



Georgia Occupational Regulation
Review Council

House Bill 569
Durable Medical Equipment
Suppliers
LC 33 6103

A Review of the Proposed Legislation
May 2016

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Executive Summary

As provided in O.C.G.A. § 43-1A, the Georgia Occupational Regulation Review Council reviews all bills proposing licensure of a profession or business referred to it by the chairperson of the legislative committee of reference. Accordingly, the council, at the request of the chairperson of the House Health and Human Services Committee, has reviewed House Bill 569 (LC 33 6103), which proposes to license durable medical equipment (DME) suppliers under the Board of Pharmacy. The legislation provides two main requirements to obtain a DME license: (1) physical location in Georgia and (2) accreditation recognized by the federal Centers for Medicare and Medicaid Services (CMS).

During the course of this review, council staff obtained information from the Georgia Association of Medical Equipment Suppliers (GAMES), the Georgia Board of Pharmacy, and the Georgia Composite Medical Board, while also performing additional research.

O.C.G.A. § 43-1A-6 requires the council to consider certain criteria when determining the need for the regulation of a business or profession. For this review, the council used these criteria to guide the development of findings related to the licensure of durable medical equipment suppliers. The council, with assistance from staff, developed the following findings during the course of this review:

- ❖ Testimony raised the possibility that the health, safety and welfare of DME customers could be at risk due to lack of employee screening, poor customer service, and/or lack of product support. No documented evidence or pattern of adverse events were presented to the council, however. In addition, the legislation contains no explicit licensure requirements that would mitigate these risks.
- ❖ DME prescribed for home use today is often complex. Many DME customers are elderly and/or disabled and may find operating this equipment difficult without substantial instruction and support. Expertise from those delivering products and instructing on the usage of equipment may be required. Some of these employees, however, may already be licensed under a separate professional license (e.g., respiratory therapists).
- ❖ Most citizens of this state that would be affected by this bill have other means of protection. All Medicare and Medicaid DME suppliers, for example, must already meet certain supplier standards, and each location must be accredited in order to retain billing privileges. Testimony presented to the council, however, questioned the current enforcement of these supplier standards. Nonetheless, the proposed legislation does not explicitly provide for additional customer protections and enforcement mechanisms beyond the current CMS standards.
- ❖ The cost effectiveness and economic impact of the regulation would offer mixed results. Licensing and other fees would likely cover the Pharmacy Board's expenses. The legislation, however, would create barriers to entry that would likely impact prices for DME paid by insurance companies and their customers. On the other hand, the "brick and mortar" licensing requirement will likely keep jobs and tax revenue within the state.
- ❖ Means other than additional state regulation could possibly protect the interests of the state, though none currently exist at an industry-wide level.

Based on the information developed and reviewed, the council finds that House Bill 569, LC 33 6103, which proposes the licensure of durable medical equipment suppliers, does not meet the statutory criteria to newly regulate a profession or a business.

Georgia Occupational Regulation Review Council Membership April-May 2016

Standing Members

Richard Dunn, Chairman
Alan Skelton
Ashley Sellers
Christopher Sanders
Sidney Barrett
Tim Fleming
Not assigned*

Representing

Office of Planning and Budget
State Accounting Office
Department of Agriculture
Department of Revenue
Department of Public Health
Office of the Secretary of State
Department of Natural Resources

Legislative Members

Representative Sharon Cooper
Senator Renee Unterman

Georgia House of Representatives
Georgia State Senate

*Due to a standing member changing positions during the HB 569 review, no representative from DNR participated in the proceedings or recommendation.

Introduction

House Bill 569 proposes the licensure of durable medical equipment suppliers in Georgia through regulation by the Georgia Board of Pharmacy. The council evaluated the legislation as introduced (LC 33 6103) and did not consider potential modifications to the bill that may be introduced at a later date.

In conducting this review, the Georgia Occupational Regulation Review Council solicited input from any interested party that wished to submit information or participate in the process. The applicant group, the Georgia Association of Medical Equipment Suppliers (GAMES), submitted a questionnaire providing background information that would support the licensing of durable medical equipment suppliers. The council also received testimony from other interested groups, including the Georgia Board of Pharmacy and the Georgia Composite Medical Board.

