GEORGIA BOARD OF PHARMACY University of Georgia College of Pharmacy 250 W Green St., Room PS303 Athens, GA 30602 June 15, 2022 9:00 a.m.

The following Board members were present:

Dean Stone, President
Michael Azzolin, Vice-President
Jim Bracewell
Michael Brinson
Young Chang
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 Clint Joiner, Attorney Brandi Howell, Business Support Analyst I

Visitors:

Becca Hallum, GHA
Sydney Habegger, GHA
Stephanie Kirkland, Eldercare
Jared Safran, Publix
Heather Hughes, Publix
Jamie Woods, Eldercare
Jonathan Marquess, GPhA-AIP
Shea Ross-Smith, Kaiser Permanente
Olivia Buckner, Nelson Mullins
Lea Brown

Public Hearing

President Stone called the public hearing to order at 9:00 a.m.

Rule 480-2-.04 Examinations

President Stone stated that the purpose of the rule amendment is to remove the requirement for the applicant to take the practical examination and to limit the number of attempts an applicant may take the NAPLEX and MPJE examinations. He further stated that the main feature of this amendment is to delete the practical examination requirement and to add a five-time limitation to the number of attempts an applicant may take the NAPLEX and MPJE examinations.

No public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-2-.04 Examinations. Mr. Chang seconded, and the Board voted in favor of the motion, with the exception of Mr. Prather, who opposed.

Rule 480-2-.05 Reciprocity

President Stone stated that the purpose of the rule amendment is to remove the requirement for reciprocity applicants to take the practical examination. He further stated that the main feature of this amendment is to delete the practical examination requirement.

Mr. Jared Safran inquired as to how the public could find this information. President Stone responded by stating the Notice of Public Hearing is posted for 30 days on the Board's website. He explained that Mr. Safran could send an email via the "Contact Us" portal on the website if he would like to be added to the Interested Parties list to receive notifications on new or proposed rules.

No additional public comments or written responses were received.

Mr. Brinson made a motion to adopt Rule 480-2-.05 Reciprocity. Mr. Page seconded, and the Board voted in favor of the motion, with the exception of Mr. Prather, who opposed.

Rule 480-2-.06 Temporary Licenses

President Stone stated that the purpose of the rule amendment is to remove the requirement for temporary licensure applicants to take the practical examination. He further stated that the main feature of this amendment is to delete the practical examination requirement.

Mr. Safran inquired as to how this came about. President Stone responded by stating that due to the pandemic, the practical could not be held in person. He added that himself, along with Mr. Azzolin and Judy Gardner, began looking into the validity of there being a practical examination. Mr. Safran asked if this was temporary. President Stone responded by stating the law states the Board could require a practical exam if they chose. Mr. Changus commented that the Board can set examinations as it decides.

No additional public comments or written responses were received.

Mr. Page made a motion to adopt Rule 480-2-.06 Temporary Licenses. Mr. Brinson seconded, and the Board voted in favor of the motion, with the exception of Mr. Prather, who opposed.

Mr. Prather commented that he has always been opposed to removing with the practical examination and did not want his name attached in any way with the Board removing with this requirement.

The public hearing concluded at 9:06 a.m.

Open Session

President Stone established that a quorum was present and called the meeting to order at 9:06 a.m.

Approval of Minutes

Mr. Chang made a motion to approve the Public Session minutes from the May 11, 2022, Conference Call as amended. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

Mr. Prather made a motion to approve the Executive Session minutes from the May 11, 2022, Conference Call. Mr. Prather seconded, and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Mr. Prather made a motion to ratify the list of licenses issued. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver or Variance

Rule Waiver Petition from AU Medical Center Employee Pharmacy, PHRE009871: The Board discussed this request for a waiver of Rule 480-6.-01. President Stone inquired if the waiver request should be for Rule 480-6-.01(3) instead of 480-6-.01. Mr. Azzolin responded by stating that

he did not see language in Rule 480-6-.01 about location changes, but thought it would be in Rule 480-10-.06. Mr. Azzolin inquired whether a waiver is needed if they are just moving down the hall and have the same physical address, but are changing the suite number only. He stated if a waiver is needed, then they need to request a waiver with the correct rule number. President Stone commented that Rule 480-6-.01(3) does state that, "Licenses shall not be transferable. Licenses become null and void upon the sale, or change of mode of operation of the business."

