# **GEORGIA BOARD OF PHARMACY**

Conference Call Agenda 2 Peachtree Street, NW, 6<sup>th</sup> Floor Atlanta, GA 30303 June 9, 2021 9:00 a.m.

The following Board members were present:

Michael Brinson, President Dean Stone, Vice-President

Carrie Ashbee Michael Azzolin Young Chang Cecil Cordle Chuck Page Bill Prather **Staff present:** 

Eric Lacefield, Executive Director Dennis Troughton, Director, GDNA

Michael Karnbach, Deputy Director, GDNA Max Changus, Assistant Attorney General Elizabeth Simpson, Assistant Attorney General

Kimberly Emm, Attorney

Brandi Howell, Business Support Analyst

**Visitors:** 

Diane Sanders Stephanie Kirkland

Becca Hallum, Georgia Hospital Association

Dr. Yolanda Y. Rhetta

### **Open Session**

President Brinson established that a quorum was present and called the meeting to order at 9:04 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 May 12, 2021, Public Session and Executive Session Conference Call minutes with the changes noted. Ms. Ashbee 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.

President Brinson stated that the Board planned on discussing the FDA Memorandum of Understanding; however, he requested it be removed from the agenda this month and placed on the Board's July agenda instead. Director Troughton explained that part of the reason that occurred was because of issues at GDNA and other agency items he had to prepare for. He thanked the Board for its understanding and stated that GDNA will be prepared to discuss the matter at the July meeting.

### **Petitions for Rule Waiver or Variance**

Rule Variance Petition from Dawn N. Parker, PDTM000124, and Devin L. Kitson,

**PDTM000123**: Vice-President Stone made a motion to grant both petitions. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

Rule Waiver Petition from Norcross Pharmacy: The Board discussed this request for a waiver of Rule 480-6-.01(3). Director Troughton explained the petition concerned an ownership change, and in the past, the Board did not allow that license for ownership to be transferred. He further explained that if the issue concerned a name change or location change, the Board permitted such. Ms. Emm agreed and stated that, in regard to an ownership change, the Board has not permitted the facility to keep the same license number as licenses are not transferrable or assignable. Mr. Changus commented that the rule cited was based on statute. Mr. Azzolin responded by stating that the Board granted a petition regarding a sale or transfer at its December meeting. Director Troughton stated that the petition Mr. Azzolin referenced was in regards to a change in name or location only and the Board decided that was not necessarily transferring or assigning a license. He further stated that the petition from Norcross Pharmacy was concerning an ownership change. Mr. Azzolin responded by asking if it is the same rule and there is a statute tied to it, how could the Board have waived it in December and not now. Mr. Changus explained that the Board has previously discussed this matter and has said that the change of location was not transferring the assignability of a pharmacy. He continued by stating that if it is in the statute, Mr. Azzolin is correct, that is not something that could not be waived. However, there is a difference between transferring ownership interest versus a change in location. Mr. Azzolin commented that he knows the Board cannot modify the statute, but inquired as to if there was a reason for the Board to discuss whether that particular law or rule hinders patient care. He stated that if the pharmacy cannot bill for a particular drug because it had to obtain a new pharmacy license and new DEA license it would hinder patient care if that patient could not get his/her medications. He inquired if the Board should bring this matter to the attention of the legislature. Director Troughton responded by stating that GDNA has never received a complaint stating that a change in ownership caused a patient safety concern or the pharmacy could not fill prescriptions. Mr. Page stated that the situation described by Mr. Azzolin is a real-world situation and patient care would be a concern. Mr. Lacefield commented that if there was a need for any further discussion, this matter could be placed on the October agenda. There being no further discussion, Ms. Ashbee made a motion to deny the rule petition. Mr. Page seconded and the Board voted unanimously in favor of the motion.

# Georgia Drugs and Narcotics Agency - Dennis Troughton

Director Troughton reported that GDNA has conducted 2412 inspections and 374 investigations for FY2021.

Director Troughton reported that GDNA has two (2) open agent positions. He stated that one position would be located in Atlanta and the other position in Southwest Georgia.

Correspondence from Timothy Koch: Director Troughton discussed this correspondence asking, "What does the delivery must be on a continuous route from the pharmacy to the patient or the patient's designee actually mean? Can a delivery driver take 10 patients' prescriptions at one time and deliver them one right after the other? The one caveat to our latest delivery offering is that we are offering in-home delivery (https://inhome.walmart.com/). Any concerns, as long as we meet the requirements below? Director Troughton stated the correspondence refers to 480-48-.01 Definitions. He further stated that he received the email the Friday before the Board's meeting and had not had time to research it. After discussion by the Board, the Board requested Mr. Koch provide additional information. Director Troughton stated he would contact Mr. Koch and report back to the Board.

