

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
February 17, 2016
9:00 a.m.

The following Board members were present:

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

Staff present:

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

Visitors:

Hootan Melamed, Alexso
Angelyn Tuttle
Frank Barker
Diane Diver
Jeff Cox
Rich Vodde
Gayle Thomas
Jim Bartling
Michael Venters, Cameron Pharmaceuticals
John McMahon, Cameron Pharmaceuticals
Shannon Cox, Cameron Pharmaceuticals
Scott Lindsay, CAPS
Karen Waters, GHA
Greg Reysold, GPhA
Sonya Nelson, Walmart
John Rocchio, CVS Health
John Sisto, ESI
Nichelle Sims
Leigh Carpenter, Hemophilia of GA
Burt Wrenn, CVS
Christin Watson, CVS
Philip Sprinkle, Balch & Bingham
Jennifer Tyler, Balch & Bingham
Burke Basquin, EGRMC

President Faulk established that a quorum was present and called the meeting to order at 9:01 a.m.

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

Executive Session

Appearances

- A.I.
- A.W.T.
- J.F.C.
- G.E.T.
- C.P.

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

Open Session

President Faulk welcomed the visitors.

Bill Prather made a motion to grant a rule variance petition for Cameron Pharmaceuticals, LLC. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the wholesaler pharmacy application for Cameron Pharmaceuticals, LLC. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Appearance

Appearance by Philip Sprinkle and Jennifer Tyler, Balch & Bingham, LLP, along with Burke Basquin, Pharmacy Director, East Georgia Regional Medical Center (EGRMC). Mr. Sprinkle discussed the position statement submitted from his office to the Board on behalf of EGRMC. Mr. Sprinkle stated that EGRMC is trying to expand space to accommodate patient care and was told by Georgia Drugs and Narcotics Agency (GDNA) that it would need a completely separate pharmacy in order to do so. Discussion was held concerning the hospital housing its wound care clinic and pain management clinic, which is adjacent and connected to the hospital. It also has an imaging center located 2.4 miles away. Ms. Tyler provided pictures to the Board to review. After further discussion, Mr. Basquin was informed that under current law, a separate license would be needed. He was also informed that he can submit a rule petition for certain items.

Approval of Minutes

Laird Miller made a motion to approve the Public and Executive Session minutes for the January 14, 2016 meeting as amended. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Petition for Rule Waiver – Hospitality Rx, LLC

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

Petition for Rule Waiver – Gateway Behavioral Health Services

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

Petition for Rule Waiver from Leither’s Enterprises, Inc., dba Leiter’s Compounding

Bill Prather made a motion to grant the rule waiver petition. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Biocompatibles, Inc.

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

Petition for Rule Waiver from Biomune Company dba Ceva Biomune

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

Correspondence from Gigi Davidson, NC State College of Veterinary Medicine

The Board considered this correspondence requesting permission to mail prescription medications and food to clients that reside in the State of Georgia. Lisa Harris made a motion to deny this request. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Heidi Bragg, Cardinal Health Pharmacy Services

The Board considered this correspondence from Ms. Bragg regarding Cardinal Health’s interest in the delivery of dispensed prescriptions to patients. For retail pharmacies within a healthcare system, often the patients of the healthcare system are not returning to the same building as the retail pharmacy for future visits. Ms. Bragg asked if the patients consented to an arrangement, if the retail pharmacy could deliver dispensed prescriptions to secured location within a clinic building. The Board directed staff to respond to Ms. Bragg by stating what she has proposed is unlawful; however, if she would like request an appearance with the Board to further discuss, she may do so.

Correspondence from Catherine Maynard-Parker, PointclickCare

The Board considered this correspondence stating that PointClickCare now has the ability to transmit Narcotic orders, not only to the integrated pharmacy, but to other outside pharmacies for discharge. Ms. Maynard-Parker included the overview and certification received from the Drummond Group for DEA Certification. The Board directed staff to respond to Ms. Maynard-Parker by stating that the Board thanks her for submitting this information and that an appearance to further discuss this matter is not necessary.

Correspondence from Griff C. Danheim, Quidel

The Board considered this correspondence from Mr. Danheim requesting to determine if the state regulations and statutes are open to a registered pharmacist providing point of care diagnostic testing for influenza and strep as well as being able to work under a collaborative practice agreement with a physician in order to prescribe and dispense based upon the test result. The Board directed staff to respond to Mr. Danheim by referring him to the law and rules on the Board’s website as what he requesting is not legal in the State of Georgia and would require a legislative change.

Correspondence from Lisa McKee, Henry Schein, Inc.

The Board considered this correspondence requesting clarification as to whether or not devices that state “Caution: federal or state law requires dispensing by or on the order of a physician” or “Professional Use only” require a wholesale license or another specific license for these devices. The Board directed staff to respond by stating it must contain the federal caution language to be a prescriptive device which requires a wholesale license.

Correspondence from James Jordan, Lamar’s Pharmacy

The Board viewed this correspondence for informational purposes only.

