

GEORGIA BOARD OF PHARMACY

Board Meeting

2 Peachtree St, NW, 5th Floor

Atlanta, GA 30303

December 12, 2018

9:00 a.m.

The following Board members were present:

Bill Prather, President
Vicki Arnold, Vice-President
Carrie Ashbee
Michael Brinson
Mike Faulk
Lisa Harris
Hal Henderson

Staff present:

Tanja Battle, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Michael Poblet, Special Agent, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Visitors:

Hice Boyett
Amanda Roberson, Eldercare Pharmacy
Stephanie Kirkland, Eldercare Pharmacy
Lindsay Burckhalter, Publix
John Lee, Publix
Susan Jackson, Wellstar
Lauren Pollow, McKesson
Vince Obsitnik, GA Veterinary Medical Association
Tyler Riddle, GAMES
Keri Conley, GHA
John Rocchio, CVS Health
Greg Reybold, GPhA
Lea Winkles, Mercer University
Helen Sloat, Kaiser / Hemophilia of GA /LifePoint
Diane Sanders, Kaiser Permanente
Rena Estep, WAG
Beth Jarrett, Walmart
Stephen Snow
Snehal Doshi, Wellstar
Michael Murphy, Wellstar
Bethany Sherrer, MAG
Shea Ross-Smith, KP
Jim Bartling
Megan Freeman, GSHP
Christian Martins, South University
Laurie Renshaw
Alicia Bennett
James Awe

Open Session

President Prather established that a quorum was present and called the meeting to order at 9:08 a.m.

Appearance

Appearance by Mr. Tyler Riddle, President, Georgia Association of Medical Equipment Suppliers (“GAMES”): Mr. Riddle thanked the Board for the opportunity to speak to its members. Mr. Riddle stated that GAMES represents about 80 DME companies in Georgia. The reason he comes to the Board is to address some issues they are seeing with the enforcement of the new DME license. He stated the law says a manufacturer or wholesale distributor who does not directly service patients is exempt. He stated one who does service or bills to a 3rd party this is addressed in the law and in the rules. He explained that what they are seeing is other states or companies, DME suppliers in other states, being granted DME licenses even though they do not have a physical location in the state. He stated that he is requesting the Board to look into this and see if licenses are being issued to eligible entities. Mr. Changus asked if Mr. Riddle is referring to manufacturers and distributors that are providing durable medical equipment to consumers. Mr. Riddle responded yes. He said they have to be licensed by the state in which they are located and they are okay with that. He explained the issue is that there are companies that are not manufacturers and wholesale distributors. He stated there are DME suppliers who do not manufacture and distribute and have just been granted licenses. Mr. Changus stated they are just people who are supplying DME directly to consumers without being a manufacturer or distributor. Mr. Riddle stated that Alabama sent out an email saying Georgia is issuing licenses to companies without a physical location. He stated that he thinks it is a matter of confusion between the rule and the law and what constitutes a wholesaler supplier and what constitutes a durable medical equipment supplier. Mr. Riddle discussed a facility that has their locations in Connecticut and Oregon, but also have Lawrenceville licensed. Mr. Changus asked Mr. Riddle if he was saying from personal knowledge they are not manufacturer distributors. Mr. Riddle said that is correct. Mr. Riddle asked how the enforcement arm of the Board of Pharmacy is coming up with what constitutes an eligible entity. Mr. Changus responded that the board office is receiving applications where people are identifying that they are exempt from the in-state location. He stated to Mr. Riddle that, if he has a list of who he believes is not compliant with the law, he can submit that to the Board office. Mr. Changus stated if there is a deficit with the application, the Board can look at that. Ms. Battle requested Mr. Riddle submit a formal complaint submission or to email her directly. He said he would and appreciated the Board’s time.

Approval of Minutes

Michael Brinson made a motion to approve the Public and Executive Session minutes from the November 14, 2018 meeting. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Vicki Arnold made a motion to ratify the list of licenses issued. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

Mike Brinson made a motion to grant the rule waiver petition from Emanuel Medical Center, PHH004239. Carrie Ashbee seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to grant the rule waiver petition from Putnam General Hospital Pharmacy, PHH006340. Mike Brinson seconded and the Board voted unanimously in favor of the motion.

