

GEORGIA BOARD OF PHARMACY
Conference Call
2 Peachtree Street, NW, 6th Floor
Atlanta, GA 30303
January 13, 2021
9:00 a.m.

The following Board members were present:

Michael Brinson, Vice-President
Carrie Ashbee
Michael Azzolin
Cecil Cordle
Chuck Page
Bill Prather
Dean Stone

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 I

Visitors:

John Rocchio, CVS Health
Bethany Sherrer, Medical Association of Georgia
Diane Sanders
Gina Ryan

Open Session

Vice-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

Mr. Stone made a motion to approve the December 16, 2020 Public and Executive Session Conference Call minutes. Mr. Page seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

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

Petitions for Rule Waiver or Variance

The Board discussed two rule waiver petitions submitted by Southside Behavioral Lifestyle Enrichment Ctr, PHOP000010. In regards to the first petition, Mr. Azzolin made a motion to grant the request for a variance of the following items only: two spatulas, one oral solid counting tray, and a refrigerator in working order with a thermometer. Additionally, the other items listed in subsections (2)(d) and (e) of Rule 480-18-.05 are still applicable. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

In regards to the second petition from Southside Behavioral Lifestyle Enrichment Ctr, PHOP000010, the facility requested a waiver of Rule 480-18-.06(3)(b)(6) and (3)(b)(9). Mr. Page made a motion to deny the request as this information is required by law. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Correspondence from Susan Brichler Trujillo, Quarles & Brady

The Board considered this correspondence regarding what personnel obligations and training the Board would require in order to qualify for a manufacturer's permit. The Board directed staff to respond by stating that there is limited guidance in the law and rules as to what personnel is necessary in this situation. The company should use its best judgement and utilize adequately trained personnel that are qualified to handle the substances and distribute a product that is safe for the public. Lastly, be mindful of all the laws and rules necessary to engage in the business.

Correspondence from Georgia Veterinary Medical Association (GVMA)

The Board considered this correspondence requesting the Board reconsider language in Rule 480-11-.02 Compounded Drug Preparations due to the unprecedented impact of the pandemic. Specifically, the letter requests increasing the requirement in subsection (d)(1) from a 96 hour supply to 14 days. Ms. Emm commented that the 96 hours was a compromise between GVMA and the Georgia Pharmacy Association. The Board recommended tabling this matter for further discussion at a future meeting.

Correspondence from J. Thomas Lindsey, Omega Pharmacy

The Board considered this correspondence regarding supervising physician information. Specifically, Mr. Lindsey's inquiry states that he continuously receives electronic prescriptions from nurse practitioners and physician's assistants without the supervising physician information. The Board directed staff to forward Mr. Lindsey's correspondence to the Georgia Board of Nursing and the Georgia Composite Medical Board.

Correspondence from Bridget O'Brien, Avita Medical

At its November 2020 meeting, the Board discussed correspondence from Ms. O'Brien, Avita Medical, requesting to confirm that a wholesale license is not required for their device. At that time, the Board requested additional information regarding what medications/drugs are put into the device. In response, Ms. O'Brien stated that the only component that has an NDC number is sterile water for injection. The Board directed staff to respond by stating that sterile water for injection is considered a "dangerous drug" and refer to O.C.G.A. § 16-13-71(b)(474) for more information. As such, a wholesale license would be required for the device.

Correspondence from Leva Jaberizadeh

The Board considered this correspondence asking if a clinical pharmacist can administer Botox and Juvéderm therapy, if he/she has specialized training/certification to do so. The Board directed staff to respond by stating that a pharmacist must determine if a prescription is for a legitimate medical purpose. As such, a clinical pharmacist would not be able to administer Botox injections for cosmetic purposes because that is not deemed "medically necessary" and would therefore fall outside the scope of practice of a pharmacist. It is suggested that Ms. Jaberizadeh may wish to contact the Georgia Composite Medical Board for additional input on this matter.

