrated Facility applicants must provide a marketing and advertising plan, if any, including:
 - (1) Any proposed logos, branding, messaging, or other marketing or advertising communications, providing exemplars of any specific advertisements.
 - (2) Any specific media outlets or platforms where the marketing or advertising campaigns or programs will be utilized.
 - (3) The identity of any media outlet or third-party individual or entity who is projected to play any role in the Integrated Facilities' marketing or advertising efforts, and copies of all contracts or contract forms proposed for use, if any, between itself and such media outlet or third-party individual or entity.
 - (4) Virtual renderings of all packaging to be provided by the Integrated Facility, demonstrating the size, color, logo, artwork, or statements appearing on the packaging, as well as all child-resistant, tamper-evident, or other safety features, demonstrating conformity with the Act and these Rules.
 - (5) Exemplars of all proposed labeling, including labels on packaging, on containers and any inserts to be included in any packages, demonstrating conformity with the Act and these Rules.

- l. Integrated Facility applicants must provide a detailed recall plan that will be followed in the event one or more of its products, including any lots or batches thereof, is determined to require recall. The plan must include, but should not be limited to, the following:
 - (1) Provisions for notifying the Integrated Facility of an adverse event;
 - (2) Factors about an adverse event that would likely necessitate a recall, and any potential for retesting or remediation;
 - (3) Responsible individuals or positions within the Integrated Facility's organization who will oversee the recall process;
 - (4) Notification protocols to other licensees and the Commission through the Statewide Seed-to-Sale Tracking System;
 - (5) Processes to ensure that the recalled product is returned, remediated (and approved as safe), or destroyed;
 - (6) Processes to report to the Commission and any other appropriate regulatory body regarding crisis response and steps taken to mitigate or avoid danger to the public;
 - (7) Steps to be taken to avoid further contamination, to preserve and protect uncontaminated cannabis or medical cannabis products, and to ensure access to said products by those who depend on it;
 - (8) Investigation and analysis of the factors that led to the unsafe condition requiring the recall, and any adjustments to internal protocols and processes to avoid recurrence.
- m. The Integrated Facility Applicant's Security Plan must include a plan for security at each facility, including but not limited to the following:
 - (1) Twenty-four-hour alarm systems must be installed in all facilities where cannabis or medical cannabis products are present. Such alarms shall be provided and installed by experts in industry-standard commercial-grade alarm systems. Alarm systems must be fully operational, securing all entry points and perimeter windows, be equipped with motion detectors and pressure switches, and must cover all areas where cannabis or medical cannabis products are delivered, received, handled, stored, prepared, processed, tested, packaged, labeled, or readied for transport.
 - (2) Reception areas and personnel adjacent to ingress and egress points shall have ready access to duress panic and hold-up alarms that may be activated in the event of access by unauthorized personnel or intruders.
 - (3) Broadcast communication devices (cell phones, intercom equipment or the like) must be:
 - (a) Carried by each employee or installed in all areas of each Integrated Facility's facility designed for regular access by humans.
 - (b) Accessible for communication by all personnel at all times, and particularly at perimeter ingress/egress stations, facility reception areas, and the security office.
 - (c) Capable of providing information with sufficient clarity to be heard and understood by all personnel and visitors within earshot of the employee receiving the communication.
 - (4) Integrated Facility licensee's facilities shall maintain an audio/video surveillance system that shall be in continuous operation 24 hours per day. Cameras shall be fixed in place covering both the interior and exterior of the facility operated by the Integrated Facility, in such quantity, with such lighting, and at such resolution as shall allow for the clear identification of individuals and activities in all reasonably accessible areas of the

premises, including but not limited to all entrances, exits, parking lots, and any area where cannabis or medical cannabis is delivered, received, handled, stored, prepared, processed, tested, packaged, labeled, or readied for transport. Audio/Video surveillance recordings must clearly and accurately display the time and date, and audio recordings must clearly and accurately capture conversations and activities within camera range to a level of 20 decibels.

- (5) The perimeter and any outdoor premises of a facility operated by an Integrated Facility must be surrounded by a sufficient fence or barrier to prevent access by unauthorized persons and must have sufficient lighting to allow for the proper functioning of video surveillance equipment at all times between dusk and dawn or at any other time when ambient lighting requires enhancement to permit identification of individuals or activities upon or immediately adjacent to the premises. Indoor premises must likewise be sufficiently lit to allow for the identification of individuals and activities.
- (6) Exterior doors of each facility operated by an Integrated Facility must be designed or reinforced to withstand unlawful forcible entry; exterior doors shall remain locked against outside intruders at all times, while allowing free egress by the facility's occupants in the event of an emergency; doors must permit ingress to employees and other appropriate persons only by means of a keycard or other similar electronic access device.
- (7) Exterior walls of each facility operated by an Integrated Facility must be reinforced to withstand unlawful forcible entry. Windows, likewise, must be reinforced to prevent breakage by outside intruders.
- (8) Integrated Facilities applicants and licensees must provide and maintain a plan for sufficient staffing of security guards at each facility where cannabis and medical cannabis is present to reasonably ensure the safety of the products stored therein; however, the integrated facility must provide, at a minimum, one (1) security guard per facility during the facility's business/operating hours.
- (9) Strict access controls shall protect areas where cannabis or medical cannabis is handled or stored – in a secured, locked room or vault.
- (10) Records, whether electronic or manual, must be kept of all persons on the premises at a facility at all times, including employees, vendors, transporters or other licensees, and all others, recording the individuals' name, date, time of ingress and egress, and (as to non-employees) the reason for their presence; such records shall be kept for a minimum of two years, and longer at the request of the Commission or law enforcement.
- (11) Audio/Video surveillance records must be kept for at least 60 days, and longer upon the request of the Commission, its inspectors, or any law enforcement personnel. Audio/Video recordings potentially reflecting an incident of actual or attempted diversion must be kept for the longer of a period of two years, or until resolution of the incident and apprehension and discipline or prosecution of the individuals involved in the actual or attempted diversion.
- (12) Employees, while on duty, shall wear identification badges that clearly identify them as employees.
- (13) Visitors, including vendors, other licensees, Commission members, inspection personnel, or other representatives must wear a "visitor pass" or "AMCC Official" pass, as applicable, at all times while on the premises.

- (14) Integrated Facilities shall maintain, review and update policies to report theft, diversion, or other loss of cannabis products to the Commission and to law enforcement as early as practicable and not more than 24 hours from the event or its discovery.
- (15) Upon request, an Integrated Facility shall make available to the Commission or its inspectors all information relating to security alarm systems, monitoring, alarm activity, maps of camera locations and camera coverage, audio/video footage, surveillance equipment maintenance logs, authorized use lists, operation instructions, and any other security-related information deemed relevant by the Commission or its inspectors.
- (16) Upon request, an Integrated Facility shall make available to the Commission or its inspectors all information relating to the Integrated Facility's security plan.
- n. The Integrated Facility Applicant must provide an affidavit signed by the responsible individual and designated contact person (or, if the Integrated Facility is an entity, the duly authorized officer, owner or interest holder and the designated contact person) that the information provided in the Application is true and correct, to the best of the Affiants' knowledge upon a diligent investigation thereof.
- o. The Integrated Facility Applicant must provide the appropriate application fee as required by § 20-2A-55(f), Code of Alabama 1975 (as amended). The application fee is nonrefundable and must be submitted electronically per instructions in the Application Form received in response to the applicant's Request for Application.
- 4. In all other respects except as expressly stated otherwise in this Rule, Integrated Facility Applicants shall be governed by and must comply with the rules for applications and licensing generally pertaining to all applicants (Chapters 3 and 4 of these Rules); any rules promulgated by the Department applicable to cultivator applicants (See Administrative Code 80-14-1-.01, et seq.); and, as applicable to the aspect of the Integrated Facility's business, the specific requirements applicable to each type of licensee, as provided in Chapter 5 (cultivators), Chapter 6 (processors), Chapter 7 (secure transporters), and Chapter 8 (dispensaries) of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.04 Post-Licensing Inspection of facilities operated by Integrated Facilities.

Post-Licensing Inspection of facilities operated by an Integrated Facility under the Act and these Rules shall be governed by Rule 538-x-4-.02 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.05 Investigation of Integrated Facility Licensees.

Investigation of Integrated Facility licensees under the Act and these Rules shall be governed by Rule 538-x-4-.03 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.06 Training and Continuing Education Requirements for Integrated Facilities.

Training and Continuing education requirements for Integrated Facilities' owners, officers, administrators, managers, and employees shall be as set forth in Rule 538-x-4-.04 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.07 Integrated Facilities' Maintenance of Proper Technology.

Integrated Facilities' duty to maintain proper technology shall be governed by Rule 538-x-4-.05 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.08 Integrated Facilities' Annual Licensing Fees; Schedule.

Integrated Facilities' duty regarding annual license fees, shall be as set forth in Rule 538-x-4-.06 of Chapter 4 of these Rules, and the schedule therefor shall be contained on the AMCC website.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.09 Integrated Facilities' Duty to Meet and Maintain Standards, Policies, Procedures and Operations Per Application.

As provided in Rule 538-x-4-.07 of Chapter 4 of these Rules, an Integrated Facility licensee has an ongoing duty to meet and maintain the standards, policies, procedures, and operations, both at the pre-commencement inspection and at all times thereafter, as it affirmed to the Commission at the time of licensing, as such standards, policies, procedures, and operations may have been amended and updated by the licensee from time to time in accordance with Rules 538-x-4-.08 and 538-x-4-.19 of Chapter 4 of these Rules. Specifically, Integrated Facility licensees shall be governed by and must comply with the rules for applications and licensing generally pertaining to all applicants (Chapters 3 and 4 of these Rules), any rules promulgated by the Department applicable to cultivator applicants (See Rules 80-14-1-.01, et seq.), and, as applicable to the aspect of the Integrated Facility's business, the specific requirements applicable to each type of licensee, as provided in Chapter 5 (cultivators), Chapter 6 (processors), Chapter 7 (secure transporters), and Chapter 8 (dispensaries) of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.10 Integrated Facilities’ Duty to Notify or Seek Permission Regarding Material Change in Licensing Information.

Integrated Facilities’ duty to notify or seek the Commission’s permission regarding any material change in licensing information shall be governed by Rule 538-x-4-.08 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.11 Integrated Facilities’ Term of Licenses.

The term of Integrated Facilities’ licenses shall be governed by Rule 538-x-4-.09 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.12 Integrated Facilities’ Applications for Renewal of License.

Integrated Facilities’ applications for renewal of license shall be governed by Rule 538-x-4-.10 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.13 Integrated Facilities’ Notifications to Apply for Renewal.

Integrated Facilities’ notifications to apply for renewal shall be governed by Rule 538-x-4-.11 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.14 Expiration of Integrated Facilities’ Licenses; Delinquent License Renewal; Failure to Apply for Renewal.

The expiration of Integrated Facilities’ licenses, renewal of delinquent licenses and consequences for failing to apply for renewal shall be governed by Rule 538-x-4-.12 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.15 Integrated Facilities' License Renewal Process and Procedures; Use of Independent Third-Party Consultants.

Integrated Facilities' renewal process and procedures, and the Commission's use of independent third-party consultants as to Integrated Facilities, shall be governed by Rule 538-x-4-.13 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.16 Integrated Facilities' License Renewal Fees.

License renewal fees for Integrated Facilities shall be governed by Rule 538-x-4-.14 of Chapter 4 of these Rules. License renewal fees shall be set forth on the schedule of fees maintained by the Commission on the AMCC website.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.17 Non-renewal of Integrated Facilities' Licenses.

Non-renewal of Integrated Facilities' licenses shall be governed by Rule 538-x-4-.15 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.18 Integrated Facilities' Transfer of Licenses; Change of Ownership.

Integrated Facilities' transfer of licenses and change of ownership shall be governed by Rule 538-x-4-.16 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.19 Marketing and Advertising by Integrated Facilities.

Integrated Facilities' duties with respect to Advertising, except as specifically modified within these Rules, shall be governed by Rule 538-x-4-.17 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.20 Relocation of Integrated Facilities' Facilities.

Relocation of Integrated Facilities' facilities shall be governed by Rule 538-x-4-.18 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.21 Material Change in Integrated Facilities' Information.

Rules regarding a material change in Integrated Facilities' Information previously provided to the Commission shall be governed by Rule 538-x-4-.19 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.22 Temporary Licenses for Integrated Facilities.

Rules regarding temporary licenses for Integrated Facilities shall be governed by Rule 538-x-4-.20 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.23 Integrated Facilities' Surrender of License; Cessation of Operations.

An Integrated Facility's surrender of license and/or cessation of operations shall be governed by Rule 538-x-4-.21 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.24 Disciplinary Actions Against Integrated Facilities.

Disciplinary Actions against Integrated Facilities shall be governed by Rule 538-x-4-.22 of Chapter 4 of these Rules.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-9-.25 Integrated Facilities' Appeals from Adverse Decisions by the Commission.

Integrated Facilities' appeals from adverse decisions by the Commission shall be governed by Rule 538-x-4-.23 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

**Alabama Medical Cannabis Commission
Rules and Regulations**

**Chapter 10
REGULATION OF STATE TESTING LABORATORIES**

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538-x-10-.01 Licensing Applications and Operations of State Testing Laboratories Generally.

State Testing Laboratories authorized pursuant to § 20-2A-66, Code of Alabama 1975 (as amended), shall be located within Alabama and operate in accordance with the provisions of the Act and this Chapter. Except as specifically provided in this Chapter, State Testing Laboratories shall be governed by the General Rules for Licensee Applications (Chapter 3 of these Rules) and the General Rules for Licensee Conduct (Chapter 4 of these Rules).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.02 Definitions.

As used in this Chapter, the following terms shall have the following meanings:

1. "Aliquot." A portion of a larger whole, especially a sample taken for chemical analysis or other treatment.
2. "Chemical Contamination." The presence of inappropriate chemical substances, or appropriate chemical substances in an inappropriately high concentration, in cannabis and medical cannabis.
3. "Growth Inhibitors/Regulators." Plant growth inhibitors are regulating substances which retard such processes as root and stem elongation, seed germination, and bud opening. Plant growth regulators (PGRs) are chemicals used to modify plant growth such as increasing branching, suppressing shoot growth, increasing return bloom, removing excess fruit, or altering fruit maturity.
4. "Heavy Metals." Metals of relatively high atomic weight including, but not limited to, arsenic, cadmium, lead and mercury.
5. "Perform Testing." To conduct tests following approved procedures.
6. "Private Testing." Testing that is conducted at the instance of a licensee by a third party or outside the official capacity of the State Testing Laboratory.
7. "Reasonably Free." Falling within anticipated and acceptable levels of defect or chemical presence with respect to a particular standard.
8. "Residual Pesticides." Detectible levels of any substance or mixture of substances in cannabis or medical cannabis resulting from the use of a pesticide; the term includes derivatives, such as degradation and conversion products, metabolites, reaction products, and impurities that are considered to be of toxicological significance.
9. "Residual Solvents." The remaining solvent that is present after the medical cannabis extraction process has been completed, usually occurring when the required processing and solvent-purging methods or steps are not properly utilized.
10. "Validated Test Methods." A test method that has been validated using ISO/IEC 17025 methodology.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.03 General Licensing and Regulation of Medical Cannabis as to State Testing Laboratories.

1. *License Required.* State Testing Laboratories are required to be licensed as set forth in Rule 2 of Chapter 3 of these Rules; State Testing Laboratories may not act in the capacity as such without a license provided by the Commission in accordance with the Act and this Chapter.
2. *Number of Licenses to be issued by the Commission.* The number of licenses to be issued to State Testing Laboratories is within the discretion of the Commission, which will award licenses to State Testing Laboratories based on merit, need, and other factors identified generally and specifically by the Act and this Chapter. (See 20-2A-51, Code of Alabama 1975 (as amended)).
3. *Authority.* A State Testing Laboratory is authorized, without the use of a Secure Transporter, to do the following:
 - a. Collect a random sample of cannabis or medical cannabis at the premises of a cultivator, processor, dispensary, or integrated facility for testing.
 - (1) The State Testing Laboratory which performs the test must collect the samples.
 - (2) If the licensee facility has segregated the lot or batch of cannabis or medical cannabis into batches smaller than the entire lot or production run, the State Testing Laboratory must sample and test each batch from the lot.
 - (3) From the time that a lot or production run has been homogenized for sample testing and eventual packaging and sale to a patient or caregiver, the facility which provided the sample shall segregate and withhold from use the entire lot or production run, except the samples that have been removed by the State Testing Laboratory for testing.
 - (4) During segregation, the facility which provided the sample shall maintain the lot or production run in a secure, cool, and dry location so as to prevent the cannabis or medical cannabis from becoming contaminated or losing its efficacy.
 - b. Take cannabis or medical cannabis from, test cannabis or medical cannabis for, and return cannabis or medical cannabis only to a respective licensed facility.
 - (1) At the time of transport, the State Testing Laboratory selecting a sample shall, using tamper-resistant products, record the name of the licensee and facility providing the sample; the batch, lot, or production run number; and the weight or quantity of the sample.
 - (2) The sample shall be sealed into a locked tamper-evident container that shall not be accessible to the State Testing Laboratory transporter during transit.
 - (3) Perform testing and analysis and report on the results of such to the licensee from which the sample was obtained.
 - (4) A single employee may transport samples of cannabis or medical cannabis from or to a State Testing Laboratory for testing; such employees and transport vehicles carrying cannabis or medical cannabis are otherwise subject to the rules and regulations applicable to Secure Transporters as set forth in Chapter 7 of these Rules.
 - c. Perform required official testing on behalf of the Commission, the results of which shall fulfill the testing requirements for cannabis and medical cannabis under the Act and these Rules; the results of official testing shall be reported to the Commission and considered dispositive for the purposes of confirming and approving batches of licensee's cannabis and medical cannabis to continue the medical cannabis production process, for ultimate use by patients in this State.

