

**NOTICE OF INTENT TO ADOPT PROPOSED CHAPTER OF THE GEORGIA STATE
BOARD OF PHARMACY RULES
CHAPTER 480-7B DURABLE MEDICAL EQUIPMENT 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 chapter to the Georgia Board of Pharmacy Rules: Chapter 480-7B DURABLE MEDICAL EQUIPMENT SUPPLIERS (hereinafter "proposed chapter").

This notice, together with an exact copy of the proposed chapter and a synopsis of the proposed chapter, 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 chapter, and a synopsis of the proposed chapter 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 November 8, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 36th Floor, Atlanta, Georgia 30303 to provide the public an opportunity to comment upon and provide input into the proposed chapter. 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 November 1, 2017. Written comments should be addressed to the Executive Director of the Georgia State Board of Pharmacy at 2 Peachtree Street NW, Atlanta, Georgia 30303 FAX: 678-717-6435. You may email your comments to tbattle@dch.ga.gov.

The proposed chapter will be considered for adoption by the Georgia State Board of Pharmacy at its meeting scheduled to begin at 9:05 AM on December 13, 2017 at the Georgia Board of Pharmacy, Department of Community Health, 2 Peachtree Street, 5th Floor, Atlanta, Georgia 30303. According to the Department of Law, State of Georgia, the Georgia State Board of Pharmacy has the authority to adopt the proposed chapter pursuant to authority contained in O.C.G.A. §§ 26-4-5, 26-4-27, 26-4-28, and 26-4-81.

At its meeting on October 12, 2017, the Board voted that the formulation and adoption of this chapter do not impose excessive regulatory cost on any licensee and any cost to comply with the proposed chapter 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 October 12, 2017, 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 13th day of Oct, 2017.



Tanja D. Battle
Executive Director
Georgia Board of Pharmacy

Posted: Oct. 13, 2017

**SYNOPSIS OF PROPOSED CHAPTER OF THE
GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-7B DURABLE MEDICAL EQUIPMENT SUPPLIERS**

Purpose of Chapter: The purpose of this chapter is to establish requirements for licensing Durable Medical Equipment Suppliers.

Main Features: The main feature of this chapter is to set forth the requirements for licensing Durable Medical Equipment Suppliers.

**PROPOSED CHAPTER OF THE GEORGIA STATE BOARD OF PHARMACY RULES
CHAPTER 480-7B DURABLE MEDICAL EQUIPMENT SUPPLIERS**

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

CHAPTER 480-7B: DURABLE MEDICAL EQUIPMENT SUPPLIERS

480-7B-.01 Definitions.

- (1) “Board” shall mean the Georgia Board of Pharmacy.
- (2) “Designated representative” means an individual proposed by a DME supplier and approved by the Board as the supervisor or manager responsible for ensuring the DME supplier’s compliance with all state and federal laws and regulations pertaining to practice as a DME supplier.
- (3) “Durable medical equipment” or “DME” shall mean equipment for which a prescription is required, including repair and replacement parts for such equipment, and which
 - (a) Can withstand repeated use;
 - (b) Has an expected life of at least three years;
 - (c) Is primarily and customarily used to serve a medical purpose;
 - (d) Generally is not useful to a person in the absence of illness or injury; and
 - (e) Is appropriate for use in the home.
- (4) “Durable medical equipment supplier” or “DME supplier” means a person or entity 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.
- (5) “GDNA Agent” or “GDNA Agents” shall mean the director, a deputy director or a special agent of the Georgia Drugs and Narcotics agency.

Authority: O.C.G.A. Sections 26-4-5, 26-4-27, 26-4-28, 26-4-29, and 26-4-51.

480-7B-.02. DME Supplier Licensing Requirements.

- (1) **Licensing requirement.** Effective August 1, 2018, 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 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;
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. Information necessary to demonstrate compliance with O.C.G.A. Title 50, Chapter 36.

(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. 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. Sections 26-4-5, 26-4-6, 26-4-27, 26-4-28, 26-4-51, 26-4-60, 43-1-19, 50-36-1, and 50-36-2.

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) Have not been convicted of a felony under the federal Food, Drug, and Cosmetic Act, any offense related to product tampering under federal or state law, or any state or federal felony that the Board deems related to the occupation for which the license is sought;
 - (e) If requested, 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
 - (f) 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.

480-7B-.04. Compliance with investigations.

A DME supplier licensee shall cooperate with the Board in any investigation involving durable medical equipment distributed by such DME supplier licensee from, into, or within this State. The licensee shall respond within ten (10) business days to all communications from the Board or its designee. Failure to respond or cooperate with the Board shall be grounds for the immediate suspension of the DME supplier license, pending a hearing on further disciplinary action by the Board. Failure to cooperate with the Board is grounds for disciplinary action by the Board.

