

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, N.W. 36th Floor
Atlanta, GA 30303
April 15, 2015
9:00 a.m.

The following Board members were present:

Laird Miller, Chairperson
Mike Faulk, Vice-Chairperson
Vicki Arnold
Jim Bracewell
Chris Jones (*departed @ 4:03 p.m.*)
Tony Moye
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:

Joe Bitterman, Pharmacy Creations
Frances Cullen
Octavia Parks
Natalie Parks
Ken Pettengill
David Smith, Carie Boyds Prescription Shop
Scott Biddulph, Target
Sonya Nelson
John Sisto, ESI
Jimmy England, Walgreens
Helen Sloat, Kaiser, Hemophilia of Georgia
Kallarin Mackey, GHA
Andy Freeman, GPhA
John Rocchio, CVS Health
Scott Lindsay, CAPS
Stephen Snow, BSL

Chairperson Miller established that a quorum was present and called the meeting to order at 9:05 a.m.

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

Executive Session

Attorney General's Report – Janet Wray

- Central Fill Pharmacies

Appearances

- P.C.
- N.N.P.
- K.P.

- C.B.P.S.

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

Public Rules Hearing

Chairperson Miller called the public hearing to order at 11:00 a.m.

Rule 480-35-.02 Pharmacist Certification

No comments or written responses were received.

Chris Jones made a motion to adopt Rule 480-35-.02 Pharmacist Certification. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Rule 480-25-.01 Definitions.Amended

No comments or written responses were received.

Jim Bracewell made a motion to adopt Rule 480-25-.01 Definitions.Amended. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Rule 480-25-.08 Equipment.Amended

No comments or written responses were received.

Mike Faulk made a motion to adopt Rule 480-25-.08 Equipment.Amended. Chris Jones seconded and the Board voted unanimously in favor of the motion.

The hearing adjourned at 11:05 a.m.

Open Session

Chairperson Miller welcomed the visitors.

Approval of Minutes

Jim Bracewell made a motion to approve the Public Session and Executive Session minutes for the March 18, 2015 meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Ratifications

Bill Prather 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 Waiver/Variance from Egalet U.S., Inc.

Bill Prather made a motion to grant the petition noting the change from wholesaler to manufacturer. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Athens Regional Oncology Pharmacy-Athens

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

Petition for Rule Waiver/Variance from Wellstar Health System, Inc.

Chris Jones made a motion to respond by stating that it is suggested they withdraw the petition as there is no applicable rule to be waived. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance from Courtney Walker

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

Correspondence from Waqas A. Gill, PHI-016969

The Board considered this correspondence requesting full accreditation or at least 75% of the hours that will be worked. Mike Faulk made a motion to grant the allowance of one (1) credit hour for every two (2) hours worked. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Patricia Morrissey

The Board considered this correspondence asking if the Board offers a military discount for the license transfer application/fee process. Jim Bracewell made a motion to direct staff to respond by stating that there is no current authority that would allow the Board to make that distinction. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Pamela J. Riggio

The Board considered this correspondence asking when it will draft rules regarding FDA registered 503B Human Drug Compounding Outsourcing Facilities. Chris Jones made a motion to direct staff to respond by stating that this has been brought to the Board's attention; however, at this time there is no specific timeframe as to when the Board will draft rules regarding this matter. Tony Moye seconded and the Board voted unanimously in favor of the motion.

Correspondence from Kimberly Vitulli

The Board considered this correspondence asking if a license is required for call center activities. Chris Jones made a motion to direct staff to respond to by stating that Ms. Vitulli did not provide enough information regarding the matter for the Board to appropriately respond to her inquiry. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Mary Lou Fleming, ACHC

The Board considered this correspondence requesting to know if a decision had been reached regarding the ACHC's presentation before the Board in December 2014. At that meeting the Board had voted to table its decision. Bill Prather made a motion to direct staff to respond by stating that the Board reconsidered the request regarding ACHC's Specialty Pharmacy Accreditation program, but at this time, it is denying the request as there has not been sufficient information received in order for the program to be approved. However, Ms. Fleming is more than welcome to resubmit the request with additional information for the Board to consider. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen gave an update on the following legislative matters:

- House Bill 1 Medical Cannabis: This bill passed. No rule by the Board is needed.
- House Bill 47 amended to Senate Bill 194: Allows early refills of ophthalmic products under certain conditions. The Board will need to promulgate a rule regarding this matter.
- House Bill 195 Biosimilars: Allows substitutions of interchangeable biological products. This bill did not pass. Identical to Senate Bill 51.

