APA-1

TRANSMITTAL SHEET FOR NOTICE OF INTENDED ACTION

Control: 540

Department or Agency: Alabama Board of Medical Examiners

Rule No.: 540-X-25 Appendix A

Rule Title: Alabama Medical Cannabis Informed Consent

Intended Action: New

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

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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

APA-2

ALABAMA BOARD OF MEDICAL EXAMINERS

NOTICE OF INTENDED ACTION

AGENCY NAME: Alabama Board of Medical Examiners

RULE NO. & TITLE: 540-X-25 Appendix A Alabama Medical Cannabis Informed Consent

INTENDED ACTION: New

SUBSTANCE OF PROPOSED ACTION:
Adopt a new rule containing the language necessary for the Alabama Medical Cannabis Informed Consent.
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)

540-X-25 Appendix A **Alabama Medical Cannabis Informed Consent.**

A certifying physician may not delegate the responsibility of obtaining written informed consent to another person. The certifying physician must explain the information in each section of this form to the patient, or the patient's parent or legal guardian, and, if applicable, the patient's registered caregiver. Prior to the certifying physician completing the certification or recommendation for medical cannabis, the certifying physician and the qualified patient, or the patient's parent or legal guardian, and, if applicable, registered caregiver must initial each section and sign indicating that the certifying physician has explained the information on this form. The original form shall be retained in the patient's medical record, and a copy shall be provided to the patient, parent, or legal guardian, and, if applicable, registered caregiver.

Patient's Printed Name _____

Classification of medical cannabis:

The federal and state government have classified cannabis as a Schedule I controlled substance. Schedule I substances are defined, in part, as having (1) a high potential for abuse; (2) no currently accepted medical use for treatment in the United States; and (3) a lack of accepted safety for use under medical supervision. Federal law prohibits the manufacture, distribution, and possession of cannabis even in states, such as Alabama, which have modified their state laws to treat cannabis as a medicine.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

The approval and oversight status of cannabis by the FDA:

Cannabis has not been approved by the Food and Drug Administration for marketing as a drug; therefore, the "manufacture" of cannabis for medical use is not subject to any federal standards, quality control, or other federal oversight. Cannabis may contain unknown quantities of active ingredients, which may vary in potency, impurities, contaminants, and substances in addition to THC, which is the primary psychoactive chemical component of cannabis.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

The current state of research on the efficacy of cannabis to treat the qualifying conditions:

There is insufficient evidence to support or refute the conclusion that cannabinoids are an effective treatment for any of the recognized qualifying medical conditions. While there is evidence that cannabinoids may provide relief for some of the symptoms associated with the qualifying medical conditions, the research is not conclusive. Research in this field remains ongoing, and the science is developing.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

The potential for addiction:

Some studies suggest that the use of cannabis by individuals may lead to a tolerance to, dependence on, or addiction to cannabis. I understand that if I require increasingly higher doses to achieve the same benefit or if I think that I may be developing a dependency on cannabis, I should contact my certifying physician.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

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:

The use of cannabis can affect coordination, motor skills, and cognition; i.e., the ability to think, judge, and reason. Driving under the influence of cannabis can significantly increase the risk of vehicular accident, which escalates if alcohol is also influencing the driver. While using medical cannabis I should not drive, operate heavy machinery, or engage in any activities that require me to be alert and/or respond quickly, and I should not participate in activities that may be dangerous to myself or others. I understand that if I drive while under the influence of cannabis, I can be arrested for "driving under the influence" (Ala. Code § 32-5A-191).

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

The potential side effects of medical cannabis use:

Potential side effects from the use of cannabis include, but are not limited to, the following: dizziness, anxiety, confusion, sedation, low blood pressure, impairment of short term memory, euphoria, difficulty in completing complex tasks, suppression of the body's immune system, an effect on the production of sex hormones that may lead to adverse effects, inability to concentrate, impaired motor skills, paranoia, psychotic symptoms, general apathy, depression, and/or restlessness. Cannabis may exacerbate schizophrenia in persons predisposed to that disorder. In addition, the use of medical cannabis may cause me to talk or eat in excess, alter my perception of time and space, and impair my judgment. Many medical authorities claim that use of medical cannabis, especially by persons younger than 25, can result in long-term problems with attention, memory, learning, drug abuse, and schizophrenia.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

The risks, benefits, and drug interactions of cannabis:

Signs of withdrawal can include feelings of depression, sadness, irritability, insomnia, restlessness, agitation, loss of appetite, trouble concentrating, sleep disturbances, and unusual tiredness.

Symptoms of cannabis overdose include, but are not limited to, nausea, vomiting, hacking cough, disturbances in heart rhythms, numbness in the hands, feet, arms or legs, anxiety attacks, and incapacitation. If I experience these symptoms, I agree to contact my certifying physician immediately or go to the nearest emergency room. Numerous drugs are known to interact with cannabis, and not all drug interactions are known. Some mixtures of medications can lead to serious and even fatal consequences.

I agree to follow the directions of my certifying physician regarding the use of prescription and non-prescription medication. I will advise all my other treating physician(s) of my use of medical cannabis.

Cannabis may increase the risk of bleeding, low blood pressure, elevated blood sugar, elevated liver enzymes, or impairment of other bodily systems when taken with herbs and supplements. I agree to contact my certifying physician immediately or go to the nearest emergency room if these symptoms occur.

I understand that medical cannabis may have serious risks and may cause low birthweight or other abnormalities in babies. I will advise my certifying physician if I become pregnant, try to get pregnant, or will be breastfeeding.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

Termination of employment and cost coverage:

The use of medical cannabis could result in termination from employment without recourse, and costs may not be covered by insurance or government programs.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

Research & compliance:

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 Act 2021-450.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

Certifications and recommendations are not prescriptions:

Certification or recommendation by a registered certifying physician does not constitute a prescription for medical cannabis.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

Registry identification card:

When in the possession of medical cannabis, the patient or the patient's caregiver(s) must have his or her medical cannabis use registry identification card in his or her possession at all times.

Cert. Physician Initials _____ Patient/Guardian/Caregiver Initials _____

I have had the opportunity to discuss these matters with the physician and to ask questions regarding anything I may not understand or that I believe needed to be clarified. I acknowledge that my certifying physician has informed me of the nature of a recommended treatment, including but not limited to, any recommendation regarding medical cannabis.

My certifying physician also informed me of the risks, complications, and expected benefits of any recommended treatment, including its likelihood of success and failure. I acknowledge that my certifying physician has explained the information in this consent form about the medical use of cannabis.

Patient's Printed Name _____ Date _____
Patient's Signature _____ Date _____
Name of Patient's Registered Caregiver (if applicable) _ Date _____
Signature of Registered Caregiver (if applicable) _____ Date _____
Name of Parent/Legal Guardian (if applicable): _____ Date _____
Signature of Parent/Legal Guardian (if applicable): _____ Date _____
Relationship to Patient: _____ Date _____

Name of Certifying Physician: _____ Date _____
Signature of Certifying Physician: _____ Date _____
Physician's AMCC Permit #: _____

Author: Alabama Board of Medical Examiners
Statutory Authority: Ala. Code §§34-24-53 and 34-24-53.1; §§20-2A-1, et. seq.
History: New Rule: Published _____; effective _____.