In addition, the council reached out to a number of other potentially interested groups, including:

- ❖ The sponsor of the bill
- ❖ The Consumer Protection Unit of the Department of Law
- ❖ The Georgia Council on Aging
- ❖ The Secretary of State's Office
- ❖ The Department of Behavioral Health and Developmental Disabilities
- ❖ The Department of Community Health
- ❖ The Georgia Public Policy Foundation

Council staff also performed additional analysis comparing durable medical equipment licensing regulations in other states to the proposed regulations in Georgia.

The council provided opportunity for other interested parties to present information during council meetings, either by verbal presentation and/or through written material. The council posted meeting dates, times and locations to the Office of Planning and Budget website (<https://opb.georgia.gov/georgia-occupational-regulation-review-council>).

Description of Proposed Legislation

House Bill 569 amends Chapter 4 of Title 26 of the Official Code of Georgia Annotated in order to provide for the licensure of durable medical equipment suppliers. The bill provides the following:

- ❖ Determines the requirements for licensure, which include completing an application to the board, maintaining a federally accredited physical location in Georgia and paying the licensing fee
- ❖ Authorizes the Board of Pharmacy to issue and renew licenses for durable medical equipment suppliers
- ❖ Defines durable medical equipment for the purposes of the bill
- ❖ Sets the license's effective duration at two years
- ❖ Authorizes the board to deny, revoke or suspend a license if the applicant or licensee makes a material misrepresentation to the board or violates any law or regulation that is related to the provision of health care services
- ❖ Specifies that the licensing requirement does not apply to certain groups, including those who do not sell, lease or rent home medical equipment and are already a licensed medical professional or medical facility, such as a pharmacist or hospital

The bill pertains to durable medical equipment requiring a prescription and also references disposable medical supplies when describing which businesses require a durable medical equipment supplier license. HB 569 is intended to regulate businesses, not individuals.

A summary of the bill and the bill text can be found in the appendices.

Current Practices

Durable Medical Equipment Suppliers

In House Bill 569, durable medical equipment (DME) is defined as "equipment, including repair and replacement parts for the same but not including mobility enhancing equipment, which:

- ❖ Can withstand repeated use;
- ❖ Is primarily and customarily used to serve a medical purpose;
- ❖ Generally is not useful to a person in the absence of illness or injury; and
- ❖ Is not worn in or on the body."

Examples of durable medical equipment include air-fluidized beds, hospital beds, nebulizers, commode chairs, blood sugar monitors and sleep apnea devices.

DME suppliers provide this type of home medical equipment, as well as related services, to consumers throughout the state. The suppliers accept prescriptions from physicians for the equipment,

and services and are generally reimbursed by private health insurers, Medicare and Medicaid. Clients of the businesses typically have a chronic illness, injury or disability for which their physician prescribed a piece of durable medical equipment, and these individuals can range significantly in terms of age and how long they need the product. For example, a client could include an elderly person with a chronic, terminal illness or a high-school age student recovering from an injury. The suppliers and their products can allow patients to remain in their homes, rather than in a long-term care facility.

Due to the nature of the industry and the population the businesses serve, clients may benefit from periodic visits and phone calls from suppliers who can demonstrate how to use the equipment and also service it. However, no uniform state standards currently require background checks or training for employees who deliver the equipment. In addition, DME providers may report to physicians on the condition of a patient if regular contact is maintained. Business is based off of physician referrals, providing an incentive for suppliers to locate near clients.

While the number of DME suppliers in Georgia is difficult to calculate, the Georgia Association of Medical Equipment Suppliers estimates that 300 to 350 DME suppliers operate in Georgia. The applicant group also noted that suppliers may employ other related professions, such as respiratory therapists, nurses and rehab specialists. Some of the professionals employed may require licenses in their industry to provide service to patients. For instance, state licensed respiratory therapists are already regulated by the Composite Medical Board.

Some groups, such as physicians and pharmacists, may occasionally provide durable medical equipment. Several of these groups would be excluded from DME licensure requirements as the bill is currently written, and the bill does not pertain to business who only provide out-of-pocket cash sales.

Insurance

Suppliers that accept Medicare or Medicaid must meet certain standards and be accredited by an organization approved by the Centers for Medicare & Medicaid Services. The CMS supplier standards for Medicare include maintaining a physical location in the United States, posting hours of operation on a sign, providing storage space for records, submitting to inspections by CMS agents, abiding by requirements related to surety bonds, remaining open for at least 30 hours a week, and instructing clients on the use of items covered by Medicare. A list of the 30 supplier standards can be found in Appendix C.

