GEORGIA BOARD OF PHARMACY Conference Call 2 Peachtree Street, NW, 6th Floor Atlanta, GA 30303 May 6, 2020 9:00 a.m.

The following Board members were present:

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

Dean Stone

Staff present:

Tanja Battle, Executive Director Eric Lacefield, Deputy 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:

Greg Reybold, GPhA
Becca Hallum, GHA
Bethany Sherrer, MAG
Shauna Markes-Wilson, Walgreens
Bijal Patel, Walgreens
Pamela Tolliver
John Rocchio, CVS Health
Amanda Roberson, Eldercare
Stephanie Kirkland, Eldercare

Open Session

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

Approval of Minutes

Mr. Brinson made a motion to approve the Public and Executive Session minutes from the April 15, 2020 Conference Call. Mr. Stone 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 issue. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

The Board discussed three rule waiver petitions submitted by Brooks County Hospital Pharmacy, PHRE005837, Grady General Hospital, PHRE007998, and Mitchell County Hospital, PHRE007316. Discussion was held regarding retail pharmacies that may or may not be located inside the hospital pharmacy. Mr. Stone stated that he does not have an issue with a retail pharmacy located at a hospital to not having a scale as long as they are not compounding. Mr. Prather stated that if the Board is not going to make them have a balance, the Board needs to discuss amending the rule regarding such. Mr. Azzolin commented that he used to work in a hospital pharmacy that also had a retail license. He stated that because they had to get a waiver for hospital, they also had to get one for the retail pharmacy. He further

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stated that a waiver was needed for both because they are located in the same space. Director Troughton confirmed that all three retail pharmacies requesting rule waivers do share the same space as the hospital. He stated that the Board has had discussions about this not happening like it used to.

Mr. Brinson made a motion to grant the rule waiver petitions submitted by Brooks County Hospital Pharmacy, PHRE005837, Grady General Hospital, PHRE007998, and Mitchell County Hospital, PHRE007316. Mr. Stone seconded. Mr. Prather, Vice-President Faulk and Mr. Henderson opposed the motion. Mr. Henderson stated that he opposed the motion because he felt the Board should not approve them until the Board can discuss further. The motion did not pass.

Mr. Prather commented that he does not have any issue with the hospital pharmacy. He stated that his issue is approving the requests for the retail pharmacies. Mr. Azzolin stated that by denying the requests, the request for the hospital would be denied as well as they share the same space. Mr. Prather responded that they can move the retail pharmacy outside the hospital pharmacy if they do not want to have the balance. Mr. Azzolin asked if there was a reason the Board cannot waive the balance requirement even though they are retail. President Harris responded that it is because the Board has not discussed it further. Mr. Prather commented that retail pharmacies from all over the state would be requesting a waiver for the balance. He stated that the Board needs to amend its rule requiring such like it did with the hospital pharmacies. Mr. Azzolin asked if the Board should require them to purchase a balance. Mr. Henderson responded that they should have met this requirement when they initially got their license. He further stated that it is his opinion that the Board needs to understand why they are asking for the waiver. President Harris responded that they mentioned ongoing maintenance and calibration creates a financial burden. Mr. Henderson stated he does not have an issue with any of that. Director Troughton commented that they may have submitted a waiver request because upon inspection they had no balance and GDNA told them they had to request a waiver so they can come into compliance before the next inspection. Mr. Azzolin stated that he was in favor of changing the rule, but in the meantime, so the facility does not have to spend the money for the balance, it would be his recommendation that the Board waive these three requests and then address the rule issue at this meeting or next meeting. Vice-President Faulk responded that the Board cannot waive the requirement for these three and not others. Mr. Azzolin stated that the Board could also grant a waiver for anyone else that requests one until the rule becomes effective. President Harris asked when would the Board needs to act on these requests. Ms. Howell responded that the petitions would need to be voted on at the June meeting. Mr. Changus commented that the Board needs to come to some sort of consensus as to whether or not to move forward by June. He stated that in the hospital setting, it took a while for the rule to get approved so the Board passed a lot of rule waivers in that time. He stated that the issue is does the Board want to change it for everyone or not. President Harris suggested tabling the matter until June. Mr. Azzolin asked if the Board has approved a rule waiver in the past for reason of hardship and if so, it would be inappropriate for the Board to not approve these requests.

