APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 538

Department or Agency: Alabama Medical Cannabis Commission

Rule No.: 538-X-1-.04

Rule Title: Definitions

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

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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-1-.04 Definitions

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-1-.04 Definitions.

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

(1) "Act." The Darren Wesley "Alo" Hall Compassion Act, §20-2A-1, et seq., Code of Ala. 1975, (as amended).

(2) "Affiliate" or "Affiliated with." An entity is an "affiliate" of, or "affiliated with", another entity if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with or by, such other entity. The term shall include sister entities (i.e., entities owned, directly or indirectly through one or more intermediaries, by the same parent entity).

(3) "Applicant." An entity or individual seeking a license under Article 4 of the Act.

(4) "Approved Solvent." Solvent-based medical cannabis products may be manufactured using only the following solvents: butane, propane, CO2, ethanol, isoprqpanol, acetone, heptane, and pentane. The use of any other solvent is expressly prohibited unless and until approved by the Commission.

(5) "Batch."

(a) "With regard to cannabis, i.e., a "harvest batch":

1. A homogenous, identified quantity of cannabis;
2. That has been cultivated and harvested together;
3. That has received identical propagation and cultivation treatment, including, but not limited to: growing media, ambient conditions, watering and light regimes and agricultural or hydroponic inputs; and
4. That has been assigned the same cultivation batch number for entry in the Statewide Seed-to-Sale Tracking System.

(b) With regard to medical cannabis, i.e., a "production batch":

1. A quantity of medical cannabis that is uniform and derived from one or more identifiable cannabis harvest batches;
2. That has been or is intended to be processed under the same processing protocol, using the same methods, equipment and ingredients;
3. That is intended to meet the same specifications for identity, strength and composition;
4. That has been assigned the same production batch number for entry in the Statewide Seed-to Sale Tracking System; and
5. That is to be packaged and labeled during the same specified period of time according to a single packaging and labeling protocol.

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

the Middle District of Alabama and coordinate appellate courts.

(14) "Cultivator." An entity licensed by the Commission ~~(or, as applicable, the Department of Agriculture and Industries) under §20-2A-62,~~ under §20-2A-62, Code of Ala. 1975, (as amended), to grow cannabis pursuant to Article 4 of the Act.

(15) "Daily Dosage" and "Maximum Daily Dosage." The total amount of one or more cannabis derivatives, including, but not limited to, cannabidiol ("CBD") and tetrahydrocannabinol ("THC") which may be present in a medical cannabis product that may be ingested by a registered qualified patient during a 24-hour period, as determined by a registered certified physician. "Maximum Daily Dosage" means the maximum total amount of one or more cannabis derivatives that may be ingested during a 24-hour period by a registered qualified patient, as determined by a registered certified physician, without a follow-up appointment and/or requiring compliance with §20-2A-33(f), Code of Ala. 1975, (as amended).

(16) "~~Department." The Department of Agriculture and Industries.~~

~~(17) "Dispensary." An entity licensed by the commission under §20-2A-64,~~ Dispensary." An entity licensed by the commission under §20-2A-64, Code of Ala. 1975, (as amended), authorized to dispense and sell medical cannabis at dispensing sites to registered qualified patients and registered caregivers pursuant to Article 4 of the Act.

~~(18)~~ (17) "Dispense." To distribute or provide medical cannabis, per the certification and recommendation of a registered certified physician, to a registered qualified patient or, if applicable, a registered caregiver.

~~(19)~~ (18) "Dispensing Site." A site operated by a dispensary licensee or an integrated facility licensee pursuant to Article 4 of the Act.

~~(20)~~ (19) "Economic Interest." The rights to either the capital or profit interests of an applicant or licensee or, if the applicant or licensee is a corporation, the rights to some portion of all classes of outstanding stock in the corporation. Particularly with respect to applicants and licensees, having a financial interest in, or relationship to, an applicant's or licensee's investments, employment, contracts, purchases, leases, sales, or other pecuniary interest in the applicant's or licensee's business, or the applicant's income or anticipated income, by which to obtain a return of capital. For purposes of these Rules, economic interest does not include interest in a publicly traded corporation unless such interest is greater than 5% of the publicly traded corporation.

