

TRANSMITTAL SHEET FOR
NOTICE OF INTENDED ACTION

Control 540 Department or Agency Alabama State Board of Medical Examiners
Rule No. 540-X-25
Rule Title: Physician Recommendation of the Use of Medical Cannabis
 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 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 

Date November 18, 2021

REC'D & FILED

(DATE FILED)
(STAMP)

NOV 18 2021

APA-2

ALABAMA STATE BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-25, Physician Recommendation of the Use of Medical Cannabis


INTENDED ACTION: Add a new chapter of rules

SUBSTANCE OF PROPOSED ACTION: Provide for the physician recommendation of the use of medical cannabis pursuant to Act No. 2021-100.

TIME, PLACE, MANNER OF PRESENTING VIEWS: All interested persons may submit data, views, or arguments concerning the proposed new rule(s) and regulation(s) in writing to: Carla H. Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or in person between the hours of 8:30 a.m. and 4:30 p.m., Monday through Friday, until and including January 4, 2022. Persons wishing to obtain copies of the text of this rule and submit data, views, or comments or arguments orally should contact Carla H. Kruger by telephone (334-242-4116) during said period in order to set up an appointment for a hearing respecting such oral data, views, or arguments. Copies can also be obtained at the Board's web site, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE: January 4, 2022

CONTACT PERSON AT AGENCY: Carla H. Kruger



(Signature of officer authorized
to promulgate and adopt
rules or his or her deputy)

RULES OF THE
ALABAMA BOARD OF MEDICAL EXAMINERS

CHAPTER 540-X-25
PHYSICIAN RECOMMENDATION OF THE USE OF MEDICAL CANNABIS

Table of Contents

540-X-25-.01	Preamble
540-X-25-.02	Definitions
540-X-25-.03	Registration of Physicians for Certifying the Use of Medical Cannabis
540-X-25-.04	Requirements for Initial Application for Alabama Medical Cannabis Certification Permit
540-X-25-.05	Physician Eligibility for an Alabama Medical Cannabis Certification Permit
540-X-25-.06	Grounds for Denial or Revocation of an Alabama Medical Cannabis Certification Permit
540-X-25-.07	Renewal of an Alabama Medical Cannabis Certification Permit
540-X-25-.08	Continuing Medical Education Requirements
540-X-25-.09	Limitations Upon Registered Certifying Physicians
540-X-25-.10	Requirements for Physician Recommendation or Certification for the Use of Medical Cannabis
540-X-25-.11	Dosage Limitations of Medical Cannabis Recommendations

540-X-25-.01 Preamble.

This Chapter implements the provisions of the Darren Wesley 'Ato' Hall Compassion Act (Act 2021-450; Ala. Code §§ 20-2A-1, et. seq.) relating to the physician recommendation of medical cannabis. This Chapter shall establish the eligibility requirements and process for a licensed physician to qualify as a registered certifying physician. This Chapter will also establish the requirements for a registered certifying physician to issue a physician certification for a patient to use medical cannabis. Nothing in this Chapter shall overrule, modify, or replace the Board's regulations on prescribing controlled substances and standards for pain management services, as these regulations also apply to a physician's recommendation of medical cannabis.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.02 Definitions.

The following definitions shall apply to the rules in this Chapter:

(1) **AMCC.** The Alabama Medical Cannabis Commission created pursuant to Ala. Code § 20-2A-20.

(2) **BOARD.** The Alabama State Board of Medical Examiners.

(3) **CANNABIS.** All parts of any plant of the genus cannabis, excluding industrial hemp or hemp regulated under Ala. Code §§ 2-8-380, et. seq., 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.

(4) **CERTIFY.** To confirm or diagnose through a medical examination in compliance with these rules that a patient has a qualifying medical condition that conventional medical treatment or therapy has failed to treat or for which medical cannabis is indicated by the current standard of care.

