

GEORGIA COMPOSITE MEDICAL BOARD

EXECUTIVE DIRECTOR
LaSharn Hughes, MBA



BOARD CHAIRPERSON
Alice House, MD

2 Peachtree Street, N.W., 36th Floor • Atlanta, Georgia 30303 • Tel: 404.656.3923 • <http://www.medicalboard.georgia.gov>
E-Mail: medbd@dch.ga.gov

GEORGIA COMPOSITE MEDICAL BOARD 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 a new Rule to the Georgia Composite Medical Board Rules, **Rule Chapter 360-36 "Low THC Oil."** An exact copy of the proposed new rule chapter is attached to this Notice.

This notice, together with an exact copy of the proposed rules and a synopsis of the proposed amendments is forwarded to all persons who have requested, in writing, that they be placed on the interested parties' mailing list. A copy of this notice, an exact copy of the proposed rules and a synopsis of the proposed rules may be reviewed during normal business hours of 8:00 a.m. to 5:00 p.m., Monday through Friday, except official State holidays, at the office of the Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303. These documents will also be available for review on the Board's website at www.medicalboard.georgia.gov.

A public hearing is scheduled to begin at **8:30 a.m. on January 7, 2016** at the 36th Floor Board Room, 2 Peachtree Street, N.W., 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 who will be affected by these rules may present his or her written comments to the Board no later than **December 21, 2015** or make comments at the public hearing. Comments may be directed to Diane Atkinson, Georgia Composite Medical Board, 2 Peachtree Street, N.W., 36th Floor, Atlanta, Georgia 30303-3465 or may be received by the Board by e-mail at matkinson@dch.ga.gov.

The proposed amendments will be considered for adoption by the Board at its meeting scheduled to begin at **8:30 a.m. on January 7, 2016** at the Board offices on the 36th Floor Board Room, 2 Peachtree Street, N.W., Atlanta, Georgia 30303

The Board voted to adopt this Notice of Intent on **November 16, 2015** teleconference meeting. The Board will consider at its meeting on **January 7, 2016 at 8:30 a.m.** the comments from the public hearing 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 at its meeting on **January 7, 2016** the Board will consider

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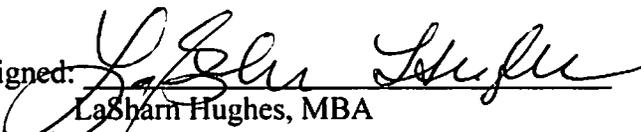
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whether it is legal or feasible in meeting the objectives of the applicable laws to adopt or implement differing actions for businesses as listed in O.C.G.A. § 50-13-4(3) (A) (B)(C)(D). This Notice is adopted and posted in compliance with O.C.G.A. § 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. Authority Section O.C.G.A. Secs. 43-34-143, 43-34-145, 43-34-148 and 43-1-33.

Date: November 17, 2015

Signed: 
LaSharn Hughes, MBA
Executive Director
Georgia Composite Medical Board

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ECONOMIC IMPACT AND SYNOPSIS FOR AMENDMENTS TO CHAPTER 360-36 Low THC Oil

ECONOMIC IMPACT:

The attached rules are promulgated under the authority of the Medical Practice Act, Title 43, Chapter 34. The Composite State Board of Medical Examiners licenses and regulates nine professions. The formulation and adoption of this rule does 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 at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D).

RULE SYNOPSIS:

Rule Chapter 360-36F "Low THC Oil"

Purpose/Main Feature: The purpose this new Rule Chapter is to implement House Bill 1 and provide guidelines for physician participating in the registry.

Authority O.C.G.A. Sections 16-12-190 and 31-2A-18, 43-34-5 and 43-34-8.

**Rule Chapter 360-36
Low THC Oil**

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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 cannabidiol 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.
 - (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 severe 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. Sections 16-12-190 and 31-2A-18.

360-36-.02 Physician Certification

(1) In order to register a patient with the Department, the physician must:

- (a) Hold an active license to practice medicine in the State of Georgia;
- (b) Have a doctor-patient relationship with the patient;
- (c) Have determined that the patient has a condition that qualifies for Low THC oil under the law;
- (d) Be treating the patient for the condition; and,
- (e) Have provided the patient with a Board approved waiver form and the patient must have signed the form.

(2) The physician must provide the following information to the Department:

- (a) The name and address of a patient and if appropriate, the name and address of the patient's caregiver;
- (b) Whether the patient is a legal resident of Georgia and how long the patient has been a resident of Georgia;
- (c) The medical condition of the patient and how long the patient has been diagnosed with the condition;
- (d) Whether the patient qualifies for the use of low THC oil under the law;
- (d) The length of time the physician has been treating the patient;
- (e) What other treatments has the patient had for the condition; and

(f) Certification that the physician has a doctor- patient relationship with the patient.

(3) The physician must keep a copy of the physician certification in the patient's medical record.

Authority O.C.G.A. Section 31-2A-18.

360-36-.03 Waiver Forms

The physician shall provide to the patient a copy of the waiver form approved by the Board advising that the use of cannabinoids and THC containing products have not been approved by the FDA and the clinical benefits are unknown and may cause harm. A signed copy of this form shall be maintained in the patient record and shall be submitted to the Department of Public Health along with the certification form for registration. The approved Board form may be found at <http://dph.georgia.gov/low-thc-oil-registry>.

Authority O.C.G.A. Section 31-2A-18.

360-36-.04 Quarterly Reports

(1) Physicians certifying patients to the Department for Low THC oil shall make quarterly 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. Such reports shall require physicians to provide information, including, but not limited to:

(a) Name, address and contact information for physician

(b) Unique patient number from 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 physician is still treating the patient and if not, why.

(h) Patient compliance with treatment

(2) Information obtained from the quarterly reports are confidential.

(3) Physicians that are no longer seeing the patients can notify the Board before the next quarterly 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 report in the patient's medical record.

Authority O.C.G.A. Sections 31-2A-18, and 43-34-5.

360-36-.05 Discipline.

Failure to comply with the rules and regulations of the Board is grounds for disciplinary action by the Board under O.C.G.A. Section 43-34-8.

Authority O.C.G.A. Sections 31-2A-18 and 43-34-8.

Updated 11/16/2015