November 1, 2017

Georgia Association of Medical Equipment Suppliers (GAMES)
3605 Sandy Plains Rd., Suite 240-470
Marietta, GA 30066

Ms. Tanja Battle
Executive Director
Georgia State Board of Pharmacy
2 Peachtree Street NW,
Atlanta, Georgia 30303

Via fax: 678-717-6435.

Dear Ms. Battle,

The Georgia Association of Medical Equipment Suppliers (GAMES) is a proactive, state-wide association providing leadership, resources and support to companies that provide medical equipment supplies and services to patients in their homes. Our mission is to facilitate business success, influence public policy, and improve patient care in the home.

From its inception, GAMES was engaged with, involved in, and in support of Senate Bill 41 as authored by Sen. Renee Unterman and signed into law by Governor Nathan Deal earlier this year.

The GAMES Board of Directors (hereafter referred to as GAMES) has reviewed the draft rules as posted for public comment by the Georgia Board of Pharmacy and would like to offer the following comments.

Section 3, line 90 – 93, of SB 41 states, “The board may provide by rules and regulations that any person accredited by organizations recognized by the federal Centers for Medicare and Medicaid Services is deemed to meet all or some of the requirements of this Code section.” GAMES requests that the rules provide for this recognition.

480-7B-.01 Definitions
GAMES believes that it is in the best interest of all parties to further define "manufacturers" and "wholesale distributors". These entities would be defined differently from a DME supplier and it is important to distinguish between each type of entity and to use care that the names are not used inter-changeably. GAMES believes that any entity that meets the definition of a DME supplier under the statute should not be exempt from the law.

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

Section 1: Licensing requirement
GAMES recommends removing "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".

We strongly disagree with providing a DME license to out of state manufacturers and wholesale distributors. If a manufacturer or distributor provides any DME item listed on the Medicare or Medicaid fee schedule to patients in Georgia, they should be held to the same standards (accreditation, back ground checks, brick and mortar, ongoing service for the supplies or items, etc.). This should apply to any manufacturer or distributor that submits a claim for reimbursement to a third party, either directly or through a contractual arrangement. Providing a DME license to out of state manufacturers and wholesale distributors defeats the original intent of the law and the patient protections it offers.

Section 2: Applications Licensure as a DME supplier
Line 6
GAMES recommends removing Line 6**.**
GAMES feels that this not only defeats the original intent of the law, it is confusing, conflicts with the law and the rules, as well as is problematic for the Pharmacy Board as the Georgia Board of Pharmacy holds no actionable authority nor any inspection authority over entities located out of state. For this reason, the provisions of the law state that a DME license holder must have a physical location within the State of Georgia.

Section 6: Exemption from Licensure Requirement
Line (a)

GAMES requests further clarification on what constitutes 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:"

There are many examples where companies have multiple divisions some of which may qualify them for exemption (i.e. a company that owns both a pharmacy division, a DME division, and a medical transport division) that may include DME. GAMES suggests further defining of this section, or placing a gross income cap derived from DME (i.e. a

company that derives 5% of revenue from the sale, or rental of DME is defined as providing DME) as a way to determine if a company would require a license.

Line 9
GAMES recommends line 9 of section 6 of 480-7B-.02. **"**Manufacturers or wholesale distributors that do not sell or rent durable medical equipment directly to consumers;" should be removed. We strongly disagree with this exemption. As previously stated, a manufacturer or distributor providing any DME item listed on the Medicare or Medicaid fee schedule should be held to the same standards of patient care (accreditation, back ground checks, brick and mortar, ongoing service for the supplies or items, etc.). This should apply to any supplier, manufacturer, or distributor that submits a claim for reimbursement to a third party, either directly or through a contractual arrangement.

Line 11
We request clarification of the exemption for "Suppliers of osteogenesis stimulators, transcutaneous electrical nerve stimulators, pneumatic compression devices, and related supplies or services." If a company provides these products in conjunction with other DME are they exempt from licensure? Or are entities that provide ONLY these products (and no other DME) exempt from licensure?

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

Section 2: continuing education
Education plans should not need to be resubmitted to the Board annually as long as accreditation standards are met and there are adequate policies and procedures in place that satisfy the accreditation requirement. License holders should be able to prove to any inspectors that education guidelines are being met upon inspection of employee files.

GAMES suggests the following verbiage be used instead:

(2) ***Continuing education.*** *Written continuing education policy for personnel must be available to the Board that includes the following information: description of training content, training method, frequency, and issuance of individual certificates of competence.*

Section 3: Background checks
GAMES fully supports background checks for all personnel who have patient contact *in the patient's home*, not for all employees that have patient contact within the place of business. We suggest adding "in the home" to "DME suppliers shall conduct background checks on any person who will have direct contact with patients" [*in the home]* in order to better clarify who should receive the background check.

We would also suggest removing the section that asks for driving records as necessary for licensure as that matter is between the DME company and their *required* insurer. Furthermore, the Pharmacy Board may not have legal authority to refuse to license a DME supplier based on an employee driving record.

Section 5: Delivery by Mail
GAMES Recommends removing this section from the rules completely as current accreditation standards require signed delivery tickets and record keeping regulations that make Line 5 unnecessary and redundant.

We thank you for your consideration. GAMES is happy to discuss any of this further, to address any of the points mentioned in this correspondence, and to respond to any questions.

Sincerely,

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