President Prather inquired about the status of amendments to Rules 480-11-.04 and 480-13-.05 that he assigned Ms. Emm, Mr. Brinson and Ms. Arnold to work on at the November meeting. Ms. Emm responded by stating that she is still working on them. There are some items that she needs to discuss with Ms. Arnold. Ms. Emm stated that the rule they are putting in their petitions is the compounding rule. She stated that a balance does not seem to be required for all compounding in practice but is required by the rules. President Prather asked if that was mentioned in the general rule. Ms. Emm responded that it is in the general compounding rule, 480-11-.04, and the specific hospital rule, 480-13-.05. She stated she needs

to further discuss the actual compounding rule with Ms. Arnold. Ms. Arnold added to just exempt the hospital rule. Ms. Emm responded by stating the citations the petitioners are putting on these waivers are not the hospital rule. President Prather asked Ms. Emm and Ms. Arnold to include Mr. Brinson on the discussion regarding this matter. Mr. Faulk requested Ms. Emm contact him to discuss as well because there is some compounding that does not require weighing.

Correspondence from Gregory Stinnett, Hamilton Medical Center

The Board considered this correspondence regarding pharmacy technician programs. Additionally, Mr. Stinnett requested the Board consider waiving the registration fee for pharmacy technician students who are not currently working in a Georgia pharmacy and are actively enrolled in an accredited pharmacy technician program. Vicky Arnold made a motion to direct staff to respond by stating that the Board is currently working to address technician education and will take this matter under advisement. Hal Henderson seconded and the Board voted unanimously in favor of the motion. In the same motion, the Board voted to deny Mr. Stinnett's request for a waiver of the registration fee.

Public Hearing

President Prather called the public hearing to order at 9:30 a.m.

Rule 480-13-.01 Definitions

No comments or written responses were received.

Rule 480-13-.04 Absence of Pharmacist

No comments or written responses were received.

Chapter 480-10A Central Filling Regulations

Public comments from Greg Reybold, GPhA, were received. Mr. Reybold stated that he appreciates the opportunity to submit written comments. He discussed two main points. The first being Georgia's PDMP reporting under this proposed rule does not draw distinction between dangerous drugs and controlled substances. He stated as the rule is written, it would create an additional burden. He stated the second point, from a legal perspective, is the guidelines missed the mark and create a truly dangerous precedent in terms of obligation. He stated there is nothing a pharmacist does that is not touched by a federal law, rule or state regulation. He continued by stating that the pharmacist has to comply with the law and rules and if he does not, there is liability. He further commented that this almost creates a *super* standard. He stated it is not enough to comply with the law and regulations, if the policies miss the mark. He stated for example, we have a standard in here regarding "all federal and state law regulations and rules." He stated he could not begin to draft that. He asked if this refers to guidelines pertaining to central fill or guidelines pertaining to pharmacy. He asked what the implications for a pharmacist that is trying to comply are. He stated he is just asking the Board for reconsideration at this time.

Public comments from John Rocchio, CVS Health, were received. Mr. Rocchio commented that he would like to restate that within the central fill rule it is important to remember there are other models of it designed to meet the patient's needs. He commented on the requirement for a return back to the original pharmacy. There are only a couple of states that mandate the return to the originating pharmacy. He stated he just wanted to make sure that is something we are keeping in mind. He commented that the other element is around the counseling by the originating pharmacy.

Mr. Faulk stated that the Board will take the comments made into consideration. He stated one thing he was not aware of is where central fill became mail order. He stated it looks like this is what is being suggested and when he looks at the federal law, it says it goes back to the pharmacy of origin. He stated he has not found anything that has changed that law. If you can show him where that changed, he will be

happy to look at it. Mr. Rocchio commented that certainly controlled substances will go back to the originating pharmacy. Mr. Faulk responded by stating the Board will do it the right way and will give it another review.

President Prather stated this is a huge step. For years, the Board of Pharmacy was opposed to central fill in the interest of patient care and protection. Now it will continue to consider the rule and the comments submitted.

Written comments from John Rocchio, CVS Health, Stephen Georgeson, Pharmacy Council of the Georgia Retail Association, and Greg Reybold, GPhA.

