

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
February 19, 2014
9:00 a.m.

The following Board members were present:

Al McConnell, Chairperson
Laird Miller, Vice-Chairperson
Jim Bracewell
Mike Faulk
Chris Jones
Tony Moye
Bill Prather
Bob Warnock

Staff present:

Tanja Battle, Executive Director
Rick Allen, GDNA
Janet Wray, Senior Assistant Attorney General
Brandi Howell, Business Operations Specialist

Visitors:

Tiffany Aiken
Chris Parker
Kathryn Myers
Chris Coleman
Jim Hinzman
Jerry Hopkins
Jim Bartling
Mike Neely, Ingles
Al Staiti, Ingles
Scott Bidulph, Target
Jeff Cornett, Hemophilia of Georgia
Melvin Smith, CVS
Paul Tran, Wal-Mart
Stephanie Kozol, Holland & Knight
Al Carter, Walgreens

Chairperson McConnell established that a quorum was present and called the meeting to order at 9:07 a.m.

Bill Prather made a motion and Chris Jones 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 Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Tony Moye, Bill Prather and Bob Warnock.

Executive Session

Appearances

- T.P.A.
- C.A.P.
- C.E.C.
- J.W.H.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following individuals:

- R.S.P. and O.A.A.
- P.P.
- S.M.S.I.
- C.M.
- J.S.

Ms. Wray presented the following consent order for acceptance:

- M.C.T.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Open Session

Appearances

Appearance by Mike Neely and Al Staiti from Ingles Pharmacy: Mr. Staiti provided the Board with a blueprint of the proposed renovation for the drive-thru of four stores. Mr. Staiti stated that what is being presented to the Board does adhere to Board rules. Rick Allen, GDNA, stated that he will send an agent out to inspect.

Appearance by Al Carter, Walgreen Co: Mr. Carter stated that Walgreens is partnering with Novartis to participate in a double blind clinical study and wanted to discuss this matter with the Board to ensure that Walgreens is in compliance with the law and Board rules. He explained that, as part of the clinical trial, they will be dispensing three different inhalers with one of the inhalers being labeled as an investigative drug. In regards to the labeling process, he asked if it was permissible to provide a clinical trial drug labeled as a study drug or specific drug “xyz” without the labeling being construed as misbranding or deceptive. Ms. Wray responded by stating that there are a few rules that would be violated and Walgreens would have to request a rule waiver. She explained that the rule requires the name of the drug on the label. She further explained that the issue is whether or not the law would be violated. Ms. Wray suggested he go back and review the law and rules to see if the law prohibits this. Mr. Carter stated that he would follow up with his legal team.

Ratifications

Chris Jones made a motion to ratify the list of issued licenses. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance and Waiver – Behavioral Health Services of South Georgia

Bob Warnock made a motion to grant the rule variance and waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – QOL Meds at Georgia Pines Behavioral Health Crisis Center Pharmacy

Bob Warnock made a motion to grant the rule waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Rejani Thekkedathu Rajan

The Board considered this correspondence and directed staff to respond to Ms. Rajan and suggest that she submit a roster request. Mr. Bracewell added that he would reach out to her as his organization may be able to provide the information needed.

Correspondence from Deborah Gale, RPH014972

The Board considered this correspondence from Ms. Gale requesting removal of the PIC restriction. Tony Moye made a motion to approve the request. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence from Daniel David Graver

The Board considered this correspondence from Mr. Graver requesting a regulatory opinion regarding a pharmaceutical manufacturer considering an arrangement with retail pharmacies through which the manufacturer would pay pharmacies to perform certain “adherence services” for patients who have been prescribed the manufacturer’s drugs, either through their pharmacists or through a contracted third party business associate. Mr. Graver is requesting to know if this program would implicate the provisions of Rule 480-5-.03(b) and Rule 480-16-.07 and/or Ga. Code § 43.1B-4; § 26-4-80. Bob Warnock made a motion to have staff respond to Mr. Graver by providing the procedure for requesting an opinion and also state that, based on the preliminary information submitted, it appears that the method of compensation he is proposing is in violation of the Board’s ethical provisions and code of conduct. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Rick Allen

No report.

