CERTIFICATION OF ADMINISTRATIVE RULES
FILED WITH THE LEGISLATIVE SERVICES AGENCY
OTHNI LATHRAM, DIRECTOR

(Pursuant to Code of Alabama 1975 §41-22-6, as amended).

I certify that the attached is/are correct copy/copies of rule/s as promulgated and adopted on the 12th day of July 2022 and filed with the agency secretary on the 12th day of July 2022.

AGENCY NAME: Alabama Department of Agriculture and Industries

____ Amendment  X  New  _____ Repeal (Mark appropriate space)

Chapter No.: Chapter 80-14-1

(If amended rule, give specific paragraph, subparagraphs, etc., being amended) Changes are noted in rules 80-14-1-.03, 80-14-1-.04(subparagraph 5(c), 18-14-1-.05, and 80-14-1-.08.

Chapter Title: Medical Cannabis Cultivation.

ACTION TAKEN: State whether the rule was adopted with or without changes from the proposal due to written or oral comments:

Chapter adopted with changes to address the majority of public comments.

NOTICE OF INTENDED ACTION PUBLISHED IN VOLUME XL
ISSUE NO. 8, DATED May 31, 2022.


(Date filed)
(For LRS Use Only)

RECD & FILED
JUL 19 2022

Certifying Officer or his or her Deputy

LEGISLATIVE SVC AGENCY

(NOTE: In accordance with §41-22-6(b), as amended, a proposed rule is required to be certified within 90 days after completion of the notice.)
TRANSMITTAL SHEET FOR
BUSINESS ECONOMIC IMPACT STATEMENT
(Section 41-22-5.1)

Control

No. ___ Department/Agency Alabama Department of Agriculture and
Industries

Rule No. 80-14-1

Rule Title: Medical Cannabis Cultivation

___ X ___ New ___ Amend ___ Repeal ___ Adopt by
Reference

Attached is a Business Economic Impact Statement filed pursuant
to Section 41-22-5.1, Code of Alabama 1975.

Signature of Filing Officer

Date 7-12-22

(DATE File)
(STAMP)
Business Economic Impact Statement for Ala. Admin Code Chapter 80-14-1- Medical Cannabis Cultivation

During the public comment period for new Ala. Admin Code Chapter 80-14-1 relating to Medical Cannabis Cultivation, the Alabama Department of Agriculture and Industries (ADAI) received various comments concerning the proposed rules. The vast majority of these comments were addressed by amendments to the proposed rules. The rules will only apply to the cultivation function of the 5 integrated facilities and 12 cultivators licensed by the Alabama Medical Cannabis Commission (AMCC). None of the rules in this chapter are the result of a federal requirement.

Comments requesting that ADAI not approve medical cannabis cultivars could not be accommodated because Ala. Code Section 20-2A-62 (d)(4) requires that cultivars, "... must be approved by the department prior to acquisition of plant material for cultivation." Similarly, comments discussing the potential for confusion or delay due to having multiple state agencies involved in the medical cannabis regulatory process cannot be addressed by administrative rule because Act 2021-450 created the structure wherein AMCC, ADAI, and other existing state agencies cooperate to implement the Act.

The reporting, recordkeeping, and other administrative costs of compliance with these rules will be minimal because most of the requirements will be in conjunction with the reporting, recordkeeping, and administrative costs required to comply with the rules proposed by the AMCC and the requirement of utilizing a seed-to-sale tracking system as required by Act 2021-450.
Alabama Department of Agriculture and Industries
Food Safety
Administrative Code

Chapter 80-14-1
Medical Cannabis Cultivation

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80-14-1-.01 Purpose.

To authorize the Alabama Department of Agriculture and Industries to regulate the cultivation of cannabis by licensed cultivators or licensed integrated facilities pursuant to Section 20-2A-1 et. seq., Code of Alabama 1975.

Author: Patrick B. Moody


History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.
80-14-1-.02 Definitions.

For the purpose of this Chapter and to further implement and expand upon the definitions set out in § 20-2A-3, Code of Alabama 1975 (as amended), the following terms are defined as follows:

(1) Alabama Medical Cannabis Commission, Commission, or AMCC means the state agency created by Act # 2021-450 to regulate the medical cannabis industry in Alabama.

(2) Cultivation. The growing of cannabis until the time of harvest. Cultivation may occur on the premises of a licensed cultivator or a licensed integrated facility.

(3) Cultivator means an individual or entity licensed by the Alabama Medical Cannabis Commission to grow cannabis.