Director Troughton commented that in the past, if the facility was keeping the same 911 address and only changing the suite number, GDNA would not direct them to submit a change in location application. He stated that the believes that may be a decision from Mr. Changus or Mr. Lacefield. Mr. Brinson commented that this also affects their address with the DEA and also where the drugs are sent to. He added that if the address was suite 3 and they move to suite 1, that would be a change in location. Director Troughton responded by stating that GDNA would certainly tell them to notify the Board of the change. He added that GDNA would have that information on its records when conducting inspections. He continued by stating that the address with the DEA and wholesaler would need to be corrected.

Mr. Lacefield commented that the procedure for location/ownership changes has changed over the years. He stated that he agreed with Director Troughton. He further stated if the suite number changed the facility would not need to apply, they would need to provide the change in suite number on company letterhead. Mr. Changus commented that the law only requires a notification to the Board. There being no further discussion, Mr. Brinson made a motion to deny the rule petition request and notify the facility they can notify the Board in writing on company letterhead that the facility is moving suites. Mr. Page seconded, and the Board voted unanimously in favor of the motion.

Correspondence

Correspondence from Alessia Gastaldi, Fidia Farmaceutici S.p.A.: The Board considered this correspondence regarding a need for a wholesale license in respect to a veterinarian medicinal product purchased by their U.S. partner in Georgia. Ms. Gastaldi's inquiry requests the Board confirm if the company should apply for any type of licensure or would the company be exempt since they do not commercialize the product in the United States. Mr. Azzolin stated that what he understood was the company was not shipping into the United States. He further stated that it was his understanding they are shipping to Boehringer who is shipping to the United States. Mr. Azzolin stated that if they are shipping into Georgia, they need to have a wholesaler license. Director Troughton commented that Boehringer does have a license in Georgia. He added that if they are doing an intercompany transfer, a wholesaler license is not needed since an intercompany transfer is an exception. Mr. Changus commented that it seems the transfer is happening in Italy and that entity is taking control at that point and would be held responsible, and as such a wholesale license is not required.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA conducted 2306 inspections and received 497 complaints for FY2022.

Director Troughton reported the budget did allow for GDNA to get two additional agent positions. He stated that the two new agent positions will be located in the middle Georgia and metro Atlanta areas. He added that currently, GDNA has one agent position open in the southwest Georgia area.

Director Troughton reported that GDNA has been designated funds by the legislature for a database; however, it has been put on hold for GDNA to justify the need for such. He stated that he has been working with the Governor's Office of Planning and Budget on this matter.

Attorney General's Report – Max Changus

No report.

Executive Director's Report – Eric Lacefield

Continuing Education Report: No report for June.

Correspondence from Andrea M. Seach, Quarles & Brady LLP: The Board considered this correspondence from Ms. Seach inquiring if the Board currently has any restrictions on pharmacists or pharmacy techs located in Georgia providing remote pharmacy work for a pharmacy located in another state. Director Troughton commented that if the individual was sitting in this state as a pharmacist, he/she would have to follow Georgia law and rules, along with the law and rules of the other state. After discussion, Mr. Changus stated that with the nature of remote work and the new world we find ourselves in, if the individual is engaged in the practice of pharmacy, he/she must be following the laws and rules of Georgia. The Board agreed to respond to Ms. Seach that the individual would need to follow the law and rules if engaging in the practice of pharmacy in Georgia.

New Staff Member: Mr. Lacefield introduced Mr. Clint Joiner as the new attorney for the board office.

Miscellaneous

2nd Quarter Newsletter: President Stone complimented Mr. Chang and Mr. Page for their hard work on the newsletter.

Mr. Page commented that the intent of the newsletter is to provide support and information. He stated he hoped everyone had a chance to read the first edition, which was posted in April, and pass along to his/her associates. Mr. Page stated that it is still a work in progress, but hopefully everyone will find the information is relevant and useful in practice. President Stone stated that the Board appreciates the associations disseminating the information to its members. Mr. Page commented that the intent is to try to distribute the newsletter to everyone in the state. He added that the Board is requesting chain pharmacies, independents, etc., to forward the newsletter to everyone in his/her organization.

Mr. Chang commented that the goal was to have the 2nd quarter newsletter out by July 1st. He stated that he appreciated everyone's feedback and suggestions. Mr. Prather commented that the newsletter is the best thing the Board has done in several years. Mr. Lacefield stated that once the newsletter is ready for distribution, he will post it to the Board's website.

