APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 538

Department or Agency: Alabama Medical Cannabis Commission

Rule No.: 538-X-4-.02

Rule Title: Post-Licensing Inspection Of Facilities

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: Tuesday, July 16, 2024

REC'D & FILED

JUL 16, 2024

LEGISLATIVE SVC AGENCY

APA-2

ALABAMA MEDICAL CANNABIS COMMISSION

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Medical Cannabis Commission

RULE NO. & TITLE: 538-X-4-.02 Post-Licensing Inspection Of Facilities

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:
The proposed action is necessary due to statutory changes in Act 2024-342.

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 (07/31/2024) and for a period of 35 days thereafter (ending on 09/04/2024).

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:
Wednesday, September 4, 2024

CONTACT PERSON AT AGENCY:
Justin Aday

John McMillan

John McMillan

(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

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 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; 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 .