(4) Cultivation Facility. The enclosed structure, or portion of an enclosed structure, where cannabis is planted, grown, harvested, and stored to await transport or processing.

(5) Department means the Alabama Department of Agriculture and Industries.

(6) Enclosed Structure. A permanent structure to cultivate cannabis using artificial light exclusively or as a supplement to natural sunlight. The term may include a greenhouse or similar structure that protects plants from variable temperature, precipitation, wind, and other elements. The enclosed structure must meet the security requirements of 20-2A-1 et. seq., Code of Alabama 1975.

(7) Integrated Facility means an entity licensed by the Alabama Medical Cannabis Commission to grow, process, transport, and dispense cannabis.

(8) Operations Plan. The detailed plan that a Cultivator or Integrated Facility submits to the Department and the Commission, describing the operating standards the Cultivator or Integrated Facility will use to ensure the health, safety, and security of the public and the integrity of medical cannabis facility operations.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.
80-14-1-.03 Cultivator or Integrated Facility license required. A medical cannabis cultivator or integrated facility must have applied to, be licensed by, and be in good standing with, the AMCC. If the AMCC revokes or suspends the license of a cultivator or integrated facility, the cultivator or integrated facility must stop growing cannabis and destroy any cannabis in its possession pursuant to §80-14-1-.11, Ala. Admin Code.

Author: Patrick B. Moody


History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.04 Operations Plan Required
(1) Prior to Cultivation and as part of the license application, each Cultivator and Integrated Facility must submit an Operations Plan to the Department and the AMCC.

(2) Once the Operations Plan is approved by the Department and the AMCC as part of the licensing process, the Cultivator or Integrated Facility must operate consistently with the approved plan. Cultivators and Integrated Facilities may operate outside their originally approved Operations Plan only if they receive written permission from the Department and Commission, as applicable, for:
(a) a waiver, such that they may operate outside the Operations Plan for a specified period of time and for good cause shown, after which time operations in accordance with the Operations Plan will resume; or (b) an amended Operations Plan, which will be in effect and must be followed from the time of the Department’s and Commission’s approval.

(3) The Operations Plan must include a security plan to ensure cannabis and medical cannabis remain secure at all times, including but not limited to requiring that all cultivation facilities are (a) fully surrounded by perimeter barriers deterring unauthorized access to and limiting visibility of the cultivation facility; (b) housed in an enclosed structure as defined herein; (c) secured at all times by locks requiring keypad, card or similar coded interface to access; and (d) monitored by 24-hour video surveillance that shows with reasonable clarity the identity and activity of persons at all entry and exit points as well as in all growing areas.
(4) The Operations Plan must include a grow plan that shall show the number of cannabis plants and methods of cultivation the Cultivator or Integrated Facility intends to utilize.

(5) In addition to the foregoing, the Operations plan must, at a minimum, include protocols to address all the following requirements:
   (a) All cultivation facilities shall be protected by a 24-hour monitored security alarm system.
   (b) All individuals entering and exiting cultivation facilities, including employees, shall be identified, logged in and out, and badged; in addition to the foregoing, all non-employees must report the purpose of their presence on the premises.
   (c) Video monitoring inside the cultivation facility must cover all entry/exit points and all areas where cannabis is present. Monitoring cameras must be of such numbers, scope and clarity as to allow for facial recognition and determine facial features of all persons in the camera’s view at all times of day, such that the identity and activities of such persons being monitored is readily visible. Monitoring cameras at vehicle entry/exit points must be of such numbers, scope, and clarity to record the license plate information and description of all vehicles entering/exiting the facility.
   (d) The Cultivator or Integrated Facility shall provide the Department and the AMCC with engineering plans and specifications of the entire cultivation facility. The plans and specifications shall include:
      (1) A detailed plan and elevation drawings of all operational areas involved with the production of cannabis plants. This should include dimensions and elevation referenced to a single facility benchmark;
      (2) Cross-sections that show the construction details and their dimensions to provide verification of construction materials, enhancement for security measures, and bio-security measures;
      (3) Identification of all employee-accessible nonproduction areas;
(4) The location, size, and capacity of all storage areas, ventilation systems, and equipment used for the production of cannabis;
(5) The location and door material specifications of all entrances and exits to the cultivation facility, as well as the physical makeup and specifications of all outer walls of the enclosed structure;
(6) The location and specifications of any windows, skylights and roof hatches;
(7) The location of all monitoring cameras and their field of view, verified to be operating 24 hours per day;
(8) The location of all alarm inputs (door contacts, motion detectors, duress/hold up devices) and alarm sirens;
(9) The location of the digital video recorder and alarm control panel;
(10) The location of all restricted, employee-accessible and public areas;
(11) The location where all plant inputs and application equipment are stored;
(12) The location of all enclosed, secure areas or loading/unloading docks out of public view for the loading/unloading of cannabis or medical cannabis into or out of any motor vehicle for secure transport.
(13) The location of any area used to store medical cannabis that has been returned to the cultivation facility from a processor or dispensary.