- d. Perform private testing on behalf of a Cultivator, Processor, Secure Transporter, Dispensary, or Integrated Facility; private testing may only occur pursuant to an advance request for a private test by a licensee (made at or before the time of collection of the batch or lot for testing). Unlike an official test, the results of such private testing shall not fulfill the requirement of testing under the Act and these Rules, and the State Testing Laboratory shall not report the results to the Commission unless a licensee requests that it do so.
4. *Limitations.*
- a. Under no circumstances shall the licensee which provided the sample sell or transfer the cannabis or medical cannabis to another licensee, patient, or caregiver, unless and until the State Testing Laboratory clears the licensee to do so based on the written results of successfully completed testing.
 - b. A licensee shall not use more than one State Testing Laboratory to perform official testing on the same batch or sample of cannabis or medical cannabis except as expressly provided in 538-x-10-.08.
 - c. A State Testing Laboratory may subcontract its testing of cannabis and medical cannabis only to another State Testing Laboratory. A transfer of samples pursuant to such a subcontract must be performed directly by the State Testing Laboratories.
 - d. A State Testing Laboratory may request additional sample material for the purposes of completing required quality assurance tests but may not use such material for the purposes of resampling or repeating quality assurance tests.
 - e. A State Testing Laboratory transporting samples may make multiple stops to collect samples if:
 - (1) Each stop is for the sole purpose of retrieving a sample from a licensee's facility; and
 - (2) All samples are clearly marked, kept separately, and remain secure at all times during transit.
 - (a) A State Testing Laboratory is not limited in the amount of usable cannabis and medical cannabis it may have on the premises of the laboratory at any given time, but the laboratory must maintain records to prove that all usable cannabis and medical cannabis on the premises are there for testing purposes only.
 - (b) A license to operate as a State Testing Laboratory does not authorize the State Testing Laboratory to cultivate, process or dispense cannabis, nor may a State Testing Laboratory perform the functions of a Secure Transporter (except as specifically stated herein) or an Integrated Facility as defined in the Act and these Rules.
5. *Restrictions.*
- a. A State Testing Laboratory is not authorized, except at the request of the Commission, to perform testing on behalf of a patient or caregiver.
 - b. A State Testing Laboratory may not perform testing for individuals and entities other than licensees under the Act and these Rules, including individuals and entities licensed under the laws of another jurisdiction.
 - c. Except as specifically authorized by the Commission, the ability of a State Testing Laboratory to transport cannabis shall be restricted to furthering its function in testing cannabis and medical cannabis; a State Testing Laboratory is prohibited from transporting any cargo except cannabis, medical cannabis and associated products, materials, packages, or containers.

- d. Applicants for a license to operate as a State Testing Laboratory, and any and all investors having any interest in a State Testing Laboratory applicant, are prohibited from having any interest in any applicant for, or a licensee that is, a Cultivator, Secure Transporter, Processor, Dispensary, Integrated Facility, a qualified recommending physician, or another State Testing Laboratory.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.04 Requirements for State Testing Laboratories.

A State Testing Laboratory must:

1. Adopt and follow minimum good laboratory practices which must, at a minimum, satisfy the OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring published by the Organization for Economic Co-operation and Development.
2. Become certified by an accreditation body, such as the American Association for Laboratory Accreditation that certifies effective implementation of ISO standards and agree to have the inspections and reports of the accreditation testing made available to the Commission.
3. Maintain equipment and testing facilities sufficient to perform testing as required by the Act and these Rules.
4. Perform tests per batch on behalf of licensees (scheduled official testing) at least once during each phase of the cannabis production during which testing is required, prior to the cannabis or medical cannabis leaving the cultivation, processing, or dispensing facility (or in the case of an integrated facility, the cultivation, processing or dispensing phase or department); testing also may occur at any time at the request of the Commission (unscheduled official testing) or informally at the request of a licensee (unscheduled unofficial testing).
5. Perform tests to ensure that all dispensed medical cannabis is reliably high grade and maintains consistency among batches as required by the Act and this Chapter.
6. Perform tests pursuant to the protocols and corresponding tolerance limits in accordance with the current minimum standards established by the Commission, which shall be available on the Commission's website, including:
 - a. Cannabinoid content and potency, including, but not limited to, all of the following:
 - (1) Total THC (THC + THCA).
 - (2) Total CBD (CBD + CBDA).
 - (3) THC/CBD ratio, if applicable.
 - (4) Percent of THC relative to original plant material (w/w).
 - b. Terpene profiles.
 - c. Heavy metals.
 - d. Chemical contamination, such as residual solvents remaining after extraction and concentration.
 - e. Microbials, including pathogenic microbials.
 - f. Mycotoxins.
 - g. Residual pesticides: (insecticides, fungicides, herbicides, and growth inhibitors/regulators) used during cultivation as follows:

- (1) No pesticides or growth regulators may be used in the cultivation or production of cannabis or medical cannabis if the pesticide appears on any list of prohibited pesticides maintained or published by the Department.
 - (2) When performing pesticide or growth regulator residue analysis, a State Testing Laboratory shall analyze for any non-prohibited pesticides, to determine whether the test product is reasonably free of residue of such pesticides.
 - (3) If a non-prohibited pesticide or growth regulator is detected at a level which exceeds the level specified by the Department or a pesticide prohibited by the Department is detected in any amount which is positively verified, the pesticide residue analysis is failed, and the product must be recalled.
- h. Residual solvents.
- i. Any other testing protocols as may be required by the current minimum standards established by the Commission, which shall be made available on the Commission's website. (See Appendix A to this Chapter).
7. Use validated test methods to determine delta-9-tetrahydrocannabinol, tetrahydrocannabinolic acid, cannabidiol, and cannabidiolic acid levels, in accordance with the current minimum standards established by the Commission, which shall be available on the Commission's website.
8. Perform tests that determine whether cannabis and medical cannabis comply with the current minimum standards for microbial and mycotoxin contents established by the Commission, which shall be available on the Commission's website.
9. Perform other tests necessary to determine licensees' compliance with good manufacturing practices, including but not limited to the following:
 - a. Tests demonstrating that medical cannabis is medical grade.
 - b. Tests demonstrating that medical cannabis contains no active ingredients other than cannabis provided by a licensee under the Act and this Chapter.
 - c. Tests demonstrating that any excipients are pharmaceutical grade within safe and effective levels, in accordance with the formulae provided by a Processor or Integrated Facility.
 - d. Any other tests as may be reasonable, necessary, and appropriate to demonstrate good manufacturing processes.
10. Have a secured laboratory space that cannot be accessed by the general public, in accordance with the Security Plan provided by the licensee at the time of licensing or pursuant to an approved amendment, waiver or variance thereto.
11. Retain and employ at least one staff member (a scientific director) with a relevant advanced degree in a medical or laboratory science from an accredited secondary educational institution.
 - a. The scientific director shall:
 - (1) Ensure that the State Testing Laboratory achieves and maintains quality standards of practice as required by the Act and this Chapter; and
 - (2) Supervise all staff of the State Testing Laboratory.
 - b. If a scientific director is no longer employed by a State Testing Laboratory, the State Testing Laboratory shall not be permitted to conduct any testing.
 - c. Upon the appointment of a new scientific director by a State Testing Laboratory, the State Testing Laboratory shall not resume any testing until the Commission conducts an inspection of the State Testing Laboratory.

12. A sample of cannabis for testing must be at least ten (10) grams and no more than thirty (30) grams; a sample of a production run of medical cannabis must be the lesser of one percent (1%) of the total product weight of the production run or ten (10) units of product. All samples must be homogenized before testing.
13. A cultivator or integrated facility shall not submit cannabis (as opposed to medical cannabis) to a State Testing Laboratory for testing unless the cannabis is destined for extraction and weighed within two (2) hours after harvest.
14. At a minimum, monitor, track, and enter the following information into the Statewide Seed-to-Sale Tracking System as to each sample to be tested, including:
 - a. The identity of the licensee for whom testing is to be performed.
 - b. Where and how the sample was obtained.
 - c. The size, count or weight, as available, of the sample obtained.
 - d. The date and time the sample was obtained.
 - e. The identity of the transporter, including any Secure Transporter, if any, including the identity of the personnel and vehicle involved in the transport.
 - f. The date and time of the sample's arrival at the State Testing Laboratory.
 - g. The tag, lot, or batch number (and any other information contained on the digital or QR code) applicable to the cannabis or medical cannabis, as available, from which each sample was obtained.
 - h. The conditions of storage upon arrival at the State Testing Laboratory.
 - i. The date and time testing commenced.
 - j. The types of tests undertaken by the State Testing Laboratory and the amount of the sample used for each test.
 - k. The date and time testing concluded.
 - l. The results of testing.
 - m. Any steps to be taken as a result of such testing.
 - n. Any steps to be taken to dispose of or return any unused sample material.
 - o. If returned, the date and time of the sample material's departure from the laboratory.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.05 Laboratory Standards.

1. A State Testing Laboratory must be shown to have met and maintained the requirements for a testing laboratory in international standard ISO/IEC 17025 published by the International Organization for Standardization, a copy of which may be obtained from the American National Standards Institute.
2. Self-Certification that the State Testing Laboratory is operating according to standards sufficient to meet ISO/IEC 17025 requirements must be provided to the Commission prior to commencing testing on behalf of licensees.
3. A State Testing Laboratory must follow:
 - a. The most current version of the Cannabis Inflorescence: Standards of Identity, Analysis, and Quality Control monograph published by the American Herbal Pharmacopoeia, and

- b. "Recommendations for Regulators -- Cannabis Operations" published by the American Herbal Products Association, and
 - c. "Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food, Dietary Supplements, and Pharmaceuticals -- An Aid to the Interpretation of ISO/IEC 17025:2005" (2015) published by AOAC International.
4. A State Testing Laboratory must use, when available, testing methods that have undergone validation by the Official Methods of Analysis of AOAC International, the Performance Tested Methods Program of the Research Institute of AOAC International, the Bacteriological Analytical Manual of the Food and Drug Administration, the International Organization for Standardization, the United States Pharmacopeia, the Microbiology Laboratory Guidebook of the Food Safety and Inspection Service of the United States Department of Agriculture, the Department, or an equivalent third-party validation study approved by the Commission. If no such testing method is available, a State Testing Laboratory may use an alternative testing method, or a testing method developed by the State Testing Laboratory, upon demonstrating the validity of the testing method to and receiving the approval of the Commission.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.06 Proficiency Testing.

In addition to the standard inspection requirements applicable to all licensees pursuant to Rule 538-x-4-.02 of Chapter 4 of these Rules, the Commission may require a State Testing Laboratory, at its own cost, to have an independent third party validate and monitor, on an ongoing basis, the State Testing Laboratory's basic proficiency to correctly execute its analytical testing methodologies.

1. The Commission will establish a proficiency testing program for State Testing Laboratories. A proficiency testing program must include, without limitation, providing rigorously controlled and standardized proficiency testing samples to State Testing Laboratories for analysis, reporting the results of such analysis and performing a statistical evaluation of the collective demographics and results of all State Testing Laboratories.
2. Each State Testing Laboratory must participate in the proficiency testing program established pursuant to this section.
3. If required by the Commission as part of being issued or renewing a license, the State Testing Laboratory must have successfully participated in the proficiency testing program within the preceding 12 months.
4. To maintain continued registration as a State Testing Laboratory, a laboratory must participate in the designated proficiency testing program with continued satisfactory performance as determined by the Commission.
5. A State Testing Laboratory must analyze proficiency test samples using the same procedures with the same number of replicate analyses, standards, testing analysts and equipment as used for product testing.
6. The scientific director of the State Testing Laboratory and all testing analysts that participated in a proficiency test must sign corresponding attestation statements.

7. The scientific director of the State Testing Laboratory must review and evaluate all proficiency test results.
8. Successful participation includes the positive identification of eighty percent (80%) of the target analytes that the State Testing Laboratory reports to include quantitative results when applicable. Any false positive or false negative results reported will be considered an unsatisfactory score for the proficiency test.
9. Unsuccessful participation in a proficiency test may result in limitation, suspension, revocation, or non-renewal of the State Testing Laboratory's license.
10. The Commission will select a proficiency testing provider to conduct the proficiency testing program and determine the schedule that the proficiency testing provider will follow when sending proficiency testing samples to State Testing Laboratories for analysis.
11. In addition to achieving the standard required pursuant to paragraph 8. of this Rule, a State Testing Laboratory successfully participates in the proficiency testing program only if the State Testing Laboratory does all of the following:
 - a. Obtains single-blind proficiency testing samples from the proficiency testing provider.
 - b. Analyzes the proficiency testing sample for all analytes required by the Act and this Chapter.
 - c. Reports the results of its analysis to the proficiency testing provider.
 - d. Analyzes a proficiency testing sample pursuant to the proficiency testing program not less frequently than once each 12 months.
 - e. Pays the costs of subscribing to the proficiency testing program.
 - f. Authorizes the proficiency testing provider to submit to the Commission the results of any test performed pursuant to this section.
12. The performance of a State Testing Laboratory is satisfactory pursuant to paragraph 4. of this Rule if the results of the testing performed pursuant to this Rule are within the limits of the acceptance range established by the proficiency testing provider.
13. A State Testing Laboratory that fails to meet the requirements of this Rule may request that the Commission allow the State Testing Laboratory to retest a proficiency testing sample once to establish satisfactory performance. If the Commission denies the request or if the State Testing Laboratory fails to meet the standard on retesting, the Commission may limit, suspend, or revoke the State Testing Laboratory's license.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.07 Accreditation.

1. A licensee operating as a State Testing Laboratory must be accredited (or, for new licensees, have at a minimum a plan to achieve accreditation within one year) by an impartial organization that operates in conformance with standard ISO/IEC 17011 of the International Organization for Standardization and is a signatory to the Mutual Recognition Arrangement of the International Laboratory Accreditation Cooperation.
2. The licensee's scope of accreditation shall demonstrate testing capabilities in the categories of cannabinoids, pesticides, toxins, metals, microbiological bacteria and/or other microbials, including pathogenic microbials.

3. A State Testing Laboratory is expected to achieve accreditation as set forth in this Rule within one year from the date of licensing by the Commission. The license of a State Testing Laboratory that fails to become accredited within two years from the date of licensing by the Commission shall be non-renewed or revoked.
4. A State Testing Laboratory that loses accreditation, as set forth in this Rule, must be re-accredited within one year or its license shall be non-renewed or revoked.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.08 Test Results; Retesting; Challenges to Test Results.

1. A State Testing Laboratory shall provide the final certificate of analysis containing the results of official testing pursuant to this Chapter to the licensee which provided the sample within two (2) business days after obtaining the results.
2. If a sample from a batch of cannabis fails an official test conducted by a State Testing Laboratory, the remainder of the batch, including any cannabis plant trim, leaf; and other usable material from the same batch automatically fails the official test.
 - a. A batch that fails an official test may be remediated and retested upon the request of the licensee. Initial retesting shall occur using the same sample at the same State Testing Laboratory; however, at the discretion of the licensee, subsequent retesting may occur at a different State Testing Laboratory, if available.
 - b. A batch of cannabis that fails a microbial screening may be used to make a CO2 or solvent-based extract. After processing, the CO2 or solvent-based extract must pass all required official tests.
3. If a sample from a batch in the production of medical cannabis fails an official test conducted by a State Testing Laboratory, the entire batch from which the sample was taken automatically fails the official testing.
4. A State Testing Laboratory shall, at the time of collection, obtain a sample large enough to undergo two tests; it shall keep any sample which fails testing for 30 days (or longer, at the request of the Commission) pending a request by the licensee to (A) seek retesting, (B) challenge the result, or (C) accept the result and seek remediation of the failed sample and/or the batch from which it was derived. A sample kept by the State Testing Laboratory pursuant to this subsection must be stored in a cool, dry area to prevent or minimize deterioration, and the sample shall be made available to the licensee upon request for further testing in furtherance of any challenge or attempt to remediate. A cannabis testing facility shall dispose of a sample kept pursuant to this subsection after 30 days have elapsed after failure of testing, barring a contrary request by the Commission.
5. Within seven (7) days following a failed test, a licensee must take at least one of the following actions:
 - a. *Accept.* Accept the results of the test and destroy the batch.
 - b. *Retest.* Request in writing (with copy to the Commission provided electronically through the Statewide Seed-to-Sale Tracking System) that the State Testing Laboratory retest the sample as to the portion of the test that failed; if the second test of the same sample passes, the

