NOTICE OF INTENT TO ADOPT RULE IN THE GEORGIA STATE BOARD OF PHARMACY RULES,
RULE 480-7B-.02 DME SUPPLIER 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 480-7B-.02 DME SUPPLIER 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 480-7B-.02 DME SUPPLIER 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 480-7B-.02 DME SUPPLIER 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 480-7B-.02. DME Supplier Licensing Requirements

(1) Licensing requirement. A person or entity located in the State of Georgia that provides durable medical equipment to a consumer and submits a claim for reimbursement by a third party, either directly or through a contractual arrangement, and any Medicare enrolled out-of-state DME manufacture or wholesale distributor that provides durable medical equipment to consumers in this state and who holds a valid license from another state must hold a license issued by the Board. Licensure as a DME supplier will be considered on the basis of the completion of a Board approved application filed with the Board, payment of a fee, a report from GDNA certifying that the applicant possesses the necessary qualifications for licensure including meeting all safety standards and requirements established by the Board, satisfactory licensure status in other states, and if located in the State of Georgia, maintenance of an office or place of business in the State of Georgia. When reviewing an application, the Board may determine that a person or entity accredited by an organization recognized by the federal Centers for Medicare and Medicaid Services has met all or some of the requirements for licensure.

(2) Applications for Licensure as a DME Supplier.

(a) The Board requires the following information from each DME supplier as part of the initial licensing procedure:

1. The name, full business address, and telephone number of the applicant;
2. All trade of business names used by the applicant;
3. Address, telephone number(s), and the name(s) of the proposed designated representative(s) for the facility and evidence showing the qualifications of the proposed designated representative(s) to serve;
4. The type of ownership or operations (i.e. partnership, corporation, or sole proprietorship);
5. The name(s) of the owner and/or operator of the applicant, including:

(i) If a person, the name of the person;

(ii) If a partnership, the name of each partner and the name of the partnership;

(iii) If a corporation, the name and title of each corporate officer and director, the corporate names, the name of the incorporation, and the name of the parent company, if any;

(iv) If a sole proprietorship, the full name of the sole proprietorship and the name of the business entity; and

6. If located out of state, proof of a valid, unexpired license to operate as a DME supplier in the compliance with the laws and rules of the other state; ~~and~~

7. ~~If located out of state, proof of a valid, unexpired license to operate as a DME supplier in the compliance with the laws and rules of the other state; and~~

(b) Application fees and renewal fees shall be set by the Board in a fee schedule and shall not be refundable.

(c) Applications are only valid for one year.

(3) Denial of Applications for Licensure.

Applications for licensure may be denied for failure to meet the minimum qualifications for a license, failure to comply with the laws or regulations of this State, the United States or any other state having to do with DME suppliers, making false representations on an application, failure to meet the safety standards established by the Board, or for any other grounds set forth in O.C.G.A. §§ 26-4-60 and 43-1-19. The denial of an application for licensure shall not be considered a contested case under the provisions of O.C.G.A. T. 50, Ch. 13, but the applicant shall be entitled to an appearance before the Board.

(4) Term of License.

Licenses are issued for thirty-six months, expire on June 30th of every third year, and may be renewed for three years upon the payment of the required fee for each place of business and the filing of a completed application for renewal. If the application for renewal is not made and the fee not paid before September 1st of the third 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.

(5) Licenses are Location Specific and Non-Transferable.

The Board shall be notified prior to the occurrence of any change to any of the information required by Rule 480-7B-.02(2)(a) to be submitted to the Board as part of an initial application for DME licensure or as part of an application for DME licensure renewal, this obligation shall be continuous and ongoing throughout the period of licensure. Where operations are conducted at more than one licensed place of business by a DME supplier, each place of business shall be licensed by the Board, and each place of business requires a separate application for licensure. If a licensed business moves locations, the license does not transfer to the new location and a new application is required.

(6) Exemption from Licensure Requirement.

(a) The following persons and entities are not required to obtain a DME supplier license from the Board, unless such person or entity has a separate company,

corporation, or division that is in the business of supplying durable medical equipment to consumers and submits a claim for reimbursement by a third party:

1. Pharmacies and pharmacists.
2. Hospitals.
3. Ambulatory surgical centers.
4. Health care facilities owned or operated by the state or federal government.
5. Skilled nursing facilities.
6. Assisted living facilities.
7. Health care practitioners who:
   (i) Provide durable medical equipment within the scope of practice of the health care practitioner's profession; and
   (ii) Are licensed in the State of Georgia to practice the health care practitioner's profession.
8. Suppliers of insulin pumps and related supplies or services;
9. Manufacturers or wholesale distributors that do not sell or rent durable medical equipment directly to consumers;
10. Renal dialysis providers licensed under O.C.G.A. § 31-44-4 and persons or entities that distribute devices necessary to perform home renal dialysis to patients with chronic kidney disease; and
11. Suppliers of osteogenesis stimulators, transcutaneous electrical nerve stimulators, pneumatic compression devices, and related supplies or services.

(b) Facilities that meet the criteria established in O.C.G.A. Section 26-4-6 are not required to be licensed as DME Suppliers.

Authority: O.C.G.A. §§ 26-4-5, 26-4-6, 26-4-27, 26-4-28, 26-4-51, 26-4-60, 43-1-19, 50-36-1, 50-36-2.