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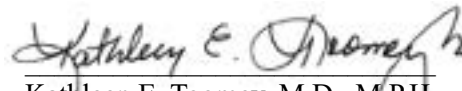
NOTICE OF ADOPTION OF REGULATIONS

Revisions to Chapter 511-5-11
"Low THC Oil Patient Registry"

The Department of Public Health hereby adopts amendments to Rule 511-5-11, "Low THC Oil Patient Registry," as provided in the Notice of Proposed Rulemaking issued on July 29, 2024. This action is taken pursuant to the Department's authority under Georgia Code Sections 31-2A-6, 31-12-5 through 31-12-7.

In accordance with Georgia Code Section 31-5-1, the above-listed amendments will take effect on October 17, 2024.

This 18th day of September, 2024.


Kathleen E. Toomey, M.D., M.P.H.
Commissioner
Georgia Department of Public Health

RESPONSE TO PUBLIC COMMENTS

Revisions to Chapter 511-5-11 “Low THC Oil Patient Registry”

The Georgia Department of Public Health received written comments to the invitation for public comments included in the Notice of Proposed Rulemaking issued on July 29, 2024. Each comment received was reviewed and considered by Department staff and the Commissioner of Public Health.

The Commissioner elected to adopt, with some revisions based on public comments, the rules proposed on July 29, 2024, and the new rules will become effective on October 17, 2024.

Although the Department is not required to respond to public comments, a brief discussion of the issues presented is provided below.

1. Eighteen commenters expressed support for the Proposed Rules as written.
2. Three commenters proposed implementing entirely new processes and procedures for issuing Low THC Oil Cards, such as a utilizing a new “certification form” prepared by the Georgia Composite Medical Board; or striking in their entirety the Department’s rules and procedures for obtaining Low THC Oil Cards. One commenter further proposes that patients should be permitted to apply for Low THC Oil Cards directly, rather than relying on their physician to submit the application. These commenters suggest that the Department’s role is simply to issue Low THC Oil Cards to anyone certifying compliance with applicable laws.

The Department disagrees with the commenters’ interpretation of O.C.G.A. § 31-2A-18. The Department maintains that it has the authority and duty, in coordination as appropriate with the Georgia Composite Medical Board, to verify applicants’ compliance with the terms of O.C.G.A. § 31-2A-18 prior to issuance of Low THC Oil Cards.

3. Five commenters propose revisions to the requirement that applicants for a Low THC Oil Card demonstrate their residency in the State of Georgia.

Based on a review of the legislative history of O.C.G.A. § 31-2A-18, the Department does not agree with comments suggesting that registration should be open to non-Georgia residents. However, the Department agrees that registrants should not be required to demonstrate the length of time they have resided in the State of Georgia and has revised the Proposed Rules accordingly.

4. Four commenters propose revisions to the Department's definition of "Low THC Oil," including some commenters requesting to expand the definition to include low THC oil delivered through product forms.

The Department agrees with comments that the definition of Low THC Oil should be revised to better comport with O.C.G.A. § 16-12-190. However, the Department disagrees that the definition should be expanded to include product forms as such definition is inconsistent with O.C.G.A. § 31-2A-18 (referencing only "oil" and not "products").

5. One commenter proposes that the Department no longer use the term "Low THC Oil permit" in its Rules and suggests shifting to the term "registration card" to better comport with O.C.G.A. § 31-2A-18. Two commenters further propose to delete references to the 20 fluid ounce limit on Low THC Oil possession.

The Department generally has no objection to use of the word "card" in place of "permit" and will therefore revise the Proposed Rules to replace "Low THC Oil Permit" with "Low THC Oil Card." However, the Department does not agree with the commenter's proposed definition of "registration card" to include Low THC delivered in product forms. Further, the Department does not agree with the commenter's suggestion to delete references to the 20 fluid ounce limit on Low THC Oil possession as this language is consistent with the provisions of O.C.G.A. § 16-12-191.

