NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-7-.01 MANUFACTURER'S PERMIT, 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 480-7-.01 MANUFACTURER'S PERMIT (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 480-7-.01 MANUFACTURER'S PERMIT

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 480-7-.01 MANUFACTURER'S PERMIT

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 480-7-.01. Manufacturer's Permit

(1) Applications for registration for a manufacturer's permit must be filed with the Office of the Georgia State Board of Pharmacy ("Board") with the required fee.

(2) Registration of a manufacturer will be considered on the basis of the application filed, 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 permit.

(3) Application fees shall NOT be refundable.

(4) 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. ~~Permits shall not be transferable. Permits become null and void upon the sale, or change of mode of operation of the business, or location of business.~~

(5) 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.

(a) 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.

~~(4)~~(6) 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.

~~(5)~~(7) Licenses are renewed for two years and expire on June 30th of each odd numbered 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 odd numbered year, the license shall lapse and shall not be renewed, and an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

~~(6)~~(8) Upon request by the Board or its designee, any manufacturer holding a permit issued by the Board that causes a dangerous drug or controlled substance product to be marketed or distributed in this state shall provide, at no cost to this state, a quantity of one gram or more of the pure compound of each such product to the Georgia Drugs and Narcotics Agency. Such quantities of pure compound will only be used for testing and analysis purposes.

(a) All quantities of a pure compound provided to the Georgia Drugs and Narcotics Agency will be accounted for using a perpetual inventory system, and a copy of each product inventory will be available for review by the manufacturer providing the compound upon written request to the Board.

(b) As the manufacturer is required by this subsection to submit the dangerous drug or controlled substance for analysis, the results of any chemical analysis shall be considered a trade secret within the meaning of Code Section 50-18-72(b)(1).

Authority: O.C.G.A. §§ 16-13-35, 16-13-45, 16-13-72, 26-4-20, 26-4-27 to 26-4-29, 26-4-60, 26-4-111, 26-4-113, 26-4-115, 26-4-120, 26-4-131, 43-1-19, 50-18-72.