In addition to meeting CMS accreditation, durable medical equipment suppliers that receive reimbursements from Medicaid in Georgia must comply with additional Georgia Medicaid supplier standards. These additional standards include requiring a physical location in Georgia or within 50 miles of the state's border and in an area in which Georgia residents typically receive care; and allowing Georgia Medicaid agents to perform on-site inspections.

Private insurance companies may have their own set of standards and requirements that suppliers must meet to do business with them. While no uniform set of standards currently exists, many in the industry consider the Medicare guidelines as the primary standard.

Complaints

Regarding complaints, the Consumer Protection Unit of the Department of Law noted that Consumer Protection had not received enough calls about Durable Medical Equipment to classify it, and thus they could not provide input at the time of the review.

The Better Business Bureau (BBB) serving Metro Atlanta, Athens and Northeast Georgia provided council staff with statistics associated with medical supplies and equipment. The bureau did not have a category explicitly for durable or home medical equipment. While durable medical equipment would likely fall into this broader category, it may potentially include other medical supplies and equipment. The following statistics should therefore be used with caution. Over the past 36 months, the BBB in this region has received 34 complaints related to the broader category of medical supplies and equipment: five for advertising, five for billing, four for delivery and 20 for a problem with a product or service.

For consumers enrolled with Medicare, Medicare's website suggests three solutions for resolving complaints related to durable medical equipment: contact the supplier directly, in which case the supplier is required to respond within 14 days; call Medicare's 1-800 number; or request that a Medicare representative submit the complaint to the Competitive Acquisition Ombudsman (CAO) as a last resort. CMS can suspend billing privileges if needed. The council could not obtain data on Georgia customer complaints to Medicare nor on the resolution of those complaints.

The Issue and Potential for Harm

The bill proposes that the Board of Pharmacy regulate purveyors of durable medical equipment requiring a prescription.

Consumer Safety

The applicant group asserts that individuals receiving durable medical equipment need a better way to identify quality, trained suppliers, noting that suppliers often enter the homes of medically fragile individuals and that the equipment can be complex to operate. Georgia currently has no training standards in place. The group also suggests that suppliers who have a physical presence in Georgia can provide greater access to care and services due to enhanced proximity for in-person visits and for addressing concerns. For this reason, the proposed House Bill 569 has a "brick and mortar" provision that would require a physical location within the state of Georgia to acquire a license. Since licensure would be required to operate, this provision would exclude any businesses with no physical location in Georgia, including internet-based businesses, from supplying in the state. Even a local contractor for an out-of-state company could not show how to use the products under the proposed licensure requirement. The applicant group argues that this requirement could help prevent packages from simply being dropped off on doorsteps with little guidance on how to assemble, use or maintain, and that it could result in more efficient responses to issues. However, the bill does not require proximity to customers, only an in-state location.

Financial Impact

No fiscal note has been prepared for HB 569. Due to uncertainty regarding the number of businesses the bill would affect, along with other factors, revenue needed to support regulatory operations and the cost to the consumer are difficult to determine. The bill states that the fee cannot “exceed the license fee for a pharmacist license.” According to the Board of Pharmacy, the highest amount for a pharmacist fee is \$550. While the new license would have a fee, it may not cover all of the costs associated with adding durable medical equipment suppliers to the Board of Pharmacy’s oversight. Fees would not necessarily translate directly into revenue for the Pharmacy Board (the board would operate based upon annual appropriations), and additional staff would likely be required, such as for inspections, complaint resolution and application review. A representative of the Pharmacy Board estimates a cost of \$90,000 for two new staff, plus any additional costs for inspections staff outside of the board, while a member of the council estimates an initial cost of \$250,000, with annual ongoing costs of \$150,000. The CMS Supplier Standards, by which the bill requires suppliers to abide, state that a supplier must allow for on-site inspections by CMS agents, though the Pharmacy Board may wish to conduct additional inspections on top of accepting CMS accreditation (this ability might need to be written into the bill if desired). Ultimately, the Georgia Drugs and Narcotics Agency would likely handle any inspections. In addition to a licensing fee, which is required in the bill, the applicant group suggested a site survey fee could help offset costs if implemented.

