

Inspections, Liability, Violations & Penalties

Alabama

Playing by the rules is essential- always. It's imperative to know the rules and to always play at or one step above what is required to ensure you maintain safe access to cannabis for your patients. **If rules are broken, employees, managers, and the business they work for may face state and/or federal law enforcement action** as well as administrative and civil liability.

When there is non-compliance, regulators will investigate to determine the severity of the violation, who was involved, and will also identify aggravating and mitigating factors in order to determine the penalties to be imposed.

Know your specific location's **standard operating procedures**. Compliance is a team endeavor. If any employee or business breaks the rules, there are consequences. We must be aware of all activity on the licensed premises. We may be held accountable for violations that occur.

Forms of Liability

In the cannabis industry, we can incur the following **three types of liability**:

1. **Criminal Liability:** A person is liable or responsible for a crime when he or she has acted with criminal intent.
2. **Civil Liability:** the legal requirement to compensate another party for causing them some form of bodily injury or property damage.
3. **Administrative Liability:** laws that govern the formation and operation of administrative agencies and the rulings made by administrative agencies. This type of law is sometimes called regulatory law.

Inspections

The Alabama Medical Cannabis Commission (AMCC) **will inspect the business regularly**. This includes immediately prior to commencing operations and then no less often than annually. **Inspections may be announced or unannounced** so it is essential for our team and facility to be compliant and prepared at all times. Inspectors may check the facility, operations, and documentation to determine if there are non-compliance or safety issues. If there are, the business and its employees may incur various penalties, the severity of which depend on who was involved and what took place.

Pre-Commencement Inspection

Once the business is ready to begin operations, they must contact the AMCC to set a date for an announced inspection. Operations cannot begin until the inspection has been passed with no critical violations and all infractions must be corrected by that time. Reinspection after a failed pre-commencement inspection will take place within 30 days. If the licensee fails its reinspection, it must petition the AMCC for permission for a further inspection. If the business fails the third inspection, its license will be revoked.

Announced Inspections

- The AMCC will notify the licensee of the date and time of the announced inspection at least 14 days prior;
- Licensees must make their facilities, personnel, operations, and documentation available for review. This can include, but is not limited to:
 - all areas of all facilities in operation since the last inspection;
 - all facilities not in operation, but anticipated to be;
 - proper credentialing, licensing, qualifications, education, suitability and experience for all personnel;

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- all operations and processes including machinery, equipment and supplies;
- all security monitoring and video surveillance files and log book;
- all IT files including test results, inventory control and tracking systems, and Metrc;
- background check certificates and/or personnel files; and
- all documents provided to the AMCC at the time of licensing.
- Licensees must have a designated compliance liaison who is knowledgeable about the business' facilities, personnel, operations, and documentation. This person will be on hand to answer questions and coordinate with additional persons when needed; and
- Licensees are expected to comply with all inspections with the highest level of integrity and transparency. Failure to do so may lead to sanctions, up to and including license revocation.

Unannounced Inspections

- May be conducted without prior notice at any time;
- Can cover any and all areas described above;
- At the time of licensing, the business will receive confidential instructions relating to procedures for the unannounced inspection. The business must follow the instructions, knowing that the inspection is authentic;
- The licensee must identify an acceptable point-of-contact who will fill the role of compliance liaison;
- Businesses have the same obligations listed above with the same consequences for failing to cooperate.

Third-Party Inspectors

The AMCC may utilize qualified independent third parties and may cooperate with State and Local Agencies in conducting announced and unannounced inspections.

Inspection Reports

After the inspection, the AMCC will issue a written report within 14 days, covering all areas inspected and listing noted infractions and critical violations.

Noted Infractions

- a minor violation or benign difference between the documentation previously provided to the AMCC and actual operations. Those that cannot be corrected immediately and repeated issues will be noted;
- Noted infractions must be corrected within 30 days. Failure to do so or repeat noncompliance of the same noted infraction within (5) years will be sanctionable.

Critical Violations

- An intentional or substantial violation or a material difference between the documentation previously provided to the AMCC and actual operations. Within that difference poses a clear and present danger to the safety of employees, patients, caregivers, or the public;
- In addition to the inspection report, critical violations will be noted in writing to the business at the time of inspection or within 48 hours of it;
- May warrant an immediate shutdown of the facility pending remediation of the violation. The shutdown is for health and safety reasons, but additional sanctions may be applied including license suspension, revocation, or non-renewal;
- Businesses must immediately address and remedy critical violations; and
- Failure to address a critical violation or a repeat of the same issue within (5) years, or more than (3) critical violations within (5) years may result in escalation of sanctions imposed.