Correspondence from Kyle McGrath

The Board considered this correspondence from Mr. McGrath asking if pharmacists are able to complete CLIA-waived tests within the community pharmacies in Georgia and if there are additional requirements to those mentioned on the application for a CLIA-waiver on CMS. The Board directed staff to respond to Mr. McGrath by referring him to the law and rules on the Board's website as what he requesting is not legal in the State of Georgia and would require a legislative change.

Correspondence from Jan Harris, Sharps, Inc.

The Board considered this correspondence from Ms. Harris stating the company has customers who want to place the DEA receptacles in their pharmacies or long-term care facilities, but are unsure as to how to register with/notify the Board in order to comply with Rule 480-50-.02(1)(a). She also asks if Sharps, as the reverse distributor to which the inner liners will be transferred via common carrier, needs to provide the Board with any documents. The Board directed staff to develop the notification form required by Rule 480-50-.02(1)(a) and bring back to the Board for consideration. The Board authorized staff to approve any notifications received until the form is developed. Additionally, the Board directed staff to respond to Ms. Harris by stating that if Sharps, Inc. is acting as a reverse distributor in Georgia, then the company would need to be registered.

Correspondence from Paulos Yohannes

The Board considered this correspondence from Mr. Yohannes regarding requirements for registration as a pharmacist whose education was obtained in another country. The Board directed staff to respond to Mr. Yohannes and request he provide documentation from NABP regarding this matter and refer him to O.C.G.A. § 26-4-41.

Georgia Drugs and Narcotics Agency Open Session – Rick Allen

Director Allen reported House Bill 900 passed.

Attorney General's Report Open Session –Janet Wray

No report.

Executive Director's Report Open Session – Tanja Battle

Ms. Battle reported that it is time for the Board to designate another member to assist NABP with writing examination items. She stated that Mr. Jones has helped in the past. Jim Bracewell made a motion to appoint Lisa Harris as the designee. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Lisa Harris made a motion to appoint Bill Prather to serve as the liaison with the pharmacy caucus. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Ms. Battle discussed correspondence received from James Cope regarding the NABP having a website that allows a pharmacist to check his/her continuing education credits/hours. He was concerned the website requiring a social security number to sign in. Ms. Battle stated she informed him that the Board has no authority over NABP's website or CE tracking mechanism. The Board agreed with Ms. Battle's response.

Miscellaneous

Chris Jones made a motion to post Chapter 480-51 Interchangeable Biological Products as amended. Jim Bracewell 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 the section 351 of the Public Health Service Act, 42 U.S.C. 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.

480-51-.02 Substituting Interchangeable Biological Products.

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

(2) Whenever a substitution is made, 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 made available for inspection by the board or its representative in accordance with the rules of the Board.

(3) If a pharmacist substitutes an interchangeable biological product for a prescribed biological product when dispensing a prescribed medication, 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, must appear on the prescription label and be affixed to the container or an auxiliary label, unless the prescribing practitioner indicated that the name of the biological product may not appear upon the prescription label; provided, however, that this paragraph shall 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.

(a) This paragraph shall 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) The board shall maintain a link on its website to the current list of all biological products determined by the federal Food and Drug Administration to be interchangeable with a specific biological product.
- (a) The link for the list shall be on the Board's website.

A motion was made by Bob Warnock, seconded by Jim Bracewell, and the Board voted that the formulation and adoption of these 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 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. § 50-13-9 16 5 9 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these 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.

President Faulk stated that the Board is continuing to work on the remainder of the rules that were on the Board's agenda and will bring them back for consideration at a later date. Those rules were 480-8-.06 Drug Distribution and Control, 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security, 480-10-.20 Required Notifications to the Board, 480-13-.06 Drug Distribution and Control, 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances, 480-18-.06 Drug Distribution and Control, 480-27-.03 Records of Dispensing, 480-33-.06 Drug Distribution and Control, 480-13-.05 Physical Requirements. Amended, 480-10-.16 Security System Approval, and 480-48-.02 Conditions for Use of Delivery by Mail.

Mr. Miller discussed "off block" hours. He stated the way the current rule is written requires internship hours to only be accrued during the times in which an intern's school or college of pharmacy is not in session. He asked if the Board could figure out a way to allow hours to be accrued during that time. Director Allen stated that he came come up with a draft that would address the issue. Ms. Wray responded that the language needs to be worked on before the Board can vote to post. Ms. Foreman suggested adding language stating "excluding school break or school holidays". Mr. Miller stated that he will contact the four pharmacy schools and maybe the Board can come up with terminology that everyone will recognize.

Chris Jones 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 Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- E.U.H.M.
- J.F.
- N.G.T.C.
- T.G.F.
- J.J.
- C.C.

Georgia Drugs and Narcotics Agency – Rick Allen

- S.P.
- W.C.

Cognizant’s Report – Chris Jones

- GDNA Case # A-31626
- GDNA Case # T-31680A
- GDNA Case # T-31680B
- GDNA Case # A16-01
- GDNA Case # T-31712
- GDNA Case # A-31579
- GDNA Case # A-31622
- GDNA Case # A-31602
- GDNA Case # A-31650
- GDNA Case # A-31675

Executive Director’s Report – Tanja Battle

- T.J.A.
- J.M.J.

