NOTICE OF INTENT TO ADOPT PROPOSED RULE OF THE GEORGIA STATE BOARD OF PHARMACY RULES RULE 480-7B-.03 DESIGNATED REPRESENTATIVES FOR DME SUPPLIERS

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 a new rule to the Georgia Board of Pharmacy Rules: Rule 480-7B-.03 DESIGNATED REPRESENTATIVES FOR DME SUPPLIERS (hereinafter "proposed rule").

This notice, together with an exact copy of the proposed rule and a synopsis of the proposed rule, 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 proposed rule, and a synopsis of the proposed rule 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 Peachtree Street, NW, Atlanta, Georgia, 30303. 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 1, 2018 at the Philadelphia College of Osteopathic Medicine, 625 Old Peachtree Road, NW, Suwanee, GA 30024 to provide the public an opportunity to comment upon and provide input into the proposed rule. 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 July 23, 2018. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, 6th Floor, Atlanta, Georgia 30303. You may email your comments to thattle@dch.ga.gov.

The proposed rule will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on August 1, 2018 at the Philadelphia College of Osteopathic Medicine, 625 Old Peachtree Road, NW, Suwanee, GA 30024. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed rule pursuant to authority contained in O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, 26-4-51, and 26-4-60.

At its meeting on April 18, 2018, the Board voted that the formulation and adoption of this rule do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule 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 April 18, 2018, 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 rule 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 <u>alst</u> day of <u>June</u>, 2018.

Tanja D. Battle
Executive Director

Georgia Board of Pharmacy

Posted: June 21 ____, 2018

SYNOPSIS OF PROPOSED RULE OF THE GEORGIA STATE BOARD OF PHARMACY RULES RULE 480-7B-.03 DESIGNATED REPRESENTATIVES FOR DME SUPPLIERS

Purpose of Rule: The purpose of this rule is to establish requirements and qualifications for individuals designated as representatives for DME Suppliers.

Main Features: The main feature of this rule is to set forth the requirements and qualifications for individuals designated as representatives for DME Suppliers.

PROPOSED RULE OF THE GEORGIA STATE BOARD OF PHARMACY RULES RULE 480-7B-.03 DESIGNATED REPRESENTATIVES FOR DME SUPPLIERS

NOTE: Struck through text is proposed to be deleted. Underlined text is proposed to be added.

480-7B-.03 Designated Representatives for DME Suppliers.

- (1) Requirement for Designated Representatives. The Board shall only issue a license to a DME supplier if a qualified individual has been approved as a designated representative for the DME supplier. The designated representative will provide sufficient and qualified supervision of the DME supplier's place of business, ensuring compliance with all state and federal laws and regulations. The designated representative shall ensure the protection of the public health and safety in the handling, storage, warehousing, distribution, and shipment of durable medical equipment in the DME supplier's place of business. Where operations are conducted at more than one licensed place of business by a DME supplier, each licensed place of business shall have at least one designated representative present.
- (2) Qualifications of Designated Representatives. In order to serve as a designated representative, an individual shall:
- (a) Be at least 18 years of age:
- (b) Submit a Board approved personnel certification form as part of the DME supplier's application to the Board;
- (c) Attest to the knowledge and understanding of applicable state and federal laws and regulations relating to the distribution of durable medical equipment, knowledge and understanding of quality control systems, and knowledge and understanding of the United States Pharmacopeia of federal Food and Drug Administration standards relating to the safe storage, handling, and transport of durable medical equipment;
- (d) Consent to provide the necessary information to conduct, and pay for a background check to be conducted by the Board, its agent or a firm or firms approved by the Board, which background check will include a criminal history, driver license history and other information as the Board deems necessary, and will authorize the Board and the Georgia Drugs and Narcotics Agency to receive the results; and
- (e) If the designated representative is a licensed pharmacist, provide the state(s) of licensure, license number(s), and license status(es) of said license(s).
- (3) Notice to Designated Representative. Any notice made to a DME supplier licensee shall be made to the designated representative on record with the Board. If notices are returned as undeliverable or unclaimed, service shall be made on the Executive Director, and any disciplinary proceedings shall proceed, or if a final decision, the decision shall become effective. Authority: O.C.G.A. Sections 26-4-5, 26-4-27, 26-4-28, 26-4-51, and 26-4-60.