(5) **CHRONIC PAIN.** A state in which pain persists beyond the usual course of an acute disease or healing of an injury (e.g., more than three (3) months), and which may or may not be associated with an acute or chronic pathological process that causes continuous or intermittent pain over a period of months or years.

(6) **CULTIVATOR.** An entity licensed by the Department of Agriculture and Industries under Ala. Code § 20-2A-62 authorized to grow cannabis pursuant to Ala. Code §§ 20-2A-1, et. seq.

(7) **DAILY DOSAGE.** The total amount of one or more cannabis derivatives, including, but not limited to, cannabidiol and tetrahydrocannabinol, 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 certifying physician.

(8) **DISPENSARY.** An entity licensed by the AMCC under Ala. Code §§ 20-2A-64 authorized to dispense and sell medical cannabis at dispensing sites to registered qualified patients and registered caregivers pursuant to Ala. Code §§ 20-2A-1, et. seq.

(9) **DISPENSING SITE.** A site operated by a dispensary licensee or an integrated facility licensee.

(10) **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.

(11) **INTEGRATED FACILITY.** An entity licensed under Section 20-2A-67 authorized to perform the functions of a cultivator, processor, secure transporter, and dispensary pursuant to Ala. Code §§ 20-2A-50, et. seq.

(12) **INTRACTABLE PAIN.** Chronic pain for which, in the generally accepted course of medical practice, the cause cannot be removed or otherwise treated.

(13) **LICENSEE OF THE AMCC.** Any person, business, or other entity possessing, or seeking to obtain, a license issued by the Alabama Medical Cannabis Commission; including, but not limited to, a cultivator, dispensary, integrated facility, processor, or secure transporter.

(14) **MEDICAL CANNABIS.** A medical grade product that contains a derivative of cannabis for medical use by a registered qualified patient and is in a form set forth in

Ala. Code § 20-2A-3(14)a. and shall not include any of the forms prohibited by Ala. Code § 20-2A-3(14)b.

(15) **MEDICAL CANNABIS CARD.** A valid card issued pursuant to Ala. Code § 20-2A-35.

(16) **MEDICAL USE or USE OF MEDICAL CANNABIS or USE MEDICAL CANNABIS.** The acquisition, possession, use, delivery, transfer, or administration of medical cannabis authorized by Ala. Code §§ 20-2A-1, et. seq. These terms do not include possession, use, or administration of cannabis that was not purchased or acquired from a licensed dispensary.

(17) **PATIENT REGISTRY.** The Alabama Medical Cannabis Patient Registry System that is an electronic integrated system that tracks physician certifications, patient 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 dispensaries.

(18) **PHYSICIAN CERTIFICATION.** A registered certifying physician's authorization for a registered qualified patient to use medical cannabis.

(19) **PROCESSOR.** An entity licensed by the AMCC under Ala. Code § 20-2A-63 authorized 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 to a dispensing site pursuant to Ala. Code §§ 20-2A-1, et. seq.

(20) QUALIFYING MEDICAL CONDITION. Any of the following conditions or symptoms of conditions, 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:

- (a) Autism Spectrum Disorder (ASD).**
- (b) Cancer-related cachexia, nausea or vomiting, weight loss, or chronic pain.**
- (c) Crohn's Disease.**
- (d) Depression.**
- (e) Epilepsy or a condition causing seizures.**
- (f) HIV/AIDS-related nausea or weight loss.**
- (g) Panic disorder.**
- (h) Parkinson's disease.**
- (i) Persistent nausea that is not significantly responsive to traditional treatment, except for nausea related to pregnancy, cannabis-induced cyclical vomiting syndrome, or cannabinoid hyperemesis syndrome.**
- (j) Post Traumatic Stress Disorder (PTSD).**
- (k) Sickle Cell Anemia.**
- (l) Spasticity associated with a motor neuron disease, including Amyotrophic Lateral Sclerosis (ALS).**
- (m) Spasticity associated with Multiple Sclerosis (MS) or a spinal cord injury.**
- (n) A terminal illness.**
- (o) Tourette's Syndrome.**

(p) A condition causing chronic or intractable pain in which conventional therapeutic intervention and opiate therapy is contraindicated or has proved ineffective.