Applications

- E.R.G.
- F.K.A.
- M.E.S.
- N.G.C.
- G.L.

Correspondences/Requests

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

- B.T.
- C.C.
- A.E.G.
- L.M.N.
- T.R.S.
- W.P.
- M.M.

Applications

- K.M.W.
- D.R.G.
- S.K.S.
- O.N.W.
- L.P.S.
- J.B.C.
- F.D.R.
- C.V.G.

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

Open Session

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

Appearances

- | | | |
|----------|----------------------------------|---|
| • A.I. | Denied Wholesale Pharmacy | Overturn denial and approve for licensure |
| • A.W.T. | Request to discuss reinstatement | Request approved |
| • J.F.C. | Request to discuss reinstatement | Request denied. Directed staff to request additional information. |
| • G.E.T. | Request to discuss reinstatement | Request approved |
| • C.P. | Pending Wholesale Pharmacy | No action taken |

Attorney General’s Report – Janet Wray

Ms. Wray presented the following consent orders:

- | | |
|-------------------------------------|--------------------------------|
| • Emory University Hospital Midtown | Public consent order accepted |
| • Joyce Franklin | Public consent order accepted |
| • Northwest GA Treatment Center | Public consent order accepted |
| • T.G.F. | Private consent order accepted |
| • J.J. | Private consent order accepted |
| • C.C. | Private consent order accepted |

Georgia Drugs and Narcotics Agency – Rick Allen

- | | | |
|--------|-----------------------|---|
| • S.P. | Non-Resident Pharmacy | Denied application |
| • W.C. | Non-Resident Pharmacy | Directed staff to send a certified letter notifying the facility its license has been placed on inactive status as the Board has been notified it no longer holds a pharmacy license in its primary state of licensure. |

Cognizant’s Report – Chris Jones

- GDNA Case # A-31626 Close case with letter of concern

- GDNA Case # T-31680A Close case with letter of concern
- GDNA Case # T-31680B Close case with letter of concern
- GDNA Case # A16-01 Accept Private Interim Consent Order
- GDNA Case # T-31712 Revoke technician registration
- GDNA Case # A-31579 Refer to Attorney General's office for discipline
- GDNA Case # A-31622 Refer case to the Florida Board of Pharmacy
- GDNA Case # A-31602 Close case with letter of concern
- GDNA Case # A-31650 Refer to the Attorney General's office for discipline
- GDNA Case # A-31675 Close case with no action

Executive Director's Report – Tanja Battle

- T.J.A. Directed GDNA to offer Voluntary Surrender
- J.M.J. No action taken

Applications

- E.R.G. Pharmacist Reciprocity Denied application
- F.K.A. Pharmacist Reinstatement Table pending receipt of additional information
- M.E.S. Pharmacist Reinstatement Approved application
- N.G.C. Pharmacist Reinstatement Table pending receipt of additional information
- G.L. Wholesaler Pharmacy Refer to the Attorney General's office for discipline

Correspondences/Requests

- A.K. Medical Malpractice Report Close case with a letter of concern
- R.R. Medical Malpractice Report Table for further investigation
- L.A. Request to terminate probation Request approved
- L.J.H. Request for CE approval Request approved
- K.L.T. Request to reschedule appearance Request approved
- B.H.I. Notice of Discipline No action taken
- M.P. Notice of Discipline No action taken
- O.M. Notice of Discipline No action taken
- P.P. Notice of Discipline No action taken
- S.Y. Notice of Discipline No action taken
- S.P. Notice of Discipline No action taken
- W. Notice of Discipline No action taken
- R.C. Notice of Discipline No action taken
- P.S. Notice of Discipline No action taken
- B.T. Request for fee waiver Request denied
- C.C. Request for release of information Request to release application information approved
- A.E.G. Request to lift consent order Request approved
- L.M.N. Request to lift consent order Request approved
- T.R.S. Request to lift consent order Request approved
- W.P. Outstanding fine No action taken
- M.M. Request for exemption Request denied

Applications

- K.M.W. Denied Pharmacy Technician Overturn denial and approve for registration
- D.R.G. Pharmacy Technician Denied registration
- Stacey K. Sites Pharmacy Technician Approved for registration
- Octavia N. Wilson Pharmacy Technician Approved for registration
- Laura P. Strovinskas Pharmacy Technician Approved for registration

- | | | |
|--------------------|---------------------|---------------------------|
| • Jasmin B. Chance | Pharmacy Technician | Approved for registration |
| • F.D.R. | Pharmacy Technician | Denied registration |
| • C.V.G. | Pharmacy Technician | Denied registration |

Bill Prather seconded and the Board voted unanimously in favor of the motion.

Ms. Battle reported that 96 individuals are currently scheduled to take the practical examination at Mercer University in March.

Chris Jones 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, examinations, investigative reports and the Assistant Attorney General’s report. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

- January practical examination

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

Open Session

There being no further business to discuss, the meeting was adjourned at 4:42 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, March 9, 2016 at 9:00 a.m. at Mercer University College of Pharmacy, 3001 University Drive, Atlanta, GA 30341.

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