Georgia Occupational Regulation Review Council
Minutes
May 5, 2016

Call to Order: The second meeting of the Georgia Occupational Regulation Review Council for the consideration of House Bill 569, related to the proposed licensure of certain purveyors of durable medical equipment, was held on Thursday, May 5, 2016, in room 450 of the Georgia State Capitol Building. The meeting convened at 10 a.m. The council members in attendance and constituting a quorum were:

Present: Rick Dunn (OPB), Tim Fleming (SOS), Christopher Sanders (DOR), Ashley Sellers (Ag), Alan Skelton (SAO), Sen. Renee Unterman and Rep. Sharon Cooper

Absent: Sidney Barrett and Mary Kathryn Yearta, who will no longer be a member of the council due to a change in position

Staff Attendees: James Taylor and Meaghan Ryan

Other participants in the discussion:

- Teresa Tatum of the Georgia Association of Medical Equipment Suppliers (GAMES)
- Tanja Battle and Laird Miller of the Georgia Board of Pharmacy

New Business:

I. Call to Order

The chairman, Rick Dunn, called the meeting to order, briefly recapped the first meeting, and discussed the goal of the meeting. Members would have a discussion evaluating the bill as introduced using the criteria outlined in code, following brief presentations on state comparisons and the draft background of the report. He noted that many of the policy issues raised at the last meeting were important but largely outside of the purview of the council.

II. Approval of the Minutes from April 21

The chairman asked if anyone had comments to make on the minutes from last meeting. They were provided to members on April 22. There were no comments, and the minutes were approved.

III. Brief Discussion of State Comparison

Meaghan Ryan (OPB) gave an overview of the states that regulate durable medical equipment. She highlighted general trends in the U.S., states surrounding Georgia, and unique elements of legislation in specific states. For example, she noted that while every state but Georgia in the Southeast regulates durable medical equipment suppliers, only 22 out of 50 states license DME suppliers. She also stated that 13 of those 22 states rely on their Pharmacy Board to regulate the DME suppliers. Fees typically are around $200 to $350, and licenses typically last one to two years. Some states have staffing requirements, which could include continuing education, and some follow Medicare's standards. Only two states had background checks, according to her research. Ryan specifically discussed requirements for licensure in Alabama, Florida, South Carolina and Tennessee. South Carolina has a much narrower licensure of DMEs, dealing with medical gases and legend devices. The chairman noted that he believed the Florida group mentioned by Ryan was a Medicaid

agency. A few states have in-state location requirements. Ryan noted that Colorado allows for a location within 50 miles of its borders. Responding to a question from Sellers, Ryan noted she pulled her information from rules and statutes.

IV. Review of Background Information

James Taylor (OPB) discussed the contents of the draft version of the GORRC report, which did not include the findings or the recommendation. The findings and recommendations would be determined based on discussion during the meeting. A list of members is included in the report. The Introduction and Description of Proposed Legislation summarize the bill and process of review. The Current Practices section defines durable medical equipment and describes the current environment for providers in Georgia, including an estimated number of suppliers. The Issue and Potential for Harm discusses the potential physical and financial impact, referencing concerns about medically fragile customers, the lack of a clause requiring proximity to customers in the bill, and the lack of a fiscal note or guarantee of budget neutrality. The draft report notes that insurance premiums could also potentially rise due to a new barrier to entry but that taxes may remain more local. Voluntary alternatives to licensure have been limited, though organizations such as GAMES exist for advocacy purposes and many suppliers abide by some set of standards, often Medicare's. A court case referenced in the annotated version of the state code deals with Medicaid setting a physical location requirement for DME suppliers and the Interstate Commerce Clause. The draft report acknowledges that the Pharmacy Board would likely be the best group to regulate suppliers. The report contains a section comparing Georgia's proposed regulation to requirements in other states. Taylor asked council members to review the draft and provide feedback in between meetings.

V. *Reading of Intent and Criteria*

Taylor read verbatim the legislative intent of the council and the specific criteria by which the council can judge the bill. These criteria would guide the discussion as outlined below.

VI. Criteria-Based Discussion

1. 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?