Correspondence from Charles Platz, RPh

The Board considered this correspondence requesting guidance on expanding immunization services to a temporary emergency satellite site. After receiving additional information from Mr. Platz during the Board's Conference Call, the Board determined his request would be permissible as long as the Georgia licensed pharmacist is on-site at all times with the appropriate number of staff and all drugs are returned to the pharmacy at the end of each day.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA has conducted 1383 inspections and 175 investigations for FY2021.

Attorney General's Report – Max Changus

No report.

Executive Director's Report – Eric Lacefield

Continuing Education Report: No report for January.

COVID-19 Vaccinations and Pharmacy Students: Mr. Lacefield reported that the Board requested to send two items to the Governor's office for consideration. He stated that the first item pertains to the U.S. Department of Health & Human Services' (HHS) declaration regarding technicians. Mr. Lacefield stated that the Governor's office is currently reviewing the matter. Additionally, Mr. Lacefield reported that a letter from Mercer University regarding increasing pharmacist to intern/extern ratios was received and posted to Sharepoint for the members to review. The Board directed Mr. Lacefield to forward the letter to the Governor's office for consideration.

Legal Services – Kimberly Emm

No report.

Miscellaneous

Cornerstone of Recovery: The Board considered this request to be a board-approved treatment facility. Mr. Prather commented that in the past, the Board would ask Dr. Bartling to review the program. Mr. Lacefield responded that it would be up to the Board to see if this facility would meet the Board's requirements. Ms. Ashbee commented that she reviewed the information and based on the Board's criteria, she would be in favor of approving it; however, she requested the Board review the criteria to make sure the information is up to date. After further discussion, Ms. Ashbee made a motion to approve Cornerstone of Recovery as a board-approved treatment facility. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Two Day Meetings: Mr. Lacefield stated that the Board previously discussed holding a 2 day meeting and President Faulk requested the members review his/her schedules for availability. Mr. Azzolin made a motion for the Board meet on February 17th and February 18th. Discussion was held. Mr. Azzolin stated that since the practical examination is not being given at this time, the Board could use the second day as a work session until the practical exam resumes. Ms. Emm commented that the two days scheduled for March are the 3rd and 4th, and for June the 9th and 10th. The Board discussed not holding a 2 day meeting in March, but instead reschedule the meeting date to later in the month. Vice-President Brinson suggested the Board not make a decision about its June meeting until President Faulk returns. There being no further discussion, Ms. Ashbee seconded and the Board voted unanimously in favor of the motion.

COVID-19 Vaccinations and Pharmacy Students: Director Troughton requested to go back to this topic as discussed by Mr. Lacefield. He requested confirmation that, at this juncture, the information has only been sent to the Governor's office to review and, at this time, the Board is not approving anything. Vice-President Brinson affirmed that was correct.

Mr. Prather made a motion and Mr. Stone 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, Cecil Cordle, Chuck Page, Bill Prather, and Dean Stone.

Appearances

- L.H.J.
- P.E.H.
- T.S.Q.
- L.A.D.

Georgia Drugs and Narcotics Agency – Dennis Troughton

- C.P.
- M.I.
- P.G.

Cognizant’s Report – Michael Brinson

- GDNA Case # T33556
- GDNA Case # A33496
- GDNA Case # A33293
- GDNA Case # B33143
- GDNA Case # A33410
- GDNA Case # A33418
- GDNA Case # A33424
- GDNA Case # A33451
- GDNA Case # A33536
- GDNA Case # A33498
- GDNA Case # A33418
- GDNA Case # A33523
- GDNA Case # A33505
- GDNA Case # B33546
- GDNA Case # B33503
- GDNA Case # B33525
- GDNA Case # B33446
- GDNA Case # B33514
- GDNA Case # B33409
- GDNA Case # B33274
- GDNA Case # B33469
- GDNA Case # B33473
- GDNA Case # B33499
- GDNA Case # B33506
- GDNA Case # B33519
- GDNA Case # B33472
- GDNA Case # B33509
- GDNA Case # B33524

Attorney General’s Report – Max Changus

Mr. Changus discussed the following:

- R.S.N.
- GDNA Case #A32861

Executive Director's Report – Eric Lacefield

No report.