Attorney General’s Report – Janet Wray

Ms. Wray discussed home school applicants. Bill Prather made a motion to adopt the below policy regarding home schooled applicants:

High school graduates include students with a diploma from a regionally accredited home study program such as the American School or the Setom Home Study School or a diploma from the Center of the Accrediting Council for Independent Study.

Chris Jones seconded and the Board voted unanimously in favor of the motion.

Executive Director’s Report – Tanja Battle

Ms. Battle discussed the upcoming NABP national meeting. She stated that the Board would need to decide on a voting delegate for the Board. The meeting is May 17th thru May 20th. The Board agreed that Mr. Miller would be the delegate. Ms. Battle indicated that she would notify NABP of such.

Due to the NABP meeting being held the same week as the Board’s monthly meeting, the Board discussed rescheduling its May 21st meeting to May 14th. Following the meeting, Ms. Howell will email the Board members to determine if a quorum could be established for May 14, 2014.

Jim Bracewell made a motion and Bill 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 Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Tony Moye, Bill Prather and Bob Warnock.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen requested advice from Ms. Wray regarding proposed Rule 480-11-.02 Compounded Drug Preparations.

Discussed HB885 Medical Cannabis.

Discussed HB965 911 Medical Amnesty Law.

Discussed SB370 Biochangeable.

Cognizant's Report – Laird Miller

- GDNA Case #A14-02
- GDNA Case #B13-78
- GDNA Case #T31016
- GDNA Case #T30996
- GDNA Case #T30975
- GDNA Case #T31012
- GDNA Case #T31018
- GDNA Case #T31020
- GDNA Case #B31022
- GDNA Case #B30616
- GDNA Case #A30919
- GDNA Case #B30886
- GDNA Case #B30914
- GDNA Case #B30860
- GDNA Case #B13-65
- GDNA Case #A13-73
- GDNA Case #B30941
- GDNA Case #B30905
- GDNA Case #B30912
- GDNA Case #A30866
- GDNA Case #B30958
- GDNA Case #B31000
- GDNA Case #B30939
- GDNA Case #B30957
- GDNA Case #B30910
- GDNA Case #B30936
- GDNA Case #B30960
- GDNA Case #B30935
- GDNA Case #B30781

Applications

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

Correspondences/Requests

- G.W.M.
- O.M.C.
- S.D.
- R.P.D.
- J.M.C.
- A.B.R.
- A.H.
- A.B.

Miscellaneous

The Board received advice from Ms. Wray regarding Rule 480-6-.02 Nonresident Pharmacy Permit and Rule 480-38-.02 Conditions for Use of Delivery by Mail.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Open Session

Mr. Prather discussed the proposed revisions to Rule 480-38-.01 Definitions and Rule 480-38-.02 Conditions for Use of Delivery by Mail and provided the Board with a copy of the suggested language.

Approval of Minutes

Bill Prather made a motion to approve the Public and Executive Session minutes for the January 22, 2014 full Board meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to approve all recommendations based on deliberations in Executive Session as follows:

Appearances

- T.P.A. Denied request to reinstate pharmacy tech registration
- C.A.P. Approved with public consent order
- C.E.C. Approved with private consent order
- J.W.H. Approved request to lift probation

Attorney General's Report – Janet Wray

Ms. Wray discussed the following individuals:

- R.S.P. and O.A.A. Inspect pharmacy and issue a Letter of Concern
- P.P. Close with Letter of Concern
- S.M.S.I. Close case and renew wholesaler license
- C.M. Void pharmacist intern license
- J.S. Denied pharmacy technician registration

Ms. Wray presented the following consent order for acceptance:

- Matthew C. Thomas Public Consent Order accepted

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen requested advice from Ms. Wray regarding proposed Rule 480-11-.02 Compounded Drug Preparations. No action taken.