The chairman started the discussion by saying that, based on testimony, there is a potential for harm because suppliers deliver equipment to the home and may instruct on how to use it, which can often require being inside the home of customers. However, as the bill stands, he was not sure how the physical location requirement would address that issue. Rep. Cooper said that suppliers deal with a vulnerable population, many who do not read above an eighth grade level or are older and who are not capable of setting up their equipment or living without it. The chairman said that the licensing requirements in the bill do not necessarily ensure good customer service. Sanders was not sure if the physical location requirement in the bill would prevent businesses from simply shipping their equipment if they wished to do so. Cooper responded that if we have licensure and board standards, we have a method of checking the business if complaints are filed. Cooper noted that there is no guarantee that the etiquette issue would happen with other licensed professionals, such as RNs, but they have not had any issues.

The chairman asked how the only two requirements in the bill (accreditation from a CMS organization and a physical location in Georgia) would affect quality. Cooper said that the

Pharmacy Board would make rules and regulations, and the bill would have to be more specific when introduced. Sen. Unterman expressed that we are dealing with life and death situations and that in-state requirements are important to get businesses to respond when issues arise. The chairman stated that Georgia Medicaid has a physical location requirement. Sen. Unterman noted that in 10 to 20 years, Georgia will be dealing with aging baby boomers nearing end of life. Sen. Unterman provided a personal anecdote where it took four months to get an in-home hospital bed delivered by Medicare for a relative of hers. She believes more infrastructure leads to better protection of the consumer.

The council discussed what the GORRC process looks like when dealing with a dead bill. The bill must be considered in its current state, not what it could be introduced as when re-written, and it must be evaluated against the stated criteria. It was believed that the GORRC process would not necessarily have to be repeated if changes were later made to the bill. Cooper asked if the missing elements in the bill could be written into the rules by the Board of Pharmacy. Tanja Battle with the Pharmacy Board said the bill would have to give the authority to promulgate rules to the board in order for that to happen. Skelton said that was the main element that is missing in the bill. Sellers said that the rules and regulations by the board must support the statute.

Cooper noted clients may not get much help when registering a complaint with Medicare except when the issue deals with reimbursement. She said that, while the members provide other perspectives, the committee is not health-based, so it is hard to understand how critical these issues are. There is a medical shift happening with more people choosing to stay at home for their health care instead of hospitals. GAMES wants to continue the process as the bill currently stands, but when it is introduced next session, they will submit an identical bill and then a substitute bill with recommendations based on the discussion and report by the council. GAMES said that the bill was kept simple on purpose so that they could amend the Pharmacy Act. Sellers said that the bill would need to back up what they want to regulate. She then asked if this legislation would resolve the issue that Unterman had, where she waited four months for a bed. Unterman replied that no it would not because it was a federal issue, but if the bed malfunctioned or was defective and the supplier would not fix it, then a consumer complaint could be filed. The chairman then said that they all acknowledge the risks, but the legislation as drafted does not provide a mechanism to deal with that risk. Cooper remarked that they would need to put in code that the Pharmacy Board can promulgate rules, and the chairman provided the example that requiring background checks would be needed in the bill. Responding to a comment by Sellers, the chairman noted that the final report might include examples of other statutes that address issues for guidance.

2. 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?

The chairman started the conversation on the second criteria by saying that since this is a business, not an occupation, this criteria may not apply. Unterman stated that businesses employ some professions, such as respiratory therapists, which require licenses, and the business would be responsible for issues with its employees. The chairman asked if this business requires specialized skills or training, noting that the bill is silent on training as written. Cooper asked does this bill have to satisfy all the criteria, because this one may not apply. Laird Miller from the Board of Pharmacy said that CMS accreditation has standards for delivery

personnel, and that they are required to show the customer how to use the equipment; but CMS seldom investigates complaints of patient care. He said CMS mostly looks at financial issues or delivery length. The chairman stated that the Board of Pharmacy cannot address issues with standards by employing rules and regulation without statutory authority. Sellers said that, in her experience, most licensing laws have four points at the beginning for authority, and this bill seems to be missing it. The information on the board's general authority provided by the Board of Pharmacy does not give them authority to make rules regarding training, inspection, etc. Battle stated that the way the bill is written it would be hard to revoke a license.