(21) RECOMMEND. To authorize the daily dose and type of medical cannabis to be used by a registered qualified patient to treat a qualifying medical condition.

(22) REGISTERED CAREGIVER. An individual who meets the requirements described in subsection (c) of Ala. Code § 20-2A-30 and is authorized to acquire and possess medical cannabis and to assist one or more registered qualified patients with the use of medical cannabis.

(23) REGISTERED CERTIFYING PHYSICIAN. A physician authorized by the Board to certify patients for the use of medical cannabis.

(24) REGISTERED QUALIFIED PATIENT. Either of the following:

(a) An adult who meets the requirements described in subsection (a) of Ala. Code § 20-2A-30 and is authorized to acquire, possess, and use medical cannabis pursuant to Ala. Code §§ 20-2A-1, et. seq.

(b) A minor who meets the requirements described in subsection (b) of Ala. Code § 20-2A-30 and is authorized to use medical cannabis pursuant to this Chapter with the assistance of a registered caregiver.

(25) SECURE TRANSPORTER. An entity licensed by the AMCC under Ala. Code § 20-2A-65 authorized to transport cannabis or medical cannabis from one licensed facility or site to another licensed facility or site.

(26) TERMINAL ILLNESS. An illness or physical condition which can reasonably be expected to result in death in six (6) months or less after the date of the certification.

(27) UNRESTRICTED. When referring to a license to practice medicine or osteopathy, an Alabama Controlled Substance Certificate (ACSC) registration, or a Drug Enforcement Administration (DEA) registration, a license, certificate, or registration which is unencumbered by any restriction or condition or which is otherwise not subject to current discipline, and which has not been revoked, suspended, placed on probation, or voluntarily surrendered within the past five (5) years.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.03 Registration of Physicians for Certifying the Use of Medical Cannabis.

Every physician licensed to practice in Alabama who certifies or recommends a patient for the use of medical cannabis within Alabama pursuant to Ala. Code §§ 20-2A-1, et. seq. or who proposes to certify or recommend a patient for the use of medical cannabis within Alabama must obtain annually an Alabama Medical Cannabis Certification Permit from the Board.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.04 Requirements for Initial Application for Alabama Medical Cannabis Certification Permit.

(1) To obtain an Alabama Medical Cannabis Certification Permit, a physician applicant shall submit the following to the Board:

(a) A completed application on a form prescribed by the Board.

(b) Proof of an active, unrestricted license to practice medicine or osteopathy in Alabama.

(c) Proof of an active, unrestricted Alabama Controlled Substances Certificate (ACSC).

(d) Proof of an active, unrestricted, Alabama-specific DEA registration.

(e) Proof of a current registration to query the Alabama Prescription Drug Monitoring Program (PDMP) that is established and maintained by the Alabama Department of Public Health.

(f) Proof of a current registration with the Alabama Medical Cannabis Patient Registry System that is established and maintained by the AMCC.

(g) Proof of completion of a four (4) hour course related to medical cannabis, and a passing grade on a subsequent examination, which has been approved by the Board and offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.

(h) The disclosure of any controlled substances certificate or registration denial, restriction, or discipline imposed on the physician applicant, or any disciplinary act against any medical or other professional license of the physician applicant.

(i) A list of all practice locations and/or addresses from which the physician applicant may certify or recommend a patient for the use of medical cannabis.

(j) An initial/reinstatement application fee of three hundred dollars (\$300), which shall be payable to the Board and non-refundable upon submission. An initial/reinstatement application fee is non-transferable.