- House Bill 211 Annual Drug Update. This bill passed. No rule by the Board is needed.
- House Bill 349: Gives Physicians Assistants the ability to prescribe any C-II controlled substance. This bill did not pass.
- House Bill 362 amended to Senate Bill 126: Allows schools to obtain Levalbuterol/Albuterol. This bill passed.
- House Bill 416: Pharmacists and all practitioners designated Doctor to wear name badges and when using any identifier to include their educational degree. This bill passed. The Board will need to promulgate a rule regarding this matter.
- House Bill 470 Pharmacy Audit Bill of Rights – MAC Pricing: This bill passed. The Board will need to promulgate a rule regarding this matter.
- House Bill 504 Vaccines-Immunization: This bill passed. The Board will need to promulgate a rule regarding this matter.
- House Bill 511: Allows pharmacy technicians to load RAMS machines. This bill passed. The Board will need to promulgate a rule regarding this matter.
- House Bill 569 Licensure of Durable Medical Equipment Suppliers by Board of Pharmacy: Held in Committee until next year.
- House Bill 588: Places restrictions on pharmacy sales of Pseudoephedrine. Held in Committee until next year.
- Senate Bill 51 Biosimilars: Allows substitutions of interchangeable biological products. This bill passed. The Board will need to determine whether or not it needs to promulgate a rule or merely rely on the law.
- Senate Bill 115: Gives Physicians Assistants the ability to prescribe C-II Hydrocodone. Held in Committee until next year.
- Senate Bill 126 Department of Public Health to regulate Auto-injection Epinephrine in Emergency Public Access Stations: Allows prescribing of Albuterol for schools. This bill passed. The Board will need to promulgate a rule regarding this matter.

Following Mr. Allen’s report, Chairperson Miller made assignments for board members and staff to address the matters that required rules. Those assignments were as follows:

HB416	Rick Allen
HB504	Janet Wray and Anil Foreman
SB194	Vicki Arnold and Bob Warnock
SB51	Mike Faulk and Jim Bracewell
SB126	Tony Moye and Laird Miller
HB511	Bill Prather and Chris Jones

Mr. Allen reported that he has been appointed to the National Methamphetamine Pharmaceutical Initiative Advisory Committee of the Office of National Drug Control Policy. The National Advisory Committee for NMPI includes four Federal and six state and local representatives. Director Allen is one of those six representatives. The Board congratulated Director Allen on this appointment and recognition of his considerable expertise.

Lastly, Mr. Allen reported that GDNA has received the appropriate funds to continue the PDMP program.

Attorney General’s Report – Janet Wray

No report.

Executive Director's Report – Tanja Battle

Ms. Battle reported that at the Board's March 2015 meeting, Ambrosia Treatment Center submitted a request to be approved as a treatment provider for the Board. The Board voted to request additional information. Mike Long, Ambrosia Treatment Centers, stated that the additional information was overnighted to the Board office, but it has not made it yet. Ms. Battle hoped to have this information prior to the end of the meeting for the Board to consider.

In regards to renewals, Ms. Battle reported that pharmacy technicians and facilities are currently renewing. She stated that renewal notices have been emailed to all license holders and registrants that have a valid email address on file. She also stated that a list of license holders and registrants that do not have a valid email address on file has been requested from the vendor so that a hard copy of the renewal notice can be sent via regular mail.

Mr. Prather requested the status on the rule change regarding security paper. Ms. Wray responded by stating that she is currently working with Ms. Foreman on a draft, but it is not yet in an acceptable form for the Board to vote to post.

Miscellaneous

Bill Prather made a motion to post Rule 480-37-.02 Licensure. Chris Jones seconded and the Board voted unanimously in favor of the motion.

480-37-.02 Licensure

(a) In order to install or operate a RAMS, a Georgia licensed pharmacy must make application for licensure to the Board on a form approved by the Board, and pay a fee. No person other than an approved licensed pharmacy may install or operate a RAMS. Each location having a RAMS must have a separate license from the Board. If more than one licensed pharmacy operates a RAMS at the same skilled nursing facility or hospice, each licensed pharmacy must maintain a registration at the skilled nursing facility or hospice. A Georgia licensed pharmacy that has paid a fee for one RAMS location will not be required to pay fees for the additional locations.