3. Whether the citizens of this state are or may be effectively protected by other means?
4. Whether there are means other than state regulation to protect the interests of the state?

These two criteria were similar and therefore discussed together. The chairman read through some CMS standards. He asked if there are any DME businesses that choose not to work with Medicare. Those that do choose have to abide by the 30 quality standards. Unterman said that businesses such as pediatric infusions are covered by Medicaid. The chairman replied that Medicaid follows the same CMS accreditation process. GAMES said that most will abide by standards even if they do not have to and that private health insurance providers have their own standards that they may or may not be enforcing. Unterman said that legislation would add local control and that the General Assembly over the next 10 years is looking at how to take care of Baby Boomers at end of life, who want to remain in communities. She said more and more people do not want to be put into nursing homes and choose palliative care instead, but our infrastructure is not set up for this shift. DME is an imperative part of this infrastructure and community-based service.

The chairman noted that most suppliers deal with Medicare and Medicaid. He asked what authority the Board of Pharmacy would have if the standards were violated or if something was dropped off at the door. He noted that the bill only requires CMS accreditation and a physical location and that the board could not take away CMS accreditation at the state level. Cooper replied that they will have to write in that the Board will have the authority to regulate DME. Sellers brought up that because of the North District case related to the violation of the Commerce Clause of the U.S. Constitution, the legislation will have to be carefully crafted with regard to regulation and probably have to meet a least-restrictive-means requirement. Skelton said the main point he is getting out of criteria three is the word effectively. In his view, passing the bill would essentially be saying that the federal agency does not enforce their own rules effectively enough to be the only rules. The bill would not be perfect and fix all issues. Tatum believes that having the Pharmacy Board would result in a group that can call the federal agency if there is an issue, though Cooper thinks complaining to the federal government is an uphill battle. Sanders said the way the bill is written now, it does not meet the criteria and would not help the four-month delay issue. Cooper said it could help small issues, for example if a bed is not working or for respiratory issues. She also said they needed to change the law and thinks she can use the council's report to help develop those changes. The chairman asked if the Board of Pharmacy could effectively enforce standards. Cooper said that regulated professions listen to the Board of Pharmacy and Composite Medical Board, so she believes they will be able to effectively enforce. She referenced how a complaint goes on a public website and can hurt a business' reputation.

5. Whether the overall cost effectiveness and economic impact would be positive for citizens of this state?

Cooper said that, with this bill, we keep business local and keep tax money in Georgia. The chairman said that it is possible that, because of CMS' bidding process, an in-state requirement could result in the awarded bids not being as low due to the elimination of out-of-state competition. This in turn could drive up premium prices and reimbursement rates, even if only slightly. GAMES thinks there is enough competition within state to keep prices down, though they admitted that they believe other states with in-state requirements have seen higher rates. Tatum said that they just know the final rates, and they are not always the lowest bid. She said there is no transparency to know why they award bids. Skelton added that if the bids are by region, the bill may not have an impact on bid prices. However, GAMES provided some clarification that regions are in Georgia, such as Atlanta and Augusta, and do not refer to the Southeast. Round two rates were just released, so GAMES will analyze rates for states with and without in-state DME license to see if there is a correlation. Tatum did note that regional bid rates have been applied to rural areas. Tatum said that CMS requires bids to abide by state laws, which could include a physical location. The chairman referenced lawsuits filed by other states against CMS seeking to prevent awarding of DME contracts to suppliers not licensed by the state. Sellers asked if we had a better estimate on the cost to regulate. Battle estimated $90,000, which would cover two new employees, one analyst (ex. for in-take) and one customer service/compliance complaint position. That does not include any new staff that may be required for inspections, which would be done by the Georgia Drugs and Narcotics Agency. Sellers noted that the number of investigators needed would depend on the scope included in the final version of the law. Battle stated that the highest amount for a pharmacist fee is $550.

The chair asked if the bill meets the criteria as written. A unanimous formal vote, 7-0, said that the bill as it is written does not meet the criteria and the report will reflect that.

VII. Open Public Comment

The audience participated in the discussion so no open comments were required at the end.

VIII. Announcement of Next Meeting

It was stated during the meeting that the next meeting would look at the final report.

IX. ***Adjourn:*** Meeting adjourned at 11:38 a.m.