(2) If a physician applicant does not complete the initial application process within ninety (90) days of his or her first submission to the Board, the application shall be closed, the application fees shall not be refunded or transferred, and the applicant shall be required to reapply for a permit.

(3) An application which is submitted to the Board may be withdrawn at any time prior to the granting or denial of registration; however, the application fees shall not be refunded or transferred.

(4) All initial applications for an Alabama Medical Cannabis Certification Permit are subject to approval by the voting members of the Board and may not be issued on a temporary or preliminary basis.

(5) 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.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.05: Physician Eligibility for an Alabama Medical Cannabis Certification Permit.

No physician shall obtain an Alabama Medical Cannabis Certification Permit unless he or she:

(1) Possesses an active, unrestricted license to practice medicine or osteopathy in Alabama;

(2) Possesses an active, unrestricted ACSC registration;

(3) Possesses an active, unrestricted, Alabama-specific DEA registration;

(4) Has satisfied one of the following experience requirements:

(a) Has been engaged in the active practice of medicine or osteopathy for at least three (3) years, excluding any practice in an internship, residency, fellowship, or other supervised training program; or

(b) Has actively practiced medicine or osteopathy for at least one (1) year, excluding any practice in an internship, residency, fellowship, or other supervised training program, and is certified by a specialty board approved by the American Board of Medical Specialties (ABMS) or the American Osteopathic Association Bureau of Osteopathic Specialists (AOABOS);

(5) Is registered to query the PDMP and has access to the PDMP in all locations where he or she certifies or recommends a patient for the use of medical cannabis;

(6) Is a registered user of the Alabama Medical Cannabis Patient Registry and has access to the registry in all locations where he or she certifies or recommends a patient for the use of medical cannabis;

(7) Has completed a four (4) hour course related to medical cannabis and has received a passing grade on a subsequent examination, which has been approved by the Board and offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™; and

(8) Has paid all fees required by this Chapter.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.06: Grounds for Denial or Revocation of an Alabama Medical Cannabis

Certification Permit.

(1) The Board may deny issuance or renewal of or revoke the Alabama Medical Cannabis Certification Permit of a physician who:

(a) Fails to meet or maintain any of the requirements set forth in Ala. Code §§ 20-2A-1, et seq., or Ala. Admin. Code R. 540-X-25-.01, et seq.;

(b) Furnishes false, misleading, untruthful, or fraudulent information in connection with an application;

(c) Discloses, or fails to disclose, any controlled substances certificate or registration denial, restriction, or discipline imposed on the applicant, or any disciplinary act against any medical license, any controlled substances certificate of registration, or any DEA registration of the physician;

(d) Has been convicted of, pled guilty to, or entered a plea of nolo contendere to a felony or a criminal offense related to the provision of medical services, fraud, or a drug offense, or is under any state or federal restriction, probation, discipline, investigation, or indictment related to a felony, the provision of medical services, fraud, or a drug offense;

(e) Holds a direct or indirect economic interest in a licensee of the AMCC;

(f) Is guilty of any of the acts or offenses listed in Ala. Code § 34-24-360; or

(g) Has violated any rules or regulations of the Board or the Medical Licensure Commission of Alabama.

(2) An applicant who is denied an Alabama Medical Cannabis Certification Permit under this section may petition the Board for reconsideration of the application.

Any petition must be filed within thirty (30) days of denial of the permit. Upon receipt of the petition, the Board shall issue the permit or set a hearing thereon. The hearing shall be considered a contested case and shall be governed by the rules on reinstatement hearings in accordance with Ala. Admin. Code R. 540-X-6-.02(1)(b)(3).

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.07 Renewal of an Alabama Medical Cannabis Certification Permit.

(1) Renewal of an Alabama Medical Cannabis Certification Permit shall be annually on or before December 31 of each year.

(2) Annual permit renewal shall occur upon completion of a renewal application in a form prescribed by the Board and payment of a renewal fee.