- sample (if available, otherwise a parallel sample taken by the licensee under subparagraph 6. of this Rule) shall be sent to another State Testing Laboratory, if available, as chosen by the Commission, to provide a tiebreak test (the Commission's function shall not be to gatekeep such a request, but merely to assign the State Testing Laboratory that will administer the subsequent retest). The results of the tiebreak test are final.
- c. *Challenge.* Following a test or failed retest by the State Testing Laboratory, a licensee may challenge the results by a request in writing (with copy to the Commission provided electronically through the Statewide Seed-to-Sale Tracking System) that two additional State Testing Laboratories be chosen by the Commission, if available; the two additional State Testing Laboratories shall provide full testing of the parallel samples taken by the licensee under subparagraph 6. of this Rule (the Commission shall not be to gatekeep such a request, but merely to assign the State Testing Laboratory that will administer the subsequent retest). If both challenge tests are deemed valid and demonstrate that the batch passed, the challenge is successful and the batch is cleared for use; otherwise, the challenge is unsuccessful, and the batch must be destroyed. The Commission shall be the final arbiter of any challenge under this rule.
 - d. *Remediate.* Attempt to remediate the batch and request in writing (with copy to the Commission provided electronically through the Statewide Seed-to-Sale Tracking System) that the State Testing Laboratory obtain new samples and retest the remediated batch. Batch Remediation effects a reset of the testing process: testing prior to remediation is not considered, but only the testing of the new, remediated batch.
6. A licensee may not challenge or request a retest by a State Testing Laboratory pursuant to this rule unless, at the time samples are initially taken for testing, the licensee ensures that three samples are collected at the same time by a State Testing Laboratory using tamper-resistant containers. One of the samples must be taken by the State Testing Laboratory for testing and the licensee must place the other two samples in a secure quarantine storage area at its facility for further retesting by a secondary State Testing Laboratory. If at any time, further testing cannot be performed due to (A) the lack of available State Testing Laboratories to conduct further or additional tests, or (B) the lack of viable samples from which to perform retesting, tiebreak testing, or challenge testing, the licensee shall have no choice but to accept the result of the failed test and destroy or attempt remediation of the batch as required under this Rule.
 7. A licensee may request a retest as often as it likes, but it may not challenge the results of the test conducted by the State Testing Laboratory more than three (3) times during a one-year period; however, a successful challenge leading to a reversal of the original failed test shall not count toward the three (3) times.
 8. A licensee requesting a retest or challenge, or seeking new testing following remediation, shall be responsible for all costs involved in any testing performed pursuant to this Rule.
 9. Barring contrary results based on a retest or challenge as provided in paragraph 5. of this Rule, if, upon retesting, a sample provided to a State Testing Laboratory sample fails the same official test, the licensee that provided the sample shall destroy and dispose of the entire batch from which the sample was taken and document the destruction and disposal of the batch to the Statewide Seed-to-Sale Tracking System. A batch so destroyed and disposed of must not be recognizable as cannabis or medical cannabis, nor shall it be usable for any legal or illegal purpose.
 10. If a sample provided to a State Testing Laboratory pursuant to this section passes the same official test upon retesting and tiebreak testing by a separate State Testing Laboratory, the licensee need

not destroy the entire batch; instead, the State Testing Laboratory shall clear the batch for further processing, packaging, labeling or sale, as appropriate, by means of certificate provided to the licensee and a notation on the Statewide Seed-to-Sale Tracking System.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.09 Applications and Applications Processing as to State Testing Laboratories.

1. *Generally.* Applicants for a license to operate as a State Testing Laboratory under the Act and these Rules shall be governed by the Rules for filing applications and seeking a license contained in Chapter 3 (538-x-3-.01, et seq.), except as specifically modified below.
2. *Procedure for Filing Application – Contents of Application Specific to State Testing Laboratories.* A State Testing Laboratory’s application filed with the Commission shall conform to the following requirements for all licensees set forth in 538-x-3-.05 of Chapter 3 of these Rules, except as noted below:
 - a. Cover Sheet – as provided in 538-x-3-.05 of Chapter 3 of these Rules.
 - b. Summary Sheet – as provided in 538-x-3-.05 of Chapter 3 of these Rules.
 - c. Application Information – as provided in 538-x-3-.05 of Chapter 3 of these Rules, except as provided otherwise below:
 - (1) The State Testing Laboratory Applicant’s Verification regarding each business entity that has any ownership interest in the applicant shall conform with paragraph 3.a. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (2) The State Testing Laboratory Applicant’s Verification regarding individuals having any ownership interest in the applicant, as to the identity, street address and responsible person of all entities with which the individual is connected, to the extent the entity is directly or indirectly involved in the cannabis industry, shall conform with paragraph 3.b. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (3) The State Testing Laboratory Applicant’s Verification regarding any criminal history as to any owner, director, board member, or individual with a controlling interest in the applicant shall conform with paragraph 3.c. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (4) The State Testing Laboratory Applicant’s verified licensing history, cannabis industry history, and tax history regarding itself or any affiliate shall conform with paragraphs 3.d., 3.e., and 3.f. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - (5) The State Testing Laboratory Applicant’s Verification regarding any public officials having any interest in the applicant shall conform with paragraph 3.g. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
 - d. State Testing Laboratory applicants must:
 - (a) identify which of the approved types of medical cannabis will be tested at each facility,
 - (b) provide a summary of the processes and methods to be utilized to test each product, including the machinery, equipment, materials, and personnel necessary to test each product, and

- (c) identify specific plans to ensure safety of personnel, facilities, and products being tested, based on the types of tests proposed to be utilized.
- (7) The State Testing Laboratory Applicant's statement of the anticipated or actual number of employees shall conform with paragraph 3.h. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
- (8) The State Testing Laboratory Applicant's statement of the number of days, if awarded a license, within which it will commence operations and reach full capacity shall conform with paragraph 3.i. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
- (9) The State Testing Laboratory Applicant's consent to the inspections, examinations, searches and seizures contemplated by § 20-2A-52(a)(3), Code of Alabama 1975 (as amended) shall conform with paragraph 3.j. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
- (10) The State Testing Laboratory Applicant's verification of the permissibility of its facilities' locations and compliance with all State and local laws shall conform with paragraph 3.k. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
- (11) The State Testing Laboratory Applicant's Verification that it and its leadership have no economic interest in any other license or Applicant for license under the Act or these Rules shall conform with paragraph 3.l. of Rule 538-x-3-.05 of Chapter 3 of these Rules.
- 3. *Procedure for Filing Application – Exhibits to State Testing Laboratory's Application.* Exhibits to the State Testing Laboratory Applicant's application information shall include all those as provided in subparagraphs 3.m.(1) through 3.m.(16) 538-x-3-.05 of Chapter 3 of these Rules, unless specifically provided otherwise as follows:
 - a. State Testing Laboratory applicants must provide, as available, sales contracts and receipts, lease agreements or other documentation demonstrating possessory interest in all machinery and equipment to be used in the testing of cannabis or medical cannabis, as well as specifications and operations manuals of such machinery.
 - b. State Testing Laboratory applicants must provide a quality control and quality assurance plan for each type of test to be performed on licensees' cannabis or medical cannabis identifying:
 - (1) A summary of the collection protocols and procedures to be implemented by the State Testing Laboratory to ensure each sample's identity, adequacy, integrity, and freedom from cross-contamination.
 - (2) A summary of the laboratory protocols and procedures to be adopted ensuring proper testing for the required safety, potency, stability, lifespan, and consistency of the cannabis or medical cannabis, whether as required by law or otherwise.
 - (3) An overview of the steps to be taken in the testing process to provide high quality test results and/or to safeguard its testing procedures. The State Testing Laboratory Applicant must identify any specific plans to ensure integrity, consistency, efficacy, efficiency, economy, and accuracy of testing being performed at each facility, including whether and to what extent the State Testing Laboratory intends to implement these plans internally or to rely on any outside source to audit, evaluate and make recommendations to improve testing quality.
 - (4) A summary of the tests that will be conducted, if any, with respect to each type of licensee or product.

- (5) A plan for reporting the results of testing upon a licensee's product, including the form to be utilized for providing said results to the licensee.
- (6) A plan for transportation of cannabis and medical cannabis to and from the State Testing Laboratory's facility.
- (7) Any steps that will be taken to differentiate between official tests and unofficial private testing performed at the request of a licensee.
- (8) A plan for managing the return and remediation or destruction of any failed test samples, including entry or monitoring the entry of the event on the Statewide Seed-to-Sale Tracking System.
- (9) Any specific plans to obtain and maintain accreditation as an ISO/IEC 17025 laboratory.
- (10) A detailed rendering of the information to be entered into the Statewide Seed-to-Sale Tracking System as to each sample obtained for testing.
- c. State Testing Laboratory applicants must provide:
 - (1) A curriculum vitae for the business, demonstrating the education, experience, and other credentials of its leadership, including but not limited to all scientists and engineers employed at each facility.
 - (2) A detailed explanation of the role each leader, scientist or engineer is to have in the processing of medical cannabis at each facility.
 - (3) A 5-year hiring plan for its leaders, scientists, and engineers, identifying the types, positions, required education, required experience, and expected roles of such personnel.
- d. State Testing Laboratory applicants must provide copies of all contracts, contingent contracts, memoranda of understanding (or, if none of the foregoing are available, exemplars) between themselves and:
 - (1) Any Cultivator or prospective Cultivator.
 - (2) Any Processor or prospective Processor.
 - (3) Any Secure Transporter or prospective Secure Transporter.
 - (4) Any Dispensary or prospective Dispensary.
 - (5) Any Integrated Facility or prospective Integrated Facility.
- e. State Testing Laboratory applicants must create a receiving and shipping plan that, at a minimum, ensures the following, in coordination with the contracted licensee:
 - (1) Individual batches of cannabis being received for testing were appropriately prepared, tagged or otherwise identified, and inserted in containers at the time of receipt.
 - (2) Batches and containers arriving from the licensee have been QR coded or otherwise digitally coded to identify, at a minimum, licensee, facility, plant tag identification number, date of harvest or processing, and the date (if any) of the last testing approval by a State Testing Laboratory.
 - (3) Incoming cannabis or medical cannabis is accompanied by a manifest and other appropriate documentation; the information thereon is accurate and has been duly executed by all appropriate parties.
 - (4) All information from the QR code relating to the incoming cannabis or medical cannabis, as well as the date and time of arrival, has been logged into the Statewide-Seed-to-Sale Tracking System.

- (5) Individual batches of medical cannabis arriving from a dispensary or from a processor after the packaging and labeling process has occurred, have been appropriately packaged, labeled, and inserted in containers prior to transport.
 - (6) Batches and containers being transported back to a licensee from the State Testing Laboratory's facility must be QR coded or otherwise digitally coded to identify, at a minimum, the State Testing Laboratory and facility, the type of product, date of testing, and the date of the State Testing Laboratory's test approving or rejecting the product.
 - (7) Outgoing test material is accompanied by an appropriate manifest and other appropriate documentation; the information thereon is accurate and has been duly executed by all appropriate parties.
 - (8) All information from the QR code relating to the outgoing medical cannabis, as well as the date and time of shipment, has been logged into the Statewide-Seed-to-Sale Tracking System.
- f. Each State Testing Laboratory must establish policies for an adequate chain of custody and requirements for samples of products provided to the laboratory for testing or research purposes, including, without limitation, policies, and requirements for:
- (1) Issuing instructions for the minimum sample and storage requirements.
 - (2) Documenting the condition of the external package and integrity seals utilized to prevent contamination of, or tampering with, the sample.
 - (3) Documenting the condition and amount of the sample provided at the time of receipt.
 - (4) Documenting all persons handling the original samples, aliquots, and extracts.
 - (5) Documenting all transfers of samples, aliquots and extracts referred to another State Testing Laboratory for additional testing or whenever requested by a client.
 - (6) Maintaining a current list of authorized medical cannabis establishment agents and restricting entry to the laboratory to only those authorized.
 - (7) Securing the laboratory during nonworking hours.
 - (8) Securing short- and long-term storage areas when not in use.
 - (9) Utilizing a secured area to log-in and aliquot samples.
 - (10) Ensuring samples are stored appropriately.
 - (11) Documenting the disposal or return of samples, aliquots and extracts following the conclusion of testing.
- g. State Testing Laboratory applicants must provide a detailed recall, return and remediation plan that will be followed in the event one or more lots or batches being tested, is determined to require recall. The plan must include, but should not be limited to, the following:
- (1) Provisions for notifying the licensee of a failed test or other adverse event.
 - (2) Factors about a failed test or adverse event that would likely necessitate a recall, and any potential for retesting or remediation of the product in question, and any guidance that will be offered to assist a notified licensee.
 - (3) Responsible individuals or positions within the State Testing Laboratory who will liaison with the licensee during the recall process.
 - (4) Notification protocols to other licensees and the Commission through the Statewide Seed-to-Sale Tracking System.
 - (5) Processes to help ensure, in cooperation with the notified licensee, that the recalled product is returned, remediated (and approved as safe), or destroyed.

- (6) Processes to report to the Commission and any other appropriate regulatory body regarding crisis response and steps taken to mitigate or avoid danger to the public.
- (7) Steps to be taken to assist the notified licensee to avoid further contamination, to preserve and protect uncontaminated cannabis or medical cannabis, and to ensure access to said products by those who depend on it.
- (8) Any assistance to be provided to the notified licensee to investigate and analyze the factors that led to the need for recall, and the process by which to make any recommendations as to adjustments to the licensee's internal protocols and processes to avoid recurrence.
- (9) As necessary, any general or specific licensee advisories that should be offered to minimize the likelihood of duplication of the factors that led to the unsafe condition requiring recall.
- (10) As necessary, any public advisories that should be offered to minimize the risk of harm to patients, caregivers, and other members of the public.
- h. The State Testing Laboratory Applicant's Security Plan must include a plan for security at each facility, including but not limited to the following:
 - (1) Twenty-four-hour alarm systems must be installed in all facilities where cannabis and/or medical cannabis are present.
 - (a) Such alarms shall be provided and installed by experts in industry-standard commercial-grade alarm systems.
 - (b) Alarm systems must be fully operational, securing all entry points and perimeter windows, be equipped with motion detectors and pressure switches, and must cover all areas where cannabis or medical cannabis is delivered, received, handled, stored, prepared, tested, or readied for transport.
 - (2) All ingress and egress points to the facility shall be equipped with digital tag in/tag out systems to preclude unauthorized access by the general public.
 - (3) All ingress and egress points to the testing area shall be equipped with digital tag in/tag out systems to limit access as to all but authorized personnel within the facility.
 - (4) Reception areas and personnel adjacent to ingress and egress points shall have ready access to duress panic and hold-up alarms that may be activated in the event of access by unauthorized personnel or intruders.
 - (5) Broadcast communication devices (cell phones, intercom equipment or the like) must be:
 - (a) Carried by each employee or installed in all areas of each State Testing Laboratory's facility designed for regular access by humans.
 - (b) Accessible for communication by all personnel at all times, and particularly at perimeter ingress/egress stations, facility reception areas, and the security office.
 - (c) Capable of providing information with sufficient clarity to be heard and understood by all personnel and visitors within earshot of the employee receiving the communication.
 - (6) A State Testing Laboratory's facility shall maintain an audio/video surveillance system that shall be in continuous operation 24 hours per day.
 - (a) Recording devices must be fully functional and fixed in place covering both the interior and exterior of the State Testing Laboratory's facility.

- (b) Recording devices must be in such quantity, with such lighting, and at such resolution as shall allow for the clear identification of individuals and activities in all reasonably accessible areas of the premises, including but not limited to all entrances, exits, parking lots, and any area where medical cannabis or medical cannabis is delivered, received, handled, stored, prepared, tested, or readied for transport.
 - (c) Audio/Video surveillance recordings must clearly and accurately display the time and date.
 - (d) Audio recordings must clearly and accurately capture conversations and activities to a level of 20 decibels within camera range.
- (7) The State Testing Laboratory facility's perimeter and any outdoor premises must be surrounded by a sufficient fence or barrier to prevent access by unauthorized persons and must have sufficient lighting to allow for the proper functioning of video surveillance equipment at all times between dusk and dawn or at any other time when ambient lighting requires enhancement to permit identification of individuals or activities upon or immediately adjacent to the premises. Indoor premises must likewise be sufficiently lit to allow for the identification of individuals and activities.
- (8) The State Testing Laboratory's facility must be housed in a stand-alone building or fully separated portion of a building accessible to and used by only authorized personnel; the area is not to be accessible to or used by scientists, engineers, or lab technicians not employed by the State Testing Laboratory. To the extent the State Testing Laboratory is housed within a larger facility, the portion dedicated to testing cannabis and medical cannabis must be self-contained or, at a minimum, segregated from the remainder of the activities being conducted in the larger facility by separate points of ingress and egress or, at a minimum, separately keyed and electronically protected entryways accessible only to employees of the State Testing Laboratory.
- (9) Exterior doors of each facility operated by a State Testing Laboratory must be designed or reinforced to withstand unlawful forcible entry; exterior doors shall remain locked against outside intruders at all times, while allowing free egress by the facility's occupants in the event of an emergency; doors must permit ingress to employees and other appropriate persons only by means of a keycard or other similar electronic access device.
- (10) Exterior walls of each facility operated by a State Testing Laboratory must be reinforced to withstand unlawful forcible entry. Windows, likewise, must be reinforced to prevent breakage by outside intruders.
- (11) State Testing Laboratory Facilities must provide and maintain a plan for sufficient staffing of security guards at each facility where cannabis and medical cannabis is present to reasonably ensure the safety of the products stored therein; however, the State Testing Laboratory's plan must provide, at a minimum, one (1) security guard per facility during the facility's business/operating hours.
- (12) Strict access controls shall protect areas where cannabis or medical cannabis is handled or stored – in a secured, locked room or vault.
- (13) Records, whether electronic or manual, must be kept of all persons on the premises at a facility at all times, including employees, vendors, transporters or other licensees, and all others, recording the individuals' name, date, time of ingress and egress, and (as to non-

employees) the reason for their presence; such records shall be kept for a minimum of two years, and longer at the request of the Commission or law enforcement.