Attorney General's Report – Max Changus

No report.

<u>Executive Director's Report – Eric Lacefield</u> <u>Continuing Education Report:</u> No report for June. Correspondence from Christopher Taylor: Mr. Lacefield stated the board office had received numerous inquiries regarding exemption of foreign cosmetic manufacturers having to perform animal testing if a certificate from a state authority can be provided. He stated that staff had responded by suggesting the individual reach out to the FDA regarding Good Manufacturing Practices for Cosmetics as the Georgia Board of Pharmacy does not issue any such certification. Mr. Lacefield further stated that he wanted to make the Board aware of the inquiries and that staff would continue to respond in this manner unless the Board stated otherwise. The Board agreed that the response provided by staff was appropriate.

**Temporary Pharmacy Technicians:** Mr. Lacefield stated that the Board set the expiration date for temporary pharmacy technician registrations to 06/30/2021 and that date is rapidly approaching. Mr. Azzolin made a motion to move the expiration date to 08/28/2021. Vice-President Stone seconded and the Board voted unanimously in favor of the motion.

### <u>Legal Services – Kimberly Emm</u>

No report.

### Miscellaneous

Pharmacy Technician Continuing Education: The Board discussed this matter that was tabled at its February meeting. President Brinson stated he would like the Board to require all technicians to receive some form of continuing education. He stated one option would be to require all pharmacy technicians to obtain ten (10) hours of continuing education prior to the next renewal on 06/30/2023. He added that as a requirement for each subsequent renewal cycle, a pharmacy technician must complete no less than twenty (20) hours of continuing education from a board-approved provider. President Brinson suggested the Board review the information provided and discuss further at the Board's July meeting. Mr. Azzolin suggested the Board add this as a topic for its two-day meeting in October. The Board agreed.

Rule 480-9-.03 Conditions: Vice-President Stone discussed amending Rule 480-9-.03(b) and (c) to reflect "ninety-six (96) day supply". Additionally, he requested the typos in sections (d) and (e) be corrected. Vice-President Stone stated the last revision was done in 2001 and since that time, technology has changed. In regards to amending sections (b) and (c), he stated that he was thinking in terms of patient safety and improving patient care. After further discussion, Ms. Emm stated that (b) would be amended to reflect "no more than a ninety-six (96) day supply" and (c) would be amended to reflect "a ninety-six (96) days or less drug supply...". Mr. Prather made a motion to accept Vice-President Stone's suggested amendments to Rule 480-9-.03 Conditions. Ms. Ashbee seconded, and the Board voted unanimously in favor of the motion. Ms. Emm will revise the rule and bring back to the Board for consideration of a vote to post.

Pharmacy Low THC Oil Specialty Dispensing Rules: Ms. Emm commented that she has not had time to review the suggested proposal. Mr. Prather stated that he was asked several months ago to draft a rule. He further stated that it was noted the Board of Pharmacy would come up with rules for pharmacies that would make available medical cannabis. Mr. Prather stated that medical cannabis is still a schedule I narcotic according to federal law and he approached it from that standpoint. Mr. Changus commented that Mr. Prather requested he review the draft, which he has done and provided comments. He stated there were revisions to the license issue that were passed since the last legislative session. He further stated that the Board probably need to wade through those first and identify how those may change things. Mr. Changus stated that he spoke with Dan Walsh, Attorney General's office, who stated the focus of the Medical Cannabis Commission at this time is on the other side of things in terms of addressing the licenses and the obligations it has. Mr. Changus stated that in order to address the Board of Pharmacy obligations under the statute, it would be worth trying to get the rules up to speed as soon as possible given the fact the rules process will take

some time. He added that Director Troughton and Mr. Lacefield may have input on any enforcement or administrative concerns. Mr. Changus thanked Mr. Prather for putting forth the draft and stated the legislation goes into effect July 1<sup>st</sup>. The Board recommended tabling this matter until its July meeting.

**Human Trafficking Continuing Education:** President Brinson stated that the Board previously considered a correspondence regarding this topic and recommended not mandating a human trafficking continuing education course. He stated that the Board previously recommended working with the various associations to see if they would be interested in offering a course for free. He inquired as to whether or not the Board could put a statement on its website. Ms. Ashbee responded that she was in full support of that idea. President Brinson requested Ms. Ashbee work with Mr. Lacefield and Ms. Emm with drafting a statement for the Board's website.