Licensing requirements may impact the price purchasers pay for the regulated item. In an attempt to contain costs, Congress in 2003 mandated that CMS institute a competitive bid process (CBP) for selected durable medical equipment, prosthetics, orthotics and supplies. Under this process, only select contract suppliers can furnish certain DME items at competitively determined prices to Medicare beneficiaries in designated bidding areas. The program began in nine metro areas in 2009 and has since been expanded to nearly 100 metro areas. In Georgia, three areas are currently participating in the program: (1) Atlanta-Sandy Springs-Marietta GA; (2) Augusta-Richmond County GA-SC; and (3) Chattanooga TN-GA. Medicare – the major purchaser of DME in the U.S. – has begun to extend pricing obtained from the CBP to other, non-participating geographic areas. The pricing results have likely influenced private insurance reimbursement, as well.

Testimony to the Council indicated that the CBP program has had a significant impact on Georgia-based DME suppliers. GAMES estimates that roughly 40 percent of its members have either closed or sold to a national provider, presumably due – at least in part – to the CBP program. Large national providers without a presence in Georgia, and thus lower overhead, can typically offer a much lower bid than in-state competitors for a contract with Medicare for a specific metropolitan area. The applicant group estimates that around 50 percent of CBP bids were awarded to out-of-state providers in the first round and that states with in-state location requirements tend to have higher bids.

The in-state requirement would likely impact who could bid to supply Medicare recipients with selected DME in the three Georgia metro areas participating in the CBP. The exclusion of these suppliers could potentially increase costs for purchasers and their customers. On the other hand, the out-of-state

suppliers could continue to do business in Georgia by opening local locations, generating local jobs and additional tax revenue in the process.

Present Requirements and Voluntary Efforts

Statutory requirements

Under current Georgia law, durable medical equipment providers are generally not subject to any additional requirements beyond what would be required for a typical business. DME providers are not subject to any state training requirements, though certain professions they employ may require training and licensing. Of course, a DME supplier would have to abide by all federal and state laws related to other areas of their business, including licensure.

Though outside the scope of the council's formal criteria for consideration, The U.S. District Court, Northern District of Georgia, ruled in 1993 that Georgia Medicaid's requirement that suppliers of DME be located in state or within a 50-mile radius of the state boundary violated the U.S. Constitution's interstate commerce clause. The court ruled that the agency's regulation discriminated against interstate commerce and was not the least burdensome means of accomplishing its stated purpose: reducing the administrative costs of the Medicaid program and protecting the citizens of Georgia. [*Nutritional Support Services. v. Miller*, 830 F. Supp. 625 (N.D. Ga. 1993)]. The applicability of that ruling to the current legislative proposal has not been evaluated.

Voluntary and Purchaser Standards

Most requirements for DME suppliers are imposed by purchasers. As a result, the requirements that a supplier must currently meet depend upon to which insurers it submits claims. For example, Medicare and Medicaid may have separate requirements from each other, and each of their sets of requirements may be distinct from those of private insurers, though standards will overlap among the groups. However, most DME suppliers already must abide by CMS' 30 Supplier Standards since most provide to either Medicare or Medicaid, which also requires CMS accreditation. The head of the applicant group estimates that up to 50 percent of a supplier's business could come from Medicare recipients.

Durable Medical Equipment suppliers can join the Georgia Association of Medical Equipment Suppliers or other organizations. However, the GAMES organization serves as more of an advocate for the industry and its businesses than a body providing oversight.

Proposed Board Authority

Under the bill, no examinations would be required to obtain or renew a license. However, the license would need to be renewed every two years. The bill states that the board "shall issue a license" if the applicant submits an application, maintains a physical location in the state accredited by an organization recognized by CMS, and pays the license fee required by the board. Based upon this

language, it is unlikely that the Pharmacy Board would be able to develop additional rules for licensure, such as setting minimum training requirements or requiring criminal background checks. The bill also provides two conditions for revoking a license: for material misrepresentations to the board or violation of any rule or regulation related to health care services. Because the legislation does not provide the board with general rulemaking authority relating to durable medical equipment suppliers, this likely limits the scope of the board's authority to take disciplinary action based upon board inspection or complaints.

Durable Medical Equipment Regulation in Other States

The applicant group provided state comparisons, and council staff also performed separate state research. Council staff research identified 22 states that have some form of DME licensure requirements. When compared to surrounding states in the Southeast, Georgia appears to be the only one without some form of licensure for DME providers.

Of the 22 states identified by council staff, nearly 60 percent (13 states) utilize their state's respective Board of Pharmacy to manage durable medical equipment suppliers' licenses. Alabama, on the other hand, has its own Home Medical Equipment Board.

The length of the license and the initial licensing fee can vary from state to state. For example, the duration of licensure can last from one year to three years, though nearly all states had licenses that must be renewed within two years or less. The fee ranges from \$50 to \$1,100, though most fees hover around the \$200 to \$350 range.