Mr. Prather asked Ms. Emm review the effected rules and present back to the Board. Ms. Emm responded that the rules that incorporate the balance would be Rules 480-10-.12, 480-11-.04, 480-18-.05 and 480-33-.05. She asked if the Board wants each rule to mimic what it did with the hospital rule. Mr. Prather responded in the affirmative. Ms. Emm asked if the Board would like for her to work with Mr. Brinson on such since she previously worked with Ms. Arnold on the hospital rule. The Board agreed. Mr. Azzolin asked Ms. Emm to copy him on that as well. Ms. Battle asked if the Board was in agreement about making this change and if so, why it could not proceed with voting on the three from the retail hospitals? She stated that the rule will not be in effect for a long time. Mr. Brinson made a motion to grant the rule waiver petitions submitted by Brooks County Hospital Pharmacy, PHRE005837, Grady General Hospital, PHRE007998, and Mitchell County Hospital, PHRE007316. Mr. Stone seconded and the Board voted unanimously in favor of the motion.

Mr. Prather made a motion to grant the rule waiver petition from Grady General Hospital, PHH006595.

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

Correspondence from Archbold Memorial Hospital, PHH004048

The Board considered this correspondence requesting permission to distribute drugs to the clinics under common ownership located on the main campus of Archbold Medical Center. The Board recommended tabling this matter pending review by GDNA.

Correspondence from George B. Launius, Thrifty Mac Discount Drug, Inc.

The Board considered this correspondence regarding repacking FDA formula hand sanitizer and concerns as to whether or not the repacking described in Mr. Launius' correspondence is allowed. In response, the Board directed staff to respond by stating that this would be permissible provided that all state and federal guidelines regarding labeling requirements were followed.

Georgia Drugs and Narcotics Agency - Dennis Troughton

Director Troughton reported that numbers are down due to the pandemic. He reported that GDNA has conducted 2104 inspections and received 369 complaints for FY2020.

Director Troughton commented that as the state is slowly opening up, GDNA is conducting routine inspections again. He added that GDNA never stopped doing investigations for impairment and/or diversion. Director Troughton stated that when going into the pharmacy, the agents will wear masks if the pharmacy asks him/her to wear a mask. He further stated that if the pharmacist is uncomfortable, the agent can come back at another time; however, if the agents are specifically looking for something such as diversion or impairment, GDNA will have to go in because it is a public health emergency.

Director Troughton reported that GDNA is in the midst of addressing the request for a 14% reduction in the budget. He stated that he is working on a plan now for GDNA and will keep the Board posted.

Director Troughton discussed the question of removing Epidiolex from being a Schedule V drug. He stated that the Board has the authority under the law to remove items from a schedule. Director Troughton stated that he has not been able to locate where the DEA is doing that. He further stated that he will not present to the Board until he has the literature from the DEA saying it has been removed.

Attorney General's Report - Max Changus

No report.

Executive Director's Report – Tanja Battle

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

| Date of | Hours | Sponsoring Group | Program Title | CE Code |
|-----------|-------|---|--|-----------|
| Program | | | | |
| 6/15/2020 | 2 | Rollins School of Public Health - Behavioral, Social | HIV Prevention Strategies for Community Pharmacies in Georgia | 2020-2006 |
| | | and Health Education | | |

Correspondence from Tyler Miller, Promises Behavioral Health: The Board viewed this correspondence for informational purposes only.

Temporary Licenses: Ms. Battle reported the number of temporary licenses that have been issued to date (46 temporary pharmacists; 97 temporary pharmacy technicians; four temporary pharmacy interns).

Budget: Ms. Battle reported that last year's budget had a cut of \$31,000. She stated that she has previously discussed travel and not being able to send all members to try and reduce costs. Ms. Battle stated that a 14% budget cut would be \$108,000. She explained that the Board is a lean organization and does not have a lot of extra money. Ms. Battle stated that she is currently waiting for guidance on such. She stated that they are doing everything possible to not reduce staff. She further stated that the Board will need to take the budget into consideration when making decisions. She stated that the Board may have to continue meeting virtually to save the per diem and travel expense. Ms. Battle stated that the Board will talk about the practical exam later, but that of course, is an expense as well and the Board will need to consider these numbers as it makes these determinations and talk about exam content in Executive Session.