Authority: O.C.G.A. Sections 26-4-5, 26-4-27, 26-4-28, 26-4-51, and 26-4-60.

480-7B-.05. Required Reporting to the Board.

(1) State or Federal Actions. A DME supplier licensee must notify the Board within ten (10) business days of the receipt of any final order or decision by any other licensing board or federal agency of the imposition of disciplinary action or restriction by such other licensing board or

federal agency in which a license or privilege was suspended or revoked. A final order or decision includes a consent order or agreement and is any decision, regardless whether there still exists an appellate right to the state or federal courts. Any revocation or suspension of a state or federal license or permit may result in the immediate suspension of the DME license by the Board, pending a final decision by the Board.

(2) **Felony convictions.** A DME supplier licensee, its owner, or designated representative who is convicted under the laws of this state, the United States, or any other state, territory, or country of a felony shall be required to notify the Board of the conviction within ten (10) days of the conviction. The failure to notify the Board of a conviction shall be considered grounds for revocation of the DME supplier license.

Authority: O.C.G.A. Sections 26-4-5, 26-4-27, 26-4-28, 26-4-28.2, 26-4-51, and 26-4-60.

480-7B-.06. Retention of Records, Safety Standards, Security, and Operations.

(1) **Consumer counseling.** All personnel engaged in delivery or in-home maintenance and repair of durable medical equipment shall instruct the patient or patient's caregiver on how to use the durable medical equipment provided.

(2) **Continuing education.** Written annual education plan procedures for each classification of personnel must be provided to the Board that includes the following information: description of training content, training method, frequency, and issuance of individual certificates of competence.

(3) **Background Checks.** DME suppliers shall conduct background checks on any person who will have direct contact with patients. Such background check will include at a minimum criminal history and driver license history. The background check shall be maintained on such persons as long as the person is still performing services for the DME supplier.

(4) **Receipt of complaints from consumers.** DME suppliers shall maintain a telephone number operational during the licensee's regular hours of operation in order to provide support for consumers. Such number shall be capable of receiving inbound calls from consumers to the licensee, and such number shall be on file with Board, and shall be included with any material sent to the consumer with the durable medical equipment.

(5) **Delivery by mail.** A DME supplier that uses delivery by mail is accountable to the Board to arrange for the appropriate mailing/shipping process. The DME supplier shall provide a method by which a patient or patient's caregiver can notify the DME supplier as to any irregularity in the delivery of their DME to include but not be limited to: timeliness of delivery; condition of the DME upon delivery; and failure to receive the DME ordered. A DME supplier using delivery by mail shall document the instances when DME have been compromised during shipment and delivery by mail or when the DME does not arrive in a timely manner, and shall maintain such documentation for two (2) years. In addition, the DME supplier shall maintain reports of patient complaints and internal/external audits about timeliness of deliveries, condition of the DME when received by patient including situations when it was compromised in delivery, the wrong equipment was provided, and the patient failed to receive the DME. Such records shall be provided to the Board, upon request.

(6) Records.

(a) A DME supplier shall maintain records for all devices shipped, mailed or delivered to patients in the State of Georgia for a period of at least two (2) years. DME suppliers shall notify the Board of each location where the required records are being maintained, and such records must be readily retrievable and produced to the Board or a GDNA Agent upon request. If the DME supplier is out located out of state, the records must be received by the Board or GDNA within fifteen (15) days of the written request.

(b) A DME supplier shall maintain records of all education plan procedures and certificates of competence, for each employee, for a period of at least two (2) years. A DME supplier shall maintain background checks for each person having in-home contact with a customer for the period that such person remains affiliated with the DME supplier. DME suppliers shall notify the Board of each location where the required records are being maintained, and such records must be readily retrievable and produced to the Board or GDNA Agent upon request. If the DME supplier is out located out of state, the records must be received by the Board or GDNA within fifteen (15) days of the written request.

Authority: O.C.G.A. Sections 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-51, and 26-4-60.

480-7B-.07. Inspections.

GDNA Agents, on behalf of the Board, may initially and/or periodically inspect a DME Supplier applicant's or licensee's office or place of business within this state. During such inspection, the GDNA Agents shall have the authority to inspect the facility and all inventories, and shall have the authority to examine, copy, or remove all records, including but not limited to purchase and sales records, repair records, employee records, background checks, and training records. At the conclusion of an inspection, the GDNA Agent(s) conducting the inspection shall have the responsibility of providing to such applicant or licensee a copy of a written inspection report on which any deficiencies or violations are made along with any recommendations. If a follow-up inspection is required due to deficiencies, the Board may charge the applicant or licensee a fee for the re-inspection as provided in its fee schedule established pursuant to paragraph (37) of subsection (a) of Code Section 26-4-28 to cover the cost of such inspection.

Authority: O.C.G.A. Sections 26-4-5, 26-4-27, 26-4-28, 26-4-29, 26-4-51, and 26-4-60.