Mr. Prather made a motion and Ms. Ashbee 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**

### **Appearance**

• C.C.R.

# **Georgia Drugs and Narcotics Agency – Dennis Troughton**

No report.

#### Cognizant's Report – Dean Stone

- GDNA Case # A33709
- GDNA Case # B33657
- GDNA Case # T33669
- GDNA Case # B33655
- GDNA Case # B33501
- GDNA Case # B33560
- GDNA Case # B33702
- GDNA Case # B33677

#### Attorney General's Report – Max Changus

The Board received legal advice regarding Rules 480-27-.01 Definitions, 480-27-.09 Patient Records, 480-31-.01 Patient Counseling, 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders, 480-37-.03 Minimum Requirements, 480-10-.01 Controlled Substances and Dangerous Drugs, 480-13-.06 Drug Distribution Control, 480-48-.01 Definitions, 480-10-.06 Licensure, Applications, and Display of License and Renewal Certificate, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances.

Mr. Changus presented the following consent orders for acceptance:

- M.P.U.
- Y.D.P.
- F.M.A.
- L.R.E.
- M.E.I.S.

Ms. Simpson discussed the following case:

• R.P.I.

Mr. Changus discussed the following case:

• M.C.

# **Executive Director's Report – Eric Lacefield**

No report.

## **Legal Services – Kimberly Emm**

No report.

# **Applications**

- N.D.B.
- S.L.R.
- M.L.T.
- T.N.R.
- G.M.R.
- R.M.O.
- G.S.R.
- P.V.S.I.
- I.P.C.
- G.
- M.P.B.
- S.P.
- M.D.C.
- M.D.C.
- M.C.
- M.D.C.
- M.D.C.
- M.D.C.
- M.D.C.
- M.C.
- M.D.C.
- M.C.
- M.D.C.
- M.D.C.
- M.D.C.I.
- E.P.
- E.P.
- D.C.
- Z.U.
- L.I.

- L.I.
- L.I.
- L.I.
- L.I.
- L.I.
- L.I.
- L.I.
- L.I.
- L.I.
- M.V.S.I.
- D.S.I.
- A.P.I.
- C.C.
- N.P.
- O.K.C.A.S.I.
- C.V.S.S.
- S.
- B.E.T.

# **Correspondences/Requests**

- U.D.S.I.
- L.I.
- W.C.M.
- A.B.C.
- J.C.A.

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

### **Open Session**

### Miscellaneous

Vice President Stone made a motion to post Rule 480-16-.06 Theft Loss, or Unaccounted for Controlled Substances as amended. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

### Rule 480-16-.06. Theft, Loss, or Unaccounted for Controlled Substances

- (1) The theft, loss, or <u>the discovery of unaccounted</u> for controlled substances <u>must</u>, within three (3) days of its discovery, must be reported to <u>the Drug Enforcement Administration and the GDNA</u>.

  (2) A written report must be made regarding any theft or <u>significant loss</u>, <u>as defined under 21 C.F.A. 1301.76</u> or <u>unaccounted for of controlled substances</u> by completing a DEA Form 106 <u>and submitted to the Drug Enforcement Administration</u>, with a copy to the GDNA.
  - (a) Within ten (10) days of receiving such DEA Form 106, the original and one copy of the report must be sent to the Drug Enforcement Administration; and
  - (b) One copy must be sent to the GDNA.
  - (3) The report shall include the following information:
  - (a) Full name and address of the pharmacy;(e) List of cost codes, or identification symbols on package stolen; and
  - (b) Pharmacy DEA registration number;
  - (c) Date of theft, loss, or discovery of missing controlled substance;
  - (d) Type of incident, i.e. theft, loss, etc.;
  - (e) List of cost codes, or identification symbols on package stolen; and
  - (f) List of the controlled substances missing.

### Miscellaneous

Mr. Lacefield reported that he received a response from Mercer University College of Pharmacy in regard to the Board's desire to meet in-person. He stated that Mercer responded that they would be able to host the Board's July 14<sup>th</sup> meeting if the Board wished to meet there in person. Mr. Lacefield stated that he also reached out to Anthem to see if they would be willing to meet with the Board to discuss Anthem's new policy change, as previously requested by the Board. He further stated that Anthem was tentatively scheduled for the Board's July meeting if it was meeting virtually. Mr. Lacefield stated that he would follow up with Anthem to see if it would be able to meet in person if the Board meets at Mercer University. The Board agreed to meet in person at Mercer University. Mr. Chang asked Mr. Lacefield to inquire if Mercer had any policies on wearing masks or social distancing. Mr. Lacefield responded that he would check with Mercer regarding such.