- (14) Audio/Video surveillance records must be kept for at least 60 days, and longer upon the request of the Commission, its inspectors, or any law enforcement personnel. Audio/Video recordings potentially reflecting an incident of actual or attempted diversion must be kept for the longer of a period of two years, or until resolution of the incident and apprehension and discipline or prosecution of the individuals involved in the actual or attempted diversion.
 - (15) Employees, while on duty, shall wear identification badges that clearly identify them as employees.
 - (16) Visitors, including vendors, other licensees, Commission members, inspection personnel, or other representatives must wear a "visitor pass" or "AMCC Official" pass, as applicable, at all times while on the premises. The State Testing Laboratory shall not be accessible by the members of the general public at any time.
 - (17) State Testing Laboratories shall maintain, review and update policies to report theft, diversion, or other loss of cannabis or medical cannabis to the Commission and to law enforcement as early as practicable and not more than 24 hours from the event or its discovery.
 - (18) Upon request, a State Testing Laboratory shall make available to the Commission or its inspectors all information relating to the State Laboratory's security plan, including but not limited to its security alarm systems, monitoring, alarm activity, maps of camera locations and camera coverage, audio/video footage, surveillance equipment maintenance logs, authorized use lists, operation instructions, and any other security-related information deemed relevant by the Commission or its inspectors.
- i. The State Testing Laboratory Applicant must provide an affidavit signed by the responsible individual and designated contact person (or, if the State Testing Laboratory is an entity, the duly authorized officer, owner or interest holder and the designated contact person) that the information provided in the Application is true and correct, to the best of the Affiants' knowledge upon a diligent investigation thereof.
 - j. The State Testing Laboratory Applicant must provide the appropriate application fee as required by § 20-2A-55(f), Code of Alabama 1975 (as amended). The application fee is nonrefundable and must be submitted electronically per instructions in the Application Form received in response to the applicant's Request for Application.
- 4. In all other respects except as expressly stated otherwise in this Rule, State Testing Laboratory Applicants shall be governed by the rules for applications and licensing generally pertaining to all applicants (Chapter 3 of these Rules).

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.10 Post-Licensing Inspection of State Testing Laboratory Facilities.

Post-Licensing Inspection of State Testing Laboratory facilities under the Act and these Rules shall be governed by Rule 538-x-4-.02 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.11 Investigation of State Testing Laboratory Licensees.

Investigation of State Testing Laboratory licensees under the Act and these Rules shall be governed by Rule 538-x-4-.03 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.12 Training and Continuing Education Requirements for State Testing Laboratories.

Training and Continuing education requirements for State Testing Laboratories' owners, officers, administrators, managers, and employees shall be as set forth in Rule 538-x-4-.04 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.13 State Testing Laboratories' Maintenance of Proper Technology.

State Testing Laboratories' duty to maintain proper technology shall be governed by Rule 538-x-4-.05 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.14 State Testing Laboratories' Annual Licensing Fees; Schedule.

State Testing Laboratories' duty regarding annual license fees shall be as set forth in Rule 538-x-4-.06 of Chapter 4 of these Rules, and the schedule therefor shall be contained on the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.15 State Testing Laboratories' Duty to Meet and Maintain Standards, Policies, Procedures and Operations Per Application.

A State Testing Laboratory licensee has an ongoing duty to meet and maintain the standards, policies, procedures, and operations, both at the pre-commencement inspection and at all times thereafter, as it affirmed to the Commission at the time of licensing, as such standards, policies, procedures, and operations may have been amended and updated by the licensee from time to time in accordance with

Rules 538-x-4-.08 and 538-x-4-.19., as provided in Rule 538-x-4-.07 of Chapter 4 of these Rules and as modified by Rule 538-x-10-.09 of this Chapter.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.16 State Testing Laboratories' Duty to Notify or Seek Permission Regarding Material Change in Licensing Information.

State Testing Laboratories' duty to notify or seek the Commission's permission regarding any material change in licensing information shall be governed by Rule 538-x-4-.08 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.17 State Testing Laboratories' Term of Licenses.

The term of State Testing Laboratories' licenses shall be governed by Rule 538-x-4-.09 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.18 State Testing Laboratories' Applications for Renewal of License.

State Testing Laboratories' applications for renewal of license shall be governed by Rule 538-x-4-.10 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.19 State Testing Laboratories' Notifications to Apply for Renewal.

State Testing Laboratories' notifications to apply for renewal shall be governed by Rule 538-x-4-.11 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.20 Expiration of State Testing Laboratories' Licenses; Delinquent License Renewal; Failure to Apply for Renewal.

The expiration of State Testing Laboratories' licenses, renewal of delinquent licenses and consequences for failing to apply for renewal shall be governed by Rule 538-x-4-.12 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.21 State Testing Laboratories' License Renewal Process and Procedures; Use of Independent Third-Party Consultants.

State Testing Laboratories' renewal process and procedures, and the Commission's use of independent third-party consultants to inspect and evaluate State Testing Laboratories, shall be governed by Rule 538-x-4-.13 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.22 State Testing Laboratories' License Renewal Fees.

License renewal fees for State Testing Laboratories shall be governed by Rule 538-x-4-.14 of Chapter 4 of these Rules. License renewal fees shall be set forth on the schedule of fees maintained by the Commission on the AMCC website.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.23 Non-renewal of State Testing Laboratories' Licenses.

Non-renewal of State Testing Laboratories' licenses shall be governed by Rule 538-x-4-.15 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.24 State Testing Laboratories' Transfer of Licenses; Change of Ownership.

State Testing Laboratories' transfer of licenses and change of ownership shall be governed by Rule 538-x-4-.16 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.25 Marketing and Advertising by State Testing Laboratories.

State Testing Laboratories' duties with respect to Advertising, except as specifically modified within these Rules, shall be governed by Rule 538-x-4-.17 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.26 Relocation of State Testing Laboratories' Facilities.

Relocation of State Testing Laboratories' facilities shall be governed by Rule 538-x-4-.18 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.27 Material Change in State Testing Laboratories' Information.

Rules regarding a material change in a State Testing Laboratories' Information previously provided to the Commission shall be governed by Rule 538-x-4-.19 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.28 Temporary Licenses for State Testing Laboratories.

Rules regarding temporary licenses for State Testing Laboratories shall be governed by Rule 538-x-4-.20 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.29 State Testing Laboratories' Surrender of License; Cessation of Operations.

A State Testing Laboratory's surrender of license and/or cessation of operations shall be governed by Rule 538-x-4-.21 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.30 Disciplinary Actions Against State Testing Laboratories.

Disciplinary Actions against State Testing Laboratories shall be governed by Rule 538-x-4-.22 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

538-x-10-.31 State Testing Laboratories' Appeals from Adverse Decisions by the Commission.

State Testing Laboratories' appeals from adverse decisions by the Commission shall be governed by Rule 538-x-4-.23 of Chapter 4 of these Rules.

Author: William H. Webster

Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).

History: New Rule: Published August 31, 2022; Effective October 15, 2022.

Appendix A to Chapter 10: TESTS AND TESTING STANDARDS OF STATE TESTING LABORATORIES

The tests required by a State Testing Laboratory, by product, shall be as follows:

Product	Tests Required	Detectible Levels
In-process medical cannabis and crude collected resins, as received	1. Moisture content	1. < 15%
	2. Potency analysis	2. N/A
	3. Terpene analysis	3. N/A
	4. Foreign matter inspection	4. None detected
	5. Mycotoxin screening	5. < 20 $\mu\text{g/kg}$ for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 $\mu\text{g/kg}$ for Ochratoxin A
	6. Heavy metal screening	6. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm
	7. Pesticide residue analysis	7. See Rule 538-x-10-.04 of this Chapter
	8. Herbicide screening	8. See Rule 538-x-10-.04 of this Chapter
	9. Growth regulator screening	9. See Rule 538-x-10-.04 of this Chapter
	10. Total yeast and mold	10. < 10,000 colony forming units per gram
	11. Total Enterobacteriaceae	11. < 1,000 colony forming units per gram
	12. Salmonella	12. None detected per gram
	13. Pathogenic E. coli	13. None detected per gram
	14. Aspergillus fumigatus	14. None detected per gram
	15. Aspergillus flavus	15. None detected per gram
	16. Aspergillus terreus	16. None detected per gram
	17. Aspergillus niger	17. None detected per gram
	18. Total coliform	18. < 1,000 colony-forming units per gram

Cannabis, as received, which is destined for extraction	1. Potency analysis 2. Terpene analysis 3. Foreign matter inspection 4. Mycotoxin screening 5. Heavy metal screening 6. Pesticide residue analysis 7. Herbicide screening 8. Growth regulator screening 9. Total yeast and mold 10. Total Enterobacteriaceae 11. Salmonella 12. Pathogenic E. coli 13. Aspergillus fumigatus 14. Aspergillus flavus 15. Aspergillus terreus 16. Aspergillus niger 17. Total coliform	1. N/A 2. N/A 3. None detected 4. < 20 Å,µg/kg for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 Å,µg/kg for Ochratoxin A 5. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm 6. See Rule 538-x-10-.04 of this Chapter 7. See Rule 538-x-10-.04 of this Chapter 8. See Rule 538-x-10-.04 of this Chapter 9. < 10,000 colony forming units per gram 10. < 1,000 colony forming units per gram 11. None detected per gram 12. None detected per gram 13. None detected per gram 14. None detected per gram 15. None detected per gram 16. None detected per gram 17. < 1,000 colony forming units per gram
Fully processed extract of cannabis, including mixtures of extracted products or oils or fats derived from natural sources, including concentrated cannabis extracted with CO2	1. Potency analysis 2. Foreign matter inspection 3. Terpene analysis 4. Mycotoxin screening	1. N/A 2. None detected 3. N/A 4. < 20 Å,µg/kg for the total of Aflatoxins B1, B2, G1 and G2

	5. Heavy metal screening 6. Pesticide residue analysis 7. Total yeast and mold 8. Total Enterobacteriaceae 9. Salmonella 10. Pathogenic E. coli 11. Aspergillus fumigatus 12. Aspergillus flavus 13. Aspergillus terreus 14. Aspergillus niger	combined and < 20 $\mu\text{g/kg}$ for Ochratoxin A 5. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm 6. See Rule 538-x-10-.04 of this Chapter 7. < 1,000 colony forming units per gram 8. < 100 colony forming units per gram 9. None detected per gram 10. None detected per gram 11. None detected per gram 12. None detected per gram 13. None detected per gram 14. None detected per gram
Extract of cannabis (solvent-based) made with any approved solvent, including concentrated cannabis extracted by means other than with CO2	1. Potency analysis 2. Terpene analysis 3. Foreign matter inspection 4. Residual solvent test 5. Mycotoxin screening 6. Heavy metal screening 7. Pesticide residue analysis 8. Total yeast and mold 9. Total Enterobacteriaceae 10. Salmonella	1. N/A 2. N/A 3. None detected 4. < 500 ppm 5. < 20 $\mu\text{g/kg}$ for the total of Aflatoxins B1, B2, G1 and G2 combined and < 20 $\mu\text{g/kg}$ for Ochratoxin A 6. Arsenic: < 2 ppm Cadmium: < 0.82 ppm Lead: < 1.2 ppm Mercury: < 0.4 ppm 7. See Rule 538-x-10-.04 of this Chapter 8. < 1,000 colony forming units per gram 9. < 100 colony forming units per gram 10. None detected per gram

	11. Pathogenic E. coli 12. Aspergillus fumigatus 13. Aspergillus flavus 14. Aspergillus terreus 15. Aspergillus niger	10. None detected per gram 11. None detected per gram 12. None detected per gram 13. None detected per gram 14. None detected per gram 15. None detected per gram
Topical cannabis-infused product, including a product which contains concentrated cannabis	1. Potency analysis 2. Terpene analysis	1. N/A 2. N/A

As used in this Appendix A, "as received" means the unaltered state in which a sample was collected, without any processing or conditioning, which accounts for all mass, including moisture content.

APA-1

TRANSMITTAL SHEET FOR NOTICE
OF INTENDED ACTION

Control: 538

Department or Agency: Alabama Medical Cannabis Commission

Rule No.: Chapter 538-X-2

Rule Title: Regulation of Patients and Caregivers

Intended Action Amend

Would the absence of the proposed rule significantly harm or endanger the public health, welfare, or safety? No

Is there a reasonable relationship between the state's police power and the protection of the public health, safety, or welfare? Yes

Is there another, less restrictive method of regulation available that could adequately protect the public? No

Does the proposed rule have the effect of directly or indirectly increasing the costs of any goods or services involved? No

To what degree?: N/A

Is the increase in cost more harmful to the public than the harm that might result from the absence of the proposed rule? NA

Are all facets of the rule-making process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public? Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule? No

.....

Does the proposed rule have an economic impact? No

If the proposed rule has an economic impact, the proposed rule is required to be accompanied by a fiscal note prepared in accordance with subsection (f) of Section 41-22-23, Code of Alabama 1975.

.....

Certification of Authorized Official

I certify that the attached proposed rule has been proposed in full compliance with the requirements of Chapter 22, Title 41, Code of Alabama 1975, and that it conforms to all applicable filing requirements of the Administrative Procedure Division of the Legislative Services Agency.

Signature of certifying officer

John McMillan
John McMillan

Date

Sunday, March 17, 2024

REC'D & FILED

MAR 18, 2024

LEGISLATIVE SVC AGENCY

ALABAMA MEDICAL CANNABIS COMMISSION

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Medical Cannabis Commission

RULE NO. & TITLE: Chapter 538-X-2 Regulation of Patients and
Caregivers

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

Revisions to existing administrative rules to address potential statutory conflicts.

TIME, PLACE AND MANNER OF PRESENTING VIEWS:

A public comment portal will be available on the Commission's website (www.amcc.alabama.gov) between the date of publication (3/29/2024) and for a period of 35 days thereafter (ending on 5/3/2024).

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Friday, May 3, 2024

CONTACT PERSON AT AGENCY:

Justin C. Aday

John McMillan

John McMillan

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

**ALABAMA MEDICAL CANNABIS COMMISSION
ADMINISTRATIVE CODE**

**CHAPTER 538-X-2
REGULATION OF PATIENTS AND CAREGIVERS**

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538-X-2-.01 Purpose.

This Chapter is promulgated to regulate qualified Patients and Caregivers in registering for, obtaining, and administering medical cannabis and in interacting with registered certifying physicians.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.02 Definitions.

As set forth in this Chapter, the following definitions apply

(1) "Administer" or "administration." The introduction of medical cannabis into the body of a human, whether through use of an inhaler, ingestion, or any other approved means, whether by a registered qualified patient (self-

administration), a registered qualified caregiver, or (improperly) by another.

~~(2) "Professional Caregiver." Someone whose career is to assist another person in a way that enables them to live as independently as possible. For the purposes of these Rules, a professional caregiver must be (A) over 21 years of age and (B) (1) licensed, having passed a basic screening test provided by the Alabama Medicaid Agency in collaboration with the Alabama Department of Rehabilitation Services and the Alabama Department of Senior Services; (2) certified by the American Caregiver Association; or (3) employed as a nurse, therapist or other healthcare provider by a hospital, long-term care facility or hospice program licensed under Alabama law.~~

~~(3)~~ (2) Refuse to grant or renew." As used in this Chapter, to deny original or continued registration for a period of at least twelve months. After twelve months or such period of time as the individual Commission order may require, a patient or caregiver or an individual who desires to attain such status by registration, and whose registration the Commission has refused to grant or renew, may make application to the Commission for issuance of a new registration in accordance with the Act and this Chapter. An individual who desires to attain patient or caregiver status by registration and whose registration the Commission has refused to grant or renew must satisfy all requirements established by the Commission.

~~(4)~~ (3) "Revoke." As used in this Chapter, to take action against a patient's or caregiver's registration, rendering such registration void; such registration may not be reissued. "Revoke" is an action that is permanent against the registration and the patient or caregiver.

~~(5)~~ (4) "Stale Registration." A submission to register as a patient or caregiver whereby the submitting party fails to complete all submission requirements within 60 calendar days of the initiation of a registration by a registered certifying physician, and after being notified by the Commission, subject to the factors that would otherwise remove the submitter from consideration under the Act and this Chapter. An individual forfeits all fees associated with a stale registration submission. The Commission shall not be required to act on, and may destroy, any stale registration submission. If the registration is stale, the submitter shall be required to reapply for registration in accordance with the Act and this Chapter, in effect at the time of resubmission.

~~(6)~~ (5) "Suspend." To take action against a registration, rendering such registration without force and effect for a period of time as determined by the Commission.

~~(7)~~ (6) "Under the Influence of Medical Cannabis." At a level that would cause the user to be violation of current State law as it pertains to marijuana (cannabis).

Author: William H. Webster; [Justin C. Aday](#)

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022. **Amended:** Published ; effective.

538-X-2-.03

Requisite Conditions To Qualify As A Registered Qualified Patient.

(1) Before medical cannabis may be dispensed to, possessed by, or administered to a prospective patient and, if applicable, the prospective patient's caregiver, the patient and caregiver, must be placed on the patient registry established by the Commission in accordance with the Act and this Chapter.

(2) A registered qualified patient 19 years of age or older or a registered caregiver acting on behalf of a registered qualified patient is not subject to arrest or prosecution for unlawful possession of marijuana, if (a) possessing no more than 70 daily dosages of medical cannabis for such registered qualified patient, and (b) having a valid medical cannabis card.