6. One commenter proposes minor revisions to the Department's definition of "cardholder."

The Department has no objection to the commenter's recommendation and will revise the Proposed Rules accordingly.

7. One commenter proposes minor revisions to the Department's definition of "caregiver."

The Department has no objection to the commenter's recommendation and will revise the Proposed Rules accordingly.

8. Two commenters propose numerous revisions to the Department's definition of "eligible patient."

The Department agrees with and will implement certain suggestions presented by one commenter as to the precise statutory definitions of the various medical conditions listed in Ga. Comp. R. & Regs. r. 511-5-11-.01(4), including the addition of inpatient or outpatient hospice as a qualifying condition.

Additionally, the Department has no objection to using the term “certified patient,” rather than “eligible patient,” to refer to an individual who has “been certified to the department by his or her physician as being diagnosed with a condition or is an inpatient or outpatient in a hospice program and has been authorized by such physician to use low THC oil as treatment.” O.C.G.A. § 31-2A-18(d).

However, the Department rejects the commenters’ proposed definitions to the extent that they: (1) do not include the requirement that a patient be a resident of Georgia; (2) suggest restructuring the registration process as a function of the Georgia Composite Medical Board, with a new “certification form.”

The Department maintains that both the residency requirement and the Department’s processes and procedures for issuing Low THC Oil Cards are consistent with and effectively implement the provisions O.C.G.A. § 31-2A-18.

9. One commenter proposes revisions to the Department’s definition of “physician.”

The Department has no objection to the commenter’s recommendation and will revise the Proposed Rules accordingly.

10. One commenter proposes revisions to the Department’s definition of “Low THC Oil Patient Registry.”

The Department does not agree with the commenter’s revised definition as it implies restructuring the process for issuing Low THC Oil Cards as a function of the Georgia Composite Medical Board, with a new “certification form.” The Department maintains that the current definition is not inconsistent with the provisions of O.C.G.A. § 31-2A-18.

11. One commenter proposes revisions to the parameters of the Department’s periodic reviews of the Low THC Oil Registry to include a review of (1) whether a patient is no longer diagnosed with the condition listed on their application for a Low THC Oil Card; and (2) whether a no longer a caregiver of the patient.

The Department has no objection to the commenter’s recommendation and will revise the Proposed Rules accordingly.

12. One commenter proposes that the Department revise its rules to allow release of confidential information containing personally identifying of cardholders to the Georgia Access to Medical Cannabis Commission.

The Department rejects the commenter's proposal as it is not consistent with the provisions of O.C.G.A. § 31-2A-18, which only allows for the release of confidential information in very limited circumstances.

13. Two commenters propose that the Department revise its rules to reflect that reports by physicians to the Georgia Composite Medical Board are completed semi-annually pursuant to O.C.G.A. §31-2A-18(e).

The Department agrees with the commenters and will revise the Proposed Rules accordingly.

14. Three commenters proposes that applicants for a Low THC Oil Card should be permitted to choose whether to receive their cards via mail or e-mail. One commenter further recommends that the Department should mail cards to the address preferred by the applicant.

The Department intends to mail Low THC Oil Cards to the most appropriate and convenient location as indicated by the applicant/cardholder. The Department maintains that it may elect to either mail or e-mail the cards as the Department deems appropriate, and that this approach is not inconsistent with the provisions of O.C.G.A. § 31-2A-18.

15. Three commenters propose that applicants for a Low THC Oil Card should be permitted to choose whether to pay for their card via phone, mail, or in-person.

The Department appreciates the commenter's concerns related to accessible payment methods and is revising the Proposed Rules accordingly. The Department intends to provide individuals with the option to pay for their card via numerous methods as appropriate to the registrant's particular circumstances.

16. Two commenters proposes that the Department stop requesting identification from individuals registering for the Low THC Oil card.

The Department rejects this commenter's suggestion and maintains that the Department's process of requiring a secure and verifiable form of identification is consistent with and effectively implements the provisions of O.C.G.A. § 31-2A-18.