Rule 480-34-.15 Additional Compounds Under Schedule V

No comments or written responses were received.

Mike Brinson made a motion to adopt Rule 480-13-.01 Definitions and Rule 480-13-.04 Absence of Pharmacist. Carrie Ashbee seconded and the Board voted unanimously in favor of the motion.

Lisa Harris made a motion to table Chapter 480-10A Central Filling Regulations. Mike Brinson seconded and the Board voted unanimously in favor of the motion.

Vicki Arnold made a motion to adopt Rule 480-34-.15 Additional Compounds Under Schedule V. Mike Brinson seconded and the Board voted unanimously in favor of the motion.

The hearing was adjourned at 9:43 a.m.

Open Session

Correspondence from Christina Nguyen

The Board considered this correspondence, regarding O.C.G.A. § 26-4-114.1(e)(6), which states “*A permit holder shall maintain a toll-free telephone number operational during the permit holder's regular hours of operation but not less than six days per week for a minimum of 60 hours per week that shall be used to provide and facilitate patient counseling. Such toll-free number shall be capable of receiving inbound calls from patients to the permit holder and shall be disclosed on the label affixed to each container of all dispensed and distributed drugs.*”

In her letter, Ms. Nguyen asks if a voicemail system with unlimited space that records patient messages during the weekend would suffice to meet the 'operational' status required for the toll-free number above. Vicki Arnold made a motion to direct staff to respond by stating that this would not be sufficient. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Tosin Adelakun

The Board considered this correspondence regarding a hospital pharmacy remote order entry project. In his letter, Mr. Adelakun request access to each hospital's policy and procedures in order to compare and contrast the differences in the hospitals' policy and operation to try to examine best practices. Vicki Arnold made a motion to deny the request and direct staff to respond by stating that each policy contains proprietary and confidential information. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jessica Adams, TelePharm

The Board considered this correspondence from Ms. Adams requesting to meet with the Board to discuss telepharmacy. The Board directed staff to schedule Ms. Adams for the next available appointment.

Correspondence from Lanette King

The Board considered this correspondence inquiring about opening a non-dispensing pharmacy and the application process for such. The Board directed staff to respond to Ms. King by requesting she submit additional information as to what services she provides as a "non-dispensing pharmacy" as her question is too vague for a definitive response.

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Attorney General’s Report – Max Changus

No report.

Executive Director’s Report – Tanja Battle

Continuing Education Report: Report presented. Lisa Harris made a motion to ratify the below continuing education programs approved since the previous meeting. Carrie Ashbee seconded and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
12/11/2018	1	Kaiser Permanente	Evaluating Common Dietary Supplements in the Community Setting	2018-0017

Legal Services – Kimberly Emm

Ms. Emm reported that Palmetto GBA reached out and is wanting to know what the Board is doing with the National Suppliers Clearinghouse List that Mr. Henderson is reviewing. Mr. Henderson responded by stating he brought it up at last month’s meeting and it appeared that no one was aware of seeing the list before. He stated there are items on there that do and do not require a license. Mr. Changus responded by stating that the list was not generated by the Board. Mr. Henderson stated that somebody had to give them some information, but did not mean to imply it was the Board. Mr. Changus stated that he has spoken with the person who put the list together. He explained that the person is a contractor outsourced by Palmetto GBA that has been tasked with compiling the list as it applies nationally concerning DME requirements. Ms. Emm stated that she will just inform them that the Board is continuing to work on it. Mr. Henderson commented that two common items on the list are beds and wheelchairs. He asked what the Board wants in regard to the list. President Prather stated that the previous discussion regarding the matter was that the Board does not have any say so and does not know how much alteration it can do to the list. President Prather asked Mr. Henderson to confer with Mr. Changus on any questions he had and report back to the Board.

Correspondence from Ben Tso, Holland & Knight: The Board considered this correspondence regarding non-resident registration of technicians. Specifically, Mr. Tso is wanting to confirm that a non-resident technician does not need to obtain a Georgia technician registration to provide technician services for individuals that are located in Georgia. The Board directed staff to respond by stating that the non-resident technician would need to follow the law and rules in his/her state. If he/she comes into Georgia, would they follow Georgia’s regulations.