<u>Legal Services – Kimberly Emm</u>

The Board discussed Rule 480-34-.16 Diclofenac Sodium Topical Gel, 1% or Less. Mr. Stone made a motion to post Rule 480-34-.16 Diclofenac Sodium Topical Gel, 1% or Less. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

Rule 480-34-.16 Diclofenac Sodium Topical Gel, 1% or Less

- (1) This rule was adopted to protect the health, safety, and welfare of the public. Diclofenac Sodium Topical Gel, 1%, is hereby deleted from the dangerous drugs list as referenced in the Official Code of Georgia Annotated (O.C.G.A.) § 16-13-71(b)(270.5).
- (2) This rule is based on the following findings of the Board:
 - (a) that Diclofenac Sodium Topical Gel, 1% or less does not have a high potential for abuse; (b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the abuse; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and
 - (c) that the drug when in topical gel form 1% or less has been approved for non-prescription status by the Federal Food and Drug Administration.

A motion was made by Hal Henderson, seconded by Dean Stone, and the Board voted that the formulation and adoption of this rule amendment does not impose excessive regulatory cost on any licensee and any cost to comply with the rule amendment cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board also voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this rule amendment will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Mr. Stone stated that he would like for the Board to talk through these matters other than at a board meeting, such as a workshop. Mr. Azzolin agreed. He stated that the Board reacts to a lot of issues in the meetings and there is not much time for back and forth. He further stated that he thinks the Board needs to be proactive. Ms. Battle stated that the Board has historically taken a day to do what Mr. Stone is suggesting. She explained that it is a public meeting and would need to be posted and scheduled.

Mr. Stone made a motion and Mr. Prather 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, Mike Faulk, Lisa Harris, Hal Henderson, Bill Prather and Dean Stone.

Executive Session

Appearances

- M.W.
- B.D.F.
- J.M.M.
- B.Z.A.

Georgia Drugs and Narcotics Agency - Dennis Troughton

• J.L.P.

Cognizant's Report - Mike Faulk

- GDNA Case # T33277
- GDNA Case # T33316
- GDNA Case # A33182
- GDNA Case # A33200
- GDNA Case # B33205
- GDNA Case # B33102
- GDNA Case # B33103
- GDNA Case # B33156
- GDNA Case # B33163
- GDNA Case # B33165
- GDNA Case # B33191
- GDNA Case # B33210
- GDNA Case # B33211
- GDNA Case # B33234

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- G.P.
- A.P.C.P.
- K.P.
- Y.K.C.

Mr. Changus discussed the following cases:

- J.S.
- A.C.P.
- A.P.
- M.C.

Executive Director's Report - Tanja Battle

- R.T.K.
- J.C.

The Board discussed the upcoming June exam.

Legal Services – Kimberly Emm

No report.

Applications

- M.L.M.
- M.J.C.
- D.M.
- Y.R.
- Z.B.G.
- L.H.J.
- M.R.
- W.R.W.
- D.N.P.
- A.R.G.
- A.C.H.I.
- W.P.H.

The Board received legal advice regarding Pharmacist Modification of Drug Therapy.

Correspondences/Requests

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

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

Open Session

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

Appearances

| • | M.W. | Denied Pharmacist Intern | Overturn denial and approve |
|---|--------|----------------------------------|--------------------------------|
| • | B.D.F. | Request to discuss reinstatement | Refer to the Department of Law |
| • | J.M.M. | Request to discuss reinstatement | Refer to the Department of Law |
| • | B.Z.A. | Request to discuss reinstatement | Refer to the Department of Law |