17. One commenter proposes that the Department cap its fee for processing and issuing Low THC Oil Cards to \$25. Another commenter proposes that the Department cap its fee to the actual administrative costs incurred by the Department associated with processing and issuing the card. Additionally, one commenter proposes that the Department implement a fee waiver in certain circumstances.

The Department maintains that Rule 511-5-11-.04 as it relates to fees for processing and issuing Low THC Oil Cards are consistent with and effectively implement the provisions of O.C.G.A. § 31-2A-18.

The Department will also revise Rule 511-5-11-.04 to allow both cardholders and certifying physicians to request a replacement for an unexpired card that is lost or stolen.

18. One commenter proposes various updates to the Frequently Asked Questions on the Department's website related to Low THC Oil Cards.

The Department will take the suggested website revisions under advisement.

19. One commenter proposes that the Department should not limit the number of caregivers per eligible patient.

The Department agrees with this comment and will revise its policies accordingly.

**RULES OF THE
DEPARTMENT OF PUBLIC HEALTH**

**CHAPTER 511-5
HEALTH PROMOTION**

**511-5-11
LOW THC OIL PATIENT REGISTRY**

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Rule 511-5-11-.01 Definitions

- (1) “Cardholder” means a certified patient registered on the Low THC Oil Patient Registry and identified on a “Low THC Oil Card” issued by the Department. A cardholder may also be such a certified patient’s caregiver who has been issued a “Low THC Oil Card” by the Department.
- (2) “Caregiver” means the parent, legal guardian, or legal custodian of a certified patient, including but not limited to:
 - (a) An individual person authorized by the Division of Family and Children’s Services of the Department of Human Services to care for a child in foster care; or
 - (b) An individual identified as such a patient's caregiver on the certification form.
- (3) “Department” means the Georgia Department of Public Health;
- (4) “Certified patient” means a resident of Georgia who has been certified by a physician licensed by the Georgia Composite Medical Board as being in an inpatient or outpatient hospice program, or as having one of the following conditions:
 - (a) Cancer, when such disease is diagnosed as end stage or the treatment produces related wasting illness, recalcitrant nausea and vomiting;
 - (b) Amyotrophic lateral sclerosis, when such disease is diagnosed as severe or end stage;
 - (c) Seizure disorders related to a diagnosis of epilepsy or trauma related head injuries;
 - (d) Multiple sclerosis, when such disease is diagnosed as severe or end stage;
 - (e) Crohn’s disease;
 - (f) Mitochondrial disease;
 - (g) Parkinson’s disease, when such disease is diagnosed as severe or end stage; or
 - (h) Sickle cell disease, when such diagnosis is severe or end stage;
 - (i) Tourette’s syndrome, when such syndrome is diagnosed as severe;
 - (j) Autism spectrum disorder, when such disorder is diagnosed for a patient who is at least 18 years of age, or severe autism, when diagnosed for a patient who is less than 18 years of age;
 - (k) Epidermolysis bullosa;
 - (l) Alzheimer’s disease, when such disease is diagnosed as severe or end stage;
 - (m) Acquired immune deficiency syndrome, when such syndrome is diagnosed as severe or end stage;
 - (n) Peripheral neuropathy, when such symptoms are diagnosed as severe or end stage;

- (o) Post-traumatic stress disorder resulting from direct exposure to or the witnessing of a trauma for a patient who is at least 18 years of age; or
- (p) Intractable pain; as defined in Code Section 31-2A-18(a)(5).
- (5) “Low THC Oil” has the definition set forth in Code Section 16-12-190;
- (6) “Low THC Oil Patient Registry” means the database maintained by the Department of all certified patients and their caregivers on whose behalf applications for a Low THC Oil Card have been submitted and approved by the Department;
- (7) “Low THC Oil Card” means a durable card issued by the Department to certified patients or their caregivers authorizing the possession of up to 20 fluid ounces of low THC oil for use by a certified patient;
- (8) “Physician” means a person licensed to practice medicine by the Georgia Composite Medical Board pursuant to Article 2 of Chapter 34 of Title 43.