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

#### **Appearance**

• C.C.R. Denied Pharmacy Technician Denial Upheld

### <u>Georgia Drugs and Narcotics Agency – Dennis Troughton</u> No report.

### Cognizant's Report - Dean Stone

•	GDNA Case # A33709	Refer to the Department of Law
•	GDNA Case # B33657	Close with letter of concern
•	GDNA Case # T33669	Revoke Technician Registration
•	GDNA Case # B33655	Refer to the Department of Law

•	GDNA Case # B33501	Close with no action
•	GDNA Case # B33560	Close with no action
•	GDNA Case # B33702	Close with no action
•	GDNA Case # B33677	Close with no action

### Attorney General's Report - Max Changus

The Board received legal advice regarding Rules 480-27-.01 Definitions, 480-27-.09 Patient Records, 480-31-.01 Patient Counseling, 480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders, 480-37-.03 Minimum Requirements, 480-10-.01 Controlled Substances and Dangerous Drugs, 480-13-.06 Drug Distribution Control, 480-48-.01 Definitions, 480-10-.06 Licensure, Applications, and Display of License and Renewal Certificate, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances.

Mr. Changus presented the following consent orders for acceptance:

•	M.P.U.	Public Consent Order accepted
•	Y.D.P.	Public Consent Order accepted
•	F.M.A.	Public Consent Order accepted
•	L.R.E.	Public Consent Order accepted
•	M.E.I.S.	Public Consent Order accepted

### Mr. Changus discussed the following cases:

R.P.I. Accept counterproposalM.C. Update provided

# **Executive Director's Report - Eric Lacefield**

No report.

### **Legal Services – Kimberly Emm**

No report.

### **Applications**

•	N.D.B.	Pharmacy Technician	Approved for registration
•	S.L.R.	Pharmacy Technician	Approved for registration
•	M.L.T.	Pharmacy Technician	Approved for registration
•	T.N.R.	Pharmacy Technician	Approved for registration
•	G.M.R.	Pharmacy Technician	Approved for registration
•	R.M.O.	Pharmacy Technician	Approved for registration
•	G.S.R.	Pharmacist Exam Applicant	Denied application and request for 4 <sup>th</sup> attempt at NAPLEX
•	P.V.S.I.	Wholesaler Pharmacy	Approved for Renewal
•	I.P.C.	Wholesaler Pharmacy	Approved for Renewal
•	G.	Wholesaler Pharmacy	Approved for Renewal
•	M.P.B.	Wholesaler Pharmacy	Approved for Renewal
•	S.P.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal

•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.	Wholesaler Pharmacy	Approved for Renewal
•	M.D.C.I.	Wholesaler Pharmacy	Approved for Renewal
•	E.P.	Wholesaler Pharmacy	Approved for Renewal
•	E.P.	Wholesaler Pharmacy	Approved for Renewal
•	D.C.	Wholesaler Pharmacy	Approved for Renewal
•	Z.U.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	L.I.	Wholesaler Pharmacy	Approved for Renewal
•	M.V.S.I.	Wholesaler Pharmacy	Approved for Renewal
•	D.S.I.	Wholesaler Pharmacy	Approved for Renewal
•	A.P.I.	Wholesaler Pharmacy	Approved for Renewal
•	C.C.	Wholesaler Pharmacy	Approved for Renewal
•	N.P.	Retail Pharmacy	Approved application
•	O.K.C.A.S.I.	Manufacturing Pharmacy	Approved for Renewal
•	C.V.S.S.	Non-Resident Pharmacy	Approved for Renewal
•	S.	Non-Resident Pharmacy	Approved for Renewal
•	B.E.T.	Non-Resident Pharmacy	Approved for Renewal

# Correspondences/Requests

•	U.D.S.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action

•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	L.I.	Notice of Discipline	No action
•	W.C.M.	Request regarding supervising pharmacist	Table pending receipt of additional information
•	A.B.C.	Request for extension of intern license	Approved request
•	J.C.A.	Request for 4 <sup>th</sup> attempt at NAPLEX	Denied request

Mr. Prather seconded, and the Board voted in favor of the motion, with the exception of Mr. Chang, who recused himself from the vote regarding C.C.R.

There being no further business to discuss, the meeting was adjourned at 1:11 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, July 14, 2021, at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 6<sup>th</sup> floor, Atlanta, GA 30303.

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