(3) Adult Patients

(a) A resident of this state who is 19 years of age or older is a registered qualified patient if meeting all of the following conditions:

1. Has been certified by a registered certifying physician as having a qualifying medical condition and has been recommended for the use of medical cannabis by a registered certifying physician.

2. Is registered with the Commission, having been placed on the patient registry established by the Commission in accordance with the Act and this Chapter.

3. Has been issued a valid medical cannabis card by the Commission.

(b) Upon meeting the foregoing conditions, such registered qualified patient may purchase, possess and use medical

cannabis, subject to the limitations of §20-2A-30(d), Code of Ala. 1975, (as amended), relating to maximum medical dosage.

(4) Minor Patients

(a) A resident of this state who is under the age of 19 years is a registered qualified patient if meeting all of the following conditions:

1. Has been certified by a registered certifying physician as having a qualifying medical condition and has been recommended to use medical cannabis by the registered certifying physician.

2. Is registered with the Commission, having been placed on the patient registry established by the Commission in accordance with the Act and this Chapter.

3. Has a qualified caregiver who is (A) the patient's parent, legal guardian, grandparent, spouse, ~~authorized professional caregiver~~, or an individual with a valid power of attorney for healthcare of the minor; (B) a resident of this state; and (C) possesses a valid caregiver's medical cannabis card issued by the Commission.

(b) Upon meeting the foregoing conditions, such minor patient may use medical cannabis obtained by a caregiver on behalf of the minor patient, but the minor patient may not purchase or possess medical cannabis. Notwithstanding the foregoing, a minor patient may not legally use medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol.

Author: William H. Webster; [Justin C. Aday](#)

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022. **Amended:** Published ; effective .

538-X-2-.04

Caregiver Qualifications.

(1) A resident of this state is a registered caregiver if he or she meets all of the following conditions:

- (a) Is registered with this Commission, having been identified to a patient who has been placed on the registry established by the Commission in accordance with the Act and this Chapter.

(b) Has been issued a valid medical cannabis card by the Commission.

(c) Is at least 21 years of age or the parent or legal guardian of, and caregiver for, a registered qualified patient.

(d) Is the patient's parent, legal guardian, grandparent, spouse, ~~authorized professional caregiver~~, or an individual with a valid power of attorney for healthcare of a registered qualified patient.

(2) A registered caregiver described above may purchase and possess medical cannabis on behalf of a registered qualified patient to whom the registered caregiver has been identified in the patient registry and may administer medical cannabis to the patient or patients to whom the registered caregiver has been identified. A registered caregiver may not use medical cannabis unless the registered caregiver is also a registered qualified patient pursuant to r. 538-x-2-.03.

Author: William H. Webster; [Justin C. Aday](#)

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022. **Amended:** [Published](#) ; [effective](#) .

538-X-2-.05 Patient Registration.

(1) To qualify for placement on the registry, a prospective patient must:

(a) Be an Alabama resident.

(b) Establish and maintain a bona fide physician-patient relationship with a registered certifying physician who (acting individually or through a designated representative) shall submit a complete patient registration submission.

(c) Become certified by a registered certifying physician who has diagnosed or confirmed a qualifying condition and has recommended the patient's use of medical cannabis.

(d) Consent to treatment with medical cannabis. If the patient is a minor or individual with a court-appointed legal guardian, the prospective patient's parent or legal guardian shall consent to treatment with medical cannabis.

(e) Remit to the Commission the application fee as set by the Commission.

(2) Only a patient, a patient's caregiver, or a registered certifying physician with whom a prospective patient has a bona fide physician-patient relationship (acting individually or through the physician's designated representative) shall submit the patient registration. For a registration submission related to a patient who is 19 years of age or older to be considered complete, a completed certification from a registered certifying physician, applicable patient registration fee, and the following items must be submitted to the Patient Registry, notwithstanding but in addition to any that may otherwise be required by the Board of Medical Examiners:

(a) Patient's full name, residential address, telephone number, date of birth, and electronic mailing address.

(b) If applicable, caregiver's full name, residential address, telephone number, date of birth, and electronic mailing address.

(c) Patient's government-issued identification (such as a driver's license, Alabama Identification Card or Social Security Card). Patients must present a registered certifying physician with an unexpired driver's license, unexpired Alabama Identification Card, unexpired passport, Social Security Card, Birth Certificate, or other documentation proving identity as may be approved by the Commission.

(d) A digital color photograph of the patient taken no more than 30 days prior to submission of the patient registration.

(e) Registered certifying physician's full name (first name and last name); specialty; professional entity or affiliation, if any; business street address; telephone number; and email address.

(f) Registered certifying physician's Alabama Medical Cannabis Certification Permit Identification Number and medical license number issued by the State Board of Medical Examiners.

(g) Date medical cannabis certification was issued by the registered certifying physician.

(h) Indication whether the certification is new or a renewal.

(i) The following written attestations of the prospective patient or caregiver:

1. That the registered certifying physician has explained the possible risks and benefits associated with the use of medical cannabis;
2. That the registered certifying physician has obtained the patient's or caregiver's consent to treatment with medical cannabis; and
3. That the patient has agreed to comply with the provisions of the Act and this Chapter.

(j) The following written attestations of the registered certifying physician:

1. That the prospective patient has a bona-fide patient-physician relationship with, and is currently under the care of, the registered certifying physician;
2. That the prospective patient has a qualifying medical condition under the Act; naming the condition; and if a terminal illness, specifying the terminal illness;
3. That conventional medical treatment or therapy has failed (as defined further below), or that use of cannabis is the standard of care under the circumstances;
4. That the patient is suitable to receive treatment or therapy through the use of medical cannabis;
5. That the registered certifying physician has complied with all requirements imposed by the Rules promulgated by the State Board of Medical Examiners; and
6. That the patient or caregiver has provided voluntary informed written consent as to the following matters required by §20-2A-33(5), Code of Ala. 1975, (as amended):

- (i) The federal and state classification of cannabis as a Schedule I controlled substance.
- (ii) The approval and oversight status of cannabis by the Food and Drug Administration.
- (iii) The current state of research on the efficacy of cannabis to treat the qualifying medical condition or conditions.
- (iv) The potential for addiction.

(v) The potential effect that cannabis may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require an individual to be alert or respond quickly.

(vi) The potential side effect of cannabis use.

(vii) The risks, benefits, and drug interactions of cannabis.

(viii) A statement that the use of medical cannabis could result in termination from employment without recourse and those costs may not be covered by insurance or government programs.

(ix) That the patient's de-identified health information contained in the patient's medical record, patient registry may be used for research purposes or used to monitor compliance with this Chapter, as further provided in §20-2A- 35(c), Code of Ala. 1975, (as amended).

(k) Such other information as the Commission may reasonably require, as set forth on the patient registry form.

(3) If a prospective patient is younger than 19 years of age or has a court-appointed legal guardian, a patient registration submission is incomplete unless it is accompanied by a caregiver registration submission in accordance with the Act and this Chapter. Patients who become 19 years of age while their prior registration remains valid may apply for a new registration either immediately or in accordance with the renewal process under paragraph 9. of this rule. A submission from a patient that includes all information found in paragraph 2. of this rule shall be considered complete.

(4) A complete patient registration submission must be received by the Commission within 60 calendar days of the date of certification by the registered certifying physician. Failure to comply with this requirement results in a "stale registration" as defined in this Chapter and renders the recommendation void.

(5) If a registration submission is determined to be inaccurate or incomplete, the Commission shall note a deficiency on the patient registry and send the prospective patient notice of the deficiency. If the deficiency is not corrected within 60 calendar days from the date the registration was submitted , the lack of

progress on the submission results in a "stale registration" as defined in this Chapter and renders the recommendation void.

(6) Prospective patients must provide proof of Alabama residency to their registered certifying physician or the physician's representative during the registration submission process. Proof of Alabama residency shall include one of the following:

(a) The prospective patient's unexpired Alabama driver's license;

(b) The prospective patient's unexpired Alabama identification card issued by the Alabama Law Enforcement Agency (ALEA);

(c) The prospective patient's unexpired United States Passport demonstrating Alabama residency;

(d) A current certificate of enrollment from a qualified Alabama public or private educational institution; or

(e) Any other identification (e.g., military I.D.), proving Alabama residency as approved by the Commission.

(7) A patient registration shall be valid from the date of issuance and expire one year later.

(8) The Commission shall send a notification to each patient 45 calendar days before the expiration date on the patient's medical cannabis card.

(9) To maintain a valid patient registration, a patient must annually renew, before the expiration date stated on the patient's medical cannabis card. Renewal submissions, fees, and required documentation must be submitted not less than 14 calendar days before the expiration date on the patient's medical cannabis card. Failure to renew a patient registration will result in an automatic expiration of the medical cannabis card.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.06

Caregiver Registration.

(1) Unless otherwise provided in paragraph 2. of this rule, only Alabama residents who are natural persons 21 years of age or

older may register with the Commission to serve as a caregiver for a qualifying patient.

(2) Notwithstanding the age limitation in paragraph 1. of this rule, a minor patient's parent or legal guardian 19 years of age or older and who otherwise meets the requirements of the Act and this Chapter, may serve as the minor patient's caregiver.

(3) No person shall serve as a caregiver for any patient before registering with the Commission as provided in the Act and this Chapter.

(4) A patient shall designate no more than two caregivers. The Commission shall register no more than two caregivers for each patient.

(5) A competent adult patient may change caregivers with 14 days' written notice to the certifying physician, who (acting individually or through a designated representative) shall notify the Commission of the change on the patient registry.

(6) An individual shall serve as a caregiver for no more than three patients. Except as provided in paragraph 8. of this rule, the Commission shall associate no more than three patients for each caregiver.

(7) A caregiver must possess a medical cannabis card, and pay an application fee, for each patient for whom the caregiver provides care.

(8) Notwithstanding the limitations in paragraphs 4. and 6. of this Rule, upon a written request, the Commission may, in its discretion, permit an individual to serve as a caregiver for more than three patients and/or for a patient to designate more than two caregivers:

(a) In order to avoid unnecessary hardship to the patient or patients;

(b) Where the patients' care is being provided in a hospital, long-term care facility, or through a hospice program licensed under Alabama law; or

(c) Where the caregiver is simultaneously caring for multiple patients who reside in the same household as the caregiver.

(9) Except upon a demonstration of extraordinary circumstances and with the express permission of the Commission, an individual caregiver may not serve in such capacity as to more than ten patients simultaneously.

(10) If a patient requests permission to change a caregiver before renewal, the licensed certifying physician or the physician's representative shall note the request on the patient registry, setting forth information relating to the proposed caregiver, so as to conform with the caregiver registration requirements under the Act and this Chapter. The Commission shall approve a new caregiver only if such individual meets the requirements of the Act and this Chapter.

(11) A patient's licensed certifying physician shall not serve as the patient's caregiver.

(12) The Commission shall deny a submission for a caregiver registration if the individual identified on the submission is included in one or more of the following databases:

(a) The list of excluded individuals and entities maintained by the office of inspector general in the United States Department of Health and Human Services pursuant to 42 U.S.C. part 1320a-7 (as amended) and 42 U.S.C. part 1320c-5 (as amended) (i.e., indicating that the individual has been sanctioned for or convicted of fraud, theft or other dishonest and illegal conduct with respect to Medicare or other Government agencies related to healthcare).

(b) The Alabama Department of Human Resources' online registry of individuals who have been determined to be indicated of abuse.

(c) The state or federal sex offender registry.

(d) The Alabama Department of Correction's or U.S. Bureau of Prisons' registry of inmates and parolees.

(e) Any governmental database indicating that the health care provider seeking caregiver status has neglected or abused a patient, a long-term care facility resident, or residential care facility resident or misappropriated property of any such resident.

(13) Medical Cannabis may not be possessed by or administered to anyone other than a registered qualified patient, unless the person is a caregiver who is placed on the registry established by the Commission in accordance with the Act and this Chapter. A registered caregiver may possess and administer medical cannabis only to those patients with whom the caregiver's registration is associated.

(14) An individual who meets the caregiver eligibility requirements under the Act and this Chapter may be registered as

a caregiver if the following are electronically submitted to the Commission through the patient registry:

- (a) Identification of a patient who is registered or attempting to register as a patient pursuant to the Act and this Chapter, and for whom the individual intends to serve as a caregiver;

- (b) Completed caregiver registration information entered into the patient registry in accordance with paragraph 14 of this rule; and

- (c) Required application fee as set by the Commission.

(15) Only the caregiver, or a licensed certifying physician with whom the patient or prospective patient has a bona fide physician-patient relationship, or the physician's representative, may submit the caregiver's registration. For a caregiver's registration submission to be considered complete, the applicable caregiver registration fee, all of the information supplied as to patients as set forth in 538-x-.05-2. of this Chapter, as well as the following items must be submitted to the Commission in a manner suitable to the Commission:

- (a) The full name, residential address, telephone number, date of birth, and email address of the caregiver and the associated patient.

- (b) Associated patient's registration number issued by the Commission, if available.

- (c) Caregivers government-issued identification number (such as a driver's license number, Alabama Identification Card number or Social Security Number). Caregivers must present a registered certifying physician with an unexpired driver's license, unexpired Alabama Identification Card, unexpired passport, Social Security Card, Birth Certificate, or other documentation proving identity as may be approved by the Commission.

- (d) A digital color photograph of the caregiver taken no more than 30 days prior to submission of the caregiver registration.

- (e) Indication whether the caregiver certification is new or a renewal.

- (f) The following written attestations of the prospective caregiver:

1. That the registered certifying physician has explained the possible risks and benefits associated with the use of medical cannabis;
2. That the registered certifying physician has obtained the caregiver's consent to treat the patient with medical cannabis; and
3. That the caregiver has agreed to comply with the provisions of the Act and this Chapter.

(g) The following written attestations of the registered certifying physician as to the caregiver, in addition to those relating to the patient under paragraph 2.j. of Rule 538-X-2-.05:

1. That the caregiver is suitable to the patient's treatment or therapy through the use of medical cannabis; and
2. That the caregiver, on behalf of the patient, has provided voluntary informed written consent as to the following matters required by §20-2A-33(5), Code of Ala. 1975, (as amended):
 - (i) The federal and state classification of cannabis as a Schedule I controlled substance.
 - (ii) The approval and oversight status of cannabis by the Food and Drug Administration.
 - (iii) The current state of research on the efficacy of cannabis to treat the qualifying medical condition or conditions.
 - (iv) The potential for addiction.
 - (v) The potential effect that cannabis may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require an individual to be alert or respond quickly.
 - (vi) The potential side effect of cannabis use.
 - (vii) The risks, benefits, and drug interactions of cannabis.

(viii) A statement that the use of medical cannabis could result in termination from employment without recourse.

(ix) A statement that the costs associated with the patient's use of medical cannabis may not be covered by insurance or government assistance programs.

(x) That the patient's de-identified health information contained in the patient's medical record within the patient registry may be used for research purposes or used to monitor compliance with this chapter, as further provided in §20-2A-35(c), Code of Ala. 1975, (as amended).

(h) Such other information as the Commission may reasonably require.

(16) All prospective caregivers shall attest to the following:

(a) That the prospective caregiver meets the qualifications for a caregiver set forth in Rule 538-X-2-.04;

(b) That the registered certifying physician has explained to the caregiver the possible risks and benefits associated with the use of medical cannabis;

(c) That the prospective caregiver agrees to serve as the caregiver for the patient identified on their registry submission;

(d) That the prospective caregiver agrees to control the dosage and frequency of the use of medical cannabis in accordance with any instruction for use provided by the certifying physician; and

(e) That the prospective caregiver agrees to comply with the Act and this Chapter.

(f) If the patient is under the age of 19, that the prospective caregiver understands the information provided by the certifying physician and knowingly consents to the use of medical cannabis by the patient.

(17) A caregiver registration shall be valid from the date of issuance and expire one year later.

(18) The Commission shall send a notification to each caregiver 45 calendar days before the expiration date on the caregiver's medical cannabis card.

(19) To maintain a valid caregiver registration, a caregiver must annually renew the caregiver registration submission, in accordance with this Rule. Renewal applications, fees, and required documentation must be submitted no less than 14 calendar days before the expiration of the caregiver's medical cannabis card.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.07 Purchase Of Medical Cannabis By Patients And Caregivers.

(1) A patient or caregiver may only purchase medical cannabis pursuant to a valid and active medical cannabis card, which may be tangible or virtual, demonstrating certification by a registered certifying physician pursuant to the Act and this Chapter.

(2) Patients under 19 years of age shall be issued a medical cannabis card identifying them as a minor, and such patients are prohibited from purchasing medical cannabis except through a caregiver.

(3) Requiring patients and caregivers to possess a medical cannabis card lawfully obtained pursuant to the Act and this Chapter does not infringe on the cardholder's state or federal constitutional rights. (§20-2A-11, Code of Ala. 1975, (as amended)).

(4) Upon entry into a dispensing site and before purchasing medical cannabis, patients and caregivers must provide their medical cannabis card; at the discretion of the dispensary or integrated facility operating the dispensing site, patients and caregivers also may be asked to provide additional photo or other approved identification, including an unexpired Alabama driver's license, an unexpired Alabama identification card issued by ALEA; passport; or any other identification proving identity as approved by the Commission.

(5) Any persons, including children or guests of patients or caregivers, who are unable to provide a medical cannabis card matching a valid patient registry profile, or who are unable to provide, upon request, additional identification to the satisfaction of dispensing site personnel, are prohibited from entering the dispensing site. This rule does not apply to employees, representatives of other licensees, Commission members

or personnel or inspectors, third parties visiting the dispensing site at the request of the Commission or the licensee, or who are entering the facility for the purpose of performing repairs or maintenance at the dispensing site.

