







Medical Cannabis Statutes

- Darren Wesley 'Ato' Hall Compassion Act (Compassion Act) passed by legislature in 2021
- Codified in Alabama Code § 20-2A-1, et seq.
- Legislative intent: to create an intrastate healthcare market for medical cannabis, including the licensing and regulation of cultivators, processors, transporters, and dispensaries

Medical Cannabis Statutes

- Compassion Act creates the following:
 - Alabama Medical Cannabis Commission (AMCC)
 - Patient Registry
 - Seed to Sale Tracking Program

Qualified Patients

- Certified by a registered certifying physician as having a qualifying condition
- Registered with the commission
- If under 19 years of age, has a qualified designated caregiver who is his or her parent or legal guardian

Qualifying Medical Conditions

- Autism Spectrum Disorder (ASD)
- Cancer-related cachexia, nausea or vomiting, weight loss, or chronic pain
- Crohn's Disease
- Depression
- Epilepsy or a condition causing seizures
- HIV/AIDS-related nausea or weight loss
- Panic disorder
- Parkinson's disease
- Persistent nausea not significantly responsive to traditional treatment, except for nausea related to pregnancy, cannabis-induced cyclical vomiting syndrome, or cannabinoid hyperemesis syndrome
- Post Traumatic Stress Disorder (PTSD)
- Sickle Cell Anemia
- Spasticity associated with motor neuron disease, including Amyotrophic Lateral Sclerosis
- Spasticity associated with Multiple Sclerosis or a spinal cord injury
- Terminal illness
- Tourette's Syndrome
- A condition causing chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or has proved ineffective

Forms of Medical Cannabis

- Allowed:
 - Oral tablet, capsule, or tincture
 - Non-sugarcated gelatinous cube, gelatinous rectangular cuboid, or lozenge in a cube or rectangular cuboid shape
 - Gel, oil, cream, or other topical preparation
 - Suppository
 - Transdermal patch
 - Nebulizer
 - Liquid or oil for administration using an inhaler
- Prohibited:
 - Raw plant material
 - Any product administered by smoking, combustion, or vaping
 - Food products with medical cannabis baked, mixed, or otherwise infused into the product, such as cookies or candies

Medical Cannabis

Summary of Rules for Certifying Physicians

Eligibility for registration as certifying physician

- Active, unrestricted Alabama medical license, Alabama Controlled Substance Certificate (ACSC), Alabama-specific DEA registration, registration and access to Prescription Drug Monitoring Program (PDMP), registration and access to the Alabama Medical Cannabis Patient Registry (AMCPR)
- Three (3) years in active practice, or if Board certified, one (1) year in active practice (excluding internships, residencies, fellowships)
- Completion of a 4-hour course developed by the Medical Association of the State of Alabama on medical cannabis and completion of accompanying exam with passing grade

Limitations on registered certifying physicians

- No acceptance, solicitation, or offer of any form of remuneration to certify a patient for use, other than fee for medical services not to exceed what is customary
- No direct or indirect economic interest in or service on board of licensees of AMCC
- No advertisements describing scope of practice as including medical cannabis other than: "Dr. _____ is qualified by the State of Alabama to certify patients for medical cannabis use under the Alabama Compassion Act."
- No certifying outside of Alabama (physician, patient, examinations must all be in Alabama)
- No certifying or recommending to patients who are pregnant, breastfeeding or attempting to conceive

Requirements for certifying for use

- Diagnose a patient with a qualifying medical condition, or confirm the diagnosis of another physician through observation and primary source verification; maximum length of certification = 90 days (30 days for patients capable of conception)
- Establish relationship, including physical exam while in the same location – applies to all examinations for certifying, recommending, re-certifying or re-recommending*
- Create a medical record, meeting established requirements for that record
- Submit appropriate information, including patient demographic information, diagnosis information, and recommended dosage, to patient registry

* Added with amended rules, certified March 2024

Requirements for certifying for use

- Create medical record documenting at minimum:
 - Patient name, date of office visits, and examinations performed
 - Description and diagnosis of qualifying medical condition
 - Assessment of medical history
 - Review of diagnostic test results, prior treatment and response, current medications, conventional therapy attempted
 - Results of a required drug screen for the presence of controlled substances – no certification or recommendation if positive drug screen and all controlled substance prescriptions must be verified through PDMP*
 - Negative pregnancy test result for any patient capable of conception*
 - Consent form signed by patient, and if applicable, patient caregiver
- * Added with amended rules, certified March 2024

Dosage Limitations

- No recommendations of medical cannabis with tetrahydrocannabinol (THC) potency greater than 3% to minors
- No recommendations of THC content exceeding the maximum daily dose for each qualifying condition as established by the AMCC.
- Subject to maximum daily dosages established by AMCC, no recommendations beyond 50 mg of Delta 9-THC, unless
 - After 90 days, physician determines and justifies in documentation a higher daily dosage is medically appropriate – cannot exceed 75 mg of Delta 9-THC, or
 - Patient has been diagnosed with a terminal illness – cannot exceed 75 mg Delta 9-THC, and patient's driver's license will be suspended

Other Medical Cannabis Rules

- Department of Agriculture and Industries Rules on Medical Cannabis Cultivation, Ala. Admin. Code 80-14-1, *et seq.*
 - Regulation for cultivators of medical cannabis
 - Require licensees to have an operation plan, including a grow plan and security plan
 - Can only sell to AMCC licensees
 - Must participate in seed to sale tracking
 - Limited to 12 licensees
- AMCC Rules, Ala. Admin. Code 538-x-1, *et seq.*
 - Regulation for processors (4 license maximum), secure transporters (no limit on licenses), testing laboratories (no limit on licenses), dispensaries (minimum of 4 licenses, 3 dispensing sites per license), and integrated licensees (5 licensees, 5 dispensing sites per license)
 - Common themes: security of medical cannabis in all stages, participation in seed to sale tracking program, intrastate nature of medical cannabis
 - Specific regulation of qualifying patients and caregivers, relevant to physicians

Medical Cannabis

Is it available now?

Medical Cannabis Timeline

LITIGATION

Compassion Act passed
May 2021

First licenses awarded
June 2023

Licenses rescinded per emergency rule/procedures
October 2023

Licenses awarded again
December 2023

Medical Cannabis Timeline

When first permits will be issued:

- No Alabama Medical Cannabis Certification Permit shall be issued until the AMCC has issued at least one license each for a cultivator, a processor, a secure transporter, and a dispensary or has issued at least one license for an integrated facility.

Reclassification of Marijuana

What does that mean for the Alabama cannabis market?

Reclassification of Marijuana

- Marijuana classified as Schedule I drug since the enactment of Controlled Substances Act
 - Schedule I means no medical value, and therefore, not available by prescription or at a pharmacy
- US Justice Dept has issued a notice of proposed rulemaking that would reclassify marijuana to Schedule III (examples of Schedule III: ketamine, anabolic steroids)
- Public comments due 60 days after publication in federal register, but otherwise, no timetable

Reclassification of Marijuana

- How does that change the Alabama market?
 - Will pharmacies be able to stock medical cannabis?
 - Will any physician with a valid DEA registration be able to prescribe?
 - Will medical cannabis dispensaries be subject to DEA rules?
- The Compassion Act is Alabama's law regarding the Alabama cannabis market, and a reclassification of marijuana will not change the Act's authority


