NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-7-.03 DRUG WHOLESALE DISTRIBUTION LICENSING REQUIREMENTS, 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-.03 DRUG WHOLESALE DISTRIBUTION LICENSING REQUIREMENTS (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-.03 DRUG WHOLESALE DISTRIBUTION LICENSING REQUIREMENTS

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-.03 DRUG WHOLESALE DISTRIBUTION LICENSING REQUIREMENTS

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-.03. Drug Wholesale Distribution Licensing Requirements

(1) Every drug wholesale distributor, wherever located, who engages in drug wholesale distribution into, out of, or within the State of Georgia must be licensed by the Georgia State Board of Pharmacy in accordance with the laws and regulations of this State before engaging in wholesale distribution of prescription drugs.

(2) Minimum Required Information for Licensure: The Board requires the following from each wholesale drug distributor 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 names of contact persons for the facility used by the licensee for the storage, handling, and distribution of prescription drugs;

(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 corporation, the name and title of each corporate officer and director, the corporate names, and the name of the incorporation; and the name of the parent company, if any;
4. If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity.

(f) Where operations are conducted at more than one location by a single drug wholesale distributor, each such location shall be licensed by the Board.

(g) Every drug wholesale distributor in this state, which is licensed by the Board, is required to be located in a commercially zoned business district and possess the appropriate local business license in order to conduct business. No drug wholesale distributor may be located in or operate out of a residential dwelling, building, or location, or a building, dwelling or location attached to a residential location. A drug wholesale distributor located in a hospital pharmacy or a retail pharmacy is deemed to meet this requirement.

(3) Applications for Licensure.

(a) Registration of a drug wholesaler distributor will be considered on the basis of the application filed with the Board, fee paid, and a report from the Director of the GDNA certifying the applicant possesses the necessary qualifications of 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. ~~Licenses become null and void upon the sale, transfer or change of mode of operation or location of the business.~~

(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.

~~(d)~~(f) 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 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 persons who engage in the wholesale distribution of prescription drugs:

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 applicant's past experience in the manufacture or distribution of prescription drugs, including controlled substances;
4. The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution;
5. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant for the manufacture or distribution of any drugs, including controlled substances;
6. Compliance with licensing requirements under previously granted licenses, if any;
7. 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 drug wholesale distributors; and
8. Any other factors or qualifications the Board considers relevant to and consistent with the public health and safety.

(b) The Board reserves the right to deny a license to any applicant if it determines that the granting of such a license would not be in the public's interest.

(5) Personnel. The licensed wholesale distributor shall employ adequate personnel with the education and experience necessary to safely and lawfully engage in the wholesale distribution of drugs.

(6) Violations:

(a) A license issued to a wholesale distributor pursuant to this part shall be subject to revocation or suspension upon conviction of the license holder for violations of Federal, State, or local drug laws and/or regulations.
(b) Violation of any of the provisions of any applicable Board laws or rules shall be grounds for the suspension or revocation of the license issued hereunder.
(c) Any revocation or suspension of a license pursuant to this part shall be carried out pursuant to the Georgia Administrative Procedure Act, O.C.G.A. Title 50 Chapter 13.
(d) Drug samples shall not be sold in any licensed pharmacy.

(7) Minimum Requirements for the Storage and Handling of Prescription Drugs and for the Establishment and Maintenance of Prescription Drugs Distribution Records. The following are required for the storage and handling of prescription drugs, and for the establishment and maintenance of prescription drug distribution records by wholesale drug distributors and their officers, agents, representatives, and employees.
(a) Facilities. All facilities at which prescription drugs are stored, warehoused, handled, held, offered, marketed, or displayed shall:
1. Be of suitable size and construction to facilitate cleaning, maintenance, and proper operations;
2. Have storage areas designed to provide adequate lighting, ventilation, temperature, sanitation, humidity, space, equipment, and security conditions;
3. Have a quarantine area for storage or prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;
4. ~~4.~~ Be maintained in a clean and orderly condition; and
~~3.~~5. ~~5.~~ Be free from infestation by insects, rodents, birds, or vermin of any kind.
(b) Security. All facilities used for wholesale drug distribution shall be secure from unauthorized entry.
1. Access from outside the premises shall be kept to a minimum and be well controlled.
2. The outside perimeter of the premises shall be well lighted.
3. Entry into areas where prescription drugs are held shall be limited to authorized personnel.
4. All facilities shall be equipped with an alarm system to detect entry after hours.
5. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion. When appropriate, the security system shall provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records.
(c) Storage. All prescription drugs or chemicals shall be stored at appropriate temperatures and under appropriate conditions in accordance with requirements, if any, in the labeling of such drugs, or with requirements in the current edition of an official compendium, such as the United States Pharmacopeia (USP) Compendium.
1. If no storage requirements are established for a prescription drug, the drug may be held at "controlled" room temperature, as defined in the official compendium, to help ensure that its identity, strength, quality, and purity are not adversely affected.

2. Appropriate manual, electromechanical, or electronic temperature and humidity recording equipment, devices, and/or logs shall be utilized to document proper storage of prescription drugs.
3. The record keeping requirements in subparagraph (f) of this section shall be followed for all stored drugs.

(d) Examination of materials.

1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated prescription drugs or prescription drugs that are otherwise unfit for distribution. This examination shall be adequate to reveal container damage that would suggest possible contamination or other damage to the contents.
2. Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.
3. The record keeping requirements in subparagraph (f) of this section shall be followed for all incoming and outgoing prescription drugs.

(e) Returned, damaged, and outdated prescription drugs.

1. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated shall be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier.
2. Any prescription drugs whose immediate or sealed outer or sealed secondary containers have been opened or used shall be identified as such, and shall be quarantined as such, and shall be quarantined and physically separated from other prescription drugs until they are either destroyed or returned to the supplier.
3. If the conditions under which a prescription drugs has been returned cast doubt on the drug's safety, identify, strength, quality, or purity, then the drug shall be destroyed, or returned to the supplier, unless examination, testing, or other investigation proves that the drug meets appropriate standards of safety, identity, strength, quality, and purity. In determining whether the conditions under which the drug has been returned cast doubt on the drug's safety, identity, strength, quality, or purity, the wholesale drug distributor shall consider, among other things, the conditions under which the drugs has been held, stored, or shipped before or during its return and the condition of the drug and its container, carton, or labeling as a result of storage or shipping.
4. The record keeping requirements in subparagraph (f) of this section shall be followed for all outdated, damaged, deteriorated, misbranded, or adulterated prescription drugs.

(f) Record keeping:

1. Wholesale drug distributors shall establish and maintain inventories and records of all transactions regarding the receipt and distribution or other disposition of prescription drugs. These records shall include the following information:
   (i) The source of the drugs, including the name and principal address of the seller or transferor, and the address of the location from which the drugs are shipped;
   (ii) The identity and quantity of the drugs received and distributed or disposed of; and
   (iii)The date of receipt and distribution or other disposition of the drugs.

(g) For each person or firm, whether located inside or outside the State of Georgia, to which a drug wholesale distributor, located inside the State of Georgia, sells to, ships to, delivers to, or otherwise distributes drugs to, such drug wholesale distributor shall request and maintain a copy of that person or firm's current license or permit which authorizes them to purchase, buy, receive, or otherwise possess drugs.

1. ~~NO~~ No drug wholesale distributor, located inside the State of Georgia, may ship to, sell to, or otherwise deliver a dangerous drug or controlled substance to a person or firm unless that person or firm holds a license or permit which authorizes them to purchase, buy, receive or otherwise possess drugs.

(h) Nothing in this chapter or Georgia law authorizes any drug wholesale distributor, located inside the State of Georgia, to sell, ship, or otherwise distribute any drugs to any person or firm located outside the United States of America or its territories without first receiving written permission to do so from the Board. Such permission can only be granted by the Board after it has received a written request from the drug wholesale distributor giving the details of the proposed transaction. The Board reserves the right to have the GDNA investigate any and all such requests, and the Board reserves the right to deny any such request.

(i) Inventories and all records required under this rule shall be made available for inspection and photocopying by any authorized official of a government agency charged with enforcement of these regulations for a period of two (2) years following deposition of the drugs.

(j) Records described in this rule that are kept at the inspection site or that can be immediately retrieved by computer or other electronic means shall be made readily available for authorized inspection during the retention period. Records kept at a central record keeping location apart from the inspection site and not electronically retrievable, shall be made available for inspection within two (2) working days of a request by an authorized official of any governmental agency charged with enforcement of these regulations.

(8) Written Policies and Procedures. Wholesale drug distributors shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security, storage, inventory, and distribution of prescription drugs, including policies and procedures for identifying recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Wholesale drug distributors shall include in their written policies the following:

(a) A procedure whereby the oldest approved stock of a prescription drug product is distributed first. The procedure may permit deviation from this requirement, if such deviation is temporary and appropriate.

(b) A procedure to be followed for handling recalls and withdrawals of prescription drugs. Such procedure shall be adequate to deal with recalls and withdrawals due to:

1. Any action initiated at the request of the FDA or other Federal, State, or local law enforcement or other government agency, including the Georgia State Board of Pharmacy;

2. Any voluntary action by the manufacturer to remove defective or potentially defective drugs from the market; or
3. Any action undertaken to promote public health and safety by replacing of existing merchandise with an improved product or new package design.

(c) A procedure to ensure that wholesale drug distributors prepare for, protect against, and handle any crisis that affects security or operation of any facility in the event of strike, fire, flood, or other natural disaster, or other situations of local, state, or natural emergency.

(d) A procedure to ensure that any outdated prescription drugs shall be segregated from other drugs and either returned to the manufacturer or destroyed. This procedure shall provide for written documentation of the disposition of outdated prescription drugs. This documentation shall be maintained for two (2) years after disposition of the outdated drugs.

(9) Responsible persons. Wholesale drug distributors shall establish and maintain lists of officer, directors, managers, and other persons in charge of wholesale drug distribution, storage, and handling, including a description of their duties and a summary of their qualifications.

(10) Compliance with Federal, State, and local laws. Wholesale drug distributors shall operate in compliance with applicable Federal, State, and local laws and regulations.

(a) Wholesale drug distributors shall permit the Georgia State Board of Pharmacy and authorized Federal, State, and local law enforcement officials to enter and inspect their premises and delivery vehicles, and to audit their records and written operation procedures, at reasonable times and in a reasonable manner, to the extent authorized by law.

(b) Wholesale drug distributors that deal in controlled substances shall register with the appropriate State controlled substance authority and with the Drug Enforcement Administration (DEA), and shall comply with all applicable State, Local, and DEA regulations.

(11) Salvaging and reprocessing. Wholesale drug distributors shall be subject to the provisions of any applicable Federal, State or local laws or regulations that relate to prescription drug product salvaging or reprocessing.

Authority: O.C.G.A. §§ 43-1-19, 26-4-37, 26-4-120, 26-4-27, 26-4-28, 26-4-113, 26-4-115, 16-13-35, 16-13-72, 16-13-72.1, 26-4-20, 26-4-60.