(6) The identification number on the medical cannabis card provided to a dispensary employee must be identical to the identification number included in the patient or caregiver's profile in the patient registry.

(7) Before purchasing medical cannabis, patients and caregivers must provide the dispensing employee their medical cannabis card; at the discretion of the dispensing site, they also may be asked to provide additional identification as described in paragraph 4. of this rule.

(8) A registered certifying physician does not prescribe medical cannabis but merely sets a recommended form of intake (i.e., oral tablet, capsule, tincture, inhaler, lotion, etc.) and THC content, up to a maximum daily dosage of medical cannabis for the patient based on the patient's diagnosis, qualifying medical condition, age, size, and other individual factors. Such determinations as to form and THC content to be recommended shall be exclusively the province of the registered certifying physician, up to the maximum daily dosage allowed by law, as described in paragraph 9 of this rule. (§20-2A-33(f)(1), Code of Ala. 1975, (as amended)).

(9) Dosages of medical cannabis purchased by a patient or caregiver shall be limited to the lower of the maximum daily dosage recommended for the patient by the licensed certifying physician, or the maximum daily dosage permitted by law under the Act and this Chapter:

(a) As to all patients, regardless of the form of administration or the patient's condition or individual factors, the initial maximum daily dosage recommended by the registered certifying physician may be lower than, but shall not exceed, 50 mg of delta-9 THC.

(b) A registered certifying physician who initially sets the maximum daily dosage at a level lower than 50 mg of delta-9 THC may increase the maximum daily dosage, to an amount less than or equal to 50 mg delta-9 THC, subject to subparagraph c., at any time upon review with the patient during a follow-up visit.

(c) If 90 days have passed during which the patient has been unsuccessfully treating with medical cannabis while under the registered certifying physician's care, and the registered

certifying physician determines that a higher dosage of medical cannabis, up to 75 mg of delta-9 THC is medically appropriate, a registered certifying physician may increase the maximum daily dosage beyond 50 mg of delta-9 THC, but not to exceed 75 mg of delta-9 THC. (§20-2A-33(f)(2)a., Code of Ala. 1975, (as amended)).

(d) A registered certifying physician may increase the maximum daily dosage beyond 75 mg of delta-9 THC at any time the patient has been diagnosed with a terminal illness, but only after the registered certifying physician notifies the patient that the patient's driver's license will be suspended. (§ 20-2A-33(f)(2)b., Code of Ala. 1975, (as amended)).

(e) A registered certifying physician may not lawfully recommend the use of medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol to any minor for any qualifying medical condition. A minor may not legally use medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol, whether or not the minor has a valid medical cannabis card. The caregiver of a minor who holds a medical cannabis card may not legally possess medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol, unless the caregiver holds a medical cannabis card based on their own qualifying medical condition or holds a caregiver medical cannabis card on behalf of a patient who is not a minor.

(10) Notwithstanding the foregoing, the number of daily doses of medical cannabis that may be purchased by a patient or caregiver at one time shall be limited to the lesser of:

(a) a 60-day supply; or

(b) the number of doses equal to the number of days since the patient's or caregiver's last purchase of medical cannabis;
or

(c) as recommended by the registered certifying physician.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.08

Restrictions On Patients And Caregivers.

(1) Patient and caregiver registrations are non-transferrable.

(2) Patients and caregivers shall not engage in the cultivation of medical cannabis or the manufacture of medical cannabis extract. Registration as a patient or caregiver is not a license under the Act or this Chapter to cultivate, produce, transport, or dispense medical cannabis.

(3) No patient or caregiver shall provide or accept samples of medical cannabis.

(4) Patients and caregivers shall purchase medical cannabis only from a certified medical cannabis dispensing site operated by a dispensary or integrated facility licensed by the Commission.

(5) Patients and caregivers shall store medical cannabis in a secure location so as to prevent theft, loss, or access by persons not authorized under the Act and this Chapter.

(6) Patients and caregivers shall carry their medical cannabis cards with them whenever they are in possession of medical cannabis. No more than a 70-day supply of medical cannabis, as then recommended by the patient's registered certifying physician, may be possessed by or on behalf of a single patient at any time.

(7) Medical cannabis shall be maintained in one of the following containers at all times until administered to, or by, a patient:

(a) The original dispensing package with an unaltered dispensary label in accordance with the Act and these Rules;
or

(b) A container for storing medical cannabis provided by a dispensary or integrated facility in accordance with the Act and these Rules.

(8) Medical cannabis shall not be possessed or administered on federal property or in federal buildings.

(9) Medical cannabis shall not be possessed or administered at state or federal correctional detention facilities, including but not limited to prisons and juvenile detention centers.

(10) Medical cannabis shall not be possessed or administered in any public or private place where medical cannabis is prohibited.

(11) Medical cannabis shall not be administered or possessed outside of its packaging on the premises of a dispensing site or any other licensed facility under the Act or these Rules.

(12) No patient shall operate a motor vehicle, watercraft, heavy machinery, or aircraft while under the influence of medical cannabis.

(13) A caregiver may receive compensation for services provided as a caregiver in addition to reimbursement for reasonable expenses incurred in the provision of services as a caregiver.

(14) The Commission shall notify patients and caregivers upon the expiration of the patient's or caregiver's registration, or if the patient's registration is suspended or revoked. In such event, patients, caregivers and, in the event of death, personal representatives of patients and caregivers, shall dispose of all medical cannabis within seven calendar days after the patient's death or expiration of their registration. Acceptable methods for the disposal of medical cannabis shall be available at the Commission's website.

(15) An Alabama Medical Cannabis Card is valid only within the State of Alabama and may only be issued to and used by Alabama Residents as defined in these Rules.

(16) Alabama Medical Cannabis Cards may not be obtained or used by non-residents, even though the non-resident is present in Alabama or is eligible to receive cannabis in any form for any reason under the laws of another jurisdiction.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.09

Voluntary Relinquishment Or Termination Of Medical Cannabis Card.

(1) At any time, a patient or caregiver may voluntarily relinquish their certification as such by written notification to the certifying physician or the Commission.

(2) The registered certifying physician or the physician's designated representative shall inform the Commission by notation on the patient registry within 72 hours of (1) receiving written notification of the patient's or caregiver's decision to voluntarily relinquish the patient's or caregiver's medical cannabis certification; (2) determining that a patient is no longer under a diagnosis of a qualifying condition; (3) being notified of the death of the patient or caregiver; or (4) learning that the caregiver has quit, been terminated, or for any

other reason is no longer acting as caregiver with respect to the patient.

~~(3) The employer of a professional caregiver employed by a hospital, long term care facility or hospice program licensed under Alabama law shall inform the Commission by notation on the patient registry within 72 hours of (1) being notified of the death of the patient or caregiver; or (2) learning that the caregiver has quit, been terminated, or for some other reason is no longer acting as caregiver with respect to the patient.~~

~~(4)~~ (3) A patient or caregiver may, upon learning from a licensed certifying physician that the patient no longer has a diagnosis of a qualifying condition:

(a) Inform the Commission, by notation on the patient registry, of the patient's intention to dispute or obtain documentation of an alternate qualifying condition (resulting in the suspension and not the revocation of the patient's certification);

(b) Obtain and cause to be submitted, within 30 days, documentation from another qualified licensed certifying physician that, despite the prior physician's change in diagnosis, the patient has a diagnosis of a qualifying condition; however, failure to submit the required documentation within 30 days shall result in the revocation of the patient's certification, thereafter requiring full documentation and payment of the application fee to resubmit.

~~(5)~~ (4) No patient or caregiver may maintain an active registration (as demonstrated by a valid medical cannabis card) without an active diagnosis of a qualifying medical condition as provided in the Act or these Rules. Medical cannabis shall not be purchased or otherwise obtained without an active certification from a licensed certifying physician as demonstrated by a valid medical cannabis card. A suspended certification prohibits the patient or caregiver from possessing, ingesting, administering, or purchasing medical cannabis.

~~(6)~~ (5) If a patient's medical cannabis card has been suspended or revoked, the medical cannabis card of the patient's caregiver applicable to that patient if any, likewise shall be suspended or revoked.

Author: William H. Webster; Justin C. Aday

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: **New Rule:** Published August 31, 2022; effective October 15, 2022. **Amended:** Published ; effective .

Circumstances Requiring Notice To The Commission.

(1) A patient or caregiver must notify the Commission within 72 hours of learning that the patient's or caregiver's medical cannabis card has been lost or stolen, used fraudulently or has otherwise been accessed without authorization. After notification that a medical cannabis card has been lost, stolen, or used fraudulently or has otherwise been accessed without authorization, the Commission may, pursuant to the provisions of this Chapter and the patient's or caregiver's payment of the medical cannabis card replacement fee provided in the Commission's schedule of fees, issue a new medical cannabis card with a new registry number.

(2) If a patient is deceased, the patient's physician, caregiver, if any, or a legal representative of the patient, shall notify the Commission as soon as possible but not later than 72 hours of learning of the patient's death.

(3) A patient or caregiver shall report to the Commission within 14 calendar days an arrest, conviction or pendency of the following charges against the patient or caregiver:

(a) Any felony offense under the laws of Alabama;

(b) Any felony offense under federal law;

(c) Any crime under the laws of another jurisdiction that would constitute a felony offense under the laws of Alabama;

(d) Any misdemeanor offense under the laws of Alabama, federal law, or the laws of another jurisdiction involving the possession, use, or distribution of illegal drugs; the operation of a motor vehicle, watercraft, or aircraft while under the influence of an illegal substance; or any crime involving fraud, theft, violence, abuse or neglect.

(4) If a patient has a caregiver, that caregiver may provide any required notification to the Commission on behalf of the patient using the same forms and process in accordance with the Act and this Chapter.

(5) A patient or caregiver must notify the Commission of any change in information (other than a change in qualifying medical condition or as set forth above) previously provided to the Commission, not later than 72 hours after learning of such change.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.11 Sanctions.

(1) The Commission, after notice and hearing in accordance with the Act and these Rules, may impose any one or more of the following sanctions on a patient or caregiver if the Commission finds the individual engaged in any of the conduct set forth in paragraph 2. of this rule:

(a) Revoke, suspend, restrict, limit, or refuse to grant or renew the patient's or caregiver's medical cannabis card;

(b) Place the patient or caregiver on probation for a period not longer than one year; or

(c) Issue a written reprimand to the patient or caregiver and include a notation of the reprimand in the patient registry.

(2) The Commission may impose the sanctions listed in paragraph 1. of this rule if the Commission finds:

(a) The prospective patient or caregiver fails to meet the requirements set forth in the Act and this Chapter;

(b) Any information provided to the Commission by the patient or caregiver was false or misleading;

(c) The prospective patient's or caregiver's registration submission is, or at any time has been, revoked, suspended, or denied by another jurisdiction;

(d) The applicant is a prospective caregiver who has attempted to or did serve as a caregiver for an impermissible number of patients;

(e) The caregiver's patient had their patient registration suspended, revoked, or inactivated and the caregiver failed to voluntarily relinquish their caregiver registration;

(f) The prospective caregiver attempted to register to serve as a caregiver for a patient whose medical cannabis card or registration has been denied or suspended, either in Alabama or under the laws of another jurisdiction;

(g) The patient (1) obtained more than the legally permissible supply of medical cannabis during a 60-day period or (2) possessed more than 70 days' supply of medical cannabis at any one time. A legally permissible supply includes the aggregate amount of medical cannabis obtained by all the patient's caregivers;

(h) The caregiver obtained more than the legally permissible supply of cannabis in a 60- day period on behalf of a single patient;

(i) The patient is no longer diagnosed with a qualifying condition and the patient or caregiver has failed to voluntarily relinquish the patient's registration and return the medical cannabis card or obtain another diagnosis and provide proper documentation as required by the Act and this Chapter;

(j) The patient or caregiver failed to report any changes in any information related to the patient or caregiver, other than a change in medical condition, required under the Act and this Chapter within 72 hours of learning of such change;

(k) The patient or caregiver failed to report actual knowledge of any act or omission by any individual or entity whereby cannabis or medical cannabis was being illegally diverted in violation of the Act or these Rules;

(l) The patient or caregiver used or maintained medical cannabis in a manner that puts others at risk or failed to take reasonable precautions to avoid putting others at risk;

(m) The patient or caregiver sold, gave, dispensed or administered a patient's medical cannabis to any other person (i.e., diverted cannabis), including other patients or caregivers);

(n) The patient or caregiver allowed another person to use the patient's or caregiver's medical cannabis card;

(o) The patient's or caregiver's medical cannabis card or registration was fraudulently used or improperly accessed by a person without authorization and the patient or caregiver failed to notify the Commission within 72 hours of learning that the card or registry was accessed without authorization;

(p) The patient consumed medical cannabis using a method of administration that is not permitted by the Act or this Chapter;

(q) A caregiver administered medical cannabis to a patient using a method of administration that is not permitted under the Act or this Chapter.

(r) The patient consumed, or the caregiver allowed medical cannabis to be consumed, in a place where consumption is prohibited by the Act or this Chapter;

(s) The patient or caregiver tampered with, falsified, altered, modified or allowed another person to tamper with, falsify, alter or modify, a patient's or caregiver's medical cannabis card;

(t) The patient operated a motor vehicle, watercraft, heavy machinery, or aircraft under the influence of medical cannabis;

(u) The patient or caregiver attempted to or did grow or cultivate, process, or transport cannabis contrary to the Act, these Rules and/or other Alabama law (i.e., illicit cannabis);

(v) The patient or caregiver knowingly misrepresented any fact or circumstance related to the medical use of cannabis to the Commission, law enforcement, licensed certifying physician, or a dispensary employee.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.12 Involuntary Suspension Of Certification.

(1) The Commission, acting as a body or through its agents, may suspend a patient's or caregiver's certification to hold a medical cannabis card by using a telephone or video conference call to review the allegations and make its determination. The Commission shall endeavor to hold the telephone or video conference at a mutually agreeable time. The patient's or caregiver's failure to appear for a telephone or video conference call required by the Commission or its agents shall be deemed evidence to support the contemplated suspension. If the Commission, acting as a body or through its agents, in consultation with the recommending physician, determines that there is clear and convincing evidence that the patient's or caregiver's medical cannabis card is being abused, such that continuing to furnish or dispense medical cannabis to the patient or caregiver, presents a danger of immediate and serious harm to

the patient, caregiver, or to others, the Commission may suspend the individual's certification without a hearing, pending final adjudication to determine whether permanent sanctions as set forth in this Chapter are appropriate.

(2) Except as stated above, the Commission shall follow the procedure for suspension of a medical cannabis card only upon holding a hearing as set forth in Chapter 1 of these Rules. The suspension shall remain in effect, unless removed by the Commission, until the Commission's final adjudication order becomes effective, except that if the Commission does not issue its final adjudication order within ninety days after the hearing, the suspension shall thereafter be void.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

538-X-2-.13 Confidential Information.

Any document that is a patient record or that contains information that is required to be kept confidential according to any state or federal law, for purposes of the administrative hearing only, may be provided to a representative of record or to a witness in any proceedings before the Commission or any appeal or other administrative or judicial proceedings arising therefrom. Confidential information may also be provided in response to a judicial order or a subpoena by any party issued from a court of competent jurisdiction. Except as stated herein, confidential information shall not be disseminated to any other person unless the confidential information is redacted.

Author: William H. Webster

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Published August 31, 2022; effective October 15, 2022.

**CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR**

(Pursuant to Code of Alabama 1975, §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on Thursday, December 7, 2023, and filed with the agency secretary on Thursday, December 7, 2023.

AGENCY NAME: Alabama Medical Cannabis Commission

INTENDED ACTION: New

RULE NO.: 538-X-3-.20

(If amended rule, give specific paragraph, subparagraphs, etc., being amended) **N/A - New Rule**

RULE TITLE: Special Procedures Relating to Certain Applications

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Adopted with changes. No comments were received. The final rule eliminates of those provisions relating to prior third party scoring, pursuant to the November 23, 2023 order of the Montgomery County Circuit Court, enjoining the Commission from utilizing the previous third-party scoring system.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XLII, ISSUE NO. 1, AAM,
DATED TUESDAY, OCTOBER 31, 2023.

STATUTORY RULEMAKING AUTHORITY: Code of Ala. 1975, §20-2A-22, as amended.

REC'D & FILED
(Date Filed)
(For LRS Use Only)
DEC 11, 2023
LEGISLATIVE SVC AGENCY

John McMillan

John McMillan

Certifying Officer or his or her
Deputy

(NOTE: In accordance with §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.)

538-X-3-.20

Special Procedures Relating to Certain Applications.

The following special procedures shall apply to all license applications that both (1) were subject to an administrative stay issued by the Commission on August 31, 2023, or the Temporary Restraining Order as referenced in orders issued by the Montgomery County Circuit Court dated August 21, 2023, August 30, 2023, and September 11, 2023; and (2) are, or become, subject to an award of license by the Commission on or after the effective date of this Rule.

Notwithstanding any other provision of the Commission's Rules:

1. Applicants whose applications were deemed submitted by the Commission but, because of file size limitations in the application portal, were either (i) unable to submit all or portions of exhibits associated with such application; or (ii) required to submit exhibits that were compressed, truncated or otherwise distorted, shall be permitted to submit, within ten (10) business days after the date on which any such applicant becomes subject to an award of license by the Commission, a full copy (PDF via USB flash drive) of such exhibits to the Commission along with the following sworn statement:

STATE OF
COUNTY OF

CERTIFICATION

I hereby attest and certify that:

1. I am [insert name]. I am [insert position] of [insert applicant name] (hereafter the "Applicant") and am authorized to submit this certification on its behalf. I have knowledge of the facts set forth in this certification.