The degree of requirements varies among states, with some states seeming to only need an application and fee. The applicant group noted that Alabama, Colorado, Tennessee, Maryland and Kentucky have similar standards to those proposed in HB 569. The group also stated in its analysis that some states currently without licensure are considering bills to license or have expressed interest in licensure, such as Arizona and Iowa. While Georgia's bill, and states such as Colorado, require accreditation by an approved CMS organization, other states appear not to link their requirements as closely to Medicare's standards.

A few states, including Alabama, Tennessee and Colorado, have some form of physical location requirement. Most of these provisions simply mandate an in-state facility, while Colorado permits a location within 50 miles of its borders. Some states also require licensees to maintain an inventory of replacement equipment.

Council staff found at least nine states with requirements related to trained or qualified staff providing equipment safely. For example, Illinois' rules include the phrase, "establishes and provides records of annual continuing education for personnel engaged in delivery, maintenance, repair, cleaning, inventory control, and financial management of home medical equipment and services." In

addition, suppliers in California must have written policies for training those giving or receiving related care, and Florida requires a background check for employees.

While some states, such as Kentucky, define durable medical equipment similarly to HB 569, other states have varying definitions, including a handful that include the phrase, “technologically sophisticated.”

Common groups that were excluded from DME licensure by multiple states include the following:

- ❖ Hospitals
- ❖ Home health agencies
- ❖ Skilled nursing facilities
- ❖ Pharmacies
- ❖ Nursing homes
- ❖ Veterinarians
- ❖ Dentists
- ❖ EMS providers
- ❖ Physicians

Findings

Pursuant to O.C.G.A. § 43-1A-6, the Georgia Occupational Regulation Review Council must review bills under their consideration according to the following criteria:

- ❖ Whether the unregulated practice of the occupation may harm or endanger the health, safety, and welfare of citizens of this state and whether the potential for harm is recognizable and not remote;
- ❖ Whether the practice of the occupation requires specialized skill or training and whether the public needs and will benefit by assurances of initial and continuing occupational ability;
- ❖ Whether the citizens of this state are or may be effectively protected by other means;
- ❖ Whether the overall cost effectiveness and economic impact would be positive for citizens of this state; and
- ❖ Whether there are means other than state regulation to protect the interests of the state.

Based on this set of criteria, the council has reviewed House Bill 569, as it was introduced, which recommends the licensure of durable medical equipment suppliers. In doing so, the council developed the following findings:

Though no definitive statistical evidence was presented, the potential for customer harm does exist. The proposed regulation provides little in terms of additional customer protections.

Suppliers often deliver equipment to individuals who may not be capable of setting up equipment on their own. DME devices may require setup or substantial instruction on use. In some circumstances, suppliers may enter a customer's home. Thus, a potential for consumer harm from lack of customer support or the presence of unethical employees does exist. No evidence on patterns of DME customers being harmed or exploited was available, however. Council staff could not say with any certainty how many of the complaints counted by the Better Business Bureau applied only to durable medical equipment suppliers, and thus the statistics could not be fully utilized.

Furthermore, it is unclear how the legislation's two major licensure requirements (in-state "brick and mortar" and CMS accreditation) would directly provide additional protection for the potential health, safety and welfare risks that may be faced by state citizens.

Some discussion at council meetings focused upon the growing reliance on community-based models of care and changing state demographics. There was general agreement among the council that demand for in-home DME would continue to grow. At least some council members believed additional state regulatory infrastructure might help the state address this forthcoming need.

A certain level of knowledge is required by those delivering products and instructing on the usage of equipment; however, many of these employees may already be licensed under a separate professional license. The proposed regulation addresses businesses and does not require any additional skills or training for individuals delivering, installing, instructing or maintaining DME.

While the bill proposes to regulate businesses and not an occupation, DME businesses employ certain professionals, such as respiratory therapists, which already require licenses. The bill as written does not require any additional specialized skills or training for individuals delivering, installing, instructing or maintaining DME. The accreditation standards by the Centers for Medicare & Medicaid Services do state that upon delivery the supplier must instruct the customer on how to use the product, and they also require a supplier to answer questions and respond to complaints from clients, though CMS may not investigate complaints of patient care as often as preferred. A representative from the Board of Pharmacy stated that CMS is more focused upon financial issues and delivery length.

