NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, RULE 480-33-.02 LICENSURE AND REGISTRATION, 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 480-33-.02 LICENSURE AND REGISTRATION (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 November 2023.

Eric R. Lacefield Executive Director

Georgia Board of Pharmacy

Posted: November 13, 2023.

SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-33-.02 LICENSURE AND REGISTRATION

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 480-33-.02 LICENSURE AND REGISTRATION

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 480-33-.02. Licensure and Registration

- (1) All outpatient clinic pharmacies shall renew biennially by June 30th of each odd numbered year with the Georgia State Board of Pharmacy. Certificates of registration shall be issued to outpatient clinic pharmacies which meet the requirements for licensure and which comply with Chapter 480-33 of the Rules of the Georgia State Board of Pharmacy.
- (2) Minimum Required Information for Licensure. The Board requires the following information from each outpatient clinic pharmacy as part of the initial licensing procedure and as part of each renewal of such license. The name, complete street address for the business (i.e., geographic location), and telephone number of the applicant/ licensee. All trade or business names used by the applicant/licensee. Address, telephone numbers, and the name(s) of the clinic administrator;
 - (a) The type of ownership or operation (i.e., partnership, corporation, or sole proprietorship);
 - (b) The name(s) of the owner and/or operator of the applicant/licensee, including:
 - 1. If a sole proprietorship, the complete name of the proprietor;
 - 2. If a partnership, the complete name of each partner, and the name of the partnership;
 - If a corporation, the name and title of each corporate officer and director, the
 corporate name and the state of incorporation, and the name of the parent company, if
 any.
 - (i) Where operations are conducted at more than one location by a single outpatient clinic pharmacy, each such location shall be licensed by the Board.
 - (ii) Applications for Licensure.
 - (I) Registration of an outpatient clinic pharmacy shall be considered filed with the Board when an application is received by the Board, a fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying that the applicant possesses the necessary qualifications for a license.
 - (II) Application fees shall not be refundable.
 - (III) 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.
 - (IV) 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.
 - I. 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.
 - (V) 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.
- (III) Licenses shall become null and void upon the sale; transfer or change of mode of operation or location of the business.
- of each odd numbered year and may be renewed upon the payment of the required fee for each place of business and the filing of an application for renewal. If the application for renewal is not filed with the Board and the fee paid before September 1st, of each odd numbered year, the license shall lapse and may not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.
- (V)(VII) Changes in any information in this section shall be submitted to the Board prior to such change.
- (iii)Minimum Qualifications.
 - (I) To obtain an outpatient clinic pharmacy license, the outpatient clinic pharmacy must employ a pharmacist-in-charge.
 - (II) The Board shall consider the following factors in determining eligibility for licensure for each person(s) in charge of the facility when considering an application for an outpatient clinic pharmacy license:
 - Any convictions of the applicant under any Federal, State, or local laws relating to drugs, wholesale or retail drug distribution, or distribution of controlled substances;
 - II. Any felony convictions of the applicant under any Federal, State, or local laws;
 - III. The furnishing by the applicant of false or fraudulent material or information in any application;
 - IV. Suspension or revocation of Federal, State, or local government of any pharmacist, pharmacy or other healthcare license currently or previously held by the applicant;
 - V. Failure to comply with any licensing requirements under a previously held license, if any;
 - VI. Failure to comply with any requirements to maintain and/or make available to the state licensing authority or to Federal, State, or local law enforcement officials, any records required to be maintained by outpatient clinic pharmacies;
 - VII. Other factors or qualifications the Board considers relevant to and consistent with the public's health and safety; and
 - VIII. 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.
- (3) An outpatient clinic pharmacy registered with the Board shall not be authorized to dispense refills on prescription drug orders.

- (4) Nothing in these regulations shall be construed to prohibit an outpatient clinic from applying for a retail pharmacy license as provided for in O.C.G.A. §§ 26-4-110 and Rule 480-6-.01. Any retail pharmacy located in an outpatient clinic holding a retail pharmacy license, shall comply with all the laws, rules and regulations applicable to such licensed retail pharmacy.
- (5) Nothing herein shall be construed to interfere with a practitioner of the healing arts practicing as authorized by law.

Authority: O.C.G.A. §§ 26-4-20, 26-4-27, 26-4-28, 26-4-37, 26-4-60, 26-4-100, 26-4-110, 26-4-111, 43-1-4, 43-1-7, 43-1-19.