(b) Licenses are renewed for two years and expire on June 30th of each odd-numbered year and may be renewed upon the payment of the required fee and the filing of an application for renewal. If the application for renewal is not made and the fee paid before September 1st of the odd-numbered year, the license shall lapse and shall not be renewable except by application for reinstatement.

~~(b)~~(c) A Georgia licensed pharmacy may only use the RAMS at a skilled nursing facility or hospice licensed as such pursuant to O.C.G.A. T. 31, Ch. 7, that does not have an on-site licensed pharmacy.

~~(e)~~(d) The Pharmacist-in-Charge (PIC) for a licensed pharmacy shall be considered the PIC for each separate license to operate a RAMS at a skilled nursing facility or hospice.

~~(d)~~(e) The RAMS must collect, control, and maintain all transaction information.

Chris Jones made a motion to post Rules 480-15-.02 Registration of Pharmacy Technicians, 480-6-.01 Pharmacy Licenses.Amended, 480-6-.02 Nonresident Pharmacy Permit, 480-7-.01 Manufacturer's Permit, 480-7-.03 Drug Wholesale Distribution Licensing Requirements, 480-7-.05 Reverse Distributors, 480-8-.02 Registration, 480-18-.02 Licensure and Registration, 480-33-.02 Licensure and Registration.Amended, and 480-49-.01 Federal Student Loan Default. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

A motion was made by Mike Faulk, seconded by Bill Prather, and the Board voted that the formulation and adoption of these amendments do 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.

Miscellaneous

The Board discussed having a meeting of multiple days to address issues that have arisen due to changes in legislation.

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, Jim Bracewell, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, Bill Prather, and Bob Warnock.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

- Discussed Third Party Logistics (3PL's) providers
- Discussed FDA regulations vs. Georgia regulations
- E.I.
- F.I.
- F.I.
- M.C.P.
- A.H.P.I.

Applications

- D.D.W.
- S.G.B.
- A.N.B.
- S.R.J.
- K.S.G.
- M.B.C.
- L.T.E.
- V.M.

Cognizant's Report – Mike Faulk

- GDNA Case #T-31319
- GDNA Case #A-15-06
- GDNA Case #A-15-07
- GDNA Case #A-15-08
- GDNA Case #B-31182
- GDNA Case #A-31320
- GDNA Case #A-31013
- GDNA Case #A-31405
- GDNA Case #B-31363
- GDNA Case #B-31366
- GDNA Case #B-31421

- GDNA Case #B-31432
- GDNA Case #B-31298
- GDNA Case #B-31399

Attorney General’s Report – Janet Wray

Ms. Wray presented the following cases:

- C.M.S.
- J.D.C.

Executive Director’s Report – Tanja Battle

- N.D.P.
- O.P.O.
- N.G.
- M.N.
- E.P.S.
- C.F.S.
- A.P.

Miscellaneous

- Eric Lacefield, Deputy Director, discussed the March examination with the Board.

Applications

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

Correspondences/Requests

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

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

Open Session

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

Attorney General's Report – Janet Wray

- The Board received advice from Ms. Wray regarding Central Fill Pharmacies.

Appearances

- | | | |
|------------|------------------------------|---|
| • P.C. | Denied Non-Resident Pharmacy | Overturn denial and approve for registration |
| • N.N.P. | Revoked Pharmacy Tech | Schedule D.L. to meet with the Board |
| • K.P. | Denied Pharmacist Applicant | Table pending receipt of additional information |
| • C.B.P.S. | Denied Non-Resident Pharmacy | Overturn denial and approve for registration |

Georgia Drugs and Narcotics Agency – Rick Allen

- The Board received advice from Ms. Wray regarding Third Party Logistics (3PL's) providers
 - Discussed FDA regulations vs. Georgia regulations: No action taken
- | | | |
|------------|-----------------------|---|
| • E.I. | Wholesaler Pharmacy | Withdraw application and refund application fee |
| • F.I. | Wholesaler Pharmacy | Withdraw application and refund application fee |
| • F.I. | Wholesaler Pharmacy | Withdraw application and refund application fee |
| • M.C.P. | Non-Resident Pharmacy | Denied registration |
| • A.H.P.I. | Non-Resident Pharmacy | Denied registration |