(3) The fee for annual permit renewal shall be two hundred dollars (\$200).

(4) Any registered certifying physician who fails to renew an Alabama Medical Cannabis Certification Permit by December 31 of the year of its expiration shall be required to reinstate the certificate by reapplying for an initial Alabama Medical Cannabis Certification Permit under the provisions set forth in this Chapter.

(5) Before renewing an Alabama Medical Cannabis Certification Permit, a physician shall have a current and appropriate registration issued by the DEA and a valid ACSC registration issued by the Board.

(6) Before renewing an Alabama Medical Cannabis Certification Permit, a physician shall have a current registration to access and query in all locations where he or she certifies or recommends a patient for the use of medical cannabis:

(a) The Alabama Medical Cannabis Patient Registry system established and maintained by the AMCC; and

(b) The PDMP.

(7) Before renewing an Alabama Medical Cannabis Certification Permit, the physician shall have completed within the last 24 months a continuing medical education (CME) course related to medical cannabis of at least two (2) AMA PRA Category 1 Credits™ that is approved by the Board and is offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.08 Continuing Medical Education Requirements.

(1) Prior to the initial issuance of, or reinstatement thereof, an Alabama Medical Cannabis Certification Permit, a physician shall have, within the two (2) years preceding their application, completed a four (4) hour course related to medical cannabis, and have received a passing grade on a subsequent examination, which has been approved by the Board and offered by a multi-specialty statewide professional organization of physicians in this state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.

(2) In order to maintain or renew an Alabama Medical Cannabis Certification Permit, a registered certifying physician shall, every two (2) years, complete a two (2) hour refresher course related to medical cannabis which has been approved by the Board and offered by a multi-specialty statewide professional organization of physicians in this

state that is recognized to accredit intrastate organizations to provide AMA PRA Category 1 Credit™.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.09 Limitations Upon Registered Certifying Physicians.

(1) Except for the limited purpose of performing a medical cannabis-related study, a registered certifying physician shall not accept, solicit, or offer any form of remuneration from or to a qualified patient, designated caregiver, or any licensee of the AMCC, including a principal officer, board member, agent, or employee of the licensee, to certify a patient, other than accepting payment from a patient for a fee, not to exceed that which is customarily charged in the locality for physician services, associated with the examination, medical consultation, or other treatment, including, but not limited to, any third party reimbursement for the same.

(2) A registered certifying physician shall not accept, solicit, or offer any form of remuneration from or to a dispensary for the purpose of referring a patient to a specific dispensary.

(3) A registered certifying physician shall not offer a discount of any other item of value to a qualified patient who uses or agrees to designate a specific registered caregiver or use a specific dispensary to obtain medical cannabis.

(4) A registered certifying physician shall not hold a direct or indirect economic interest in a licensee of the AMCC.

(5) A registered certifying physician shall not serve on the Board of Directors or as an employee of a licensee of the AMCC.

(6) A registered certifying physician shall not refer qualified patients to a specific caregiver or a specific dispensary.

(7) A registered certifying physician shall not advertise in a dispensary.

(8) A registered certifying physician, or any practice, facility, business, or other entity with which they are affiliated, shall not advertise on a website, in brochures, or via any other media that generally describe the scope of practice of the physician as a "medical cannabis" or "medical marijuana" physician or doctor, or otherwise advertises his or her status as a registered certifying physician, other than stating the following: "Dr. _____ is qualified by the State of Alabama to certify patients for medical cannabis use under the Alabama Compassion Act."

(9) A registered certifying physician shall not be located in the same office space as a dispensary or a dispensing site.

(10) A registered certifying physician shall not certify or recommend a patient for the use of medical cannabis unless both the registered certifying physician and the patient are physically located in Alabama, and any examination, visit, or other consultation occurs while both parties are physically located in Alabama.