Mr. Brinson made a motion and Mr. Chang seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h) and § 43-1-2(h) 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 Michael Azzolin, Jim Bracewell, Michael Brinson, Young Chang, Chuck Page, Bill Prather, and Dean Stone.

Executive Session

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Cognizant's Report - Michael Azzolin

- GDNA Case # B34247
- GDNA Case # B34269
- GDNA Case # A34238
- GDNA Case # B34097
- GDNA Case # A34280

Appearance

• L.B.

Cognizant's Report - Michael Azzolin

- GDNA Case # A34141
- GDNA Case # B34180
- GDNA Case # B34220
- GDNA Case # B34246
- GDNA Case # B34166
- GDNA Case # B34217
- GDNA Case # B34203
- GDNA Case # B34249
- GDNA Case # B34232

Attorney General's Report - Max Changus

Mr. Changus discussed pending litigation.

Mr. Changus presented the following consent orders for acceptance:

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

Mr. Changus discussed the following case:

• C.H.P.

Ms. Simpson discussed the following case:

• M.P.P./P.I.C.

Executive Director's Report - Eric Lacefield

• G.A.F.P./M.A.G.

Applications

- K.A.M.
- V.A.R.
- J.L.C.
- S.A.S.
- J.M.I.

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

Correspondences/Requests

- D.F.I.
- E.S.P.
- H.V.
- H.V.
- H.V.
- P.P.S.
- P.H.I.P.H.I.
- O.I.S.
- P.I.
- C.P.
- E.P.I.

- P.P.
- R.C.M.
- A.H.F.
- K.P.
- A.L.R.V.
- R.H.P.
- P.C.P.
- W.A.M.C.
- C.H.I.
- R.T.K.
- K.T.N.

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

Open Session

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

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Cognizant's Report - Michael Azzolin

| • | GDNA Case # B34247 | Close with letter of concern |
|---|--------------------|--------------------------------|
| • | GDNA Case # B34269 | Close with letter of concern |
| • | GDNA Case # A34238 | Close with letter of concern |
| • | GDNA Case # B34097 | Close with letter of concern |
| • | GDNA Case # A34280 | Refer to the Department of Law |

Appearance

• L.B. Denied Pharmacy Technician Overturn denial and approve for registration

Cognizant's Report - Michael Azzolin

| GDNA Case # A34141 | Refer to the Department of Law |
|--------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------|
| GDNA Case # B34180 | Close with no action |
| GDNA Case # B34220 | Close with no action |
| GDNA Case # B34246 | Close with no action |
| GDNA Case # B34166 | Close with no action |
| GDNA Case # B34217 | Close with no action |
| GDNA Case # B34203 | Close with no action |
| GDNA Case # B34249 | Close with no action |
| GDNA Case # B34232 | Close with no action |
| | GDNA Case # B34180 GDNA Case # B34220 GDNA Case # B34246 GDNA Case # B34166 GDNA Case # B34217 GDNA Case # B34203 GDNA Case # B34249 |

Attorney General's Report - Max Changus

Mr. Changus discussed pending litigation.

Mr. Changus presented the following consent orders for acceptance:

A.M.E.I. Public Consent Order accepted
 T.L.B. Private Consent Order accepted

P.C.S.I. Private Consent Order accepted
C.V.S.P. Public Consent Order accepted
C.E.W. Private Consent Order accepted
R.R.S. Private Consent Order accepted
W.P. Private Consent Order accepted
E.P.I. Public Consent Order accepted
R.W.B. Public Consent Order accepted

Mr. Changus discussed the following case:

• C.H.P. Deny counterproposal

Ms. Simpson discussed the following case:

• M.P.P./P.I.C. Deny counterproposal

Executive Director's Report - Eric Lacefield

• G.A.F.P./M.A.G. Correspondence

Board directed staff to respond by stating based on Georgia Board of Pharmacy law and rules, the Board will not take any further action regarding this matter.

