

**Alabama Medical Cannabis Commission
Rules and Regulations**

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

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538-x-1-.01 Scope.

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

Author: William H. Webster

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

History: New Rule Filed:

538-x-1-.02 Construction.

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

Author: William H. Webster

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

History: New Rule Filed:

538-x-1-.03 Time.

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

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

Author: William H. Webster

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

History: New Rule Filed:

538-x-1-.04 Definitions.

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

1. "Act." The Darren Wesley "Ato" Hall Compassion Act, § 20-2A-1, et seq., Code of Alabama 1975.
2. "Affiliate" or "Affiliated with." An entity is an "affiliate" of, or "affiliated with", another entity if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with or by, such other entity. The term shall include sister entities (i.e., entities owned, directly or indirectly through one or more intermediaries, by the same parent entity).
3. "Applicant." An entity or individual seeking a license under Article 4 of the Act.
4. "Board." The State Board of Medical Examiners.
5. "Batch." With regard to cannabis means a homogenous, identified quantity of cannabis no greater than ten pounds that is harvested during a specified time period from a specified cultivation area, and with regard to medical cannabis means an identified quantity that is uniform, that is intended to meet specifications for identity, strength, and composition, and that is processed, packaged, and labeled on a single day and during a specified period of time according to a single processing, packaging, and labeling protocol.
6. "CBD." Cannabidiol, a nonintoxicating cannabinoid found in cannabis and hemp.
7. "Cannabis." All parts of any plant of the genus cannabis, whether growing or not, including the seeds, extractions of any kind from any part of the plant, and every compound, derivative, mixture, product, or preparation of the plant; but excluding industrial hemp or hemp regulated under § 2-8-11, Code of Alabama 1975 and also excluding cannabis that is cultivated, processed, transported, stored, possessed, or used outside the Statewide Seed-to-Sale Tracking System.
8. "Commission." The Alabama Medical Cannabis Commission, also sometimes referred to as "AMCC," created pursuant to § 20-2a-20, Code of Alabama 1975.
9. "Confidential." Not to be shared, except within the Commission and the party or parties who own or are responsible for the information, or upon judicial or administrative order.

10. "Court of Competent Jurisdiction." A court having authority to act as to particular parties or subject matter; with respect to the Commission, its members and representatives, courts of competent jurisdiction are the Circuit Courts of Montgomery County and coordinate appellate courts, and the United States District Court for the Middle District of Alabama and coordinate appellate courts.
11. "Cultivator." An entity licensed by the Commission (or, as applicable, the Department of Agriculture and Industries) under § 20-2A-62, Code of Alabama 1975, to grow cannabis pursuant to Article 4 of the Act.
12. "Daily Dosage" and "Maximum Daily Dosage." The total amount of one or more cannabis derivatives, including, but not limited to, cannabidiol ("CBD") and tetrahydrocannabinol ("THC") which may be present in a medical cannabis product that may be ingested by a registered qualified patient during a 24-hour period, as determined by a registered certified physician. "Maximum Daily Dosage" means the maximum total amount of one or more cannabis derivatives that may be ingested during a 24-hour period by a registered qualified patient, as determined by a registered certified physician, without a follow-up appointment and/or requiring compliance with § 20-2A-33(f), Code of Alabama 1975.
13. "Department." The Department of Agriculture and Industries.
14. "Dispensary." An entity licensed by the commission under Section 20-2A-64, authorized to dispense and sell medical cannabis at dispensing sites to registered qualified patients and registered caregivers pursuant to Article 4 of the Act.
15. "Dispense." To distribute or provide medical cannabis, per the certification and recommendation of a registered certified physician, to a registered qualified patient or, if applicable, a registered caregiver.
16. "Dispensing Site." A site operated by a dispensary licensee or an integrated facility licensee pursuant to Article 4 of the Act.
17. "Economic Interest." The rights to either the capital or profit interests of an applicant or licensee or, if the applicant or licensee is a corporation, the rights to some portion of all classes of outstanding stock in the corporation.
18. "Enclosure." or "Enclosed Facility." A fully floored, walled, roofed, locked and secured building, room, greenhouse, or warehouse facility, for cultivating, storing, processing, or dispensing cannabis or medical cannabis, at which security is maintained and that is accessible only to persons who are employed or contracted by a licensee, or who have been given permission to come onto the premises and have provided state or federally issued photo identification.
19. "Extraordinary Circumstances." Circumstances that are unforeseen, unusual, and unlikely to be repeated.
20. "Facility" or "Medical Cannabis Facility." Any facility or land associated with a facility, of a licensee.
21. "Food Product." An edible offered for sale or provided for consumption as such.
22. "Good Manufacturing Practices." Manufacturing Practices meeting the minimum standards for the methods, facilities, and controls used in manufacturing, processing, and packing of medical cannabis, to assure the product's safety, integrity, intended strength, and expected shelf-life. See 21 CFR Part 210.
23. "Integrated Facility." An entity licensed under Section 20-2A-67.