Correspondence from Luis Lanz, Quarles & Brady, LLP: The Board considered this correspondence requesting guidance on the Board’s position regarding investigational drugs and licensure for entities distributing and dispensing investigational drugs. The Board directed staff to respond to Mr. Lanz by suggest he refer to the law and rules to investigate whether a researcher’s permit would be appropriate.

Vicki Arnold made a motion and Lisa Harris seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and § 43-1-2(k) to deliberate and to receive information on applications, investigative reports and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Carrie Ashbee, Vicki Arnold, Michael Brinson, Mike Faulk, Lisa Harris, Hal Henderson, and William Prather.

Executive Session

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Attorney General's Report – Max Changus

Mr. Changus discussed the following:

Organizational changes going on with the Attorney General's office that will impact disciplinary cases.
Expectations regarding opioid litigation records request.

Mr. Changus presented the following consent orders for acceptance:

- C.D.C.
- I.P.C.
- E.C.H.

Legal Services – Kimberly Emm

- M.D.I.
- D.A. / D.B.P.

Appearances

- C.C.M.
- L.D.R.
- A.E.B.
- J.B.A.

Applications

- J.L.L.
- V.D.C.
- J.M.A.
- K.M.G.
- A.L.T.
- J.J.
- C.E.C.
- K.S.M.
- K.L.C.
- A.D.B.
- C.A.W.
- C.A.N.
- G.N.A.
- H.S.C.
- L.K.C.
- M.C.C.
- O.A.

- J.W.C.
- C.B.
- K.A.B.
- A.I.
- K.N.V.
- D.K.P.
- C.H.A.

Correspondences/Requests

- A.R.W.P.
- A.
- A.P.D.
- D.P.S.
- D.S.P.D.
- B.H.I.I.
- C.D.
- C.D.
- P.P.S.
- S.P.
- S.P.
- S.P.
- W.P.N.
- W.P.I.
- C.P.S.
- K.J.D.
- M.A.
- J.A.U.
- I.J.
- R.E.H.
- K.M.D.
- O.F.O.
- D.R.P.
- R.I.M.
- M.H.U.M.C.
- P.P.S.
- J.W.T.

Cognizant's Report – Vicki Arnold

- GDNA Case # A32717
- GDNA Case # B32673
- GDNA Case # A32663
- GDNA Case # B32658
- GDNA Case # B32690
- GDNA Case # B32701
- GDNA Case # B32694
- GDNA Case # B32683
- GDNA Case #A32613
- GDNA Case # A32541

No voted were taken in Executive Session. President Prather declared the meeting back in Open Session.

Open Session

President Prather stated that the Board needs to nominate officers for the upcoming year. Vicki Arnold made a motion for Lisa Harris to serve as Cognizant and Vice-President. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion for Bill Prather to serve as President. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion for the Board to take the following actions:

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Attorney General’s Report – Max Changus

Mr. Changus discussed the following:

Organizational changes going on with the Attorney General’s office that will impact disciplinary cases. Expectations regarding opioid litigation records request.

Mr. Changus presented the following consent orders for acceptance:

- Cantrell Drug Company Public Consent Order accepted
- Ideal Pharmacy Corp Public Consent Order accepted
- Effingham County Hospital Public Consent Order to be accepted and signed with express permission

Legal Services – Kimberly Emm

- M.D.I. Request NC Board of Pharmacy Table
- D.A. / D.B.P. Open Records Request Approved request

Appearances

- C.C.M. Pharmacist Intern Applicant Refer to the Department of Law
- L.D.R. Request to Return to Practice Denied request
- A.E.B. Request to Return to Practice Refer to the Department of Law
- J.B.A. Self-Report No action

Applications

- Jawonica L. Lewis Pharmacy Technician Approved for registration
- Vaughn D. Church Pharmacy Technician Approved for registration
- Jennifer M. Anderson Pharmacy Technician Approved for registration
- Kayonna M. Glenn Pharmacy Technician Approved for registration
- Anne L. Thompson Pharmacy Technician Approved for registration
- Jeranise Jefferson Pharmacy Technician Approved for registration
- C.E.C. Pharmacy Technician Denied registration
- K.S.M. Pharmacy Technician Denied registration
- Kelly L. Crowley Pharmacist Reinstatement Approved application
- Amber D. Brandt Pharmacist Renewal Approved for renewal
- C.A.W. Pharmacist Renewal Schedule for Investigative Interview
- Crystal A. Nguyen Pharmacist Renewal Approved for renewal

