

**NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF
PHARMACY RULES,
RULE 480-52-.01 DEFINITIONS, AND NOTICE OF PUBLIC HEARING**

TO ALL INTERESTED PERSONS AND PARTIES:

Notice is hereby given that pursuant to the authority set forth below, the Georgia State Board of Pharmacy (hereinafter "Board") proposes adoption of new Georgia Board of Pharmacy Rules, Rule 480-52-.01 DEFINITIONS (hereinafter "proposed amendments").

This notice, together with an exact copy of the proposed amendments and a synopsis of the proposed amendments, is being forwarded to all persons who have requested, in writing, that they be placed on an interested parties list. A copy of this notice, an exact copy of the rule including the proposed amendments, and a synopsis of the rule including the proposed amendments 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 Department of Community Health at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. These documents will also be available for review on the Georgia State Board of Pharmacy's web page at www.gbp.georgia.gov.

A public hearing is scheduled to begin at 9:00 AM on June 14, 2023 at University of Georgia College of Pharmacy, 250 West Green Street, Athens, Georgia 30602 to provide the public an opportunity to comment upon and provide input into the proposed amendments. At the public hearing, anyone may present data, make a statement, comment or offer a viewpoint or argument whether orally or in writing. Lengthy statements or 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. Written comments are welcome. To ensure their consideration, written comments must be received prior to June 7, 2023. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. You may email your comments to elacefield@dch.ga.gov.

The proposed amendments will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:00 AM on June 14, 2023 at University of Georgia College of Pharmacy, 250 West Green Street, Athens, Georgia 30602. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed amendments pursuant to authority contained in O.C.G.A. §§ 16-12-206, 26-4-28, and 26-4-110.

At its meeting on March 8, 2023, the Board voted that the formulation and adoption of these rule amendments do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed amendments cannot be reduced by a less expensive alternative that fully accomplishes the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22.

Also, at its meeting on March 8, 2023, the Board voted that it is not legal or feasible to meet the objectives of O.C.G.A §§ 26-4-27, 26-4-28, 16-13-22 to adopt or implement differing actions for

businesses as listed at O.C.G.A. § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this chapter will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

For further information, contact the Board office at 404-651-8000.

This notice is given in compliance with O.C.G.A. §50-13-4.

This 1 day of May, 2023.



Eric R. Lacefield
Executive Director
Georgia Board of Pharmacy

Posted: May 1, 2023.

**SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-52-.01 DEFINITIONS**

- Purpose:** To carry out the directive of the General Assembly in O.C.G.A. § 16-12-206, directing the Georgia State Board of Pharmacy to develop a licensure scheme and guidelines for the appropriate dispensing of low THC oil to qualified patients.
- Main Features:** Definition of specific terms.

**TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE
RULE 480-52-.01 DEFINITIONS**

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

Text of the proposed rule is attached hereto.

Rule 480-52-.01 Definitions

- (1) **“Board”** shall mean the Georgia Board of Pharmacy.
- (2) **“Consultation room”** is an area adjacent to the pharmacy where patient or customer consultations are done, and more in-depth pharmacy care may be provided.
- (3) **“Direct supervision”** shall mean that a pharmacist is physically present, providing care at the address listed on the pharmacy license, and is in the prescription department, consultation room, vaccination room, or areas where over-the-counter drugs, devices, or durable medical equipment are displayed. The supervising pharmacist is professionally responsible and accountable for all activities performed by authorized pharmacy personnel and is available to provide assistance and direction to authorized pharmacy personnel. This shall not require a pharmacist to maintain a direct line of sight to authorized pharmacy personnel. The supervising pharmacist shall provide a final check of prepared products and document final checks before any prescription drug is dispensed.
- (4) **“Immediate notification”** shall mean written notification sent within twenty-four hours of the event.
- (5) **“Low THC oil”** shall mean an oil that contains an amount of cannabidiol and not more than 5 percent by weight of tetrahydrocannabinol, tetrahydrocannabinolic acid, or a combination of tetrahydrocannabinol and tetrahydrocannabinolic acid which does not contain plant material exhibiting the external morphological features of the plant of the genus Cannabis. Such term shall not mean products approved by the federal Food and Drug Administration under Section 505 of the federal Food, Drug, and Cosmetic Act.
- (6) **“Low THC Pharmacy Dispensary”** shall mean a retail pharmacy, previously licensed by the Georgia Board of Pharmacy, which has obtained a permit Low THC Pharmacy Dispensary license.
- (7) **“Low THC Product”** shall mean low THC oil delivered through an oil, tincture, transdermal patch, lotion, or capsule, except as prohibited by O.C.G.A. § 16-12-234, but not including any food products infused with low THC oil, including, but not limited to, cookies, candies, or edibles.
- (8) **“Pharmacy”** shall mean all areas of a facility when the prescription department is not closed or locked separately from the facility or only the area of the prescription department in those facilities where the prescription department is locked and separated.
- (9) **“Pharmacy care”** shall mean those services related to the interpretation, evaluation, or dispensing of prescription drug orders, the participation in drug and device selection, drug administration, and drug regimen reviews, and the provision of patient counseling related thereto.
- (10) **“Predicate Retail License”** shall mean the presently active Retail Pharmacy license, previously issued by the Georgia Board of Pharmacy, to the applicant for, or licensee of a Low THC Pharmacy Dispensary license.
- (11) **“Predicate Retail Licensee”** shall mean the entity licensed by the Georgia Board of Pharmacy as a Retail Pharmacy and attendant to whose licensure a Low THC Pharmacy Dispensary license has been applied for or obtained.
- (12) **“Preparation”** shall mean the functions of preparing a prescription to be dispensed, including product selection, data entry into a pharmacy dispensing system, and any other functions required to have the prescription ready to be verified, checked, and dispensed by a pharmacist or pharmacy intern working under the direct supervision of a pharmacist.

- (13) **“Prescription Department”** shall mean an area set aside for the preparation and dispensing of prescription drugs and Low THC Products. In a facility offering other departments and types of merchandise not requiring a pharmacist to be open for business, this term shall apply only to the area in which prescriptions are prepared and dispensed.
- (14) **“Registered Patient”** means an individual who is legally authorized to possess and use low THC oil and products pursuant to O.C.G.A. § 31-2A-18.
- (15) **“Significant adverse drug reaction”** shall mean any reaction which requires any medical treatment beyond a consultation between Pharmacist/patient, Pharmacist/Prescriber, patient/prescriber or Pharmacist/patient/Prescriber.
- (16) **“Vaccination room”** is an area adjacent to the pharmacy where vaccinations are administered.
- (17) **“Written notification”** shall mean in writing and sent by statutory overnight delivery or by email.