24. "Ingested." Eaten, chewed, swallowed, or consumed by mouth in any other manner; inhaled, sniffed, snorted, sprayed, or introduced into the breathing passages in any other manner; injected or otherwise introduced into the body in any manner, including through the skin or other membrane.
25. "Injury." Any wrong or harm done by a licensee or to the body, rights, reputation or property of an individual or entity.
26. "Leaders" or "Leadership." In an Applicant's or Licensee's organization, the individuals who hold a position of interest, responsibility or power within the organization, including but not limited to the owners, shareholders, board members, officers, or managers of the company.
27. "License." Authorization by the Commission (or as applicable, the Department) in accordance with the Act and this Chapter to operate as a cultivator, processor, secure transporter, dispensary, integrated facility, or state testing laboratory.
28. "Licensee." A cultivator, processor, secure transporter, state testing laboratory, dispensary, or integrated facility licensed by the Commission under Article 4.
29. "Loss." Economic, physical or emotional damage sustained by an individual or entity.
30. "Material Breach." A substantial violation in the performance of, or a failure to perform an obligation, created by a promise, duty, or law; as to licensees, a significant difference between circumstances as affirmed to the Commission and current reality, often including a risk of danger or harm to individuals or property.
31. "Medical Cannabis." A medical grade product grown and processed within the State of Alabama, in one of the approved forms set forth in § 20-2A-3(14), Code of Alabama 1975, that contains a derivative of cannabis for medical use by a registered qualified patient pursuant to the Act and this Chapter.
32. "Medical Cannabis Card." A valid card, which may be tangible or virtual, issued by the Commission to a registered qualified patient or a registered qualified caregiver pursuant to §§ 20-2A-35 and -36.
33. "Medical use" or "use of medical cannabis" or "use medical cannabis." The acquisition, possession, use, delivery, transfer, or administration of medical cannabis authorized by the Act and this Chapter, but not including possession, use, or administration of cannabis that was not purchased from a dispensing site as defined by the Act and this Chapter.
34. "Minor." An individual who has not yet reached nineteen years of age.
35. "Package" or "Packaging." A closed and sealed container in which a processor or integrated facility may provide medical cannabis, in accordance with the Act and this Chapter; the term does not include any carry-out bag or other similar container.
36. "Patient Registry." The Alabama Medical Cannabis Patient Registry System that is an electronic integrated system that tracks physician certifications, patient and caregiver registrations, medical cannabis cards, the daily dosage and type of medical cannabis recommended to qualified patients by registered certifying physicians, and the dates of sale, amounts, and types of medical cannabis that were purchased by registered qualified patients at licensed dispensing sites.
37. "Pharmaceutical Grade." Manufactured to the same standard or grade as any active or inactive drug, biologic, reagent or other pharmaceutical, in accordance with Good Manufacturing Practices (GMP) and approved, conditionally approved or indexed by the