Legal Services – Kimberly Emm

No report.

Applications

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

Correspondences/Requests

- M.D.I.
- V.C.P.
- V.C.P.
- B.E.T.P.
- E.S.P.
- H.I.
- T.A.P.
- T.A.P.
- A.P.
- A.
- G.R.
- A.P.I.
- B.I.E.
- D.W.W.
- S.P.L.
- W.C.M.
- R.A.S.

- L.D.R.
- A.S.I.
- N.M.C.
- S.A.I.
- F.C.P.

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

Open Session

Mr. Cordle made a motion for the Board to take the following actions:

Appearances

- | | | |
|----------|---|--------------------------------|
| • L.H.J. | Denied Pharmacy Technician | Overturn denial and approve |
| • P.E.H. | Request to Reinstate Pharmacist License | Refer to the Department of Law |
| • T.S.Q. | Request to Reinstate Pharmacist License | Policy 3A |
| • L.A.D. | Denied Pharmacy Technician | Denial upheld |

Georgia Drugs and Narcotics Agency – Dennis Troughton

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|--------|------------------------------------|------------------|
| • C.P. | Request for approval of drive thru | Approved request |
| • M.I. | Update provided | |
| • P.G. | Update provided | |

Cognizant’s Report – Michael Brinson

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|----------------------|--|
| • GDNA Case # T33556 | Accept Signed Voluntary Surrender |
| • GDNA Case # A33496 | Refer to the Department of Law |
| • GDNA Case # A33293 | Refer to the Department of Law |
| • GDNA Case # B33143 | Refer to the Department of Law |
| • GDNA Case # A33410 | Letter of concern/Refer to the Department of Law |
| • GDNA Case # A33418 | Refer to the Department of Law |
| • GDNA Case # A33424 | Refer to the Department of Law |
| • GDNA Case # A33451 | Schedule Investigative Interview |
| • GDNA Case # A33536 | Refer to the Department of Law |
| • GDNA Case # A33498 | Refer to the Department of Law |
| • GDNA Case # A33418 | Refer to the Department of Law |
| • GDNA Case # A33523 | Misfill Policy #2 |
| • GDNA Case # A33505 | Misfill Policy #1 |
| • GDNA Case # B33546 | Close with a letter of concern |
| • GDNA Case # B33503 | Misfill Policy #1 |
| • GDNA Case # B33525 | Close with a letter of concern |
| • GDNA Case # B33446 | Misfill Policy #1 |
| • GDNA Case # B33514 | Misfill Policy #1 |
| • GDNA Case # B33409 | Close with no action |
| • GDNA Case # B33274 | Close with no action |
| • GDNA Case # B33469 | Close with no action |
| • GDNA Case # B33473 | Close with no action |
| • GDNA Case # B33499 | Close with no action |
| • GDNA Case # B33506 | Close with no action |

- GDNA Case # B33519 Close with no action
- GDNA Case # B33472 Close with no action
- GDNA Case # B33509 Close with no action
- GDNA Case # B33524 Close with no action

Attorney General’s Report – Max Changus

Mr. Changus discussed the following:

- R.S.N. Wholesaler Pharmacy Close case and approve application
- GDNA Case #A32861 Modified initial referral

Executive Director’s Report – Eric Lacefield

No report.

Legal Services – Kimberly Emm

No report.