- G.N.A. Pharmacist Renewal Approved pending receipt of additional information
- H.S.C. Pharmacist Renewal Table pending receipt of additional information
- Lynn K. Carter Pharmacist Renewal Approved for renewal
- Melody C. Castro Pharmacist Renewal Approved for renewal
- O.A. Pharmacist Renewal Approved pending receipt of additional information
- Joseph W. Crager Pharmacist Renewal Approved for renewal
- Christopher Brannen Pharmacist Renewal Approved for renewal
- Kurt A. Boesger Pharmacist Renewal Approved for renewal
- Amenate Iberahme Pharmacist Renewal Approved for renewal
- K.N.V. Pharmacist Reciprocity Denied application
- Daniel K. Postell Pharmacist Renewal Approved for renewal
- Craig H. Albritton Nuclear Pharmacist Approved application

Correspondences/Requests

- A.R.W.P. Notice of Discipline No action
- A. Notice of Discipline No action
- A.P.D. Notice of Discipline No action
- D.P.S. Notice of Discipline No action
- D.S.P.D. Notice of Discipline No action
- B.H.I.I. Notice of Discipline No action
- C.D. Notice of Discipline Table pending receipt of additional information
- C.D. Notice of Discipline Table pending receipt of additional information
- P.P.S. Notice of Discipline No action
- S.P. Notice of Discipline No action
- S.P. Notice of Discipline No action
- S.P. Notice of Discipline No action
- W.P.N. Notice of Discipline No action
- W.P.I. Notice of Discipline No action
- C.P.S. Request to take MPJE a 4th time Approved request
- K.J.D. Request to take MPJE a 4th time Approved request
- M.A. Request to take MPJE a 4th time Approved request
- J.A.U. Request to take NAPLEX and the Practical a 4th time Denied request to take the NAPLEX / Approved request to take the Practical
- I.J. Request re Purchase Late Score Transfer Board directed staff to respond by stating that the only route is for the individual to apply for licensure by reciprocity.
- R.E.H. Correspondence No action taken
- K.M.D. Request to terminate probation Approved request
- O.F.O. Request to terminate probation Approved request
- D.R.P. Request to terminate probation Approved request
- R.I.M. Remote order entry Table pending receipt of additional information
- M.H.U.M.C. Remote order entry Table pending receipt of additional information

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| | | information |
| • P.P.S. | Policies and Procedures | Table until January 2019 meeting |
| • J.W.T. | Request to lift PIC restriction | Approved request |

Cognizant’s Report – Vicki Arnold

- GDNA Case # A32717 Accept Private Interim Consent Order for Assessment
- GDNA Case # B32673 Refer to the Department of Law
- GDNA Case # A32663 Refer to the Department of Law
- GDNA Case # B32658 Misfill Policy #1
- GDNA Case # B32690 Close with no action
- GDNA Case # B32701 Misfill Policy #1
- GDNA Case # B32694 Misfill Policy #1
- GDNA Case # B32683 Letter of concern / Refer to the Department of Law
- GDNA Case #A32613 Refer to the Department of Law
- GDNA Case # A32541 Table until January 2019 meeting

Lisa Harris seconded and the Board voted in favor of the motion, with the exception of Hal Henderson, who recused himself from the vote regarding GDNA #A32541.

Ms. Battle stated that the Board will need to address the matter of ownership and facilities as board staff receive questions regarding this regularly. She would like the Board to provide staff with guidance on what to advise people when they inquire about such. Mr. Changus indicated that he believes this is a matter for his office to research and will discuss the matter with Ms. Emm.

There being no further business to discuss, the meeting was adjourned at 2:40 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, January 16, 2019 at 9:00 a.m., at South University College of Pharmacy, 709 Mall Boulevard, Savannah, GA 31406.

Minutes recorded by Brandi Howell, Business Support Analyst I
 Minutes edited by Tanja D. Battle, Executive Director