NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES, RULE 480-8-.02 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 480-8-.02 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 480-8-.02 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 480-8-.02 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 480-8-.02. Registration

- (1) Every prison clinic pharmacy, wherever located within the State of Georgia must be licensed by the Georgia State Board of Pharmacy ("Board") in accordance with the laws and regulations of this State. All prison clinic pharmacies shall renew biennially by June 30th of the odd-numbered years with the Georgia State Board of Pharmacy; certificates of registration shall be issued only to those prison clinic pharmacies as follows:
- (2) Minimum Required Information for Licensure: The Board requires the following information from each prison clinic pharmacy as part of the initial licensing procedure and as part of any renewal of such license.
 - (a) The name, full business address, and telephone number of the licensee;
 - (b) All trade or business names used by the licensee;
 - (c) Address, telephone numbers, and the name(s) of the Prison Clinic Administrator;
 - (d) The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship); and
 - (e) The name(s) of the owner and/or operator of the licensee, including;
 - 1. If a person, the name of the person;
 - 2. If a partnership, the name of each partner, and the name of the partnership;
 - 3. If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.
 - 4. If a corporation, the name and title of each corporate officer and director, the corporate names and the name of the State of incorporation; and the name of the parent company, if any.
 - (f) Where operations are conducted at more than one location by a single prison clinic pharmacy, each such location shall be licensed by the Board.
- (3) Administration of Applications for Licensure.
 - (a) Registration of a prison clinic pharmacy will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the Georgia Drugs and Narcotics Agency (GDNA) certifying the applicant possesses the necessary qualifications for a license.
 - (b) Application fees shall not be refundable.
 - (c) 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.
 - (d) 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.
 - (e) (e) 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. Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.

- Licenses are renewed for two years periods and expire on June 30th 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 made and the fee paid before September 1st, of the odd numbered year, the license shall lapse and shall not be renewed. An application for reinstatement shall be required. Reinstatement shall be at the sole discretion of the Board.
- (e)(g) Changes in any information in this section shall be submitted to the Board prior to such change.

(4) Minimum Qualifications.

- (a) The Board will consider the following factors in determining eligibility for licensure for person(s) in charge of the facility and are applying for a prison clinic pharmacy:
 - 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 license currently or previously held by the applicant.
 - 5. Compliance with licensing requirements under previously granted licenses, if any;
 - 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 prison clinic pharmacies; and
 - 7. Other factors or qualifications the Board considered relevant to and consistent with the public health and safety. 8. 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.

Authority: O.C.G.A. §§ 26-4-37, 26-4-27, 26-4-28, 26-4-110, 26-4-111, 26-4-113, 16-13-35, 16-13-37, 43-1-19, 26-4-60, 26-4-20.