(11) At all times in the certification or recommendation of medical cannabis, a registered certifying physician shall only evaluate, diagnose, or certify those qualifying medical conditions for which he or she possesses the education, training, experience, and specialty training to evaluate, diagnose, or treat in his or her usual medical practice. A physician who recommends medical cannabis to a patient for treatment of a qualifying medical condition that the physician is not trained to treat with conventional medical treatment shall be in violation of these rules.

(12) A registered certifying physician is strictly prohibited from certifying or recommending, or recertifying or re-recommending, the use of medical cannabis to any patient who is pregnant, breastfeeding, or attempting to conceive.

(13) A registered certifying physician is prohibited from certifying or recommending, or recertifying or re-recommending, the use of medical cannabis to any patient who has been diagnosed with a condition for which cannabis is contraindicated under the current standard of care or by evidence-based research.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.10 Requirements for Physician Recommendation or Certification for the Use of Medical Cannabis.

(1) In order to recommend a patient for the use of medical cannabis, a registered certifying physician shall, within the scope of his or her usual medical practice or specialty, diagnose a patient with at least one qualifying medical condition or shall confirm, through personal, direct observation and assessment and primary source verification, that the patient has been medically diagnosed, by a physician, with at least one qualifying medical condition.

(2) A registered certifying physician shall establish a bona fide physician-patient relationship with the patient for the provision of medical services in an in-person visit that complies with this Chapter and for which there is an expectation that the physician will provide care to the patient on an ongoing basis.

(a) Prior to certifying or recommending, or recertifying or re-recommending, a patient for the use of medical cannabis, the registered certifying physician shall have

conducted a physical examination while physically present in the same room as the patient and obtained a full assessment of the patient's medical history.

(3) A registered certifying physician shall create and maintain a medical record that satisfies the provisions of Ala. Admin Code R. 545-X-4-.09 and shall also include, at a minimum, the following:

- (a) The patient's name and date or dates of office visits or treatments;
- (b) A description of the patient's qualifying medical condition;
- (c) Documented assessment of the patient's medical history, including relevant prescription history and any history of substance use disorder;
- (d) Documented review of any available relevant diagnostic test results;
- (e) Documented review of prior treatment and the patient's response to the treatment;
- (f) Documented review of the patient's current medication to identify possible drug interactions, including all controlled substances;
- (g) Documented review that conventional medical treatment or therapy has been attempted;
- (h) A registered certifying physician may obtain a drug screen on the patient. It is within the physician's discretion to decide the nature of the screen and which type of drug to be screened. Results of any such drug screen shall be maintained in the medical record along with documentation of any proscriptive measures taken due to an unsatisfactory screen;
- (i) The registered certifying physician's performance of a physical examination relevant to the patient's current medical condition;

(j) The physician's diagnosis of the patient's qualifying medical condition; and

(k) If the patient has been previously diagnosed with a qualifying medical condition by another qualified physician, the registered certifying physician may confirm the diagnosis provided that the registered certifying physician obtains a copy of the medical records or a detailed written summary indicating the diagnosis, and the registered certifying physician is satisfied that he or she can rely on those records to confirm diagnosis of a qualifying medical condition. The registered certifying physician shall maintain a copy of any record or report of any other physician on which the registered certifying physician relied for purposes of meeting the requirements under this paragraph. The registered certifying physician shall verify and document the diagnosing physician's continuing diagnosis of the patient's qualifying medical condition prior to each recertification.

(4) If the registered certifying physician diagnoses or confirms the diagnosis of a qualifying medical condition, the physician shall document in the medical record compliance with all of the following actions when certifying or recommending treatment with medical cannabis:

(a) Development of a treatment plan, including consideration of whether treatment with medical marijuana is complementary to standard medical treatment.

(b) The review of the patient's controlled drug prescription history in the PDMP. The review shall cover at least the twenty-four (24) months immediately preceding the date of the certification or recertification.

(c) Discussion with the patient regarding any indicators of possible abuse or diversion of controlled substances that are reflected on the PDMP report.

