

GEORGIA BOARD OF PHARMACY
Board Meeting
South University College of Pharmacy
709 Mall Blvd
Savannah, GA 31406
January 11, 2017
9:00 a.m.

The following Board members were present:

Chris Jones, President
Bob Warnock, Vice-President
Vicki Arnold
Mike Faulk
Lisa Harris
Laird Miller
Bill Prather

Staff present:

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

Visitors:

Mike Long, Elements Behavioral Health
Andy Freeman
Mike King, Publix
Sonya Nelson, Walmart
John Rocchio, CVS Health
John Sisto, Express Scripts
Rodney Lester
Brant Zauner
Jim Bartling
David D. Hasley
Mary Margaret Knight, Eldercare Pharmacy
Young Chang, Walgreens
Brian Robinson, Walgreens

President Jones established that a quorum was present and called the meeting to order at 9:04 a.m.

Bill Prather made a motion and Laird Miller 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 Vicki Arnold, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Correspondence

- P.S.H.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

- K.M.
- GDNA Cases #A-31634 and #A-31761

Ms. Wray presented the following consent orders:

- K.W.S.
- D.I.
- M.S.

Applications

- S.M.A.

Appearances

- R.F.L.
- B.M.Z.

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

Open Session

President Jones welcomed the visitors.

Appearance

Appearance by Mike Long, Elements Behavioral Health. Mr. Long thanked the Board for the opportunity to speak to its members. The purpose of Mr. Long’s appearance is to request Promises and COPAC be considered as approved treatment providers. Mr. Long presented the Board with information packets on each facility’s program. Following his presentation, Mr. Warnock asked if each facility would provide an advocate to meet with the Board, along with the licensee, since both facilities are located out of state. Mr. Long stated that he would find that information out and report back to the Board. President Jones stated that once that information is received, the Board will further discuss and get back to Mr. Long regarding his request.

Approval of Minutes

Mike Faulk made a motion to approve the Public Session minutes for the December 14, 2016 meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to approve the Executive Session minutes for the December 14, 2016 meeting. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the Public Session minutes for the December 20, 2016 conference call. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the Executive Session minutes for the December 20, 2016 conference call. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Mike Faulk made a motion to ratify the list of licenses issued. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Milliken Healthcare Products, LLC

Bill Prather made a motion to approve the rule waiver petition. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Joan Green-Fowler

Bill Prather made a motion to deny the rule waiver petition; however, if Ms. Green-Fowler can provide evidence that the education she obtained is equivalent to what is required per Board Rule 480-15-.02, the Board will reconsider her request. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Cheryl L. McSwain

Mike Faulk made a motion to deny the rule waiver petition. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Bhumika Patel

Bill Prather made a motion to deny the rule waiver petition; however, states that staff should advise Ms. Patel that, based on the information provided with the petition, she may be eligible for licensure under O.C.G.A. § 26-4-42 License transfers for pharmacist licensed in another jurisdiction. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Gateway 341 Pharmacy, PHH005598

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

Correspondence from Dr. Gina Talbot

The Board considered this correspondence regarding automatic refills. Lisa Harris made a motion to direct staff to respond to Dr. Talbot by thanking her for her correspondence and advising her that this matter is not within the Board's purview. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Correspondence from Olivia Steltenpohl

The Board considered this correspondence inquiring as to the legality of pharmacists conducting various point of care tests. Laird Miller made a motion to direct staff to respond by referring Ms. Steltenpohl to O.C.G.A. Sections §§ 26-4-50 and 43-34-24 for more information regarding this matter. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Erik Heikkenen

The Board considered this correspondence regarding camera monitoring in Georgia. Laird Miller made a motion to direct staff to schedule Mr. Heikkenen for an appearance to present this information to the Board. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Correspondence from Emily Marvel, May Architecture + Interiors

The Board considered this correspondence regarding USP 800 regulation. Lisa Harris made a motion to direct staff to respond to Ms. Marvel by stating that the effective date is July 1, 2018 and that the Board will comply with the regulations at such time. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Aquila Ingram, Renew Merchandise

The Board considered this correspondence requesting to meet with the Board to discuss Renew Merchandise's proposed smart machine. Mike Faulk made a motion to direct staff to schedule Ms. Ingram for an appearance to present this information to the Board. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Bent Gay, Gayco Healthcare