While the public could benefit from increased assurance that suppliers have the capability to set up and instruct on the use of medically vital equipment, most suppliers already abide by some set of standards as a result of their agreements with insurance providers. If these standards and their enforcement do not currently ensure quality, there is no guarantee that the current bill would offer any greater protections. Admittedly, no uniform set of standards is required for all DME suppliers. That being said, the risk for harm may stem as much from customer service and ethics issues as from a training issue, given that the primary concerns seem to be the following: That delivery personnel can

enter the homes of vulnerable populations, that suppliers can simply ship products to customers with little to no assistance after purchase, and that suppliers should repair products as needed.

Most citizens of this state that would be affected by this bill have other means of protection, though the effectiveness of that protection is unclear. In addition, the proposed regulation does not appear to offer any additional protections from the risk of harm for these citizens.

Through the standards established by CMS and through the supplier agreements of private insurance providers, requirements promoting quality of service already exist. These standards include, for example, the mandates to provide instruction on use of the equipment and to address customer complaints. Since most durable medical equipment suppliers accept payments from Medicare or Medicaid, most suppliers are already subject to the 30 CMS standards required in the bill, and the Board of Pharmacy would have to accept the accreditation as determined by a CMS-approved organization. It could not overturn the accreditation or enforce accreditation criteria.

The in-state requirement guarantees neither that a business will be located within a reasonable proximity to its client nor that the business would provide better services than an out-of-state provider. Merely requiring a business to locate in-state could still result in a north Georgia business shipping supplies to a south Georgia customer. In this instance and even for instances in which the business is located much closer to its client, the beneficiary depends on the customer service standards of its supplier and the enforcement measures of its payer regarding that payer's own standards (ex. the 30 Quality Standards for Medicare).

In addition, the current bill does not allow for the Board of Pharmacy to promulgate rules and regulations that might offer greater assurances of quality, such as background checks or training requirements. The bill provides limited grounds for the board to revoke a license. However, licensure could offer a central location for complaints to be filed, recorded and addressed, to the extent that the authority of the board allows.

The cost effectiveness and economic impact of the regulation would offer mixed results, with both positive and negative financial implications. However, the exact impact could not be determined.

The primary potential economic benefit is the following: An in-state location requirement could keep revenue from going to out-of-state locations and thus could keep more tax revenue local and in Georgia. On the other hand, barriers to entry created by a new in-state requirement could result in higher prices.

The additional workload placed on the Board of Pharmacy would also likely result in at least two new positions: One analyst for in-take and other purposes and one customer service/complaint resolution position. A representative with the Board of Pharmacy estimated the cost for these two new positions would be around \$90,000. One or more additional staff for inspections may also be required

by the Georgia Drugs and Narcotics Agency, depending on the scope included in the final version of the bill. These positions would add to the total estimated cost, with approximately 300 businesses or more requiring a license. These costs could be offset by the fee to acquire a license, which at current pharmacy license rates would be no higher than \$550.

Given that no fiscal note exists for the bill, the exact economic and financial impact was not available.

Means other than additional state regulation could possibly protect the interests of the state, though none currently exist at an industry-wide level.

As discussed above, many DME suppliers must already meet the CMS Supplier Standards, which are enforced by federally approved accrediting organizations, and any supplier can adopt these standards for use in their business. Other insurance providers require their own set of standards for suppliers to do business with their clients.

Georgia's Medicaid program already has additional standards that suppliers must meet on top of the overarching CMS standards that many DME providers must also meet. For example, Georgia Medicaid has a version of the in-state location requirement already in place.

While the Georgia Association of Medical Equipment Suppliers and other active groups can bring members together to help advance the industry, the council was not made aware of any industry-wide, self-regulating measures, such as a certification program. Such measures could help customers distinguish between suppliers of higher and lower quality.

Recommendation

Nothing in this document prior to this section, including background information and findings, constitutes a recommendation for bill modification or otherwise. It also does not preclude others from using the information for that purpose. The following is the council's only official recommendation:

The council finds that House Bill 569 as introduced (LC 33 6103), which proposes licensure of durable medical equipment suppliers, does not meet the statutory criteria to newly regulate a profession or business.

The council voted and approved this recommendation unanimously on May 5, 2016.