Discussed HB885 Medical Cannabis. No action taken.

Discussed HB965 911 Medical Amnesty Law. No action taken.

Discussed SB370 Biochangeable. No action taken.

Cognizant’s Report – Laird Miller

- GDNA Case #A14-02 Accept Private Interim Consent Order
- GDNA Case #B13-78 Table
- GDNA Case #T31016 Accept Voluntary Surrender
- GDNA Case #T30996 Accept Voluntary Surrender
- GDNA Case #T30975 Accept Voluntary Surrender
- GDNA Case #T31012 Accept Voluntary Surrender
- GDNA Case #T31018 Accept Voluntary Surrender
- GDNA Case #T31020 Revoke technician registration
- GDNA Case #B31022 Close with no action
- GDNA Case #B30616 Close with no action
- GDNA Case #A30919 Close with Letter of Concern
- GDNA Case #B30886 Close with no action
- GDNA Case #B30914 Close with no action
- GDNA Case #B30860 Close with Letter of Concern
- GDNA Case #B13-65 Refer to the Attorney General’s office for discipline
- GDNA Case #A13-73 Close with Letter of Concern
- GDNA Case #B30941 Close with no action
- GDNA Case #B30905 Close with no action
- GDNA Case #B30912 Close with no action
- GDNA Case #A30866 Refer to the Attorney General’s office for discipline
- GDNA Case #B30958 Close with no action
- GDNA Case #B31000 Refer to the Attorney General’s office for discipline
- GDNA Case #B30939 Close with no action
- GDNA Case #B30957 Close with Letter of Concern
- GDNA Case #B30910 Close with no action
- GDNA Case #B30936 Close with Letter of Concern
- GDNA Case #B30960 Close with no action
- GDNA Case #B30935 Close with no action
- GDNA Case #B30781 Close with no action

Applications

- D.K. Pharmacy Technician Denied registration
- J.P. Pharmacy Technician Denied registration
- Jasmine C. Stalnaker Pharmacy Technician Approved for renewal
- T.B. Pharmacy Technician Denied registration
- Joy B. Kafouni Pharmacist Intern Approved application
- Joseph J. Campanelli Pharmacist Intern Approved application
- A.L.K.A.I. Wholesaler Pharmacy No action taken
- C.M.P.D. Researcher Pharmacy Refer to GDNA

- William A. Hill Pharmacist Reinstatement Grant request for waiver of reinstatement fee and approved application
- M.E.R. Pharmacist Reciprocity Approve pending receipt of additional information

Correspondences/Requests

- G.W.M. Appearance request Approved request
- O.M.C. Remote Order Entry Table pending receipt of additional information
- S.D. Request to lift supervision requirement Approved request
- R.P.D. Correspondence requesting guidance Directed
- J.M.C. Correspondence Directed staff to request additional information
- A.B.R. Requesting termination of No action taken
- A.H. Request to lift supervision requirement Approved request
- A.B. Appearance request Approved request

Miscellaneous

The Board received advice from Ms. Wray regarding Rule 480-6-.02 Nonresident Pharmacy Permit and Rule 480-38-.02 Conditions for Use of Delivery by Mail. No action taken.

Chris Jones seconded and the Board voted in favor of the motion, with the exception of Bill Prather, who recused himself from the vote regarding J.W.H.

Bob Warnock made a motion to approve C.A.P. for reinstatement with a public consent order. Laird Miller seconded and the Board voted, with the exception of Bill Prather, Mike Faulk and Chris Jones, in favor of the motion.

Mike Faulk made a motion to approve C.E.C. for reinstatement with a private consent order. Chris Jones seconded and the Board voted, with the exception of Jim Bracewell, in favor of the motion.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, March 19, 2014, at 9:00 a.m. at Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 3:38 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist
 Minutes edited by Tanja D. Battle, Executive Director