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- When determining sanctions, the AMCC may consider whether the conduct was knowing, willful, reckless or negligent, the prior conduct of the licensee, the business' compliance history, and the swiftness with which the licensee addressed and remedied the critical violation.

Re-inspection

If necessary, a re-inspection may be performed to determine if noted infractions or critical violations have been properly remedied. They will be performed no less than 30 days and no more than 45 days from the date of the notice or at a mutually agreeable time and date after the licensee announces they are ready.

Investigation of Licensees

The AMCC may investigate at any time, including when they are acting on reported information or for other reasonable cause or suspicion.

Additional Information

To ensure we are maintaining safety and compliance, we may have other announced and unannounced visits from other agencies. This can include, but is not limited to:

- Local or State Law Enforcement
- Fire Department
- Local and State Health Department
- Dept. of Agriculture
- Permit-granting agents
- Other agencies

If an inspector or investigator arrives at your establishment, invite them to complete the visitor log, request and review their ID if required by the House Policy where you work* (their city or state badge - Driver License usually not required), supply them with a Visitor Pass, and inform your manager. A compliance liaison will escort them to all requested areas and provide access to all requested items.

AMCC Disciplinary Action

Disciplinary measures may include the following:

- 1) **Oral Warning** - For the lightest infractions or matters that must be immediately corrected either while the inspector is present or prior to their submission of the report, with proof of correction by the licensee. Oral warnings are not included on any permanent record.
- 2) **Written Warning** - Provided in instances where an oral warning has been issued or would not be warranted, but a written reprimand is not appropriate. Written warnings are not included on any permanent record, but will be maintained by the AMCC for (1) year after its issuance.
- 3) **Reprimand** - A writing from the AMCC issued where an oral or written warning has been imposed or is not warranted due to the circumstances. May be the least stringent discipline imposed for willful, reckless, or intentional misconduct. The reprimand will include the date, name of licensee, and reasons for issuance and must be kept by the licensee for up to 10 years. May compromise ability to renew the license or lead to future sanctions based on any instances of similar conduct.
- 4) **Administrative Penalties and Fines** - Appropriate where less stringent discipline has been imposed previously or is not warranted. Particularly appropriate to provide restitution for the licensee's misconduct, to defray the costs of administrative intervention, or to emphasize a need to correct misconduct, including willful, reckless, repeated, or intentional misconduct.
- 5) **Probation** - May be implemented in addition to a reprimand and any administrative penalty or fine. Indicates that any further misconduct warranting a reprimand will result in the nonrenewal, suspension or revocation of the license. May be imposed for a maximum of (3) years and will be accompanied by an appropriate penalty or fine.

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- 6) Suspension of License - A temporary restriction on a licensee's ability to lawfully operate its business. Imposed for an anticipated period of time. May not be issued for a period longer than (1) year. Will be noted on the reprimand issued in connection with the misconduct that required suspension. In most cases, will include a penalty or fine and may involve a period of probation following the suspension.
- 7) Revocation of License - The most serious disciplinary measure for grave misconduct by the licensee, usually upon repeated instances of serious misconduct, or posing a serious risk of loss to property, injury, or death, or involving overtly intentional disregard for the authority of the AMCC or other laws. In most cases, 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 when a clear pattern of misconduct has become apparent.
- 8) Civil Penalties, Restitution and Damages - In addition to the disciplinary measures above, the AMCC may notify appropriate civil authorities regarding the licensee's misconduct and will cooperate fully in any civil or administrative proceeding or judgement that may result in civil penalties, restitution, or damages.
- 9) Criminal Penalties - In addition to the disciplinary measures listed above, the AMCC may notify appropriate authorities regarding the licensee's misconduct and will cooperate fully in any criminal investigation that may lead to charges and penalties against the licensee or any associated entity or individual.

CHAPTER 538-X-4 LICENSEE REQUIREMENTS – GENERALLY

538-X-4-.02 Post-Licensing Inspection Of Facilities.

(1) Generally. Inspections of licensees 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.

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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 parttime) 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.

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(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.

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

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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.

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.