~~(21)~~ (20) "Enclosure" or "Enclosed Facility." A fully floored, walled, roofed, locked and secured building, room, greenhouse, or warehouse facility, for cultivating, storing, processing, or dispensing cannabis or medical cannabis, at which security is maintained and that is accessible only to persons who are employed or contracted by a licensee, or who have been given permission to come onto the premises and have provided state or federally issued photo identification.
~~(22)~~ (21) "Extraordinary Circumstances." Circumstances that are unforeseen, unusual, and unlikely to be repeated.
~~(23)~~ (22) "Facility" or "Medical Cannabis Facility." Any facility or land associated with a facility, of a licensee.
~~(24)~~ (23) "Food Product." An edible offered for sale or provided for consumption as such.
~~(25)~~ (24) "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-1ife. See 21 CFR Part 210.
~~(26)~~ (25) "Ingested." Eaten, chewed, swallowed, or consumed by mouth in any other manner; inhaled, sniffed, snorted, sprayed, or introduced into the breathing passages in any other manner; injected or otherwise introduced into the body in any manner, including through the skin or other membrane.
~~(27)~~ (26) "Injury." Any wrong or harm done by a licensee or to the body, rights, reputation or property of an individual or entity.
~~(28)~~ (27) "Integrated Facility." An entity licensed under §20-2A-67, Code of Ala. 1975, (as amended).
~~(29)~~ (28) "Leaders" or "Leadership." In an Applicant's or Licensee's business, the individuals who hold a position of interest, power or responsibility for the day-to-day operations of the business, including but not limited to the owners, shareholders, board members, officers, directors, executives, or managers of the business.
~~(30)~~ (29) "License." Authorization by the Commission~~ (or as applicable, the Department)~~ in accordance with the Act and these Rules to operate as a cultivator, processor, secure transporter, dispensary, integrated facility, or state testing laboratory.
~~(31)~~ (30) "Licensee." A cultivator, processor, secure transporter, state testing laboratory, dispensary, or integrated facility licensed by the Commission under Article 4 of the Act.
~~(32)~~ (31) "Loss." Economic, physical or extreme emotional damage sustained by an individual or entity, including but

not limited to such damages resulting from loss of product, loss of income, loss of production, and loss of reputation.
~~(33)~~ (32) "Material Breach." A substantial violation in the performance of, or a failure to perform an obligation, created by a promise, duty, or law; as to licensees, a significant difference between circumstances as affirmed to the Commission and current reality, often including a risk of danger or harm to individuals or property.
~~(34)~~ (33) "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 Ala. 1975, (as amended), that contains a derivative of cannabis for medical use by a registered qualified patient pursuant to the Act and these Rules.
~~(35)~~ (34) "Medical Cannabis Card." A valid card, which may be tangible or virtual, issued by the Commission to a registered qualified patient or a registered qualified caregiver pursuant to §§20-2A-35 and -36, Code of Ala. 1975, (as amended).
~~(36)~~ (35) "Medical Grade." Manufactured in accordance with Good Manufacturing Practices (GMP) and tested and approved by a State Testing Laboratory or audited by a third-party auditor, to meet or exceed the same standards applicable within the United States for products manufactured for medical use.
~~(37)~~ (36) "Medical use" or "use of medical cannabis" or "use medical cannabis." The acquisition, possession, use, delivery, transfer, or administration of medical cannabis authorized by the Act and these Rules, but not including possession, use, or administration of cannabis that was not purchased from a dispensing site as defined by the Act and this Chapter.
~~(38)~~ (37) "Minor." An individual who has not yet reached nineteen years of age.
~~(39)~~ (38) "Minority Group." Individuals of African American, Native American, Asian or Hispanic descent.
~~(40)~~ (39) "Package" or "Packaging." A closed and sealed container in which a processor or integrated facility may provide medical cannabis, in accordance with the Act and these Rules; the term does not include any carry-out bag or other similar container.
~~(41)~~ (40) "Patient Registry." The Alabama Medical Cannabis Patient Registry System that is an electronic integrated system that tracks physician certifications, patient and caregiver registrations, medical cannabis cards, the daily dosage and type of medical cannabis recommended to qualified patients by registered certifying physicians, and the dates of sale, amounts, and types of medical cannabis that were

purchased by registered qualified patients at licensed dispensing sites.

~~(42)~~ (41) "Pharmaceutical Grade." Manufactured to meet or exceed the same standard or grade as any active or inactive drug, biologic, reagent, or other pharmaceutical, in accordance with Good Manufacturing Practices ("GMP"), as tested and approved by (A) the Food and Drug Administration (FDA) in the case of clinically available pharmaceutical grade excipients under these Rules; or otherwise by (B) a State Testing Laboratory or an independent third- party auditor performing tests or audits in accordance with the same FDA standards and protocols as required for pharmaceuticals available in the United States.

~~(43)~~ (42) "Physician Certification." A registered certifying physician's authorization for a registered qualified patient to use medical cannabis in a recommended daily dosage that shall include a recommended maximum daily dosage.

~~(44)~~ (43) "Processor." One who is licensed by the Commission under §20-2A-63, Code of Ala. 1975, (as amended), authorized pursuant to Article 4 of the Act and these Rules to purchase cannabis from a cultivator and extract derivatives from the cannabis to produce a medical cannabis product or products for sale and transfer in packaged and labeled form back to the contracting cultivator, if applicable, or to a dispensary or integrated facility where the packaged and labeled product may be offered for sale at a dispensary site to holders of a valid, unrevoked and unexpired Medical Cannabis Card.

~~(45)~~ (44) "Qualifying Medical Condition." One of the various conditions or symptoms of conditions provided in §20-2A-3(21), Code of Ala. 1975, (as amended), but only after documentation indicates that conventional medical treatment or therapy has failed, unless current medical treatment indicates that use of medical cannabis is the standard of care.