Appendix A: Summary of Proposed Legislation

Summary of HB 569

- The Georgia State Board of Pharmacy would regulate through licensure those who deliver or accept a physician order to provide disposable medical supplies or durable medical equipment requiring a prescription.
- The license will be a durable medical equipment supplier license, which would require a fee and be effective for 24 months.
- The license requires a physical location in Georgia that also meets certain standards set by the Centers for Medicare & Medicaid Services.
- Durable medical equipment, excluding mobility enhancing equipment, can withstand repeated use, is primarily and customarily used to serve a medical purpose, generally is not useful to a person in the absence of illness or injury, and is not worn in or on the body.
- Certain groups, which are listed in the bill, are excluded from the applicability of this code.

Appendix B: Complete Text of House Bill 569 (LC 33 6103)

House Bill 569

By: Representatives Petrea of the 166th, Stephens of the 164th, Harbin of the 122nd, and Nix of the 69th

A BILL TO BE ENTITLED
AN ACT

1 To amend Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to
2 pharmacists and pharmacies, so as to provide for the licensure of durable medical equipment
3 suppliers; to provide for related matters; to repeal conflicting laws; and for other purposes.

4 BE IT ENACTED BY THE GENERAL ASSEMBLY OF GEORGIA:

5 style="text-align:center">**SECTION 1.**

6 Chapter 4 of Title 26 of the Official Code of Georgia Annotated, relating to pharmacists and
7 pharmacies, is amended in Code Section 26-4-5, relating to definitions, by adding a new
8 paragraph to read as follows:

9 "(14.05) 'Durable medical equipment' means equipment, including repair and
10 replacement parts for the same but not including mobility enhancing equipment, which:

11 (A) Can withstand repeated use;

12 (B) Is primarily and customarily used to serve a medical purpose;

13 (C) Generally is not useful to a person in the absence of illness or injury; and

14 (D) Is not worn in or on the body."

15 style="text-align:center">**SECTION 2.**

16 Said chapter is further amended in Code Section 26-4-28, relating to the powers, duties, and
17 authority of the Georgia State Board of Pharmacy, by adding a new paragraph to subsection
18 (a) to read as follows:

19 "(14.1) The issuance, suspension, denial, and renewal of licenses for suppliers of durable
20 medical equipment pursuant to Code Section 26-4-51;"

SECTION 3.

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Said chapter is further amended by adding a new Code section to read as follows:

"26-4-51.

(a) Any person who delivers disposable medical supplies or durable medical equipment for which a prescription is required and any person who accepts a physician order to provide disposable medical supplies or durable medical equipment shall possess a durable medical equipment supplier license issued by the board.

(b) The board shall issue a license to an applicant for licensure as a durable medical equipment supplier if the applicant:

(1) Completes the license application required by the board;

(2) Maintains a physical location in the State of Georgia, which location is accredited by an accrediting organization recognized by the federal Centers for Medicare and Medicaid Services; and

(3) Pays the license fee required by the board, which in no event shall exceed the license fee for a pharmacist license.

(c) Licenses issued pursuant to this Code section shall be effective for 24 months from the date of issuance and shall not be transferable or assignable.

(d) The board may deny, revoke, or suspend a license issued pursuant to this Code section upon a finding that the applicant or licensee:

(1) Made a material misrepresentation to the board; or

(2) Has violated any state or federal law or regulation that is related to the provision of health care services, including disposable medical supplies and durable medical equipment.

If a license is denied, revoked, or suspended pursuant to this subsection, the applicant or licensee may appeal the board's decision in the same manner as provided in Code Section 26-4-60.

(e) This Code section shall not apply to the sale of disposable medical supplies or durable medical equipment for which a prescription is required by:

(1) Licensed pharmacists or physicians who do not sell, lease, or rent home medical equipment;

(2) Suppliers of insulin infusion pumps and related supplies or services; or

(3) Persons who do not sell, lease, or rent home medical equipment and have an existing state license or permit to operate:

(A) A pharmacy;

(B) A skilled nursing facility;

(C) A hospital;

(D) An ambulatory surgical center;

- 58 (E) A health care facility owned or operated by the state or federal government;
59 (F) An assisted living facility that provides disposable medical supplies or durable
60 medical equipment only to its residents; or
61 (G) A manufacturer or wholesale distributor that provides disposable medical supplies
62 or durable medical equipment directly to consumers."

63 **SECTION 4.**

64 All laws and parts of laws in conflict with this Act are repealed.

Appendix C: CMS Supplier Standards

DMEPOS SUPPLIER STANDARDS FOR MEDICARE ENROLLMENT

Below is an abbreviated summary of the standards every Medicare DMEPOS supplier must meet in order to obtain and retain their billing privileges. These standards, in their entirety, including the surety bond provisions, are listed in 42 CFR § 424.57(c) and (d) and can be found at http://www.cms.gov/MedicareProviderSupEnroll/10_DMEPOSSupplierStandards.asp#TopOfPage.