(d) The explanation of the risks and benefits of treatment with medical cannabis as it pertains to the patient's qualifying medical condition and medical history.

(e) The registered qualified patient's voluntary and informed written consent prior to completing a certification or recommendation for treatment with medical cannabis. If the patient is a minor, the physician shall obtain the voluntary and informed written consent of the patient's parent or legal guardian prior to completing a certification or recommendation for treatment with medical cannabis for the patient. The voluntary and informed written consent for all registered qualified patients and/or legal guardians shall be memorialized on a form authorized by the Board, a copy of which shall also be provided to the patient or legal guardian. The voluntary and informed written consent form shall, at a minimum, include:

1. The federal and state classification of cannabis as a Schedule I controlled substance.

2. The approval and oversight status of cannabis by the Food and Drug Administration.

3. The current state of research on the efficacy of cannabis to treat the qualifying medical condition or conditions.

4. The potential for addiction.

5. The potential effect that cannabis may have on a patient's coordination, motor skills, and cognition, including a warning against operating heavy machinery, operating a motor vehicle, or engaging in activities that require an individual to be alert or respond quickly.

6. The potential side effects of cannabis use.

7. The risks, benefits, and drug interactions of cannabis.
8. A statement that the use of medical cannabis could result in termination from employment without recourse and that costs may not be covered by insurance or government programs.
9. That the patient's de-identified health information contained in the patient's medical record, physician certification, and patient registry may be used for research purposes or used to monitor compliance with Ala. Code §§ 20-2A-1, et. seq.
10. A statement that a certification or recommendation by a registered qualifying physician does not constitute a prescription for medical cannabis.
11. Whether the patient requires the use of a registered caregiver to assist in the use or administration of medical cannabis. If the patient requires or utilizes a registered caregiver, the physician shall document the name of the registered caregiver designated by the patient or the patient's legal representative.
 - (5) In certifying or recommending treatment with medical cannabis, a registered certifying physician or his or her delegate shall determine from the patient registry whether the patient has an active registration for the use of medical cannabis.
 - (a) If the patient is not registered or if the patient's registration will expire within thirty (30) days, the registered certifying physician shall submit the patient's application for registration or renewal to the patient registry.
 - (b) The electronic certification or recommendation for treatment with medical cannabis that is submitted to the patient registry shall include:
 - 1 The registered qualified patient's full legal name, date of birth, and home address;

2. The registered qualifying physician's name and Alabama Medical Cannabis Certification Permit number;

3. The name of the patient's registered caregiver, if applicable;

4. A description of the qualifying medical condition(s) and indication whether the qualifying condition is a terminal illness for which the registered qualified patient has a life expectancy of six (6) months or less;

5. The daily dosage of medical cannabis (as measured by potency of delta-9-tetrahydrocannabinol) that the registered certifying physician is recommending to the registered qualified patient. Any daily dosage recommended by a registered certifying physician shall not exceed the limitations set forth by the AMCC for each of the qualifying medical conditions;

6. The type or permissible forms of medical cannabis that the registered certifying physician recommends;

7. The permissible length of duration of the certification, which shall not exceed ninety (90) days;

8. A statement from the registered certifying physician certifying that a bona fide physician-patient relationship exists between the registered certifying physician and registered qualified patient;

9. A statement from the registered certifying physician affirming that the registered qualified patient has been diagnosed with at least one qualifying medical condition by either the registered certifying physician or another qualified physician;

10. A statement from the registered certifying physician that he or she has, prior to certifying the use of medical cannabis, attempted conventional medical treatments or

therapies for the patient's qualifying medical condition, and that said conventional treatments and/or therapies have failed to result in successful outcomes, or that current conventional medical treatment indicates that the use of medical cannabis is the standard of care for the patient's qualifying medical condition;

