

### **DISCLAIMER**

The following information is presented for educational purposes only and does not constitute legal advice. The views expressed during this presentation do not necessarily represent the views of the Alabama State Board of Medical Examiners or the State of Alabama.



#### **THE PLAYERS**

- **Board of Medical Examiners (BME)** solely responsible for <u>Registered Certifying Physicians</u> in their recommendation of medical cannabis to patients.
- Alabama Medical Cannabis Commission (AMCC) responsible for regulation of Cultivators, Processors, Secure Transporters, Dispensaries, Integrated Facilities, and State Testing Laboratories. Also responsible for maintaining Patient Registry and Seed-to-Sale Tracking System databases.
- Department of Agriculture co-regulates Cultivators with AMCC.
- Medical Association of the State of Alabama responsible for creating and providing the course of education required for physician registration.
- course of education required for physician registration.

  Registered Certifying Physician a physician authorized by BME (and trained by MASA) to certify patients for the use of medical cannabis.
- Registered Qualified Patient a patient with a qualifying medical condition who has been certified by a physician for the use of medical cannabis.
- Registered Caregiver an individual authorized to acquire and possess medical cannabis and assist a patient with its use.

#### THE PLAYERS (cont.)

- · Cultivator authorized to grow medical cannabis in Alabama.
- Processor extracts derivatives from cannabis and produces medical cannabis products in an authorized form as well as packages products in accordance with requirements of law.
- Dispensary dispenses and sells medical cannabis to patients and caregivers (not a pharmacy).
- Secure Transporters authorized to transport medical cannabis between cultivators, processors, and dispensaries.
- Integrated Facility a vertically integrated license type issued by the AMCC that allows an
  entity to engage in all aspects of the medical cannabis supply chain (seed to sale).

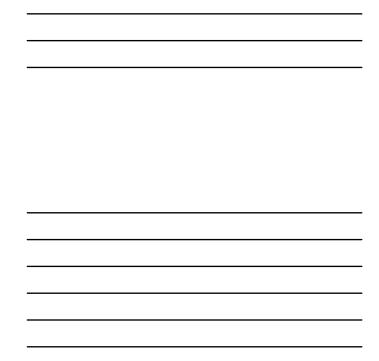
#### **TIMELINE OF MEDICAL CANNABIS IN ALABAMA**

- 2010/2011 Medical cannabis legislation first introduced in Alabama.
- May 31, 2019 SB236 (Act 2019-511), sponsored by Sen. Tim Melson (R-Florence), passes the Alabama Legislature and establishes the Medical Cannabis Study Commission to review and make recommendations to the Legislature relating to the use of medical cannabis in Alabama.
- May 17, 2021 SB46 (Act 2021-450) passes the Legislature, sponsored by Sen. Melson and Rep. Mike Ball (R-Madison). Entitled the Darren Wesley 'Ato' Hall Compassion Act.
- August 12, 2021 AMCC is convened. Steve Stokes, MD elected Chairman.
- September 9, 2021 John McMillan selected as Executive Director of AMCC.

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#### TIMELINE (cont.)

- November 18, 2021 BME proposes draft rules for physician recommendation of medical cannabis.
- March 17, 2022 BME adopts final rules for physician recommendation.
- May 15, 2022 BME rules for physicians are effective.
- June 9, 2022 AMCC proposes draft rules for cultivators, processors, dispensers, transporters, caregivers, etc.
- July 14, 2022 AMCC holds public hearing on proposed rules.
- . ???? AMCC rules are adopted and effective.
- September 1, 2022 AMCC required to begin accepting applications for cultivators, processors, transporters, dispensaries, and integrated facilities.
- 4Q 2022/1Q 2023 AMCC to issue licenses.