- Food and Drug Administration (FDA) or for which a chemical purity standard has been established by recognized compendia.
38. "Physician Certification." A registered certifying physician's authorization for a registered qualified patient to use medical cannabis in a recommended daily dosage that shall include a recommended maximum daily dosage.
 39. "Processor." – One who is licensed by the Commission under § 20-2A-63, Code of Alabama 1975, authorized pursuant to Article 4 of the Act and this Chapter to purchase cannabis from a cultivator and extract derivatives from the cannabis to produce a medical cannabis product or products for sale and transfer in packaged and labeled form to a dispensing site where the packaged and labeled product may be offered for sale to Medical Cannabis Card holders.
 40. "Qualifying Medical Condition." One of the various conditions or symptoms of conditions provided in § 20-2A-3(21) of the Act, but only after documentation indicates that conventional medical treatment or therapy has failed unless current medical treatment indicates that use of medical cannabis is the standard of care. For purposes of this definition, the determination as to whether "conventional medical treatment or therapy has failed" shall be within the sole discretion of the registered certifying physician acting in compliance with § 20-2A-7(b), Ala. Code 1975; the terms "failure" and "proved ineffective" need not entail "exhaustion" of conventional medicine or therapies, if the registered certifying physician is reasonably satisfied that the patient's treatment and care cannot be adequately provided without resort to medical cannabis.
 41. "Registered Caregiver." An individual who meets the requirements described in § 20-2A-30(c) and is authorized to acquire and possess medical cannabis and to assist one or more registered qualified patients with the use of medical cannabis pursuant to the Act and this Chapter.
 42. "Registered Certifying Physician." A licensed physician who is authorized by the State Board of Medical Examiners to certify patients for the use of medical cannabis under the Act and this Chapter.
 43. "Registered Qualified Patient." Either an adult who meets the requirements of § 20-2A-30(a) and is authorized to acquire, possess, and use medical cannabis pursuant to the Act and this Chapter, or a minor who meets the requirements described in § 20-2A-30(b) and is authorized to use medical cannabis pursuant to this chapter with the assistance of a registered caregiver
 44. "Representative." Employee, leader, contracted agent or other designated person authorized to act or speak on behalf of another.
 45. "Resident" or "Non-Resident." – For purposes of the Act and these Rules, a Resident or Non-Resident is:
 - a. As to individuals, a resident is domiciled in the State of Alabama or has otherwise established residency in Alabama within the requirements of § 40-2-18, Code of Alabama 1975; a non-resident is one who is not domiciled in Alabama and has not otherwise established residency in Alabama within the requirements of § 40-2-18.
 - b. As to business entities, a resident is an entity that is registered with the Secretary of State of Alabama to do business in Alabama and that has its principal place of business in Alabama; a non-resident is an entity that is not registered with the Secretary of

State of Alabama to do business in Alabama or does not have its principal place of business in Alabama.

46. "Secure Transporter." An entity licensed by the Commission under § 20-2A-65, Code of Alabama 1975, authorized to transport cannabis or medical cannabis from one licensed facility or site to another licensed facility or site.
47. "Self-Reporting." A licensee's report to the Commission as the result of an incident or condition involving an injury, loss or material breach that has occurred at its facilities or involving one or more of its representatives.
48. "State Testing Laboratory." – An entity licensed under § 20-2A-66, Code of Alabama 1975, authorized to test cannabis and medical cannabis to ensure the product meets safety qualifications and efficacy requirements as provided in the Act and these Rules.
49. "Statewide Seed-to-Sale Tracking System." The tracking system established pursuant to § 20-2A-54, Code of Alabama 1975, that tracks all medical cannabis and cannabis destined for processing as medical cannabis in the state of Alabama.
50. "THC." Tetrahydrocannabinol; either of two physiologically active isomers $C_{21}H_{30}O_2$ from hemp plant resin, including, especially, delta-9 THC, the chief intoxicant in cannabis.
51. "These Rules." The Rules and Regulations of the Alabama Medical Cannabis Commission.
52. "This Chapter." Within the specified portion or the same portion of the Rules and Regulations of the Alabama Medical Cannabis Commission.
53. "Transfer." An exchange of titular, possessory or custodial interest, usually, but not always involving physical movement. As used in these Rules, the right to "transfer" products does not necessarily include the right to "transport" such products.
54. "Transit." The period of transportation during which actual movement takes place.
55. "Transport." The process of preparing for, loading or unloading, and physically moving a item from one place to another, usually but not always coinciding with "transfer." As used in these Rules, the right to "transport" products is separate from the "transfer" of products.
56. "Universal State Symbol." The image to be established by the Commission pursuant to Section § 20-2A-53, Code of Alabama 1975, made available to processors, which indicates the package contains medical cannabis.

Author: William H. Webster

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

History: New Rule Filed:

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

The Commission shall have authority to administer and enforce these Rules in accordance with § 20-2A-22(b).

Author: William H. Webster

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

History: New Rule Filed:

538-x-1-.06 Fees.

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

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule Filed:

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

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

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule Filed:

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

The Commission shall have the authority, upon the request of any applicant, licensee, patient or caregiver, to issue a variance of the Rules of this Chapter, provided that the requested variance does not conflict with the Act.

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule Filed:

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

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

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule Filed:

538-x-1-.10 Hearings.

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

Author: William H. Webster
Statutory Authority: §20-2A-22, Code of Alabama 1975 (as amended).
History: New Rule Filed:

538-x-1-.11 Appeals.

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

Author: William H. Webster

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

History: New Rule Filed: