GEORGIA BOARD OF PHARMACY

Conference Call Agenda
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
May 19, 2021
9:00 a.m.

The following Board members were present: Staff present:

Michael Brinson, President
Dean Stone, Vice-President
Carrie Ashbee

Michael Azzolin Young Chang Cecil Cordle

Chuck Page Visitors:

Bill Prather Carol Ann Wilson, PharmD

Travis Clark

Becca Hallum, Georgia Hospital Association Bethany Sherrer, Medical Association of GA

Eric Lacefield, Executive Director

Kimberly Emm, Attorney

Dennis Troughton, Director, GDNA

Max Changus, Assistant Attorney General

Brandi Howell, Business Support Analyst

Open Session

President Brinson established that a quorum was present and called the meeting to order at 9:03 a.m.

Mr. Lacefield asked the visitors on the call to send an email via the "Contact Us" portal on the website if he/she would like his/her name reflected as being in attendance in the minutes.

Approval of Minutes

Vice-President Stone made a motion to approve the April 14, 2021 Public Session and Executive Session Conference Call minutes with the changes noted. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Vice-President Stone made a motion to ratify the list of licenses issued. Mr. Prather seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

Rule Waiver Petition from Robert Stover: The Board discussed this request for a waiver of O.C.G.A. § 26-4-42(a)(5). Vice-President Stone made a motion to deny the waiver as proof of initial licensure by examination and proof that such license is in good standing is required by law for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist by license transfer in this state. However, the Board will administratively accept Mr. Stover's application for license transfer if he submits proof that he has an active pharmacist license, in good standing, in Tennessee. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Rule Variance Petition from Ghassan M. Hourani: The Board discussed this request for a variance of O.C.G.A. § 26-4-42(a)(5). Vice-President Stone made a motion to deny the waiver as proof of initial licensure by examination and proof that such license is in good standing is required by law for a pharmacist currently licensed in another jurisdiction to obtain a license as a pharmacist

by license transfer in this state. However, the Board will administratively accept Mr. Hourani's application for license transfer if he submits proof that he has an active pharmacist license, in good standing, in Florida. Mr. Azzolin seconded and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Atlanta Metro Treatment Center, PHOP000020: Vice-President Stone made a motion to grant the petition. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Encompass Health Rehabilitation Hospital of Cumming: Mr. Azzolin made a motion to grant the petition. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Good Samaritan Health & Wellness Center, Inc., PHRE010198: Mr. Azzolin made a motion to grant a variance of the following items only: Class A Balance, Class I or II Electronic Balance, assortment of weights: metric and apothecary, only if utilizing a Class A Balance, ointment slab, and two mortars and pestles of assorted sizes. Additionally, the other items listed in subsections (1)(a), (b), (c), (d), (e), (f), (g) and (h) of Rule 480-10-.12 are still applicable. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from North Fulton Treatment Center, PHOP000004: Vice-President Stone made a motion to grant a variance of the following items only: a refrigerator in working order with a thermometer; if compounding onsite using components which must be weighed, Class A Balance with an assortment of metric weights or a Class I or II Electronic Balance. Additionally, the other items listed in subsections (1), (2)(a), (b), (c), (d), (e), (f), and (g) of Rule 480-18-.05 are still applicable. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Correspondence from Sean Wilden, Houston Medical Center

The Board considered this correspondence regarding a new policy change effective April 1, 2021 implementing Anthem's Designated Specialty Pharmacy Network, which requires specific drugs be provided through Anthem's Specialty Vendor, CVS Pharmacy. President Brinson commented that the Board discussed a similar correspondence last month. He stated that this concerns "white bagging" medication, which means the drug never goes to the patient, but from pharmacy to provider for mixing and after mixing, the drugs are given to the patient. President Brinson stated that there are numerous concerns over this.

Mr. Azzolin commented that there are many issues concerning this matter. He stated the biggest concern is patient safety. Mr. Azzolin stated that what the hospital pharmacies do in preparation of the drugs involves more than just the dispensation of the drugs. He explained that it involves assessing the patient's labs, looking at the patient's past medical history, etc. Mr. Azzolin stated that the retail pharmacy, which dispenses the drugs from an offsite location, does not have access to the same data as the hospital pharmacy and that is a major concern from a patient safety perspective. Mr. Azzolin mentioned that the only pharmacy Anthem has contracted with is CVS Specialty Pharmacy. He explained that he is only mentioning CVS Specialty Pharmacy because there is no other pharmacy Anthem has contracted with, which is a concern from a steering perspective. Mr. Azzolin commented that they are using the hospital's pharmacy to mix these drugs and prepare for the patient. He stated that it is an unusual situation with significant patient-care related issues.

President Brinson agreed with Mr. Azzolin. He stated that this is a concern amongst hospital pharmacy directors. In regards to steering, President Brinson stated that he thinks the associations need to get together and look at this to see if it is steering.

Mr. Azzolin commented that one of the concerns is liability. He questioned who would be liable if something happens to the patient. Mr. Azzolin stated that in regards to the correspondence from Mr. Wilden, Mr. Wilden referenced Rule 480-9-.04 Redispensing by a Different Pharmacy. Mr. Azzolin commented that he read through the rule and it does put a significant burden on the secondary dispensing pharmacy. In regards to steering, Mr. Azzolin stated that he believes the Board needs to do some research in that area. President Brinson stated that he would like for the associations to get involved. Mr. Azzolin asked Mr. Changus and Ms. Emm what could the Board do to research the steering component of this matter. Mr. Changus inquired as to whether or not this correspondence is the same as correspondence discussed by the Board at its April meeting. Mr. Lacefield answered affirmatively. Mr. Changus commented, that in terms of obtaining more information, the Board could extend an invitation to Anthem to attend a board meeting to provide insight and address some of the Board's concerns.

In terms of a response to Mr. Wilden, Mr. Lacefield stated that the Board reviewed correspondence from Ricky Benjamin at its April meeting concerning the same issues and staff were directed to respond to Mr. Benjamin by requesting he provide specific information as to what laws/rules such a policy violates and specific instances where a potential violation may have occurred that can be investigated. After further discussion was held, the Board directed staff to invite Anthem to meet with the Board. Additionally, the Board directed staff to send the same response that was sent to Mr. Benjamin to Mr. Wilden. Lastly, the Board requested Mr. Changus and Ms. Emm to research the issue of steering.

Correspondence from John Alford, Jr., Maynard Cooper Gale:

The Board considered this correspondence regarding wholesale distributor licensure and medical devices. In his inquiry, Mr. Alford stated that his client has obtained a wholesale distributor's license and is questioning if an additional license is required for devices such as medicated gauze. The Board directed staff to respond to Mr. Alford by stating a wholesaler license covers both drugs and devices.

Georgia Drugs and Narcotics Agency - Dennis Troughton

Director Troughton reported that GDNA has one agent position open.

Director Troughton reported that GDNA has conducted 2301 inspections and 335 investigations for FY2021.

Attorney General's Report - Max Changus

No report.

Executive Director's Report – Eric Lacefield

Continuing Education Report: Report presented. Mr. Prather made a motion to ratify the below continuing education programs approved since the previous meeting. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

Date of	Hours	Sponsoring Group	Program Title	CE Code
Program				
04/22/2021	1	Kaiser Permanente	Outpatient Pharmacy Anticoagulation	2021-0004
			Service Refresher Training	
05/19/2021	1	Kaiser Permanente	H_I_V_ Not as Easy as 1-2-3: HIV	2021-0005
			Treatment and Prevention Updates	

Georgia Pharmacy Convention: Mr. Lacefield commented that registration information regarding the annual meeting had been forwarded to each member. He stated the meeting will be held June 17-20 at the Omni Amelia Island Resort.

Legal Services – Kimberly Emm

Correspondence from Richard Marasco: Ms. Emm discussed this correspondence requesting clarification as to whether or not a pharmacy that dispensed medications as 30 or 90 day supplies, but packages multi-dose punch cards for 30 day intervals, could hold and store the remaining medications in a separate and secure part of the pharmacy until it was needed to prepare the next month's multi-dose punch card. Ms. Emm explained that Rule 480-9-.03(b) only allows for the total quantity of drugs dispensed to be no more than 34 day supply in multipack doses. She continued by stating this pharmacist does not appear to be the pharmacy dispensing the drugs. She stated that it seems he is putting an additional burden on the dispensing pharmacy to hold 60 days' worth of a prescription that has already been dispensed to a patient. Ms. Emm further stated that as far as she knows, this practice is not permitted. She explained that once the drug has been dispensed, it is the property of that patient and is no longer the responsibility of the pharmacy. President Brinson agreed. Director Troughton added that GDNA has seen this in the past and it has been consistent in terms of enforcement. He stated that there is nothing in the law or rules that would permit the pharmacy to hold the scripts as there are a number of legal issues surrounding it.

