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

RULE 480-7A-.04 REQUIREMENTS FOR LICENSURE AS A LISTED CHEMICAL WHOLESALE DISTRIBUTOR, 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 480-7A-.04 REQUIREMENTS FOR LICENSURE AS A LISTED CHEMICAL WHOLESALE DISTRIBUTOR (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 Navember , 2023.

Eric R. Lacefield

Executive Director Georgia Board of Pharmacy

Posted: November 13, 2023.

SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-7A-.04 REQUIREMENTS FOR LICENSURE AS A LISTED CHEMICAL WHOLESALE DISTRIBUTOR

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 480-7A-.04 REQUIREMENTS FOR LICENSURE AS A LISTED CHEMICAL WHOLESALE DISTRIBUTOR

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 480-7A-.04. Requirements for Licensure as a Listed Chemical Wholesale Distributor

- (1) Listed chemical wholesale distributors that provide services within this State, whether the listed chemical wholesale distributor is located within this State or outside this State, shall be licensed by the Board and shall biennially renew their permit or license with the Board using an application provided by the Board.
- (2) Where listed chemical wholesale distribution operations are conducted at more than one location, each such location shall be licensed by the Board.
- (3) A person or firm holding a valid permit issued by the Board and licensed as a wholesale distributor under Code Section 26-4-113 shall not be required to obtain an additional license under this Code section; Wholesale distributors licensed under Code Section 26-4-113 shall be subject to the provisions of this Code section in the same manner as chemical wholesale distributors licensed under this Code section.
- (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.
- (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. Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business:
- (5)(7) The Board requires the following and such additional information as found on an approved Board application from each listed chemical wholesale distributor as part of the initial licensing procedure and as part of any biennial renewal of such license:
 - (a) The name, trade or business name, full business address, and telephone number of the applicant. Trade or business names cannot be identical to that of another Board licensee.
 - (b) The type of ownership or operations (i.e., partnership, corporation, or sole proprietorship).
 - (c) Name(s) of the owner and operator of the licensee (if not the same person), including:
 - 1. If a person: the name, address, and social security number;
 - 2. If a partnership: the name, address, and social security number of each partner, and the name of the partnership and federal employer identification number;
 - 3. If a corporation: the name, address, social security number, and title of each corporate officer and director, the corporate names, the name of the State of incorporation, federal employer identification number, and the name of the parent company, if any; the name, address, and social security number of each shareholder owning ten percent

- (10%) or more of the voting stock of the corporation, including over-the-counter stock, unless the stock is traded on a major stock exchange and not over-the-counter;
- 4. If a sole proprietorship: the full name, address, and social security number of the sole proprietor, and the name and federal employer identification number of the business entity;
- 5. If a limited liability company, the name of each member, the name of each manager, the name of the limited liability company and federal employer identification number, and the name of the state in which the limited liability company was organized; and
- 6. Any other relevant information that the Board requires.
- (d) Name(s), address(es), telephone number(s), date(s) of birth of a person(s) to serve as the designated representative(s) for listed chemicals and additional information as required.
- (e) A non-refundable application and/or renewal fee as determined by the Board and set forth in the fee schedule.
- (6)(8) By submitting an application for licensure as a listed chemical wholesale distributor, said applicant consents to a criminal background check of the applicant, all personnel involved in the operations of the listed chemical wholesale distributor, all shareholders involved in operations, and anyone owning or being involved in operations to determine if an applicant or others associated with the ownership, management, or operations of the listed chemical wholesale distributor has committed criminal acts that would constitute grounds for denial of licensure. The background check will be conducted in compliance with any applicable state laws, at the applicant's expense, and will be sufficient to include all states of residence since the person has been an adult.
- (7)(9) Each facility which engages in listed chemical wholesale distribution must undergo an inspection on behalf of the Board by an agent with the GDNA for the purpose of inspecting the in-state listed chemical wholesale distribution operations prior to initial licensure and periodically thereafter in accordance with a schedule to be determined by the Board but no less than once every three (3) years.
- (8)(10) Each facility which is located outside the State and engages in listed chemical wholesale distribution must undergo a background investigation by GDNA on behalf of the Board and be approved by the GDNA prior to being approved for licensure, and as necessary submit to an inspection by either GDNA or an agent contracted with by GDNA.

Authority: O.C.G.A. Sees. §§ 16-13-30.3, 16-13-30.4, 26-4-28, 26-4-111 to 26-4-113, 26-4-115.