At its December 2016 meeting, the Board considered this correspondence from Mr. Gay regarding his submitted policy and procedures for medication destruction via reverse distributor. At that time, the Board voted to table the correspondence to allow additional time for the Board to review. Mike Faulk made a motion to approve Mr. Gay's submission. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Toni Bowen, Genoa

Ms. Bowen appeared before the Board at its December 2016 meeting to discuss crisis stabilization units. At such time, the Board informed Ms. Bowen that it would further discuss the matter and get back to her. Bob Warnock made a motion to direct staff to respond to Ms. Bowen by stating that the Board does have the authority to establish categories of licenses per Georgia law. Towards that end, the Board is requesting she further research the rules and regulations pertaining to the suggestions noted in her letter addressed to President Mike Faulk, i.e., emergency kits, crash cart medications, providing floor stock for the CSU, etc. Once she has done this research, please notify the Board how the facilities fit under existing regulations and what would most meet the needs of her operation. Upon receipt of that information, the Board will review and see how to best classify the facility. Laird Miller 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

No report.

Executive Director's Report – Tanja Battle

Renewals: Ms. Battle reported 13,426 pharmacists have renewed to date. She stated there are currently 747 that are in "Lapsed-Late Renewal" status.

Continuing Education Report: Ms. Battle reported that no additional programs have been approved for this time period.

Miscellaneous

Mike Faulk made a motion to post Chapter 480-51: Interchangeable Biological Products with the suggested changes. Bill Prather seconded and the Board voted unanimously in favor of the motion.

CHAPTER 480-51: INTERCHANGEABLE BIOLOGICAL PRODUCTS

480-51-.01 Definitions.

(1) "Biological product" means a biological product as defined in subsection (i) of section 351 of the Public Health Service Act, 42 U.S.C. Section 262.

(2) "Interchangeable biological product" means a biological product that the federal Food and Drug Administration has determined meets the standards set forth in subsection (k)(4) of 42 U.S.C. 262 or has been deemed therapeutically equivalent by the federal Food and Drug Administration.

(3) "Substitution" means to dispense pharmaceutically equivalent and therapeutically equivalent drug products as regulated by the board in place of the drug prescribed.

Authority: O.C.G.A. Sections 26-4-5, 26-4-27, 26-4-28, and 26-4-81.

480-51-.02 Substituting Interchangeable Biological Products.

(1) If a practitioner of the healing arts prescribes a biological product by its nonproprietary name, the pharmacist may substitute the biological product with an interchangeable biological product, but shall dispense the lowest retail-priced interchangeable biological product, which is in stock.

(2) Substitutions as provided in this rule are authorized for the express purpose of making available to the consumer the lowest retail priced interchangeable biological product which is in stock.

(3) Whenever a substitution is made:

(a) The pharmacist shall record on the original prescription the fact that there has been a substitution and the identity of the dispensed interchangeable biological product and its manufacturer. Such prescription shall be maintained for two years and shall be available for inspection by the board or its representative.

(b) The pharmacist shall affix to the prescription label or container or an auxiliary label, the name of the interchangeable biological product, with an explanation of "interchangeable biological product for (insert name of prescribed biological product)" or similar language to indicate substitution has occurred, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label.

1. This labeling requirement does not apply to biological products dispensed for in-patient hospital services, to hospital administered biological products for outpatients, or to biological products in specialty packaging for dosing purposes. ~~as defined by the board.~~ This labeling requirement does apply to hospital retail pharmacies and to any biological products dispensed by a hospital for a patient's use or administration at home.

(4) The substitution of any biological product by a registered pharmacist pursuant to this rule section does not constitute the practice of medicine.

(5) A patient for whom a prescription biological product order is intended may instruct a pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product.

(6) A practitioner of the healing arts may instruct the pharmacist not to substitute an interchangeable biological product in lieu of a prescribed biological product by including the words "brand necessary" in the body of the prescription.

(a) When a prescription is a hard copy biological product order, such indication of brand necessary must be in the practitioner's own handwriting and shall not be printed, applied by rubber stamp, or any such similar means.

(b) When the prescription is an electronic prescription drug or biological product order, the words "brand necessary" are not required to be in the practitioner's own handwriting and may be included on the prescription in any manner or by any method.