## TIMELINE (cont.)

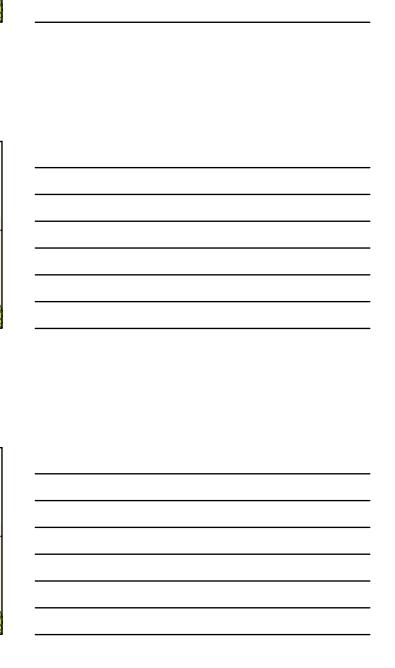
- Spring/Summer 2023 MASA to begin offering courses for physician certification.
- · Spring/Summer 2023 cultivators to begin growing.
- Summer 2023 BME to begin issuing Alabama Medical Cannabis Certification Permits to physicians (rules require AMCC to issue a license for each link of the supply chain first).
- · ???? Medical Cannabis products available to Registered Qualified Patients.

### **TECHNOLOGY**

- Patient Registry database that tracks physician certifications, patient registrations, medical cannabis cards, and recommendation details (dosage and product type), as well as dates of sale, amounts, and types purchased by patients and caregivers.
  - · 'Hybrid PDMP and E-prescribing system'
- Seed-to-Sale Tracking System- database that tracks all medical cannabis in the state from the time the seed is planted in the ground until the time it is dispensed to the patient.

#### **KEY PROVISIONS OF LAW**

- Physician issues a <u>recommendation</u> and certifies a patient for medical cannabis use. A physician <u>DOES NOT prescribe</u> medical cannabis.
  - Cannabis remains a Schedule-I Controlled Substance on both the state and federal controlled substance lists.
- Every element of the medical cannabis program must be 100% <u>intrastate</u>. This includes all physician interactions as well as the entire growing and supply chain process. Medical cannabis cannot be first-line treatment.
  - Conventional medical treatment or therapy must have been attempted and failed prior to physician recommending medical cannabis.
  - Exception if medical cannabis is the standard of care.
  - Must be documented in patient record.



### **QUALIFYING MEDICAL CONDITIONS**

- · Autism Spectrum Disorder
- Cancer related cachexia, nausea or vomiting, weight loss, or chronic pain.
- · Crohn's Disease
- Depression
- Epilepsy or any other condition causing seizures
- HIV/AIDS-related nausea or weight-loss
- Panic Disorder
- · Parkinson's Disease
- Persistent Nausea (must not be responsive to traditional treatment); excludes nausea related to pregnancy, cannabis/CBD induced vomiting syndromes)
- · Post-Traumatic Stress Disorder
- · Sickle Cell Anemia



#### QUALIFYING MEDICAL CONDITIONS (cont.)

- Spasticity associated with ALS or any other motor neuron disease
- Spasticity associated with MS or any spinal cord injury
- A terminal illness (expected to result in death within 6 months)
- · Tourette's Syndrome
- A condition causing chronic (>3 months) or intractable (cause cannot be removed/treated) but <u>only if</u> conventional therapeutic intervention and opiate therapy is contraindicated or has proved ineffective
- · Ala. Code 20-2A-3(21) •





#### **PERMISSIBLE MEDICAL CANNABIS PRODUCTS**

- · Oral tablet, capsule, or tincture
- Non-sugarcoated gelatinous cube, gelatinous rectangular cuboids, or a lozenge in a cube or rectangular cuboid shape (no shaped or sugarcoated 'gummies')
- Gel, oil, cream, or other topical preparation
- Suppository
- · Transdermal patch
- Nebulizer
- · Liquid or oil administered via inhaler
- NO RAW PLANT MATERIAL
- NO smokable or vapable product
- NO edibles or baked food products (e.g., brownies, cookies, candies)
- Ala. Code 20-2A-3(14)