Authority: O.C.G.A. §§ 16-12-190, 16-12-191, 31-2A-6, 31-2A-18.

Rule 511-5-11-.02 Low THC Oil Patient Registry

- (1) The Department shall maintain a database of certified patients and their caregivers, and shall periodically review the database to determine whether the Low THC Oil Cards of such cardholders are to remain active based on the following information maintained by or submitted to the Department:
 - (a) The expiration date as printed on the registration card;
 - (b) The cardholder has become deceased;
 - (c) The cardholder, specifically the certified patient, no longer has a condition as defined in Code Section 31-2A-18 or is no longer an inpatient or outpatient in hospice care; or
 - (d) The cardholder, specifically the caregiver, is no longer a caregiver of the certified patient.
- (2) All applications for and information stored in the Low THC Oil Patient Registry shall be confidential except as follows:
 - (a) Upon request by a peace officer or prosecuting attorney, the Department shall confirm or deny that a particular individual appears in the Low THC Oil Patient Registry as a cardholder;
 - (b) Information in the Low THC Oil Patient Registry may be shared with the Georgia Composite Medical Board to assist in the preparation of the semiannual reports required by Code Section 31-2A-18(e);
 - (c) An individual or caregiver registered with the Department under this Rule may request information pertaining to their application and Low THC Oil Card;

(d) Information in the Low THC Oil Patient Registry may be disclosed to government entities and other entities for statistical, research, educational, instructional, drug abuse prevention, or grant application purposes after removing all personal identifiers from the health information and removing all information that could be used to identify prescribers.

Authority: O.C.G.A. §§ 31-2A-6, 31-2A-18, 31-5-5, 31-12-2.

Rule 511-5-11-.03 Applications for the Low THC Oil Patient Registry

(1) The Department shall establish and maintain an internet portal through which physicians may submit applications for the Low THC Oil Patient Registry on behalf of their patients and their patients' caregivers.

(2) The Department shall require such information as may be determined by the Georgia Composite Medical Board, including but not limited to the following:

- (a) Name, address, and date of birth of the patient;
- (b) Name, address, and Georgia license number of the physician providing the certification;
- (c) The medical condition or conditions that make the patient eligible for the Low THC Oil Patient Registry;
- (d) Whether the certifying physician has a doctor-patient relationship with the patient; and
- (e) Whether the certifying physician is treating the patient for the medical condition or conditions that make the patient eligible for the Low THC Oil Patient Registry.

(3) A physician's certification of a patient for the Low THC Oil Patient Registry shall not constitute a prescription.

Authority: O.C.G.A. §§ 31-2A-6, 31-2A-18.

Rule 511-5-11-.04 Issuance of Low THC Oil Cards

(1) The Department shall print and issue a Low THC Oil Card upon receipt and review of an application certified by the patient's physician and showing eligibility as provided by law. The Low THC Oil Card shall be valid for five years from issuance or the death of the cardholder, whichever happens first.

(2) A Low THC Oil Card may be renewed only by submission of an application certified by a physician and meeting all the requirements of a new application.

(3) Low THC Oil Cards shall be mailed to an approved County Health Department nearest to the patient's home if they do not have a mailing address or have a PO Box and shall be released in-person upon presentation of the applicant's secure and verifiable identification by the applicant or his or her designee.

- (4) The Department shall deliver such card either via certified mail or by secure electronic means, including email. The method of delivery will be at the Department's discretion.
- (5) The fee for a Low THC Oil Card shall be set forth on the Department's website.
- (6) Replacements for an unexpired Low THC Oil Card that has been lost or damaged may be ordered by the cardholder or certifying physician. Replacement cards shall be subject to the same fee as original cards.

Authority: O.C.G.A. §§ 31-2A-6, 31-2A-18.