Applications

- Johan S. Lainez Pharmacy Technician Approved for registration
- K.J.S. Pharmacy Technician Tabled pending additional information
- Jasmine A. Miles Pharmacist Intern Approved for registration
- Chad T. Lee Nuclear Pharmacist Approved application
- Jacob C. Tichinel Nuclear Pharmacist Approved application
- F.K.A. Pharmacist Reinstatement Policy 3A
- K.S.J. Pharmacist Reciprocity Approved to sit for the exam
- Kathryn L. Hatch Temporary Pharmacist Approved application
- A.N.P. Pharmacist Renewal Approved for renewal
- A.J.C. Pharmacist Renewal Approved for renewal
- E.A.M. Pharmacist Renewal Approved for renewal
- J.L.D. Pharmacist Renewal Schedule Investigative Interview
- M.P.V. Pharmacist Renewal Approved for renewal
- R.W.M. Pharmacist Renewal Approved for renewal
- S.S.C. Pharmacist Renewal Denied renewal
- T.H.U. Pharmacist Renewal Approved for renewal
- T.K. Pharmacist Renewal Approved for renewal
- V.M.B. Pharmacist Renewal Approved for renewal
- W.T. Pharmacist Renewal Approved for renewal
- J.A.S. Pharmacist Exam Denied application
- Sleepwell DME Suppliers Approved application
- D.H.L.S.C. Third Party Distributor Approved pending receipt of additional information
- Everwell Specialty Pharm Non-Resident Pharmacy Approved application

Correspondences/Requests

- M.D.I. Notice of Discipline No action
- V.C.P. Notice of Discipline No action
- V.C.P. Notice of Discipline No action

• B.E.T.P.	Notice of Discipline	No action
• E.S.P.	Notice of Discipline	No action
• H.I.	Notice of Discipline	No action
• T.A.P.	Notice of Discipline	No action
• T.A.P.	Notice of Discipline	No action
• A.P.	Notice of Discipline	No action
• A.	Notice of Discipline	No action
• G.R.	Notice of Discipline	No action
• A.P.I.	Notice of Discipline	No action
• B.I.E.	Request for 4 th attempt at MPJE	Approved request
• D.W.W.	Request for 5 th attempt at MPJE	Approved request
• S.P.L.	Request for 6 th attempt at MPJE	Approved request
• W.C.M.	Appearance request	Denied request
• R.A.S.	Request to lift PIC restriction	Approved request
• L.D.R.	Request to lift PIC restriction	Approved request
• A.S.I.	Request to export	Approved request
• N.M.C.	Request for Suspended Status	Denied request
• S.A.I.	Product recall	The Board viewed this correspondence for informational purposes only.
• F.C.P.	Correspondence regarding audit	Board directed staff to respond as appropriate.

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

Miscellaneous

Mr. Page notified the Board that during the meeting he received a phone call from Kimberly Hazelwood, Director, Georgia Department of Public Health, regarding the Board's view on technicians administering vaccinations. Ms. Emm responded that the board office has provided the Governor's office with all laws and rules that would prohibit such. Mr. Lacefield added that the matter is currently with the Governor's office and they are looking at a number of issues. He stated that a statement has been posted to the Board's website with links to the HHS guidelines and Governor's Executive Orders. Mr. Azzolin asked if the Board could send a letter to the Governor's office stating the Board feels it is appropriate to have technicians who have received the appropriate training administer vaccinations during the State of Emergency. Mr. Azzolin continued by stating that GPhA has posted information regarding training. Mr. Stone stated that he has been asked that question and always refers the individual to the Board's website for further information. He continued by stating that he believes the Board should send a statement to the Governor stating the Board is in support of this. Mr. Lacefield requested the Board draft the letter and staff can submit it to the Governor's office. Mr. Cordle suggested the letter recap what staff previously submitted. Mr. Lacefield responded by explaining that staff have only submitted the laws and rules that would prohibit technicians from giving vaccinations. He stated that the Board has not previously said it was in support of technicians giving vaccines. Mr. Azzolin offered to assist Ms. Emm with drafting the letter. The Board agreed and stated it would review the letter prior to submitting it to the Governor's office.

Mr. Lacefield stated he received notification from NABP regarding the MPJE review coming up in March. He stated that the Board nominates a member to work with GDNA on this matter. He added that the designee is currently Mr. Stone. He asked if the Board is interested in Mr. Stone continuing to be the designee. The Board agreed.

There being no further business to discuss, the meeting was adjourned at 4:08 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, February 17, 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