#### THE PHYSICIAN PERMIT

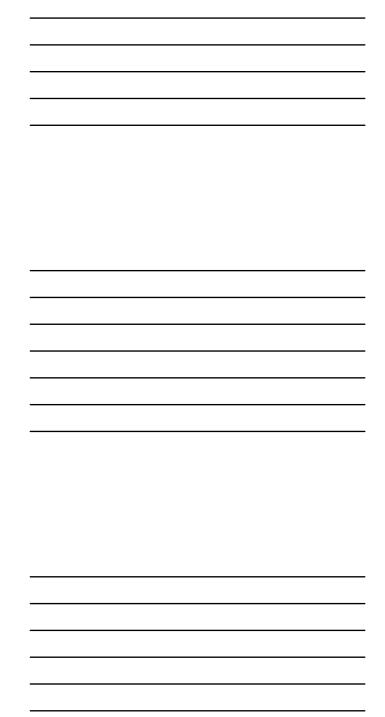
- In order to obtain an Alabama Medical Cannabis Certification Permit, a physician must:
  - 1) Have an unrestricted medical license, ACSC, and DEA registration;
  - Have registered access to PDMP and AMCC Patient Registry at each location;
  - Have actively practiced medicine for at least 3 years post-training or have practiced 1 year and be board certified;
  - Have no criminal conviction related to the practice of medicine, fraud, or drug offense;
  - s) Have completed the 4-hour MASA medical cannabis course and passed the examination; and
  - Pay application fee of \$300
- Renewal of permit is \$200/year and requires 2-hour refresher course every 2 years.

#### THE PHYSICIAN RECOMMENDATION

- A bona fide physician-patient relationship must exist and there must be an
  expectation that the patient will provide care to the patient on an ongoing
  basis.
- Physician must certify:
  - The patient has a <u>Qualifying Medical Condition</u> (through either his/her own examination or through the primary-source verification of another *physician's* diagnosis); and
  - 2) That conventional treatment/therapy has been attempted and failed.
- The physician must recommend the appropriate daily dose and the type of medical cannabis to be used.

## THE PHYSICIAN RECOMMENDATION (cont.)

- All physician certifications (and re-certifications) must occur within the state and take place during the course of an <u>in-person examination</u>.
- Physician may only recommend medical cannabis for qualifying conditions which are within the scope of their training, specialty, and usual medical practice.
- Patient must execute an informed consent form provided by the BME that discusses the risks and legalities associated with medical cannabis.
- Specific dosage thresholds and accompanying requirements contained in statute and BME rules.



## PROHIBITIONS ON RECOMMENDATION

- Physicians are <u>prohibited from recommending/certifying</u> medical cannabis for any patient who:
  - Is <u>pregnant</u>, breastfeeding, or attempting to conceive.
  - Has been diagnosed for a condition in which cannabis is contraindicated.
  - Is suspected of <u>abusing or diverting</u> medical cannabis.
  - Is no longer suffering from the qualifying medical condition or its symptoms.

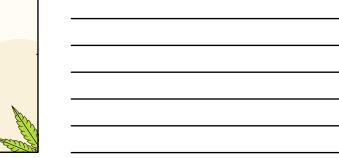
### SPECIAL CONSIDERATIONS FOR PHYSICIANS

- A Registered Certifying Physician shall not have an economic interest (direct or indirect) in any cultivator, dispensary, integrated facility, processor, or secure transporter.
  - Prohibition on serving as director or employee as well.
- No kickbacks or referral fees (dispensaries, caregivers, etc.).
- Cannot refer patients to a specific dispensary or caregiver.
- . Cannot be located in same office as a dispensary.
- Generally, cannot advertise medical cannabis practice.
  - Only permissive statement: "Dr. X is qualified by the State of Alabama to certify patients for medical cannabis use under the Alabama Compassion Act."



## SPECIAL CONSIDERATIONS FOR LTC FACILITIES

- Reimbursement Medicare/Medicaid (and likely most private insurance) will not reimburse for medical cannabis or charges associated with its administration.
- Banking funds associated with medical cannabis cannot be deposited in the federal banking system, must be segregated, and are potentially subject to forfeiture.
- Caregivers facility likely would be required to have staff serve the role of "Certified Caregiver" and be subject to the law's provisions on these individuals.
- Informed Consent informed consent from patient required by law and/or from the surrogate/agent/guardian.
- Staff employees involved in direct patient care who are utilizing medical cannabis.
- Compliance potential adverse effect on CMS regulations and ability to attest to compliance with applicable federal regulations.



#### **RESOURCES**

- BME: https://www.albme.gov/
- AMCC: https://amcc.alabama.gov/
- AMDA: https://paltc.org/?q=amda-white-papers-and-resolution-position-statements/use-marijuana-nursing-homes
- Act 2021-450: https://arc-sos.state.al.us/ucp/L0624084.Al1.pdf
- BME Rules: http://www.alabamaadministrativecode.state.al.us/docs/mexam/540-X-25.pdf
- . AMCC Rules: https://amcc.alabama.gov/about/resources/



