

APA-1

TRANSMITTAL SHEET FOR NOTICE
OF INTENDED ACTION

Control: 540

Department or Agency: Alabama Board of Medical Examiners

Rule No.: 540-X-25-.10

Rule Title: Requirements For Physician Recommendation Or
Certification For The Use Of Medical Cannabis

Intended Action Amend

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? No

To what degree?: N/A

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

Are all facets of the rule-making 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

William M. Perkins
William M Perkins

Date

Friday, January 19, 2024

REC'D & FILED
JAN 19, 2024
LEGISLATIVE SVC AGENCY

ALABAMA BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-25-.10 Requirements For Physician Recommendation
Or Certification For The Use Of Medical Cannabis

INTENDED ACTION: Amend

SUBSTANCE OF PROPOSED ACTION:

Amend to clarify that any certification, re-certification, recommendation, or re-recommendation of a patient for the use of medical cannabis must occur with the parties physically present in the same room; clarify the use of drug screens and the prescription drug monitoring data bank and consider the polypharmacy and possible interactions of these substances; to obtain a negative pregnancy test on any patient capable of conception immediately prior to certifying, re-certifying, recommending, or re-recommending a patient for the use of medical cannabis; add registered caregivers as parties to the informed consent; clarify the details to submit to the patient registry; to limit the length of duration of certification for patients capable of conception to 30 days; delete the requirement of an annual report.

This amendment meets the "protection of public health" exemption from the moratorium on rule amendments contained in Governor Ivey's Executive Order No. 735, Reducing "Red Tape" on Citizens and Businesses.

TIME, PLACE AND 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 Kruger, Office of the General Counsel, Alabama State Board of Medical Examiners, Post Office Box 946, Montgomery, Alabama 36101-0946, by mail or email (bme@albme.gov), until and including March 6, 2024. Persons wishing to submit data, views, or comments in person should contact Carla Kruger by telephone (334-242-4116) during the comment period. Copies of proposed rules may be obtained at the Board's website, www.albme.gov.

FINAL DATE FOR COMMENT AND COMPLETION OF NOTICE:

Wednesday, March 6, 2024

CONTACT PERSON AT AGENCY:

Carla Kruger

William M. Perkins

William M Perkins

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

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. Any certification or recommendation, or recertification or re-recommendation, of a patient for the use of medical cannabis must also occur with the registered certifying physician and the qualified patient physically present in the same room.

(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~~Prior to initially certifying or recommending a patient for the use of medical cannabis, a registered certifying physician shall obtain a drug screen on the patient for the presence of controlled substances. A physician shall not certify or recommend the use of medical cannabis for any patient who has a positive drug screen for any illicit or controlled substances for which they are not prescribed, excluding cannabis. The registered certifying physician shall confirm any controlled substance prescriptions by querying the patient's PDMP profile and shall consider the polypharmacy and possible interactions of these substances with cannabis prior to certifying or recommending a patient for the use of medical cannabis. Results of the drug screen shall be maintained in the medical record~~along with documentation of any prescriptive 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) Immediately prior to certifying or recommending, or recertifying or re-recommending, a patient for the use of medical cannabis, a registered certifying physician shall obtain a negative pregnancy test result on any patient capable of conception. The results of the pregnancy test shall be maintained in the medical record;

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

~~(k)~~ (l) 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 and, if applicable, registered caregivers shall be memorialized on a form authorized by the Board, a copy of which shall also be provided to the patient or legal guardian and, if applicable, registered caregiver. 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 Code of Ala. 1975, §§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. The registered caregiver must also review and sign the voluntary and informed written consent form in the presence of the registered certifying physician.

(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~~ social security number;

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

3. The full legal name, date of birth, and social security number of the patient's registered parent or legal guardian and/or 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~~form(s) of medical cannabis that the registered certifying physician recommends;
7. The permissible length of duration of the certification, which shall not exceed thirty days for a patient capable of conception, or ninety (90) days for all other patients;
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, prior to certifying the use of medical cannabis, he or she has, or has confirmed through primary source verification of the patient's medical records that another qualified physician has, 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 certifying physician that the patient is suffering from an illness or physical condition which the registered certifying 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~~qualified 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: Code of Ala. 1975, §§34-24-53, 34-24-53.1; Act 2021-450 (Code of Ala. 1975, §§20-2A-1, et. seq.)

History: New Rule: Published March 31, 2022; effective May 15, 2022. **Amended:** Published _____; effective _____.