Applications

- | | | |
|------------------------|---------------------|---|
| • D.D.W. | Pharmacy Technician | Denied registration |
| • S.G.B. | Pharmacy Technician | Denied registration |
| • Ali N. Butt | Pharmacy Technician | Approved registration |
| • Stephanie R. Johnson | Pharmacy Technician | Approved registration |
| • K.S.G. | Pharmacy Technician | Table pending receipt of additional information |
| • M.B.C. | Pharmacy Technician | Denied registration |
| • L.T.E. | Pharmacy Technician | Denied registration |
| • V.M. | Pharmacy Technician | Table pending receipt of additional information |

Cognizant's Report – Mike Faulk

- GDNA Case #T-31319 Revoke technician registration
- GDNA Case #A-15-06 Accept Private Interim Consent Order
- GDNA Case #A-15-07 Accept Private Interim Consent Order
- GDNA Case #A-15-08 Accept Public Interim Consent Order
- GDNA Case #B-31182 Close case with no action
- GDNA Case #A-31320 Close case with no action
- GDNA Case #A-31013 Schedule for an investigative interview
- GDNA Case #A-31405 Refer to the Attorney General's office
- GDNA Case #B-31363 Table pending receipt of additional information

- GDNA Case #B-31366 Close case with no action
- GDNA Case #B-31421 Close case with no action
- GDNA Case #B-31432 Close case with letter of concern
- GDNA Case #B-31298 Close case with letter of concern
- GDNA Case #B-31399 Close case with letter of concern

Attorney General’s Report – Janet Wray

Ms. Wray presented the following cases:

- C.M.S. Approve change of location and issue with letter of concern
- J.D.C. Close case with letter of concern

Executive Director’s Report – Tanja Battle

- N.D.P. Non-Resident Pharmacy Approved registration
- O.P.O. Correspondence No action taken
- N.G. Request regarding roster history Request denied
- M.N. Appearance request Directed staff to respond by stating that, based on the information submitted, it does not meet the requirements.
- E.P.S. Request regarding intern hours Request denied
- C.F.S. Correspondence Directed staff to respond by referring the individual to the appropriate code section
- A.P. Request for information regarding A.P. Request denied

Miscellaneous

- Eric Lacefield, Deputy Director, discussed the March examination with the Board. The Board recommended rescheduling the August 2015 meeting/exam date and location at South University to August 5th and 6th at Philadelphia College of Osteopathic Medicine (PCOM).

Applications

- Breane A. Charles Pharmacist Cert of DTM Approved application
- Darshini J. Mehta Pharmacist Cert of DTM Approved application
- Lisa M. Woolard Pharmacist Cert of DTM Approved application
- Naomi Y. Yates Pharmacist Cert of DTM Approved application
- Nicole M. West Pharmacist Cert of DTM Approved application
- Mollie L. Allen Pharmacist Applicant Approved application
- Radina Raytcheva Pharmacist Applicant Approved application
- Sohini H. Veean Pharmacist Applicant Approved application
- Timothy Kyburz Pharmacist Applicant Approved application
- Brian Fernandez Pharmacist Applicant Approved application
- P.J.C. Pharmacist Applicant Denied application
- C.H. Non-Resident Pharmacy Table pending receipt of additional information

Correspondences/Requests

- D.V.D. Request regarding intern Request denied

	hours	
• F.H.P. and T.M.C.	Request for refund	Request denied
• S.Y.C.P.M.I.	Correspondence	For informational purposes only
• K.L.A.	Supervising pharmacist request	Approved C.D.M.
• S.H.I.	Correspondence	Refer to GDNA
• D.H.S.	Correspondence	Directed staff to respond by stating that until a completed application is received by our office, the Board is unable to make a determination regarding this matter. It is up to the facility as to who is considered an "owner".
• C.P.	Request for exemption	Request approved
• W.P.N.	Request for use of pneumatic tube system	Request approved with stipulations
• S.R.H.	Remote Order Entry	Denied

Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, May 13, 2015 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.

The Board meeting adjourned at 4:30 p.m.

Minutes recorded by Brandi P. Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director