(e) A detailed plan for the destruction and disposal of cannabis plants, including parts thereof, and any related materials that cannot or will not be processed, transported, or dispensed.
(f) A detailed plan to ensure chain of custody of cannabis and medical cannabis within the cultivation facility.
(g) A detailed plan to inventory and track cannabis and medical cannabis within the facility and to interface with the Statewide Seed-to-Sale Tracking system.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.05 Insurance Requirements for Cultivators
Cultivators and Integrated Facilities are required to maintain a minimum of two million dollars ($2,000,000) of liability and casualty insurance and shall establish and at all times maintain the minimum level of other financial guarantees, if appropriate and required by the Commission for all licensees. Liability insurance shall include, at a minimum, workers' compensation insurance as well as insurance against loss, damage or injury to any non-employee while on the premises; loss, damage or injury to the body or personal property of any third party as a proximate result of the acts of the Cultivator or Integrated Facility or its personnel; and loss, damage or injury to any foreseeable person as the result of any products derived from cannabis that had once been in the custody or control of the Cultivator or Integrated Facility. At a minimum the cultivator or integrated facility must be insured against, fire, flood, wind, or other acts of God.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.06 Enclosed Structure & Cultivation Requirements
(1) All cannabis must be cultivated in an enclosed structure; each cannabis plant or batch of cannabis plants must be cultivated in an individual receptacle containing soil or growing media, so as to foster portability, limit cross-contamination, and facilitate proper monitoring of each plant.

(2) Containers may be for individual plants or for batches of plants as long as each plant is clearly identified and traceable.

(3) No cultivation is allowed outdoors or directly in the ground.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.
80-14-1-.07 Cultivars must be approved by Department
(1) Cultivators and Integrated Facilities may only cultivate cannabis cultivars approved by the department prior to acquisition of plant material. Cultivars cannot be derived from hemp or industrial hemp as defined by Ala. Admin. Code Rule 80-10-21-.02 (19) but must be derived from cannabis plants that have a high likelihood of producing medical cannabis.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.08 Location and Visibility
(1) To deter cross-pollination, cross-contamination and erosion of the yield, Cultivators and Integrated Facilities shall not be located within 1 mile (5,280 feet) of any other cultivator or integrated facility, hemp grower licensed by the department, or any known stands of cannabis not licensed by the department or AMCC.

(2) Cultivators and Integrated Facilities should take steps to limit the visibility of cannabis, in any form, from outside the perimeter barrier of the cultivation facility.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.09 Background Checks
(1) Cultivators and Integrated Facilities must comply with the background check requirements mandated by the AMCC pursuant to Ala. Code Section 20-2A-59.

(2) Cultivators and Integrated Facilities must present evidence to the Department, upon request, that all employees comply with the requirements of §20-2A-62(d)(3), Code of Alabama 1975 (as amended), relating to crimes involving controlled substances.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.
80-14-1-.10 Inspections.
Cultivators and Integrated Facilities shall submit to all inspections required by §20-2A-52, Alabama Code 1975 (as amended). The Department will conduct inspections of cultivators and the cultivation facilities of integrated facilities at least twice per calendar year. Cultivators and Integrated Facilities must allow their cultivation facilities to be inspected by the Department at any time.
Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.11 Destruction and Disposal Procedures
Any cannabis material that is not used in medical cannabis must be destroyed in such a way as to render the material unusable and unrecognizable. Each Cultivator and Integrated Facility must include their destruction and disposal procedures in their operations plan. Cultivators and Integrated Facilities must enter destruction and disposal records into the Statewide Seed-To-Sale Tracking System.
Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.12 Sales of Cannabis; Prohibited Activities
(1) Cultivators and Integrated Facilities shall only sell or transfer cannabis to other licensees of the AMCC as provided by the Act, these rules, or rules adopted by the AMCC. Cultivators may not process, transport, or dispense cannabis in any form or for any reason.
Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.13 Pesticide Usage and Testing
(1) Cultivators and Integrated Facilities shall fully comply with all laws and administrative rules relating to the usage of pesticides in the State of Alabama.
(2) The Department may perform pesticide testing on a random basis or if the representatives of the Department have reason to believe that a pesticide may have been applied to cannabis in violation of the product label.