Ms. Emm stated that Rule 480-9-.01 defines "Multi-Drug Single-Dosing Container" as "A multi-drug single-dosing container is a customized single-dosing package labeled by a pharmacy for a specific patient, and such package contains two or more solid, oral dosage form drugs to be administered to or taken by a specific patient at the same dosage time from a single container." Ms. Emm further stated that Rule 480-9-.03(b) states, "The total quantity of drugs dispensed may not be more than a thirty-four (34) day supply". The Board directed Ms. Emm to respond to Mr. Marasco with this information.

Miscellaneous

President Brinson discussed House Bill 316 and House Bill 367, both of which have been signed by the Governor. He inquired as to whether or not pharmacies can have four (4) technicians as long as two (2) are certified since the bill has been signed into law. Ms. Emm responded by stating that the law is not effective until July 1st. She further stated that she will need to update the current rule. Ms. Emm explained that the rule process is timely; however, as of July 1st, the law supersedes the current rule. President Brinson requested Ms. Emm review the current rule and report back to the Board in June.

Request from James Flanigan, Flanigan's Counseling and Evaluation Services: The Board considered this request to become a board-approved treatment provider. The Board directed staff to request additional information and to send Mr. Flanigan a copy of the Board's program criteria.

Medical Marijuana: Vice-President Stone inquired about rules pertaining to medical marijuana. Mr. Prather, who serves on the Medical Cannabis Commission, responded that he will bring back to the Board a draft rule to discuss.

Mr. Page made a motion and Mr. Azzolin 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, Michael Azzolin, Michael Brinson, Young Chang, Cecil Cordle, Chuck Page, Bill Prather, and Dean Stone.

Executive Session

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Cognizant's Report - Dean Stone

- GDNA Case # B33682
- GDNA Case # B33576
- GDNA Case # B33615
- GDNA Case # B33608
- GDNA Case # A33601
- GDNA Case # A33676
- GDNA Case # A33693
- GDNA Case # A33690

Appearance

• B.H.S.

Cognizant's Report - Dean Stone

- GDNA Case # B33695
- GDNA Case # A33699
- GDNA Case # B33725
- GDNA Case # B33611
- GDNA Case # B33615
- GDNA Case # B33593
- GDNA Case # B33462
- GDNA Case # B33697
- GDNA Case # A33239

Attorney General's Report - Max Changus

Mr. Changus presented the following consent orders for acceptance:

- I.P.
- B.E.T.P.
- G.H.
- T.S.Q.
- N.
- H.C.
- J.Q.H.
- T.M.S.
- V.S.S.I.
- A.U.M.I.P.
- W.C.M.

Executive Director's Report – Eric Lacefield

Received legal advice regarding O.C.G.A. § 26-4-25 and § 45-7-21.

<u>Legal Services – Kimberly Emm</u>

• B.M.

Applications

- A.A.P.
- T.L.C.
- K.C.C.
- M.L.F.
- K.M.C.
- C.L.B.
- D.R.P.
- B.G.K.
- C.M.G.
- J.R.F.
- B.J.K.
- E.M.E.
- C.A.F.
- B.S.I.S.
- D.S.I.G.
- D.S.I.G.
- D.S.I.G.
- D.S.I.G.
- C.P.
- J.J.P.
- S.R.
- N.P.

Correspondences/Requests

- C.P.
- B.
- P.V.S.I.
- R.C.
- C.V.S.P.
- A.R.
- S.B.
- J.L.A.
- J.B.
- A.S.D.
- C.N.C.
- R.H.
- R.T.K.

No votes were taken in Executive Session. President Brinson declared the meeting back in Open Session.

Open Session

Vice-President Stone made a motion for the Board to take the following actions:

Georgia Drugs and Narcotics Agency - Dennis Troughton

No report.

Cognizant's Report - Dean Stone

•	GDNA Case # B33682	Accept Voluntary Surrender
•	GDNA Case # B33576	Refer to Legal Services
•	GDNA Case # B33615	Letter of Concern to Pharmacist #1 / Misfill Policy #1 for
		Pharmacist #2
•	GDNA Case # B33608	Misfill Policy #2
•	GDNA Case # A33601	Refer to the Department of Law
•	GDNA Case # A33676	Null and void permit
•	GDNA Case # A33693	Refer to the Department of Law
•	GDNA Case # A33690	Null and void permit

Appearance

• B.H.S.

Cognizant's Report - Dean Stone

•	GDNA Case # B33695	Refer to the Department of Law
•	GDNA Case # A33699	Refer to the Department of Law
•	GDNA Case # B33725	Refer to the Department of Law
•	GDNA Case # B33611	Close case and refer to the FDA
•	GDNA Case # B33615	Close case and refer to the FDA
•	GDNA Case # B33593	Close case with no action
•	GDNA Case # B33462	Close case with no action
•	GDNA Case # B33697	Close case with no action
•	GDNA Case # A33239	Close case with no action

<u>Attorney General's Report – Max Changus</u>

Mr. Changus presented the following consent orders for acceptance:

•	I.P.	Public Consent Order accepted
•	B.E.T.P.	Public Consent Order accepted
•	G.H.	Public Consent Order accepted
•	T.S.Q.	Private Consent Order accepted
•	N.	Public Consent Order accepted
•	H.C.	Public Consent Order accepted (ratification)
•	J.Q.H.	Public Consent Order accepted
•	T.M.S.	Public Consent Order accepted
•	V.S.S.I.	Public Consent Order accepted (ratification)
•	A.U.M.I.P.	Denied counterproposal
•	W.C.M.	Public Consent Order accepted

Open records request

Executive Director's Report – Eric Lacefield

Received legal advice regarding O.C.G.A. § 26-4-25 and § 45-7-21.

<u>Legal Services – Kimberly Emm</u>

• B.M.

Applications		
• A.A.P.	Pharmacy Technician	Approved for registration
• T.L.C.	Pharmacy Technician	Approved for registration
• K.C.C.	Pharmacy Technician	Approved for registration

Denied request

•	M.L.F.	Pharmacy Technician	Approved for registration
•	K.M.C.	Pharmacy Technician	Approved for registration
•	C.L.B.	Pharmacy Technician	Approved for registration
•	D.R.P.	Pharmacy Technician	Approved for registration
•	B.G.K.	Pharmacy Technician	Approved for registration
•	C.M.G.	Pharmacy Technician	Approved for registration
•	J.R.F.	Pharmacist Intern	Approved application
•	B.J.K.	Pharmacist Reciprocity	Approved application
•	E.M.E.	Pharmacist Examination	Approved application
•	C.A.F.	Nuclear Pharmacist	Approved application
•	B.S.I.S.	Non-Resident Pharmacy	Approved for Renewal
•	D.S.I.G.	Non-Resident Pharmacy	Approved for Renewal
•	D.S.I.G.	Non-Resident Pharmacy	Approved for Renewal
•	D.S.I.G.	Non-Resident Pharmacy	Approved for Renewal
•	D.S.I.G.	Non-Resident Pharmacy	Approved for Renewal
•	C.P.	Non-Resident Pharmacy	Approved for Renewal
•	J.J.P.	Non-Resident Pharmacy	Approved for Renewal
•	S.R.	Manufacturing Pharmacy	Approved for Renewal
•	N.P.	Retail Pharmacy	Tabled until June 2021 meeting

Correspondences/Requests Notice of Disciplin

•	C.P.	Notice of Discipline	No action
•	B.	Notice of Discipline	No action
•	P.V.S.I.	Notice of Discipline	No action
•	R.C.	Notice of Discipline	No action
•	C.V.S.P.	Request to extend temporary closure	Approved request
•	A.R.	Request for 4 th attempt at MPJE	Approved request
•	S.B.	Request for 5 th attempt at MPJE	Approved request
•	J.L.A.	Correspondence	The Board viewed this correspondence for informational purposes only.
•	J.B.	Request to terminate probation	Approved request
•	A.S.D.	Correspondence	Table pending receipt of additional information.
•	C.N.C.	Correspondence	The Board viewed this correspondence for informational purposes only.
•	R.H.	Request regarding misfill course	Denied request
•	R.T.K.	Appearance request	Denied request

No votes were taken in Executive Session. President Brinson declared the meeting back in Open Session.

Mr. Page seconded and the Board voted unanimously in favor of the motion.

Miscellaneous

In regards to in-person meetings, Mr. Lacefield commented that he would reach out to each of the pharmacy schools to see if their protocols would allow in-person meetings and if they would be willing to host, since the Department of Community Health still requires meetings be held virtually. President Brinson stated the Board would continue to meet virtually for the June meeting, unless it was advised otherwise.

There being no further business to discuss, the meeting was adjourned at 2:02 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, June 9, 2021 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6th floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I Minutes edited by Eric Lacefield, Executive Director