2. The Applicant attempted in good faith to submit the exhibits listed below on or before the application deadline of December 30, 2022 but, because of file size limitations in the application portal, was either (i) previously not submitted; or (ii) compressed, truncated or otherwise distorted:

[insert description of exhibits]

3. For each exhibit listed above, I have attached a true and correct copy of metadata confirming (a) the date and time of such exhibit's creation and modification, reflecting the existence of such exhibit as of the application deadline; and (b) that such exhibits have not been altered since such date.

SIGNED this the ____ day of _____, 202_.

[insert name]

SWORN TO and subscribed before me on this the ____ day of _____, 202_.

NOTARY PUBLIC

My Commission Expires:

[SEAL]

2. After submission of full copies of any exhibits referenced in Paragraph 1 above, the Commission shall make available to the public copies of all application materials for each applicant. The application materials so disclosed shall be in unredacted form, except for (a) personally identifiable information and (b) trade secrets or competitively sensitive information.

Information bearing on the financial ability of the applicant shall generally not be deemed competitively sensitive information for this purpose, however, nothing in this paragraph shall require disclosure of information obtained by the Commission from third parties and exempt from the Open Records Act under Ala. Code § 20-2A-55 (c) and (d). Applicants which have previously submitted a public copy of their application with redactions not permitted under this paragraph shall submit a new redacted copy (PDF via USB flash drive) to assist the agency staff with publication requirement within ten (10) business days after the date on which any applicant becomes subject to an award of license by the Commission, and the agency staff reserves the right to make further revisions to the redactions as required to meet the requirements of this paragraph. The Commission shall follow the procedure set forth in Ala. Code § 20-2A-56(a) regarding this information and the submission and receipt of public comment and shall permit additional public comments to be filed within thirty (30) days after the date on which any applicant becomes subject to an award of license by the Commission.

3. The Commission will provide notice to all applicants who are preliminarily determined to have failed one or more pass/fail items under Ala. Code § 20-2A-56(b) and Ala. Admin. Code § 538-x-3-.14, and any such applicant shall have ten (10) business days to show cause, through a written submission, as to why their application should not be rejected due to such pass/fail item(s).

4. Each Applicant will be given an opportunity, but not the obligation, to address their application and to answer questions from the Commissioners or the Commission staff, subject to the following time limitations:

License Category	Individual Time Limitation
Integrated Facility	45 Minutes
Cultivator	20 Minutes
Secure Transporter	20 Minutes
State Testing Laboratory	20 Minutes
Processor	20 Minutes
Dispensary	20 Minutes

The presentations will be scheduled by the Commission, to be conducted not earlier than thirty (30) days after the date on which any applicant becomes subject to an award of license by the Commission. The presentations shall be open to the public. Those participating in the presentations on behalf of the applicant must be physically present at the meeting site designated by the Commission, however, members of the Commission may observe and ask questions in person or by virtual means. As part of such presentation, and without extending the time limitation provided herein, Applicants may present video evidence or a written brief, not exceeding 20 pages, regarding the applicant's existing or proposed facilities, ~~other matters identified in their application, or the appropriateness and application of the previous scoring results, which may include, but is not limited to, identification of instances where the applicant asserts that the scoring results were impacted by truncated, compressed, distorted or missing exhibits permitted to be submitted in full as provided in Paragraph 1 above~~ and other matters identified in their application. (Example: An applicant who is allowed 20 minutes for a presentation and who has submitted a 10-minute video will be permitted, at the presentation, to show the video and make a 10-minute live presentation.) Any such video evidence or written brief shall be submitted to the Commission at least five (5) business days in advance of the applicant's scheduled presentation. Applicants presenting a video must submit the video via USB flash drive. Applicants presenting a written brief must submit an original electronic version (PDF via USB flash drive) and twenty (20) hard copies. The presentation sessions shall be managed by the Commission's Chair or his or her designee, who may extend the time limitations as needed to accommodate questions from Commissioners. Each applicant making a presentation shall be responsible for the cost for the court reporter and preparation of a transcript of their presentation and question and answer session. Presentation sessions may be videotaped to be available for later review by Commissioners.

~~5. Regarding third party scoring data and tabulations previously generated for applications:~~

~~a. Within ten (10) business days after the date on which any applicant becomes subject to an award of license by the Commission, the Commission will make available to all applicants:~~

~~(i) General scoring criteria utilized by the third party scorers, along with information in the Commission's possession regarding each scorer's training and qualifications, excluding personal identifying information.~~

~~(ii) Notice of any instance where the same scorer was not used in scoring the same sections of applications within a license category.~~

~~b. In addition to the general disclosures identified in Subparagraph a. above, the Commission will, upon written request received by the Commission within thirty (30) days after the date on which any applicant becomes subject to an award of license by the Commission, provide any such requesting Applicant with the opportunity to inspect scoring sheets and any specific notes of third party evaluators for such Applicant in the Commission's possession, subject to the prior redaction of personal identifying information of the evaluator or third parties other than the applicant. Fees for the compilation, redaction and copying of such material by the Commission shall be subject to the same payment(s) as permitted to be imposed by the Commission for public records requests.~~

~~c. As provided in Ala. Admin. Code § 538-X-3-.12, the Commission remains the primary decisionmaker with regard to licensing and each Commissioner retains full discretion to act independently of the previously generated third-party scoring and evaluations in applying the statutory and regulatory criteria.~~

~~6.~~ As soon as practicable after the presentations are completed for an individual license category, the Commission will conduct a meeting to deliberate and award licenses in such license category. In order to determine the order in which Applicants should be considered, each Commissioner will be given an opportunity to submit, in an open meeting, a written form providing an overall preliminary rank, in descending order, of each of the Applicants in the license category, giving due consideration to all statutory and regulatory criteria. Such forms shall be tabulated and averaged by the Commission staff and used solely to determine the order in which individual Applicants are subsequently considered. In those instances where two or more applicants receive identical average rankings, the order shall be determined by a drawing. The Chair will call for a motion to approve or deny each application in the order established above. Following such motion, duly seconded, the Chair will provide an opportunity for further deliberations and a vote.

~~7~~6. The Applicant has the sole responsibility to ensure proper and timely submission of any form, document, video, or other item submitted to the Commission pursuant to the provisions of this rule. Any form, document, video, or other item submitted to the Commission pursuant to the provisions of this rule shall be mailed or hand-delivered to the Commission at the address provided below.

Alabama Medical Cannabis Commission
RSA Dexter Avenue Building

445 Dexter Avenue, Suite 8040
Montgomery, AL 36104

[~~8~~7](#). If any provision of this Rule, as amended, or the application of such provision or amendment to any person or circumstance is invalidated by a Court, the remainder of this Rule, as amended, and the application of the provisions of such to any person or circumstance shall not be affected thereby.

Author: Mark D. Wilkerson

Statutory Authority: Code of Ala. 1975, §§20-2A-22, as amended.

History: New Rule: Adopted October 12, 2023; Filed October 18, 2023; [Effective February 12, 2024](#).

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

CHAPTER 540-X-25
PHYSICIAN RECOMMENDATION OF THE USE OF MEDICAL CANNABIS

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540-X-25-.01 Preamble.

This Chapter implements the provisions of the Darren Wesley ‘Ato’ Hall Compassion Act (Act 2021-450; Ala. Code §§ 20-2A-1, et. seq.) relating to the physician recommendation of medical cannabis. This Chapter shall establish the eligibility requirements and process for a licensed physician to qualify as a registered certifying physician. This Chapter will also establish the requirements for a registered certifying physician to issue a physician certification for a patient to use medical cannabis. Nothing in this Chapter shall overrule, modify, or replace the Board’s regulations on prescribing controlled substances and standards for pain management services, as these regulations also apply to a physician’s recommendation of medical cannabis.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.02 Definitions.

The following definitions shall apply to the rules in this chapter:

(1) AMCC. The Alabama Medical Cannabis Commission created pursuant to Ala. Code § 20-2A-20.

(2) BOARD. The Alabama State Board of Medical Examiners.

(3) CANNABIS. All parts of any plant of the genus cannabis, excluding industrial hemp or hemp regulated under Ala. Code §§ 2-8-380, et. seq., whether growing or not, including the seeds, extractions of any kind from any part of the plant, and every compound, derivative, mixture, product, or preparation of the plant.

(4) CERTIFY. To confirm or diagnose through a medical examination in compliance with these rules that a patient has a qualifying medical condition that conventional medical treatment or therapy has failed to treat or for which medical cannabis is indicated by the current standard of care.

(5) CHRONIC PAIN. A state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three (3) months), and which may or may not be associated with an acute or chronic pathological process that causes continuous or intermittent pain over a period of months or years.

(6) CULTIVATOR. An entity licensed by the Department of Agriculture and Industries under Ala. Code § 20-2A-62 authorized to grow cannabis pursuant to Ala. Code §§ 20-2A-1, et. seq.

(7) DAILY DOSAGE. The total amount of one or more cannabis derivatives, including, but not limited to, cannabidiol and tetrahydrocannabinol, which may be present in a medical cannabis product that may be ingested by a registered qualified patient during a 24-hour period, as determined by a registered certifying physician.

(8) DISPENSARY. An entity licensed by the AMCC under Ala. Code §§ 20-2A-64 authorized to dispense and sell medical cannabis at dispensing sites to registered qualified patients and registered caregivers pursuant to Ala. Code §§ 20-2A-1, et. seq.

(9) DISPENSING SITE. A site operated by a dispensary licensee or an integrated facility licensee.

(10) ECONOMIC INTEREST. The rights to either the capital or profit interests of an applicant or licensee or, if the applicant or licensee is a corporation, the rights to some portion of all classes of outstanding stock in the corporation.

(11) INTEGRATED FACILITY. An entity licensed under Section 20-2A-67 authorized to perform the functions of a cultivator, processor, secure transporter, and dispensary pursuant to Article 4.

(12) INTRACTABLE PAIN. Chronic pain for which, in the generally accepted course of medical practice, the cause cannot be removed or otherwise treated.

(13) LICENSEE OF THE AMCC. Any person, business, or other entity possessing, or seeking to obtain, a license issued by the Alabama Medical Cannabis Commission; including, but not limited to, a cultivator, dispensary, integrated facility, processor, or secure transporter.

(14) MEDICAL CANNABIS. A medical grade product that contains a derivative of cannabis for medical use by a registered qualified patient and is in a form set forth in

Ala. Code § 20-2A-3(14)a. and shall not include any of the forms prohibited by Ala. Code § 20-2A-3(14)b.

(15) MEDICAL CANNABIS CARD. A valid card issued pursuant to Ala. Code § 20-2A-35.

(16) MEDICAL USE or USE OF MEDICAL CANNABIS or USE MEDICAL CANNABIS. The acquisition, possession, use, delivery, transfer, or administration of medical cannabis authorized by Ala. Code §§20-2A-1, et. seq. These terms do not include possession, use, or administration of cannabis that was not purchased or acquired from a licensed dispensary.

(17) PATIENT REGISTRY. The Alabama Medical Cannabis Patient Registry System that is an electronic integrated system that tracks physician certifications, patient registrations, medical cannabis cards, the daily dosage and type of medical cannabis recommended to qualified patients by registered certifying physicians, and the dates of sale, amounts, and types of medical cannabis that were purchased by registered qualified patients at licensed dispensaries.

(18) PHYSICIAN CERTIFICATION. A registered certifying physician's authorization for a registered qualified patient to use medical cannabis.

(19) PROCESSOR. An entity licensed by the AMCC under Ala. Code § 20-2A-63 authorized to purchase cannabis from a cultivator and extract derivatives from the cannabis to produce a medical cannabis product or products for sale and transfer in packaged and labeled form to a dispensing site pursuant to Ala. Code §§ 20-2A-1, et. seq.

(20) QUALIFYING MEDICAL CONDITION. Any of the following conditions or symptoms of conditions, but only after documentation indicates that conventional medical treatment or therapy has failed unless current medical treatment indicates that use of medical cannabis is the standard of care:

- (a) Autism Spectrum Disorder (ASD).
- (b) Cancer-related cachexia, nausea or vomiting, weight loss, or chronic pain.
- (c) Crohn's Disease.
- (d) Depression.
- (e) Epilepsy or a condition causing seizures.
- (f) HIV/AIDS-related nausea or weight loss.
- (g) Panic disorder.
- (h) Parkinson's disease.
- (i) Persistent nausea that is not significantly responsive to traditional treatment, except for nausea related to pregnancy, cannabis-induced cyclical vomiting syndrome, or cannabinoid hyperemesis syndrome.
- (j) Post Traumatic Stress Disorder (PTSD).
- (k) Sickle Cell Anemia.
- (l) Spasticity associated with a motor neuron disease, including Amyotrophic Lateral Sclerosis (ALS).
- (m) Spasticity associated with Multiple Sclerosis (MS) or a spinal cord injury.
- (n) A terminal illness.
- (o) Tourette's Syndrome.

(p) A condition causing chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or has proved ineffective.

(21) RECOMMEND. To authorize the daily dose and type of medical cannabis to be used by a registered qualified patient to treat a qualifying medical condition.

(22) REGISTERED CAREGIVER. An individual who meets the requirements described in subsection (c) of Ala. Code § 20-2A-30 and is authorized to acquire and possess medical cannabis and to assist one or more registered qualified patients with the use of medical cannabis.

(23) REGISTERED CERTIFYING PHYSICIAN. A physician authorized by the Board to certify patients for the use of medical cannabis.

(24) REGISTERED QUALIFIED PATIENT. Either of the following:

(a) An adult who meets the requirements described in subsection (a) of Ala. Code § 20-2A-30 and is authorized to acquire, possess, and use medical cannabis pursuant to Ala. Code §§ 20-2A-1, et. seq.

(b) A minor who meets the requirements described in subsection (b) of Ala. Code § 20-2A-30 and is authorized to use medical cannabis pursuant to this chapter with the assistance of a registered caregiver.

(25) SECURE TRANSPORTER. An entity licensed by the AMCC under Ala. Code § 20-2A-65 authorized to transport cannabis or medical cannabis from one licensed facility or site to another licensed facility or site.

(26) TERMINAL ILLNESS. An illness or physical condition which can reasonably be expected to result in death in six (6) months or less after the date of the certification.

(27) UNRESTRICTED. When referring to a license to practice medicine or osteopathy, an Alabama Controlled Substance Certificate (ACSC) registration, or a Drug Enforcement Administration (DEA) registration, a license, certificate, or registration which is unencumbered by any restriction or condition or which is otherwise not subject to current discipline, and which has not been revoked, suspended, placed on probation, or voluntarily surrendered within the past five (5) years.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.03 Registration of Physicians for Certifying the Use of Medical Cannabis.

Every physician licensed to practice in Alabama who certifies or recommends a patient for the use of medical cannabis within Alabama pursuant to Ala. Code §§ 20-2A-1, et. seq. or who proposes to certify or recommend a patient for the use of medical cannabis within Alabama must obtain annually an Alabama Medical Cannabis Certification Permit from the Board.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.04 Requirements for Initial Application for Alabama Medical Cannabis Certification Permit.

(1) To obtain an Alabama Medical Cannabis Certification Permit, a physician applicant shall submit the following to the Board:

- (a) A completed application on a form prescribed by the Board.
- (b) Proof of an active, unrestricted license to practice medicine or osteopathy in Alabama.
- (c) Proof of an active, unrestricted Alabama Controlled Substances Certificate (ACSC).
- (d) Proof of an active, unrestricted, Alabama-specific DEA registration.
- (e) Proof of a current registration to query the Alabama Prescription Drug Monitoring Program (PDMP) that is established and maintained by the Alabama Department of Public Health.
- (f) Proof of a current registration with the Alabama Medical Cannabis Patient Registry System that is established and maintained by the AMCC.
- (g) Proof of completion of a four (4) hour course related to medical cannabis, and a passing grade on a subsequent examination, which has been approved by the Board and offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.
- (h) The disclosure of any controlled substances certificate or registration denial, restriction, or discipline imposed on the physician applicant, or any disciplinary act against any medical or other professional license of the physician applicant.
- (i) A list of all practice locations and/or addresses from which the physician applicant may certify or recommend a patient for the use of medical cannabis.

(j) An initial/reinstatement application fee of three hundred dollars (\$300), which shall be payable to the Board and non-refundable upon submission. An initial/reinstatement application fee is non-transferable.

(2) If a physician applicant does not complete the initial application process within ninety (90) days of his or her first submission to the Board, the application shall be closed, the application fees shall not be refunded or transferred, and the applicant shall be required to reapply for a permit.

(3) An application which is submitted to the Board may be withdrawn at any time prior to the granting or denial of registration; however, the application fees shall not be refunded or transferred.

(4) All initial applications for an Alabama Medical Cannabis Certification Permit are subject to approval by the voting members of the Board and may not be issued on a temporary or preliminary basis.

(5) No Alabama Medical Cannabis Certification Permit shall be issued until the AMCC has issued at least one license each for a cultivator, a processor, a secure transporter, and a dispensary.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.05 Physician Eligibility for an Alabama Medical Cannabis Certification Permit.

