NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-7C-.02 THIRD-PARTY LOGISTICS PROVIDER 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 480-7C-.02 THIRD-PARTY LOGISTICS PROVIDER 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 August 21, 2024 at Philadelphia College of Osteopathic Medicine, College of Pharmacy, 625 Old Peachtree Road, NW, Suwanee, Georgia 30024 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 August 19, 2024. 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 james.joiner@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 August 21, 2024 at Philadelphia College of Osteopathic Medicine, College of Pharmacy, 625 Old Peachtree Road, NW, Suwanee, Georgia 30024. 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, 26-4-60, 43-1-19. 50-36-1, and 50-36-2.

At its meeting on January 10, 2024, 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 January 10, 2024, 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 19 day of July, 2024.

J. Clinton Joiner, II
Executive Director
Georgia State Board of Pharmacy

Posted: July 19, 2024.

SYNOPSIS OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-7C-.02 THIRD-PARTY LOGISTICS PROVIDER LICENSING REQUIREMENTS

Purpose: To establish a state licensure requirement for third-party logistics providers operating in the State of Georgia.

Main Features: The proposed rule estabilishes a state licensure requirement for operation as a third-party logistics provider, setting out the qualifications for same, the application procedure for same, and requirements for operation thereunder.

TEXT OF PROPOSED GEORGIA STATE BOARD OF PHARMACY RULE RULE 480-7C-.02 THIRD-PARTY LOGISTICS PROVIDER 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 480-7C-.02 Third-Party Logistics Provider Licensing Requirements

(1) Every third-party logistics provider, in 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 before providing third-party logistics services involving dangerous drugs and controlled substances.

(2) Minimum required information for licensure: An applicant for initial licensure or renewal of a Third-Party Logistics Provider License shall provide the following:.

(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 dangerous drugs and controlled substances;

(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 third-party logistics provider, each such location shall be licensed by the Board.

(g) Every third-party logistics provider located in this state is required to be located in a commercially zoned business district and possess the appropriate local business license. No third-party logistics provider 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.

(3) Applications for Licensure.

(a) Registration of a third-party logistics provider will be considered based on 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 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.

(d) Prior to any change in name, ownership, mode of operation or location of a third-party logistics provider, 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) 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.

(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.

(4) Minimum Qualifications.

(a) The Board will consider the following factors in determining eligibility for licensure for persons who engage in third-party logistics services involving prescription drugs:

1. Any convictions of the applicant under any Federal, State, or local laws relating to dangerous drugs and 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 dangerous drugs and controlled substances;

4. The furnishing by the applicant of false or fraudulent material in any application to the Board;

5. Suspension or revocation by Federal, State, or local government of any license currently or previously held by the applicant related to third-party logistics services involving dangerous drugs and 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 third-party logistics providers; and

8. Any other factors or qualifications the Board considers relevant to and consistent with 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) Violations:

(a) A license issued to a third-party logistics provider pursuant to this rule shall be subject to revocation or suspension upon conviction of the license holder of 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.

(6) The following are required for the storage and handling of dangerous drugs and controlled substances, and for the establishment and maintenance of distribution records by a third-party logistics provider.

(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 of dangerous drugs and controlled substances that are outdated, damaged, deteriorated, misbranded, or adulterated, or that are in immediate or sealed, secondary containers that have been opened;

4. Be maintained in a clean and orderly condition; and

5. Be free from infestation by insects, rodents, birds, or vermin of any kind.

(b) Security. All facilities used for third-party logistics services 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 dangerous drugs and controlled substances are held shall be limited to authorized personnel.

4. All facilities shall be equipped with a security system that will provide suitable protection against theft and diversion.

(c) Storage. All dangerous drugs and controlled substances shall be stored at appropriate temperatures and under appropriate conditions in accordance with United States Pharmacopeia (USP) standards or manufacturer's recommendations.

1. If no storage requirements are established for a dangerous drug and controlled substance, the drug may be held at controlled room temperature, as defined in USP, to help ensure that its identity, strength, quality, and purity are not adversely affected.

2. Appropriate manual or electronic temperature and humidity recording equipment and/or logs shall be utilized to document proper storage of prescription drugs. If ~~electronic~~ temperature alarms/alerts for excursions are not in place, the temperature recordings shall be reviewed at least once daily during operations.

3. Prescription drugs exposed to temperature and humidity excursions shall be evaluated and quarantined (if applicable) according to the manufacturer's recommendations.

(d) Examination of materials.