1. A supplier must be in compliance with all applicable Federal and State licensure and regulatory requirements.
2. A supplier must provide complete and accurate information on the DMEPOS supplier application. Any changes to this information must be reported to the National Supplier Clearinghouse within 30 days.
3. A supplier must have an authorized individual whose signature is binding sign the enrollment application for billing privileges.
4. A supplier must fill orders from its own inventory or contract with other companies for the purchase of items necessary to fill orders. A supplier cannot contract with any entity that is currently excluded from the Medicare program, any State health care programs, or any other Federal procurement or non-procurement programs.
5. A supplier must advise beneficiaries that they may rent or purchase inexpensive or routinely purchased durable medical equipment, and of the purchase option for capped rental equipment.
6. A supplier must notify beneficiaries of warranty coverage and honor all warranties under applicable State law, and repair or replace free of charge Medicare covered items that are under warranty.
7. A supplier must maintain a physical facility on an appropriate site and must maintain a visible sign with posted hours of operation. The location must be accessible to the public and staffed during posted hours of business. The location must be at least 200 square feet and contain space for storing records.
8. A supplier must permit CMS or its agents to conduct on-site inspections to ascertain the supplier's compliance with these standards.
9. A supplier must maintain a primary business telephone listed under the name of the business in a local directory or a toll free number available through directory assistance. The exclusive use of a beeper, answering machine, answering service or cell phone during posted business hours is prohibited.
10. A supplier must have comprehensive liability insurance in the amount of at least \$300,000 that covers both the supplier's place of business and all customers and employees of the supplier. If the supplier manufactures its own items this insurance must also cover product liability and completed operations.
11. A supplier is prohibited from direct solicitation to Medicare beneficiaries. For complete details on this prohibition see 42 CFR § 424.57(c)(11).
12. A supplier is responsible for delivery of and must instruct beneficiaries on the use of Medicare covered items, and maintain proof of delivery and beneficiary instruction.
13. A supplier must answer questions and respond to complaints of beneficiaries and maintain documentation of such contacts.
14. A supplier must maintain and replace at no charge or repair cost either directly or through a service contract with another company, any Medicare-covered items it has rented to beneficiaries.
15. A supplier must accept returns of substandard (less than full quality for the particular item) or unsuitable items (inappropriate for the beneficiary at the time it was fitted and rented or sold) from beneficiaries.
16. A supplier must disclose these standards to each beneficiary it supplies a Medicare-covered item.
17. A supplier must disclose any person having ownership, financial or control interest in the supplier.
18. A supplier must not convey or reassign a supplier number; i.e., the supplier may not sell or allow another entity to use its' Medicare billing number.
19. A supplier must have a complaint resolution protocol established to address beneficiary complaints that relate to these standards. A record of these complaints must be maintained at the physical facility.
20. Complaint records must include: the name, address, telephone number and health insurance claim number of the beneficiary, a summary of the complaint, and any actions taken to resolve it.
21. A supplier must agree to furnish CMS any information required by the Medicare statute and regulations.
22. A supplier must be accredited by a CMS-approved accreditation organization in order to receive and retain a supplier billing number. The accreditation must indicate the specific products and services for which the supplier is accredited in order for the supplier to receive payment for those specific products and services (except for certain exempt pharmaceuticals).
23. A supplier must notify their accreditation organization when a new DMEPOS location is opened.
24. All supplier locations, whether owned or subcontracted, must meet the DMEPOS quality standards and be separately accredited in order to bill Medicare.
25. A supplier must disclose upon enrollment all products and services, including the addition of new product lines for which they are seeking accreditation.
26. A supplier must meet the surety bond requirements specified in 42 CFR § 424.57(d).
27. A supplier must obtain oxygen from a state-licensed oxygen supplier.
28. A supplier must maintain ordering and referring documentation consistent with provisions found in 42 CFR § 424.516(f).
29. A supplier is prohibited from sharing a practice location with other Medicare providers and suppliers.
30. A supplier must remain open to the public for a minimum of 30 hours per week except physicians (as defined in section 1848(j) (3) of the Act), physical and occupational therapists or DMEPOS suppliers working with custom made orthotics and prosthetics.