No physician shall obtain an Alabama Medical Cannabis Certification Permit unless he or she:

(1) Possesses an active, unrestricted license to practice medicine or osteopathy in Alabama;

(2) Possesses an active, unrestricted ACSC registration;

(3) Possesses an active, unrestricted, Alabama-specific DEA registration;

(4) Has satisfied one of the following experience requirements:

(a) Has been engaged in the active practice of medicine or osteopathy for at least three (3) years, excluding any practice in an internship, residency, fellowship, or other supervised training program; or

(b) Has actively practiced medicine or osteopathy for at least one (1) year, excluding any practice in an internship, residency, fellowship, or other supervised training program, and is certified by a specialty board approved by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS);

(5) Is registered to query the PDMP and has access to the PDMP in all locations where he or she certifies or recommends a patient for the use of medical cannabis;

(6) Is a registered user of the Alabama Medical Cannabis Patient Registry and has access to the registry in all locations where he or she certifies or recommends a patient for the use of medical cannabis;

(7) Has completed a four (4) hour course related to medical cannabis and has received a passing grade on a subsequent examination, which has been approved by the Board and offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™; and

- (8) Has paid all fees required by this Chapter.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.06 Grounds for Denial or Revocation of an Alabama Medical Cannabis Certification Permit.

(1) The Board may deny issuance or renewal of or revoke the Alabama Medical Cannabis Certification Permit of a physician who:

(a) Fails to meet or maintain any of the requirements set forth in Ala. Code §§ 20-2A-1, et seq., or Ala. Admin. Code R. 540-X-25-.01, et seq.;

(b) Furnishes false, misleading, untruthful, or fraudulent information in connection with an application;

(c) Discloses, or fails to disclose, any controlled substances certificate or registration denial, restriction, or discipline imposed on the applicant, or any disciplinary act against any medical license, any controlled substances certificate of registration, or any DEA registration of the physician;

(d) Has been convicted of, pled guilty to, or entered a plea of nolo contendere to a felony or a criminal offense related to the provision of medical services, fraud, or a drug offense, or is under any state or federal restriction, probation, discipline, investigation, or indictment related to a felony, the provision of medical services, fraud, or a drug offense;

(e) Holds a direct or indirect economic interest in a licensee of the AMCC;

(f) Is guilty of any of the acts or offenses listed in Ala. Code § 34-24-360; or

(g) Has violated any rules or regulations of the Board or the Medical Licensure Commission of Alabama.

(2) An applicant who is denied an Alabama Medical Cannabis Certification Permit under this section may petition the Board for reconsideration of the application. Any petition must be filed within thirty (30) days of denial of the permit. Upon receipt of the petition, the Board shall issue the permit or set a hearing thereon. The hearing shall be considered a contested case and shall be governed by the rules on reinstatement hearings in accordance with Ala. Admin. Code R. 540-X-6-.02(1)(b)(3).

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.07 Renewal of an Alabama Medical Cannabis Certification Permit.

(1) Renewal of an Alabama Medical Cannabis Certification Permit shall be annually on or before December 31 of each year.

(2) Annual permit renewal shall occur upon completion of a renewal application in a form prescribed by the Board and payment of a renewal fee.

(3) The fee for annual permit renewal shall be two hundred dollars (\$200).

(4) Any registered certifying physician who fails to renew an Alabama Medical Cannabis Certification Permit by December 31 of the year of its expiration shall be required to reinstate the certificate by reapplying for an initial Alabama Medical Cannabis Certification Permit under the provisions set forth in this Chapter.

(5) Before renewing an Alabama Medical Cannabis Certification Permit, a physician shall have a current and appropriate registration issued by the DEA and a valid ACSC registration issued by the Board.

(6) Before renewing an Alabama Medical Cannabis Certification Permit, a physician shall have a current registration to access and query in all locations where he or she certifies or recommends a patient for the use of medical cannabis:

(a) The Alabama Medical Cannabis Patient Registry system established and maintained by the AMCC; and

(b) The PDMP.

(7) Before renewing an Alabama Medical Cannabis Certification Permit, the physician shall have completed within the last 24 months a continuing medical education (CME) course related to medical cannabis of at least two (2) AMA PRA Category 1 Credits™ that is approved by the Board and is offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.08 Continuing Medical Education Requirements.

(1) Prior to the initial issuance of, or reinstatement thereof, an Alabama Medical Cannabis Certification Permit, a physician shall have, within the two (2) years preceding their application, completed a four (4) hour course related to medical cannabis, and have received a passing grade on a subsequent examination, which has been approved by the

Board and offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.

(2) In order to maintain or renew an Alabama Medical Cannabis Certification Permit, a registered certifying physician shall, every two (2) years, complete a two (2) hour refresher course related to medical cannabis which has been approved by the Board and offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021. Certified Rule Filed March 21, 2022. Effective Date: May 15, 2022.

540-X-25-.09 Limitations Upon registered certifying physicians.

(1) Except for the limited purpose of performing a medical cannabis-related study, a registered certifying physician shall not accept, solicit, or offer any form of remuneration from or to a qualified patient, designated caregiver, or any licensee of the AMCC, including a principal officer, board member, agent, or employee of the licensee, to certify a patient, other than accepting payment from a patient for a fee, not to exceed that which is customarily charged in the locality for physician services, associated with the examination, medical consultation, or other treatment, including, but not limited to, any third party reimbursement for the same.

(2) A registered certifying physician shall not accept, solicit, or offer any form of remuneration from or to a dispensary for the purpose of referring a patient to a specific dispensary.

(3) A registered certifying physician shall not offer a discount of any other item of value to a qualified patient who uses or agrees to designate a specific registered caregiver or use a specific dispensary to obtain medical cannabis.

(4) A registered certifying physician shall not hold a direct or indirect economic interest in a licensee of the AMCC.

(5) A registered certifying physician shall not serve on the Board of Directors or as an employee of a licensee of the AMCC.

(6) A registered certifying physician shall not refer qualified patients to a specific caregiver or a specific dispensary.

(7) A registered certifying physician shall not advertise in a dispensary.

(8) A registered certifying physician, or any practice, facility, business, or other entity with which they are affiliated, shall not advertise on a website, in brochures, or via any other media that generally describe the scope of practice of the physician as a “medical cannabis” or “medical marijuana” physician or doctor, or otherwise advertises his or her status as a registered certifying physician, other than stating the following: “Dr. _____ is qualified by the State of Alabama to certify patients for medical cannabis use under the Alabama Compassion Act.”

(9) A registered certifying physician shall not be located in the same office space as a dispensary.

(10) A registered certifying physician shall not certify or recommend a patient for the use of medical cannabis unless both the registered certifying physician and the patient are physically located in Alabama, and any examination, visit, or other consultation occurs while both parties are physically located in Alabama.

(11) At all times in the certification or recommendation of medical cannabis, a registered certifying physician shall only evaluate, diagnose, or certify those qualifying medical conditions for which he or she possesses the education, training, experience, and specialty training to evaluate, diagnose, or treat in his or her usual medical practice. A physician who recommends medical cannabis to a patient for treatment of a qualifying medical condition that the physician is not trained to treat with conventional medical treatment shall be in violation of these rules.

(12) A registered certifying physician is strictly prohibited from certifying or recommending, or recertifying or re-recommending, the use of medical cannabis to any patient who is pregnant, breastfeeding, or attempting to conceive.

(13) A registered certifying physician is prohibited from certifying or recommending, or recertifying or re-recommending, the use of medical cannabis to any patient who has been diagnosed with a condition for which cannabis is contraindicated under the current standard of care or by evidence-based research.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

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540-X-25-.10 Requirements for Physician Recommendation or Certification for the Use of Medical Cannabis.

(1) In order to recommend a patient for the use of medical cannabis, a registered certifying physician shall, within the scope of his or her usual medical practice or specialty, diagnose a patient with at least one qualifying medical condition or shall confirm, through personal, direct observation and assessment and primary source verification, that the patient has been medically diagnosed, by a physician, with at least one qualifying medical condition.

(2) A registered certifying physician shall establish a bona fide physician-patient relationship with the patient for the provision of medical services in an in-person visit that complies with this Chapter and for which there is an expectation that the physician will provide care to the patient on an ongoing basis.

(a) Prior to certifying or recommending, or recertifying or re-recommending, a patient for the use of medical cannabis, the registered certifying physician shall have conducted a physical examination while physically present in the same room as the patient and obtained a full assessment of the patient's medical history.

(3) A registered certifying physician shall create and maintain a medical record that satisfies the provisions of Ala. Admin Code R. 545-X-4-.09 and shall also include, at a minimum, the following:

- (a) The patient's name and date or dates of office visits or treatments;
- (b) A description of the patient's qualifying medical condition;
- (c) Documented assessment of the patient's medical history, including relevant prescription history and any history of substance use disorder;
- (d) Documented review of any available relevant diagnostic test results;

(e) Documented review of prior treatment and the patient's response to the treatment;

(f) Documented review of the patient's current medication to identify possible drug interactions, including all controlled substances;

(g) Documented review that conventional medical treatment or therapy has been attempted;

(h) A registered certifying physician may obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug to be screened. Results of any such drug screen shall be maintained in the medical record along with documentation of any proscriptive measures taken due to an unsatisfactory screen;

(i) The registered certifying physician's performance of a physical examination relevant to the patient's current medical condition;

(j) The physician's diagnosis of the patient's qualifying medical condition; and

(k) If the patient has been previously diagnosed with a qualifying medical condition by another qualified physician, the registered certifying physician may confirm the diagnosis provided that the registered certifying physician obtains a copy of the medical records or a detailed written summary indicating the diagnosis, and the registered certifying physician is satisfied that he or she can rely on those records to confirm diagnosis of a qualifying medical condition. The registered certifying physician shall maintain a copy of any record or report of any other physician on which the registered certifying physician relied for purposes of meeting the requirements under this paragraph. The registered certifying physician shall verify and document the diagnosing physician's

continuing diagnosis of the patient's qualifying medical condition prior to each recertification.

(4) If the registered certifying physician diagnoses or confirms the diagnosis of a qualifying medical condition, the physician shall document in the medical record compliance with all of the following actions when certifying or recommending treatment with medical cannabis:

(a) Development of a treatment plan, including consideration of whether treatment with medical marijuana is complementary to standard medical treatment.

(b) The review of the patient's controlled drug prescription history in the PDMP. The review shall cover at least the twenty-four (24) months immediately preceding the date of the certification or recertification.

(c) Discussion with the patient regarding any indicators of possible abuse or diversion of controlled substances that are reflected on the PDMP report.

(d) The explanation of the risks and benefits of treatment with medical cannabis as it pertains to the patient's qualifying medical condition and medical history.

(e) The registered qualified patient's voluntary and informed written consent prior to completing a certification or recommendation for treatment with medical cannabis. If the patient is a minor, the physician shall obtain the voluntary and informed written consent of the patient's parent or legal guardian prior to completing a certification or recommendation for treatment with medical cannabis for the patient. The voluntary and informed written consent for all registered qualified patients and/or legal guardians shall be memorialized on a form authorized by the Board, a copy of which shall also be

provided to the patient or legal guardian. The voluntary and informed written consent form shall, at a minimum, include:

1. The federal and state classification of cannabis as a Schedule I controlled substance.
2. The approval and oversight status of cannabis by the Food and Drug Administration.
3. The current state of research on the efficacy of cannabis to treat the qualifying medical condition or conditions.
4. The potential for addiction.
5. The potential effect that cannabis may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require an individual to be alert or respond quickly.
6. The potential side effects of cannabis use.
7. The risks, benefits, and drug interactions of cannabis.
8. A statement that the use of medical cannabis could result in termination from employment without recourse and that costs may not be covered by insurance or government programs.
9. That the patient's de-identified health information contained in the patient's medical record, physician certification, and patient registry may be used for research purposes or used to monitor compliance with Ala. Code §§ 20-2A-1, et. seq.
10. A statement that a certification or recommendation by a registered qualifying physician does not constitute a prescription for medical cannabis.

11. Whether the patient requires the use of a registered caregiver to assist in the use or administration of medical cannabis. If the patient requires or utilizes a registered caregiver, the physician shall document the name of the registered caregiver designated by the patient or the patient's legal representative.

(5) In certifying or recommending treatment with medical cannabis, a registered certifying physician or his or her delegate shall determine from the patient registry whether the patient has an active registration for the use of medical cannabis.

(a) If the patient is not registered or if the patient's registration will expire within thirty (30) days, the registered certifying physician shall submit the patient's application for registration or renewal to the patient registry.

(b) The electronic certification or recommendation for treatment with medical cannabis that is submitted to the patient registry shall include:

1 The registered qualified patient's full legal name, date of birth, and home address;

2. The registered qualifying physician's name and Alabama Medical Cannabis Certification Permit number;

3. The name of the patient's registered caregiver, if applicable;

4. A description of the qualifying medical condition(s) and indication whether the qualifying condition is a terminal illness for which the registered qualified patient has a life expectancy of six (6) months or less;

5. The daily dosage of medical cannabis (as measured by potency of delta-9-tetrahydrocannabinol) that the registered certifying physician is recommending to the registered qualified patient. Any daily dosage recommended by a registered certifying

physician shall not exceed the limitations set forth by the AMCC for each of the qualifying medical conditions;

6. The type or permissible forms of medical cannabis that the registered certifying physician recommends;

7. The permissible length of duration of the certification, which shall not exceed ninety (90) days;

8. A statement from the registered certifying physician certifying that a bona fide physician-patient relationship exists between the registered certifying physician and registered qualified patient;

9. A statement from the registered certifying physician affirming that the registered qualified patient has been diagnosed with at least one qualifying medical condition by either the registered certifying physician or another qualified physician;

10. A statement from the registered certifying physician that, prior to certifying the use of medical cannabis, he or she has, or has confirmed through primary source verification of the patient's medical records that another qualified physician has, attempted conventional medical treatments or therapies for the patient's qualifying medical condition, and that said conventional treatments and/or therapies have failed to result in successful outcomes, or that current conventional medical treatment indicates that the use of medical cannabis is the standard of care for the patient's qualifying medical condition;

11. If the qualifying medical condition is based upon a terminal illness as defined in this Chapter, a statement from the registered certifying physician that the patient is suffering from an illness or physical condition which the registered certifying

physician professionally and reasonably expects to result in the patient's death in six (6) months or less after the date of the certification; provided, a registered certifying physician shall not recertify a patient as having a terminal illness if the patient has been certified as having a terminal illness for a period of twenty-four (24) months or more;

12. An affirmation from the registered certifying physician that he or she, or his or her delegate, has obtained from the PDMP a report of information related to the registered qualified patient that includes, at a minimum, the twenty-four (24) months immediately preceding the date of the certification or recertification; and

13. An affirmation from the registered certifying physician that he or she has informed the registered qualified patient of the risks and benefits of medical cannabis as it pertains to the patient's qualifying medical condition and medical history.

(c) Absent any extenuating circumstances, a registered certifying physician shall, within twenty-four (24) hours, input into the patient registry any certification, recertification, or any updates thereto. Any deactivation shall be entered into the patient registry immediately upon the registered certifying physician becoming aware of the reason for the deactivation.

(6) A registered certifying physician who certifies or recommends treatment with medical cannabis shall be available to provide follow-up care and treatment to the patient, including physical examinations relevant to the patient's condition to determine the efficacy of medical cannabis in treating the patient's qualifying medical condition.

(7) A registered certifying physician shall deactivate a current certification or decline to issue a new certification for medical cannabis under any of the following circumstances:

(a) The registered certified patient no longer has the diagnosis of or symptoms of the qualifying medical condition.

(b) The registered certifying physician no longer possesses a valid Alabama Medical Cannabis Certification Permit.

(c) Based on the registered certifying physician's clinical judgment, the registered qualified patient or registered caregiver is abusing or diverting medical cannabis.

(d) The registered qualified patient is deceased.

(8) The records required for the certification or recommendation of medical cannabis may be kept with the patient's other medical records and shall be retained for at least seven (7) years in accordance with Ala. Admin. Code R. 540-X-9-.10.

(9) The registered certifying physician shall submit to the Board an annual report, in a manner prescribed by the Board, describing the physician's observations regarding the effectiveness of medical cannabis in treating patients. The report shall not contain patient-identifying information.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

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540-X-25-.11 Dosage Limitations of Medical Cannabis Recommendations.

(1) A registered certifying physician may not lawfully recommend the use of medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol to any minor for any qualifying medical condition.

(2) A registered certifying physician shall not recommend a dosage of tetrahydrocannabinol content which exceeds the maximum daily dosage of medical cannabis for the applicable qualifying medical condition, as established by rule of the AMCC.

(3) Subject to the maximum daily dosages established by rule of the AMCC, a maximum daily dosage shall not exceed 50 mg of delta-9-tetrahydrocannabinol; provided, however, that the maximum daily dosage may be increased but still subject to the maximum daily dosages established by rule of the AMCC under either of the following circumstances:

(a) A registered certifying physician may increase a patient's daily dosage if, after 90 days of continuous care under the physician during which time the patient was using medical cannabis, the physician determines that a higher daily dosage is medically appropriate; provided that the maximum daily dosage under this paragraph may not exceed 75 mg of delta-9-tetrahydrocannabinol, and that the physician shall clearly articulate in the patient's medical record the justification for the higher daily dosage; or

(b) A registered certifying physician may increase a patient's daily dosage if the patient has been diagnosed with a terminal illness; provided that, if the recommended daily dosage exceeds 75 mg of delta-9-tetrahydrocannabinol, the physician shall notify the patient that the patient's driver's license will be suspended.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

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