~~(46)~~ (45) "Registered Caregiver." An individual who meets the requirements described in §20-2A-30(c), Code of Ala. 1975, (as amended), and is authorized to acquire and possess medical cannabis and to assist one or more registered qualified patients with the use of medical cannabis pursuant to the Act and these Rules.

~~(47)~~ (46) "Registered Certifying Physician." A licensed physician who is authorized by the State Board of Medical Examiners to certify patients for the use of medical cannabis under the Act and these Rules.

~~(48)~~ (47) "Registered Qualified Patient." Either an adult who meets the requirements of §20-2A- 30(a), Code of Ala. 1975, (as amended), and is authorized to acquire, possess, and use medical cannabis pursuant to the Act and these Rules, or a

minor who meets the requirements described in §20-2A-30(b), Code of Ala. 1975, (as amended), and is authorized to use medical cannabis pursuant to these Rules with the assistance of a registered caregiver.

~~(49)~~ (48) "Remediation." One of various methods whereby cannabis or medical cannabis that has failed an official test by a State Testing Laboratory may be subjected to further processing to remove dangerous substances or other contaminants or otherwise bring the cannabis or medical cannabis within appropriate testing ranges. For purposes of these Rules, remediation may include processes conducted by, and at the facility of, the licensee whose cannabis or medical cannabis failed the test or another licensee acting at the request of such licensee; such processes shall include those that change the form or chemical makeup of the regulated cannabis or medical cannabis (i.e., formal remediation), or not (i.e., decontamination). Nothing in this definition shall preclude a licensee that is subject to official testing from performing its own tests and implementing processes in an effort to bring non-compliant cannabis or medical cannabis within proper testing parameters at any time prior to official testing by a State Testing Laboratory.

~~(50)~~ (49) "Representative" Employee, leader, contracted agent or other designated person authorized to act or speak on behalf of another.

~~(51)~~ (50) "Resident" or "Non-Resident." - For purposes of the Act and these Rules, a Resident or Non-Resident is:

(a) As to individuals, a resident is domiciled in the State of Alabama or has otherwise established residency in Alabama within the requirements of §40-18-2, Code of Ala. 1975, (as amended); a non-resident is one who is not domiciled in Alabama and has not otherwise established residency in Alabama within the requirements of §40-18-2, Code of Ala. 1975, (as amended).

(b) As to business entities, a resident is an entity that is registered with the Secretary of State of Alabama to do business in Alabama and that has its principal place of business in Alabama; a non-resident is an entity that is not registered with the Secretary of State of Alabama to do business in Alabama or does not have its principal place of business in Alabama.

~~(52)~~ (51) "Secure Transporter." An entity licensed by the Commission under §20-2A-65, Code of Ala. 1975, (as amended), authorized to transport cannabis or medical cannabis from one licensed facility or site to another licensed facility or site.

~~(53)~~ (52) "Self-Reporting." A licensee's report to the Commission as the result of a reported incident or condition

involving an injury, loss (including, but not limited to loss of product, loss of production, or loss of reputation) or material breach that has occurred at its facilities or involving one or more of its representatives.

~~(54)~~ (53) "State Testing Laboratory." -An entity licensed under §20-2A-66, Code of Ala. 1975, (as amended), authorized to test cannabis and medical cannabis to ensure the product meets safety qualifications and efficacy requirements as provided in the Act and these Rules.

~~(55)~~ (54) "Statewide Seed-to-Sale Tracking System." The tracking system established pursuant to §20-2A-54, Code of Ala. 1975, (as amended), that tracks all medical cannabis and cannabis destined for processing as medical cannabis in the state of Alabama.

~~(56)~~ (55) "THC." Tetrahydrocannabinol; either of two physiologically active isomers C21H30O2 from cannabis plant resin, including, especially, delta-9 THC, the chief intoxicant in cannabis.

~~(57)~~ (56) "These Rules." The Rules and Regulations of the Alabama Medical Cannabis Commission.

~~(58)~~ (57) "This Chapter." Within the specified portion or the same portion of the Rules and Regulations of the Alabama Medical Cannabis Commission.

~~(59)~~ (58) "Transfer." An exchange of titular, possessory or custodial interest, usually, but not always involving physical movement. As used in these Rules, the authority to "transfer" products does not necessarily include the authority to "transport" such products.

~~(60)~~ (59) "Transit." The phase of transportation during which cannabis or medical cannabis is physically moved from one facility to another.

~~(61)~~ (60) "Transport." The process of loading or unloading and physically moving harvested and prepared cannabis or medical cannabis from one facility to another, usually but not always coinciding with "transfer" of cannabis or medical cannabis.

~~(62)~~ (61) "Universal State Symbol." The image to be established by the Commission pursuant to Section §20-2A-53, Code of Ala. 1975, (as amended), made available to processors, which indicates the package contains medical cannabis.

~~(63)~~ (62) "Verification," "Verified" and "Verifying." As to a document or statement, the act or condition of having the document or statement be affirmed in writing to be accurate and bearing the printed name and signature of the individual making such affirmation, and date provided.

Author: William H. Webster; 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 ____.