Georgia Drugs and Narcotics Agency – Dennis Troughton

• J.L.P. Pharmacist Reciprocity Applicant Approved to sit for the exam

Cognizant's Report - Mike Faulk

| • | GDNA Case # T33277 | Accept Voluntary Surrender |
|---|--------------------|--------------------------------|
| • | GDNA Case # T33316 | Accept Voluntary Surrender |
| • | GDNA Case # A33182 | Refer to the Department of Law |
| • | GDNA Case # A33200 | Refer to the Department of Law |
| • | GDNA Case # B33205 | Refer to the Department of Law |
| • | GDNA Case # B33102 | Close case with no action |
| • | GDNA Case # B33103 | Close case with no action |
| • | GDNA Case # B33156 | Close case with no action |
| • | GDNA Case # B33163 | Close case with no action |
| • | GDNA Case # B33165 | Close case with no action |
| • | GDNA Case # B33191 | Close case with no action |
| • | GDNA Case # B33210 | Close case with no action |
| • | GDNA Case # B33211 | Close case with no action |
| • | GDNA Case # B33234 | Close case with no action |

Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

| • | G.P. | Public Consent Order to be accepted and signed with express permission |
|---|------|--|
| | | upon receipt of the original |

| • | A.P.C.P. | Public Consent Order to be accepted and signed with express permission |
|---|----------|--|
| | | upon receipt of the original |

Public Consent Order to be accepted and signed with express permission K.P.

upon receipt of the original

Private Consent Order to be accepted and signed with express permission Y.K.C.

upon receipt of the original

Mr. Changus discussed the following cases:

Update provided • J.S. Close with no action A.C.P. Accept counterproposal • A.P. Update provided • M.C.

Executive Director's Report – Tanja Battle

| • | K. I . K. | Request regarding treatment facility | Demed request |
|---|-----------|--------------------------------------|------------------------------|
| • | J.C. | Pending Pharmacist Exam Applicant | Approved to sit for the exam |

The Board discussed the upcoming June exam.

<u>Legal Services – Kimberly Emm</u>

No report.

Applications

| • | M.L.M. | Pharmacy Technician | Denied application |
|---|---------------------|---------------------|---------------------------|
| • | Mi'Esha J. Carnegie | Pharmacy Technician | Approved for registration |
| • | Danielle Moynihan | Pharmacy Technician | Approved for registration |
| • | Yaricxa Reinert | Pharmacy Technician | Approved for registration |
| • | Zarria B. Gaillard | Pharmacy Technician | Approved for registration |
| • | L.H.J. | Pharmacy Technician | Denied application |

| • | Michelle Raguindin | Temporary Pharmacist | Approved application |
|---|--------------------|-------------------------------------|---|
| • | W.R.W. | Pharmacist Exam | Approved to sit for the exam |
| • | D.N.P. | Pharmacist Certification of DTM | Denied application |
| • | AnovoRx Group | Non-Resident Pharmacy | Approved application |
| • | A.C.H.I. | Durable Medical Equipment Suppliers | Overturn denial and approve application |
| • | W.P.H. | Durable Medical Equipment Suppliers | Overturn denial and approve Application |

The Board received legal advice regarding Pharmacist Modification of Drug Therapy.

Correspondences/Requests

| <i>,</i> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,, | sponuciices/ requests | | |
|--|-----------------------|--|------------------|
| • | S.P. | Notice of Discipline | No action |
| • | K.C.P. | Notice of Discipline | No action |
| • | C.V.S.P. | Notice of Discipline | No action |
| • | A.H.G. | Notice of Discipline | No action |
| • | M.B.S. | Notice of Discipline | No action |
| • | P.P. | Notice of Discipline | No action |
| • | B.P.I. | Notice of Discipline | No action |
| • | G.P. | Notice of Discipline | No action |
| • | H.P. | Notice of Discipline | No action |
| • | E.P. | Notice of Discipline | No action |
| • | C.B.R. | Request to terminate probation | Approved request |
| • | W.P.D. | Request to terminate probation | Approved request |
| • | W.H.B. | Request to terminate probation | Approved request |
| • | H.P. | Request for approval of drive thru plans | Approved request |
| | | | |

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

There being no further business to discuss, the meeting was adjourned at 2:56 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held via conference call on Wednesday, June 17, 2020 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 Tanja D. Battle, Executive Director