(3) At least quarterly, Cultivators and Integrated Facilities shall, at their own cost, have their cannabis sampled by the State Testing Laboratory licensed by the AMCC pursuant to Ala. Code §20-2A-66 to ensure that no pesticides or other hazardous substances are present in the cannabis material. Cultivators and Integrated Facilities must maintain records of these tests for at least two years and provide the results to the department and AMCC, upon request. Nothing herein shall preclude a Cultivator or Integrated Facility from conducting or seeking, at its own cost, in-house or independent third-party testing of cannabis at any other time before, at, or after the time of harvest.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.14 Hazardous Waste and Chemical Waste
(1) Cultivators and Integrated Facilities shall establish and maintain standards, procedures, and requirements for hazardous and chemical waste product storage and disposal, and chemical storage that comply with Chapters 27 and 30 of Title 22, Code of Alabama, 1975.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.15 Transportation of Cannabis and Medical Cannabis
(1) A Cultivator may only transport cannabis or medical cannabis to another AMCC licensee by utilizing the services of a secure transporter licensed by the AMCC.

(2) An Integrated Facility may only transport cannabis or medical cannabis to its own facilities or another AMCC licensee by utilizing its own vehicles as authorized by the AMCC or by using the services of a secure transporter licensed by the AMCC.
80-14-1-.16 Records and Video Retention:

(1) All records related to the cultivation of cannabis, destruction and disposal of cannabis, and storage of medical cannabis in a cultivation facility shall be kept for at least 2 years and made available to the Department and AMCC upon request. This includes all records related to individuals entering and exiting the cultivation facility.

(2) Cultivators and Integrated Facilities must preserve video from all cameras covering the cultivation facility for a minimum of 60 days.

80-14-1-.17 Statewide Seed-to-Sale Tracking System and Chain of Custody

(1) Cultivators and Integrated Facilities must enter all transactions into the statewide seed-to-sale tracking system operated by the AMCC. At a minimum, these transactions must include the inventory of cannabis plants in the cultivation facility, the location of the cannabis when it leaves the cultivation facility, and the documentation showing any plants or cannabis material that were destroyed and disposed of at the cultivation facility.

(2) Cultivators and Integrated Facilities must ensure that they can account for all cannabis plants and other materials that have ever been in the custody or control of the Cultivator or Integrated Facility, at all times from planting to disposal or from planting to such time as a medical cannabis product is dispensed through a dispensary or Integrated Facility dispensary site.
(3) As part of its Operations Plan, a Cultivator or Integrated Facility must submit a plan to show a continuous chain of custody protocol for all cannabis plants and cannabis material. At a minimum, the chain of custody protocol must ensure that at any time, no fewer than two employees of the Cultivator or Integrated Facility are responsible for the location and security of all cannabis plants or related materials within the custody or control of the Cultivator or Integrated Facility. As with other operations protocols provided to and approved by the Commission and the Department, Cultivators and Integrated Facilities may not alter their chain-of-custody protocols, without first receiving written permission from the AMCC and the Department.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.18 Advertising and Signage
(1) Cultivators and Integrated Facilities must comply with all provisions of Ala. Code Section 20-2A-61 and any rules of the AMCC related to advertising. Advertising or marketing materials, if any, must be appropriate to the subject matter and suitable for the target market to whom a Cultivator or Integrated Facility may sell.

(2) Cultivators and Integrated Facilities shall not display any signage, logos, products, paraphernalia, or other identifying characteristics on the outside of buildings to alert the public that cannabis is being grown or stored at the cultivation facility.

Author: Patrick B. Moody
History: New Rule Filed: July 12, 2022, Effective: September 12, 2022.

80-14-1-.19 Medical Cannabis Storage
(1) Cultivators and Integrated Facilities that store medical cannabis on-site after processing, must conform to the same security and storage rules required by the AMCC for processors and dispensaries.
80-14-1-.20 Violations

(1) The Department shall report any violation of these rules to the AMCC. As with violations of any of the rules of this Chapter, violations of may result in oral or written reprimands, fines, suspension of licenses, or revocation of licenses by the AMCC.