(c) When a practitioner has designated "brand necessary" on an electronic biological product order or interchangeable biological product shall not be substituted without the practitioner's express consent, which shall be documented by the pharmacist on the prescription and by the practitioner in the patient's medical record.

(7) Within forty-eight (48) hours, excluding weekends and holidays, following the dispensing of a biological product, the dispensing pharmacist or the pharmacist's designee shall communicate to the prescriber the specific product provided to the patient, including the name of the biological product and the manufacturer.

(a) The communication shall be conveyed by making an entry into an interoperable electronic medical records system or through electronic prescribing technology or a pharmacy record that is electronically accessible by the prescriber. Otherwise, the pharmacist shall communicate the biological product dispensed to the prescriber by using facsimile, telephone, electronic transmission, or other prevailing means, provided that communication shall not be required where:

1. There is no interchangeable biological product approved by the federal Food and Drug Administration for the prescribed product; or
2. A refill prescription is not changed from the product dispensed on the prior filling of the prescription.

(8) A link for the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable with a specific biological products is available on the Board's website.

A motion was made by Laird Miller, seconded by Vicki Arnold, and the Board voted that the formulation and adoption of the proposed rules does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rules 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 the proposed rules will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Bill Prather made a motion and Vicki Arnold 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 Vicki Arnold, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

- Requested guidance and legal advice regarding DEA requirements pertaining to Naloxone.
- Shared data regarding PDMP
- Discussed legality of access and disclosure of PDMP data

Executive Director's Report – Tanja Battle

- P.M.H.E.

Cognizant's Report – Bob Warnock

- GDNA Case # A-16-20
- GDNA Case # T-32047
- GDNA Case # T-32039
- GDNA Case # B-31989
- GDNA Case # A-31946
- GDNA Case # B-31949
- GDNA Case # B-31833
- GDNA Case # B-31990
- GDNA Case # B-31991

- GDNA Case # A-16-21

Applications

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

Correspondences/Requests

- P.V.H.
- H.S.
- R.H.T.
- T.M.L.
- J.M.J.
- J.B.O.
- V.A.E.
- B.P.
- C.V.S.S.
- E.S.
- M.I.
- O.P.S.
- M.P.

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

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

Open Session

Miscellaneous

Ms. Battle discussed correspondence received from Leigh Carpenter, Director of Pharmacy, Hemophilia of Georgia, in December regarding its pharmacy wanting to enclose a conspicuous leaflet that would be seen by the patient when first opening the box. The Board will take this under advisement.

Ms. Battle stated that correspondence from Brad Schraut, InstyMeds, was received concerning his meeting with the Board in July 2016. Mr. Schraut presented information regarding the InstyMeds system at that time. Mr. Schraut recently submitted additional information in response to his meeting with the Board and that information will be placed on the February 8th agenda for consideration.

Laird Miller made a motion for the Board to take the following actions:

Correspondence

- P.S.H. Request to bring attorney has advocate Denied request.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

- K.M. Request to change summary suspension to traditional impairment order Approved request
- GDNA Cases #A-31634 and #A-31761 No action taken

Ms. Wray presented the following consent orders:

- K.W.S. Public Consent Order to be accepted and signed with express permission upon receipt of the original
- D.I. Private Consent Order to be accepted and signed with express permission upon receipt of the original
- M.S. Private Consent Order to be accepted and signed with express permission upon receipt of the original

Applications

- Sarah M. Arthur Pharmacist Intern Approved application

Appearances

- R.F.L. Denied Pharmacist Intern Overturn denial and refer to the Attorney General's office
- B.M.Z. Denied Pharmacist Reinstatement Overturn denial and refer to the Attorney General's office

Georgia Drugs and Narcotics Agency – Rick Allen

- Requested guidance and legal advice regarding DEA requirements pertaining to Naloxone.
- Shared data regarding PDMP
- Discussed legality of access and disclosure of PDMP data

Executive Director's Report – Tanja Battle

- P.M.H.E. Clinic Pharmacy Application and Absence of Pharmacy Policy Approved application and policy

Cognizant's Report – Bob Warnock

- GDNA Case # A-16-20 Accept Private Interim Consent Order
- GDNA Case # T-32047 Accept Voluntary Surrender
- GDNA Case # T-32039 Accept Voluntary Surrender
- GDNA Case # B-31989 Close case with no action
- GDNA Case # A-31946 Allow pharmacist to place license on inactive status
- GDNA Case # B-31949 Close case with no action
- GDNA Case # B-31833 Close case with letter of concern
- GDNA Case # B-31990 Close case with no action
- GDNA Case # B-31991 Misfill Policy #1
- GDNA Case # A-16-21 Accept Private Interim Consent Order

Applications

- A.B.D. Pharmacist Renewal Schedule for Investigative Interview
- Ayodeji O. Odunsi Pharmacist Renewal Approved renewal
- Chirag M. Amin Pharmacist Renewal Approved renewal
- David D. Hasley Pharmacist Renewal Approved renewal
- Jack McGuire Pharmacist Renewal Approved renewal
- Kevin A. Long Pharmacist Renewal Approved renewal
- Mark S. Faulk Pharmacist Renewal Approved renewal
- Reed Ligin Pharmacist Renewal Approved renewal
- Sharon H. May Pharmacist Renewal Approved renewal
- Shemeeka C. Dortch Pharmacist Renewal Approved renewal
- Perry S. Jones Pharmacist Renewal Approved renewal
- A.E.E. Pharmacist Renewal Approve renewal and schedule for investigative interview
- B.K.B. Pharmacist Reciprocity Approved to sit for the exam
- B.N.L. Pharmacist Reciprocity Approved to sit for the exam
- E.K. Pharmacist Reciprocity Approved to sit for the exam
- L.M.W. Pharmacist Reciprocity Denied application
- S.B.M. Pharmacist Reciprocity Approved to sit for the exam
- S.A.B. Pharmacist Reciprocity Approve pending receipt of additional information
- T.D.T. Pharmacist Reciprocity Approved to sit for the exam

- R.B.T. Pharmacist Examination Approved to sit for the exam
- Kent D. Coleman Pharmacist Reinstatement Approved application
- S.R.B. Pharmacist Reciprocity Approved to sit for the exam
- Latasha Stallworth Pharmacist Renewal Approved renewal
- D.L.S. Pharmacist Renewal Schedule for Investigative Interview
- T.K.C. Pharmacist Reinstatement Table pending receipt of additional information
- Jontasha Kendrick Pharmacy Technician Approve for registration
- M.L.F. Pharmacy Technician Schedule for Investigative Interview
- Adesikemi Ewedemi Pharmacy Technician Approve for registration
- L.M.T. Pharmacy Technician Table pending receipt of additional information
- M.D.H. Denied Pharmacy Tech Overturn denial and approve for registration

Correspondences/Requests

- P.V.H. Request for waiver of late renewal fee Denied request
- H.S. Request for exemption of intern hours Approved request
- R.H.T. Request regarding intern hours Denied request
- T.M.L. Request regarding intern hours Approved request
- J.M.J. Appearance request Approved request
- J.B.O. Request to take NAPLEX a 4th time Denied request
- V.A.E. Request to take MPJE a 4th time Approved request
- B.P. Letter of admonition No action taken
- C.V.S.S. Notice of discipline No action taken
- E.S. Notice of discipline No action taken
- M.I. Notice of discipline No action taken
- O.P.S. Notice of discipline No action taken
- M.P. Notice of discipline No action taken
- D.S.P.D. Notice of discipline No action taken
- R.R.V.P. Notice of discipline No action taken
- E.P. Notice of discipline No action taken
- H.S.W.R.H. Remote Order Entry Approved
- C.H.B. and C.T.C. Remote Order Entry Table pending receipt of additional information
- S.P. Notice of discipline No action taken
- A.A.L. Request to take MPJE a 4th time Approved request
- M.H.F. Request to renew license Approved request
- H.M.C.P. Notice of discipline No action taken
- K.P.K. Request to take MPJE a 5th time Approved request
- R.H.A. Request to take MPJE a 5th time Approved request
- L.M.N. Request to terminate consent order Approved request
- C.W.T. Medical malpractice payment report Board directed staff to place with investigate file
- J.J.K. Correspondence regarding change in ownership Approved request

Bob Warnock seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 3:34 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, February 8, 2017 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director