

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 80 Department or Agency Department of Agriculture and Industries
Chapter No.: 80-14-1
Chapter Title: Medical Cannabis Cultivation

X New Amend Repeal Adopt by Reference

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 and, if so, to what degree?

No

Is the increase in cost, if any, more harmful to the public than the harm that might result from the absence of the proposed rule?

No

Are all facets of the rulemaking process designed solely for the purpose of, and so they have, as their primary effect, the protection of the public?

Yes

Does the proposed action relate to or affect in any manner any litigation which the agency is a party to concerning the subject matter of the proposed rule?

No

Does the proposed rule have any economic impact?

Yes

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 *Paul Moss*

Date: 5-17-2022

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REC'D & FILED

MAY 17 2022

LEGISLATIVE SVC AGENCY

(DATE FILED)
(STAMP)

APA-2

ALABAMA DEPARTMENT OF AGRICULTURE AND INDUSTRIES
Food Safety

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Department of Agriculture and Industries

Rule NO. & TITLE: 80-14-1 Medical Cannabis Cultivation

INTENDED ACTION: New Chapter


SUBSTANCE OF PROPOSED ACTION: 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.

TIME, PLACE, MANNER OF PRESENTING VIEWS: Views may be presented in writing to the contact person below by email or by mail. Written comments must be received by 5:00 pm on Monday, July 11, 2022. Views may be presented in person on Tuesday, July 12, 2022, at 10:00 a.m., in the auditorium of the Richard Beard Building, 1445 Federal Drive, Montgomery, Alabama, 36107.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: July 12, 2022.

CONTACT PERSON AT AGENCY: Patrick B. Moody, Deputy Commissioner, Department of Agriculture and Industries, 1445 Federal Drive, Montgomery, Alabama 36107-1123, Telephone No. (334) 240-7106, email patrick.moody@agi.alabama.gov.

5-17-22
Date



Rick Pate
Commissioner of Agriculture
and Industries

ECONOMIC IMPACT STATEMENT
FOR APA RULE
(Section 41-22-23 (f))

Control No. 80 Department or Agency Agriculture & Industries

Chapter No. 80-10-14

Chapter Title: Medical Cannabis Cultivation

X New _____ Amend _____ Repeal _____ Adopt by Reference

_____ This rule has no economic impact.

X This rule has an economic impact as explained below:

1. NEED/EXPECTED BENEFIT OF RULE: These rules are required by Act # 2021-450, codified as Ala. Code Section 20-2A-1 et. seq., to regulate the cultivation of medical cannabis pursuant to the Darren Wesley 'Ato' Hall Compassion Act.

2. COST/BENEFITS OF RULE AND WHY RULE IS THE MOST EFFECTIVE, EFFICIENT, AND FEASIBLE MEANS FOR ALLOCATING RESOURCES AND ACHIEVING THE STATED PURPOSE: These rules are the most effective, efficient, and feasible means for implementing the Darren Wesley 'Ato' Hall Compassion Act because they allow the licensed cultivators and integrated facilities to create an operations plan that meets statutory requirements and fits the business model of the licensee. The Department of Agriculture & Industries (ADAI) will ensure that a licensee cultivates cannabis consistent with the operations plan the licensee submitted to the Alabama Medical Cannabis Commission (AMCC) as part of the licensing process.

3. EFFECT OF THIS RULE ON COMPETITION: This rule should have no effect on competition since all cultivators and integrated facilities licensed by the AMCC will be subject to these rules and operating under their individual operations plan.

4. EFFECT OF THIS RULE ON COST-OF-LIVING AND DOING BUSINESS IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED: There should be no impact on cost-of-living and doing business in Alabama due to these rules.

5. EFFECT OF THIS RULE ON EMPLOYMENT IN THE GEOGRAPHICAL AREA WHERE THE RULE IS TO BE IMPLEMENTED: This rule will allow for the cultivation of

medical cannabis and should result in an increase in employment by licensees of the AMCC.

6. SOURCE OF REVENUE TO BE USED FOR IMPLEMENTING AND ENFORCING THIS RULE: At the present time, revenue for implementing and enforcing this rule will be from the AMCC's general fund appropriation to reimburse ADAI for the implementation and enforcement of these rules and/or from ADAI's general fund appropriation. ADAI receives no license fees or other revenue related to the Compassion Act.

7. THE SHORT-TERM/LONG-TERM ECONOMIC IMPACT OF THIS RULE ON AFFECTED PERSONS, INCLUDING ANALYSIS OF PERSONS WHO WILL BEAR THE COSTS AND THOSE WHO WILL BENEFIT FROM THE RULE: These rules will only impact the cultivation function of integrated facilities and cultivators licensed by the AMCC to cultivate medical cannabis. We cannot determine the short-term/long-term economic impact of these rules because we do not yet know the economic impact costs/benefits that medical cannabis cultivation will have on licensees and the State. Without these rules, there will be no regulation of medical cannabis cultivation.

8. UNCERTAINTIES ASSOCIATED WITH THE ESTIMATED BENEFITS AND BURDENS OF THE RULE, INCLUDING QUALITATIVE/QUANTITATIVE BENEFITS AND BURDEN COMPARISON: There are numerous uncertainties associated with the estimated benefits and burdens of these rules. At this time, no one has a firm idea of the potential demand for medical cannabis in the State so each licensee will have to develop an operations plan that meets its business goal.

9. THE EFFECT OF THIS RULE ON THE ENVIRONMENT AND PUBLIC HEALTH: These rules should not impact the environment and will not impact public health beyond regulating the cultivation of medical cannabis.

10. DETRIMENTAL EFFECT ON THE ENVIRONMENT AND PUBLIC HEALTH IF THE RULE IS NOT IMPLEMENTED: If these rules are not implemented, there will be no rules in place to regulate the cultivation of cannabis.

"New Chapter"

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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 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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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 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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

80-14-1-.05 Insurance Requirements for Cultivators

Cultivators and IFs 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

Statutory Authority: Code of Alabama 1975, §§20-2A-52, 20-2A-53, 2-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed:

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.

Author: Patrick B. Moody

Statutory Authority: Code of Alabama 1975, §§20-2A-50, 20-2A-52, 20-2A-53, 20-2A-62

History: New Rule Filed: