NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,

RULE 480-52-.07 LICENSURE, APPLICATIONS, AND DISPLAY OF LICENSE AND RENEWAL CERTIFICATE, 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-.07 LICENSURE, APPLICATIONS, AND DISPLAY OF LICENSE AND RENEWAL CERTIFICATE (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 December 13, 2023 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334 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 December 6, 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 December 13, 2023 at Department of Community Health, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, Georgia 30334. 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. §§ 26-4-27, 26-4-28, and 26-4-110.

At its meeting on August 16, 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 August 16, 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 13 day of Novale, 2023.

Eric R. Lacefield
Executive Director

Georgia Board of Pharmacy

Posted: November 13, 2023.

SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-52-.07 LICENSURE, APPLICATIONS, AND DISPLAY OF LICENSE AND RENEWAL CERTIFICATE

Purpose: To amend the rule language to eliminate automatic nullification and

voiding of a license in the event of a change of ownership of the licensee pharmacy. To provide a process by which a licensee may request to retain a license number in the event of a change of ownership of the licensee pharmacy. To identify events which constitute a change of ownership. To clarify that change of ownership events must be reported to the Board.

Main Features: Elimination of automatic nullification and voiding of a license in the

event of a change of ownership. Provision of a process by which a license number may be retained, at the Board's discretion, upon request of the licensee. Identification of events which constitute a change of ownership. Clarification of a licensee's obligation to report changes of ownership to

the Board.

TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-52-.07 LICENSURE, APPLICATIONS, AND DISPLAY OF LICENSE AND RENEWAL CERTIFICATE

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-.07. Licensure, Applications, and Display of License and Renewal Certificate

- (1) Licensure and Applications
 - (a) Every Low THC Pharmacy Dispensary must be licensed by the Board in accordance with the laws and regulations of this State. The term "Low THC Pharmacy Dispensary" shall have the meaning ascribed in Board Rule 480-52-.01.
 - (b) All Low THC Pharmacy Dispensary licensees shall renew this license annually by June 30th with the Georgia State Board of Pharmacy; pharmacy dispensary licenses shall be issued only to those pharmacies who comply with this rule.
 - (c) Low THC Pharmacy Dispensary licenses shall be issued only to those licensed retail pharmacies who meet the following requirements:
 - 1. Submission of an application with the following information:
 - i. The name, full business address, telephone number, and current Georgia Board of Pharmacy license number of the licensee;
 - ii. All trade or business names used by the licensee;
 - iii. Address, telephone number, and the name of the Pharmacist in Charge;
 - iv. The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship);
 - v. The name(s) of the owner and/or operator of the licensee, including:
 - (I) If a person, the name of the person;
 - (II) If a partnership, the name of the partnership and the name of each partner;
 - (III) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; or
 - (IV) If a corporation, the corporate name, the name and title of each corporate officer and director, the state of incorporation; and the name of the parent company, if any.
 - vii. Documentation of one of the following:
 - (I) Written certification from the applicant that the applicant's operation of a Low THC Pharmacy Dispensary at the proposed location would comply with the location restrictions imposed by O.C.G.A. § 16-12-215(a); or
 - (II) Certified copy of an Order from the local zoning authority permitting the applicant to operate a Low THC Pharmacy Dispensary in the proposed location, as provided by O.C.G.A. § 16-12-215(a).
 - 2. Payment of an application fee. Application fees shall not be refundable.
 - 3. Filing a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.
 - (d) No license issued under this Rule shall be transferred or assigned by a licensee. However, the Board may reassign a license to a licensee or successor entity by request upon application to the Board. Low THC Pharmacy Dispensary licenses shall be nontransferrable.

- (e) Prior to any change in name, ownership, mode of operation or location of a pharmacy, licensees shall apply for approval of such change by submitting a Board-approved application to the Board and paying a fee. To comply with the requirements of this Rule, applications must be made and approved prior to the change.
 - 1. A change of ownership is deemed to have occurred upon the closure of any transaction which results in a change to any of the ownership information submitted to the Board as part of the licensee's initial application for licensure or renewal of licensure.
- (f) Licensees shall notify the Board in writing of the occurrence of any change to any of the information submitted to the Board as part of the licensee's initial application for licensure or application for renewal of licensure. This shall not apply to any event the occurrence of which these rules require immediate notification to the Board, in which event such immediate notification shall be made.
- (eg) Low THC Pharmacy Dispensary licenses are renewed annually and expire on June 30th of each year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st, of the same year, the license shall lapse and shall not be renewed except by application for a new license.
- (fh) Changes in any information in this rule shall be submitted to the Board prior to such change.
- (gi) The Board will consider the following factors in determining eligibility for licensure of applicants in charge of the facility and the applicant licensee who are applying for a Low THC Pharmacy Dispensary license:
 - 1. Any convictions of the applicant under any Federal, State, or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances;
 - 2. Any felony convictions of the applicant under Federal, State, or local laws;
 - 3. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
 - 4. Suspension or revocation by Federal, State, or local government of any pharmacist, pharmacy or other health care license currently or previously held by the applicant;
 - 5. Compliance with licensing requirements under previously granted licenses:
 - 6. Compliance with requirements to maintain and/or make available to the State Licensing Authority or to Federal, State, or local law enforcement officials, those records required to be maintained by the licensee pharmacy and by a Low THC Pharmacy Dispensary;
 - 7. The disciplinary history of the Predicate Retail Licensee, if any; and
 - 8. Other factors or qualifications the Board considers relevant to and consistent with the public health and safety.
- (hi) The Board reserves the right to deny a license to an applicant if it determines that the granting of such a license would not be in the best interest of the public.

- (2) The Low THC Pharmacy Dispensary wall certificate issued by the Georgia State Board of Pharmacy (Board), along with the current renewal license of each full-time Pharmacist employed at the Low THC Pharmacy Dispensary, as well as any letter(s) from the Board which have granted a licensee any exception(s) and/or exemption(s) from this, or any other rule, shall be displayed in the same manner as that required by Rule 480-10-.06 for the Predicate Retail Licensee;
- (3) No pharmacist or intern/extern shall display his or her license in any Low THC Pharmacy Dispensary where he or she is not employed or engaged in the practice of pharmacy and dispensing of Low THC Products, and shall not knowingly permit any other person to use his or her license for the purpose of misleading anyone to believe that such person is the holder or recipient of said license or intern certificate.

Authority: O.C.G.A. §§ 16-12-206, 26-4-28, and 26-4-110.