11. If the qualifying medical condition is based upon a terminal illness as defined in this Chapter, a statement from the registered qualifying physician that the patient is suffering from an illness or physical condition which the registered qualifying physician professionally and reasonably expects to result in the patient's death in six (6) months or less after the date of the certification; provided, a registered certifying physician shall not recertify a patient as having a terminal illness if the patient has been certified as having a terminal illness for a period of twenty-four (24) months or more;

12. An affirmation from the registered certifying physician that he or she, or his or her delegate, has obtained from the PDMP a report of information related to the registered qualified patient that includes, at a minimum, the twenty-four (24) months immediately preceding the date of the certification or recertification; and

13. An affirmation from the registered certifying physician that he or she has informed the registered qualified patient of the risks and benefits of medical cannabis as it pertains to the patient's qualifying medical condition and medical history.

(c) Absent any extenuating circumstances, a registered certifying physician shall, within twenty-four (24) hours, input into the patient registry any certification, recertification, or any updates thereto. Any deactivation shall be entered into the patient registry immediately upon the registered certifying physician becoming aware of the reason for the deactivation.

(6) A registered certifying physician who certifies or recommends treatment with medical cannabis shall be available to provide follow-up care and treatment to the patient, including physical examinations relevant to the patient's condition to determine the efficacy of medical cannabis in treating the patient's qualifying medical condition.

(7) A registered certifying physician shall deactivate a current certification or decline to issue a new certification for medical cannabis under any of the following circumstances:

(a) The registered certified patient no longer has the diagnosis of or symptoms of the qualifying medical condition.

(b) The registered certifying physician no longer possesses a valid Alabama Medical Cannabis Certification Permit.

(c) Based on the registered certifying physician's clinical judgment, the registered qualified patient or registered caregiver is abusing or diverting medical cannabis.

(d) The registered qualified patient is deceased.

(8) The records required for the certification or recommendation of medical cannabis may be kept with the patient's other medical records and shall be retained for at least seven (7) years in accordance with Ala. Admin. Code R. 540-X-9-.10.

(9) The registered certifying physician shall submit to the Board an annual report, in a manner prescribed by the Board, describing the physician's observations regarding the effectiveness of medical cannabis in treating patients. The report shall not contain patient-identifying information.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.

540-X-25-.11 Dosage Limitations of Medical Cannabis Recommendations.

(1) A registered certifying physician may not lawfully recommend the use of medical cannabis with a potency greater than three percent (3%) tetrahydrocannabinol to any minor for any qualifying medical condition.

(2) A registered certifying physician shall not recommend a dosage of tetrahydrocannabinol content which exceeds the maximum daily dosage of medical cannabis for the applicable qualifying medical condition, as established by rule of the AMCC.

(3) Subject to the maximum daily dosages established by rule of the AMCC, a maximum daily dosage shall not exceed 50 mg of delta-9-tetrahydrocannabinol; provided, however, that the maximum daily dosage may be increased but still subject to the maximum daily dosages established by rule of the AMCC under either of the following circumstances:

(a) A registered certifying physician may increase a patient's daily dosage if, after 90 days of continuous care under the physician during which time the patient was using medical cannabis, the physician determines that a higher daily dosage is medically appropriate; provided that the maximum daily dosage under this paragraph may not exceed 75 mg of delta-9-tetrahydrocannabinol, and that the physician shall clearly articulate in the patient's medical record the justification for the higher daily dosage; or

(b) A registered certifying physician may increase a patient's daily dosage if the patient has been diagnosed with a terminal illness; provided that, if the recommended

daily dosage exceeds 75 mg of delta-9-tetrahydrocannabinol, the physician shall notify the patient that the patient's driver's license will be suspended.

Author: Alabama Board of Medical Examiners

Statutory Authority: Ala. Code §§ 34-24-53, 34-24-53.1; Act 2021-450 (Ala. Code §§ 20-2A-1, et. seq.)

History: Approved for publication: November 18, 2021.