Applications

| plı | <u>cations</u> | | |
|-----|----------------|---------------------------------|-------------------------------------|
| • | K.A.M. | Pharmacy Technician | Approved for registration |
| • | V.A.R. | Pharmacy Technician | Approved for registration |
| • | J.L.C. | Pharmacy Technician | Approved for registration |
| • | S.A.S. | Pharmacy Technician | Approved for registration |
| • | J.M.I. | Pharmacy Technician | Denied registration |
| • | J.J.C. | Pharmacy Technician | Approved for registration |
| • | J.M.C. | Pharmacist Intern | Approved application |
| • | N.R. | Pharmacist Intern | Approved extension thru 12/31/2023. |
| • | B.B.W. | Temporary Pharmacist | Approved application |
| • | B.B.W. | Pharmacist Examination | Approved application |
| • | I.C.I. | Pharmacist Examination | Approved application |
| • | L.S.D. | Pharmacist Reinstatement | Denied application |
| • | N.C.C. | Nuclear Pharmacist | Approved application |
| • | R.L.B. | Pharmacist Reciprocity | Approved application |
| • | T.S.S. | Pharmacist Reciprocity | Approved application |
| • | A.J.B. | Pharmacist Certification of DTM | Approved application |
| • | A.N.D. | Pharmacist Certification of DTM | Approved application |
| • | A.I.A. | Pharmacist Certification of DTM | Approved application |
| • | B.K.L. | Pharmacist Certification of DTM | Approved application |
| • | C.C.D. | Pharmacist Certification of DTM | Approved application |
| • | D.J.S. | Pharmacist Certification of DTM | Approved application |
| • | J.J.P. | Pharmacist Certification of DTM | Approved application |
| • | K.G.F. | Pharmacist Certification of DTM | Approved application |
| • | K.T.M. | Pharmacist Certification of DTM | Approved application |
| • | K.H. | Pharmacist Certification of DTM | Approved application |
| • | K.P.C. | Pharmacist Certification of DTM | Approved application |
| | | | |

| • | K.F.B. | Pharmacist Certification of DTM | Approved application |
|---|--------|---------------------------------|----------------------|
| • | M.I.A. | Pharmacist Certification of DTM | Approved application |
| • | M.A.W. | Pharmacist Certification of DTM | Approved application |
| • | M.J.S. | Pharmacist Certification of DTM | Approved application |
| • | S.E.C. | Pharmacist Certification of DTM | Approved application |
| • | A.O.A. | Pharmacist Certification of DTM | Approved application |
| • | C.W.C. | Pharmacist Certification of DTM | Approved application |
| • | D.A.H. | Pharmacist Certification of DTM | Approved application |
| • | E.T. | Pharmacist Certification of DTM | Approved application |
| • | G.T.D. | Pharmacist Certification of DTM | Approved application |
| • | J.P.J. | Pharmacist Certification of DTM | Approved application |
| • | K.D.M. | Pharmacist Certification of DTM | Approved application |
| • | L.M.W. | Pharmacist Certification of DTM | Approved application |
| • | M.M. | Pharmacist Certification of DTM | Approved application |

Correspondences/Requests

| • D.F.I. | Notice of Discipline | No action |
|----------|----------------------|-----------|
| • E.S.P. | Notice of Discipline | No action |
| • H.V. | Notice of Discipline | No action |
| • H.V. | Notice of Discipline | No action |
| • H.V. | Notice of Discipline | No action |
| • P.P.S. | Notice of Discipline | No action |
| • P.H.I. | Notice of Discipline | No action |
| • P.H.I. | Notice of Discipline | No action |
| • O.I.S. | Notice of Discipline | No action |
| • P.I. | Notice of Discipline | No action |
| • C.P. | Notice of Discipline | No action |
| • E.P.I. | Notice of Discipline | No action |
| • P.P. | Notice of Discipline | No action |
| • R.C.M. | Notice of Discipline | No action |
| | - | |

• A.H.F. Request regarding offsite storage of records Board directed staff to

respond by stating there is no requirement in the laws and rules that records be maintained for more than two years. There may be additional federal statutes or regulations on this topic that may apply to your

operations.

| • | K.P. | Request to terminate probation | Approved request |
|---|----------|--------------------------------|-------------------------------------------------|
| • | A.L.R.V. | Petition to lift consent order | Schedule individual to meet with the Board |
| • | R.H.P. | Request to terminate probation | Approved request |
| • | P.C.P. | Notice of adverse event | Table pending receipt of additional information |
| • | W.A.M.C. | Remote order entry | Approved request |
| • | C.H.I. | Remote order entry | Approved request |
| • | R.T.K. | Appearance request | Approved request |

• K.T.N.

Correspondence

The Board viewed this correspondence for informational purposes only.

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

There being no further business to discuss, the meeting was adjourned at 1:08 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, July 13,2022 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