1. Upon receipt, each outside shipping container shall be visually examined for identity and to prevent the acceptance of contaminated dangerous drugs and controlled substances 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 dangerous drugs and controlled substances products and to ensure that there is no delivery of 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 dangerous drugs and controlled substances.

(e) Returned, damaged, and outdated dangerous drugs and controlled substances.

1. Dangerous drugs and controlled substances 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. If the conditions under which a dangerous drug or controlled substance has been returned cast doubt on the drug's safety, identity, 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 third-party logistics provider 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.

(f) Record keeping:

1. Third-party logistics providers shall maintain a list of all product manufacturers, wholesale distributors, and dispensers for whom the third-party logistics provider provides services at such facility.

2. Third-party logistics providers shall maintain (or have immediate access to) inventories and records of all transactions regarding the receipt and distribution or other disposition of dangerous drugs and controlled substances. 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 were 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.

(iv) Any transaction data required to be kept in compliance with the Federal Drug Supply Chain Security Act.

(g) When a third-party logistics provider ships/receives dangerous drugs or controlled substances, it shall be the responsibility of the third-party logistics provider or the owner of the drugs to ensure the person or firm shipping/receiving the drugs is properly licensed, permitted, or otherwise authorized to purchase or receive such drugs.

(h) Inventories and all records required under this rule shall be made immediately available for inspection and photocopying by the Board or GDNA for a period of two (2) years following deposition of the drugs.

(7) Written Policies and Procedures. Third-party logistics providers shall establish, maintain, and adhere to written policies and procedures, which shall be followed for the receipt, security,

storage, inventory, and distribution of dangerous drugs and controlled substances, including policies and procedures for identifying recording, and reporting losses or thefts, and for correcting all errors and inaccuracies in inventories. Third-party logistics providers shall have written policies and procedures to:

(a) address receipt, security, storage, inventory, shipment, and distribution of a dangerous drugs and controlled substances;

(b) identify, record, and report confirmed losses or thefts in the United States;

(c) correct errors and inaccuracies in inventories;

(d) provide support for manufacturer recalls;

(e) prepare for, protect against, and address any reasonably foreseeable crisis that affects security or operation at the facility, such as a strike, fire, or flood;

(f) ensure that any expired dangerous drug or controlled substance is segregated from other products and returned to the manufacturer or repackager or destroyed;

(g) maintain the capability to trace the receipt and outbound distribution of a product (as defined in the DSCSA), and supplies and records of inventory; and

(h) quarantine or destroy a suspect dangerous drug and controlled substance if directed to do so by the respective manufacturer, wholesale distributor, dispenser, or an authorized government agency;

(8) Responsible persons. Third-party logistics providers shall establish and maintain lists of officers, directors, managers, and other persons with access to dangerous drugs and controlled substances including a description of their duties and a summary of their qualifications. Such information shall be readily available during inspections by the Board or GDNA.

(9) Events requiring immediate notification to the Board. The following occurrences require written notification to the Board at its address of record, within 24 hours of the occurrence.

(a) Permanent closing of a licensed third-party logistics provider's facility. Notification shall include the name and contact information for the person responsible for maintaining the facility's records after the facility has closed and the location of such records.

(b) Change of ownership or location of a licensed third-party logistics provider's facility.

(c) Any theft or loss of drugs or devices in the custody and control of a licensed third-party logistics provider. This notification must also be made to the Georgia Drugs and Narcotics Agency, and if involving controlled substances, the third-party logistics provider must comply with Rule 480-16-.06.

(d) Any known conviction of any employee of a licensed third-party logistics provider of any violation of state or federal drug laws, not previously reported.

(e) Theft, destruction, or loss of dangerous drug or controlled substance records of a licensed third-party logistics provider.

(10) Compliance with Federal, State, and local laws. Third-party logistics providers shall operate in compliance with applicable Federal, State, and local laws and regulations.

(a) Third-party logistics providers shall permit the Board and GDNA to enter and conduct unannounced inspections of their premises and delivery vehicles, and to audit their records and written operation procedures. In the event the records, or any other information, required by this rule are maintained by the owner of the dangerous drug or controlled substance, it shall be the responsibility of the third-party logistics provider to have immediate access to such records during inspections by the Board or GDNA.

(b) Third-party logistics providers that deal in controlled substances shall register with the appropriate controlled substance authority, and shall comply with all applicable State, Local, and DEA regulations.

(c) Third-party logistics providers shall report to and/or be licensed by the Food and Drug Administration (FDA) and shall comply with all applicable State, Local, and FDA regulations.

Authority: O.C.G.A. §§ 26-4-27, 26-4-28, 26-4-60, 43-1-19, 50-36-1, and 50-36-2.