

ALABAMA MEDICAL CANNABIS COMMISSION
ADMINISTRATIVE CODE

CHAPTER 538-X-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: Code of Ala. 1975, §§20-2A-22, as amended.

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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 Ala. 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 credentialing, 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: Code of Ala. 1975, §§20-2A-22, 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 Ala. 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: Code of Ala. 1975, §§20-2A-22, 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 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: Code of Ala. 1975, §§20-2A-22, 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 Ala. 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 Ala. 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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 Ala. 1975, (as amended)).

(12) The following documents, labeled, and in the following order:

(a) The resume 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 Ala. 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 Ala. 1975, (as amended)); the Statewide Seed-to-Sale Tracking System (§20-2A-54, Code of Ala. 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:

(i) Required testing shall be conducted by a State Testing Laboratory (as detailed in 538-X-10-.01, et seq. of these Rules).

(ii) 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.

(iii) 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.

(iv) 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:

(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, 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.

(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 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.

(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) 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.

(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 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.

(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 shall wear identification badges that clearly identify them as employees while on duty.

(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) 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 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.

(xv) 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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 Ala. 1975, (as amended).

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-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 Ala. 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 Ala. 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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: Code of Ala. 1975, §§20-2A-22, 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 Ala. 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 Ala. 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: Code of Ala. 1975, §§20-2A-22, 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 Ala. 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), Code of Ala. 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: Code of Ala. 1975, §§20-2A-22, as amended.
History: New Rule: Published August 31, 2022; effective October 15, 2022.