Georgia Composite Medical Board

Executive Director LaSharn Hughes, MBA



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NOTICE OF INTENT TO AMEND AND ADOPT RULES

TO ALL INTERESTED PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia Composite Medical Board (hereinafter "Board") proposes amendments to the Georgia Composite Medical Board Rules by amending Rule Chapter 360-36 Low THC Oil, Rule 360-36-.01 "Definitions" and Rule 360-36-.04 "Low THC Oil." An exact copy of the proposed rules is attached to this Notice.

This notice, together with an exact copy of the proposed rules and a synopsis of the proposed amendments may be reviewed between 8:00 a.m. and 4:00 p.m., Monday through Friday, except official state holidays, at 2 Peachtree Street, NW., 6th Floor, Atlanta, GA 30303. These documents can also be reviewed online at http://medicalboard.georgia.gov/notice-intent-amendadopt-rules.

A public hearing is scheduled to begin at 8:00 a.m. on June 13, 2019 at 2 Peachtree Street, N.W., 5th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed rules. At the public hearing, any interested person may present data, make a statement or comment, or offer a viewpoint or argument orally or in in writing. Lengthy statements and statements of a considerable technical or economic nature, as well as previously recorded messages, must be submitted for the official record. Oral statements should be concise and will be limited to 5 minutes per person. Additional comments should be presented in writing. To ensure their consideration, submit all written comments by June 6, 2019 to Diane Atkinson at matkinson@dch.ga.gov or via mail to the Georgia Composite Medical Board Rules Committee at 2 Peachtree Street, N.W., 6th Floor, Atlanta, Georgia 30303.

The Board voted to adopt this Notice of Intent on April 11, 2019. Upon conclusion of the public hearing on June 13, 2019, the Board will consider whether the formulation and adoption of these proposed rule amendments imposes excessive regulatory costs on any license or entity, and whether any cost to comply with the proposed rule amendments could be reduced by a less expensive alternative that accomplishes the objectives of the statutes which are the basis of the proposed rule. Additionally, the Board will consider whether it is legal or feasible in meeting the objectives of the applicable laws to adopt or implement differing actions for businesses as listed in O.C.G.A. § 50-13-4(3)(A),(B),(C), and (D).

This Notice is adopted and posted in compliance with O.C.G.A. § 50-13-4 of the Georgia Administrative Procedures Act. A synopsis of the proposed rules and an economic impact statement are attached to this Notice. The authority for promulgation of these rules is O.C.G.A. §§§16-12-190, 31-2A-18 and 43-34-5

Issued this day May 7, 2019.

LaSharn Hughes, MBA

Executive Director

Georgia Composite Medical Board

ECONOMIC IMPACT AND SYNOPSIS FOR

RULE CHAPTER 360-36

ECONOMIC IMPACT:

The attached rules are promulgated under the authority of the Medical Practice Act, Title 43, Chapter 34. The Georgia Composite Medical Board licenses and regulates nine professions. The formulation and adoption of these rules do not impose excessive regulatory cost on any licensee, and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated. Additionally, it is not legal or feasible to meet the objectives of the Article 2 of Chapter 34 of Title 43 of the Official Code of Georgia Annotated to adopt or implement differing actions for businesses listed in O.C.G.A. §50-13-4(a)(3)(A), (B), (C) and (D).

RULE SYNOPSIS:

Rule 360-36-.01 "Definitions"

<u>Purpose/Main Features</u>: The purpose of the proposed amendment is to mirror the statutory definition for "condition" contained in O.C.G.A. §31-2A-18(a)(3). The statute was changed in 2018 to add three additional conditions.

Rule 360-36-.04 "Low THC Oil"

<u>Purpose/Main Features</u>: The purpose of the proposed amendment is to mirror the statutory requirement to change the report requirement from being on a quarterly basis to a semi-annual basis.

Authority: O.C.G.A. §§43-34-5(c) and 31-2A-18(a)(3)

Chapter 360-36 LOW THC OIL

Rule 360-36-.01 Definitions

As used in these rules, the following shall mean:

- (1) 'Board' means the Georgia Composite Medical Board.
- (2) 'Department' means the Department of Public Health.
- (3) 'Low THC oil' means an oil that contains not more than 5 percent by weight of tetrahydrocannabinol and an amount of cannabinol equal to or greater than the amount of tetrahydrocannabinol.
- (4) 'Physician' means an individual licensed to practice medicine pursuant to Article 2 of Chapter 34 of Title 43.
- (5) 'Registry' means the Low THC Oil Patient Registry.
- (6) 'Doctor-patient relationship' means the physician must be the patient's primary care or specialist physician treating the patient for the specific condition requiring treatment by Low THC oil, and must be maintaining patient records supporting the diagnosis and treatment of the patient.
- (7) 'Caregiver' means the parent, guardian, or legal custodian of an individual who is less than 18 years of age or the legal guardian of an adult.
- (8) 'Condition' means for the purpose of those conditions listed in O.C.G.A. 31-2A-18(a)(3).
 - (a) Cancer, when such diagnosis is end stage or the treatment produces related wasting illness, recalcitrant nausea, and vomiting;
 - (b) Amyotrophic lateral sclerosis, when such diagnosis is sever or end stage;
 - (c) Seizure disorders related to diagnosis of epilepsy or trauma related head injuries;
 - (d) Multiple sclerosis, when such diagnosis is severe or end stage;
 - (e) Crohn's disease;
 - (f) Mitochondrial disease;
 - (g) Parkinson's disease, when such diagnosis is severe or end stage; or
 - (h) Sickle cell disease, when such diagnosis is severe or end stage.

Authority: O.C.G.A. §§ 16-12-190, 31-2A-18.

Rule 360-36-.04 Quarterly Reports

- (1) Physicians certifying patients to the Department for Low THC oil shall make quarterly semi-annual reports to the Board by filing the report online at http://dph.georgia.gov/low-thc-oil-registry. The reports should be submitted within ten (10) days of the reporting period ending March 31st, June 30th, September 30th, and December 31st. April and October. Such reports shall require physicians to provide information, including, but not limited to:
 - (a) Name, address, and contact information for the physician;
 - (b) Unique patient number from the registration card;
 - (c) Condition being treated;
 - (d) Amount or concentration of THC oil reported by the patient;
 - (e) Drug interactions, if any;
 - (f) Adverse effects, if any;
 - (g) If the physician is still treating the patient, and if not, why; and
 - (h) Patient compliance with treatment.
- (2) Information obtained from the quarterly semi-annual reports are confidential.
- (3) Physicians that are no longer seeing the patients can notify the Board before the next quarterly semi-annual report is due by submitting the report early in writing.
- (4) Failure to submit the reports as required herein will be reported to the Department and may affect the physician's eligibility to participate on the registry.
- (5) A physician should maintain a copy of each quarterly <u>semi-annual</u> report in the patient's medical record.

Authority: O.C.G.A. §§ 31-2A-18, 43-34-5.