

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
May 10, 2017
8:30 a.m.

The following Board members were present:

Chris Jones, President
Bob Warnock, Vice-President (*departed @ 11:20 a.m.*)
Vicki Arnold
Mike Faulk
Lisa Harris
Laird Miller
Bill Prather
Jim Bracewell

Staff present:

Tanja Battle, Executive Director
Rick Allen, Director, GDNA
Janet Wray, Senior Assistant Attorney General
Max Changus, Assistant Attorney General
Anil Foreman, Attorney
Brandi Howell, Business Support Analyst I

Visitors:

Lindsay Wall
Laurie King
Jim Bartling
J. Daniel Parrish
Stephen Snow
Donna Hatcher, GHA
Ryan Loke, McKesson
Greg Reybold, GPhA
Kimberly Ramseur, MAG
Nancy Smith, Fannin Regional Hospital
John Vanderpool
Drew Umberger, Cardinal Health
Cecil Cordle, CVS Pharmacy
Diane Sanders, Kaiser Permanente
Mike King, Publix
Jesse Weathington, GAMES
Sonya Nelson, Walmart

President Jones established that a quorum was present and called the meeting to order at 8:30 a.m.

Jim Bracewell made a motion and Lisa Harris 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

Cognizant's Report – Bob Warnock

- GDNA Case # A-17-06
- GDNA Case # T-32151
- GDNA Case # T-32155
- GDNA Case # T-32002

- GDNA Case # T-32165
- GDNA Case # B-32046
- GDNA Case # B-32064
- GDNA Case # A-32152
- GDNA Case # B-32132
- GDNA Case # B-32024
- GDNA Case # B-32138

Appearances

- L.M.W.
- L.K.

Applications

- A.P.M.
- A.T.S.
- A.D.W.
- A.R.P.
- E.C.F.
- C.H.S.

Attorney General's Report - Janet Wray

Ms. Wray presented the following consent orders:

- M.P.
- A.W.B.
- D.S.G.
- H.W.
- G.M.
- S.E.W.
- M.P.

Mr. Changus discussed the following case:

- P.P.S.

Mr. Changus discussed the following individuals:

- C.C.A.

Appearance

- J.D.P.

Georgia Drugs and Narcotics Agency - Rick Allen

Director Allen presented a report regarding CSU inspections.

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 from Nancy Smith, Pharmacy Director at Fannin Regional Hospital: Ms. Smith introduced herself and thanked the Board for the opportunity to speak to its members. Ms. Smith explained that she created adhesive pediatric dosing stickers for emergency medications. She stated that she wanted to make sure the Board would support these labels as auxiliary labels. Ms. Smith passed around labels for the Board to view. After discussion by the Board, President Jones stated that he considers what she presented to be a dosing label. Ms. Smith asked if it is considered a dosing label, is the Board okay with affixing it directly on the box? She stated the alternative would be to put it in a bag; however, she believes that creates more confusion. President Jones stated this seems to be more of a hospital policy as it is not going to a patient and is being used in emergency situations. He suggested she contact the Joint Commission and the hospital's legal counsel regarding this matter to see if they are comfortable with the labels. President Jones also suggested using a barcode for such. Ms. Smith responded that was an excellent idea and that the purpose of her request was to make sure the Board did not consider this as misleading or misbranding.

Approval of Minutes

Bill Prather made a motion to approve the Public Session minutes from the April 12, 2017 meeting. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to approve the Executive Session minutes from the April 12, 2017 meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

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

Petition for Rule Waiver from Ultragenyx Pharmaceutical, Inc. and Petition for Rule Waiver from Impax Laboratories, Inc.

Laird Miller made a motion to approve both rule waiver petitions. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Susan Massoud

The Board considered this correspondence regarding pharmacy consultations. Bill Prather made a motion to direct staff to respond by stating the Board suggests Ms. Massoud review O.C.G.A. § 26-4-4 and O.C.G.A. § 26-4-40(a) for more information regarding this matter. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Sean Reed

The Board considered this correspondence regarding MTM services. Bill Prather made a motion to direct staff to respond by stating the Board suggests Mr. Reed review O.C.G.A. § 26-4-4 and O.C.G.A. § 26-4-40(a) for more information regarding this matter. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Greg Reybold, GPhA

The Board considered this correspondence regarding this year's Georgia Pharmacy Convention. Mr. Reybold, who was present at the meeting, stated that he apologized for the invitation going out late this year. He added that this is a program the GPhA members are really interested in and would love to hear from the Board and GDNA as well.

Correspondence from Hank Rahe, Containment Technologies Group, Inc.

The Board considered this correspondence regarding Non-Compliance of CETA CAG-002-2006 Guide to the ISO 14644-1:2015(S) Standard. Laird Miller made a motion to direct staff to respond by stating the Board thanks him for the correspondence and will take this matter under advisement. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jacqueline von Zwehl, Scripps Safe

The Board viewed this correspondence for informational purposes only.

Georgia Drugs and Narcotics Agency - Rick Allen

No report.

Attorney General’s Report - Janet Wray

No report.

Executive Director’s Report - Tanja Battle

June Meeting: Ms. Battle reported that the June meeting will be held at the University of Georgia, College of Pharmacy, in Athens. She stated that for the July meeting, the Board will discuss all of the open session agenda items first so that the visitors do not have to wait.

Addiction Program Criteria: Ms. Battle stated that Mr. Prather received the information presented to the Board from Mr. Bartling. President Jones asked the board members to please review if they had not had a chance to do so yet and to submit any suggested changes to Ms. Battle.

Continuing Education Report: Report presented. Bill Prather made a motion to ratify the below named continuing education programs approved since the previous meeting. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Date of Program	Sponsoring Group	Program Title	Contact Person	CE Code	Date Notified
6/7/17 - 6/8/17	National Association of Drug Diversion Investigators	Southern Regional Conference	Adrienne Baker	2017-0004	Approved 5/2/17

Miscellaneous

Mike Faulk made a motion to post Rule 480-27-03 Records of Dispensing. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

480-27-.03 Records of Dispensing.

(1) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for two years and shall include, but not be limited to:

- (a) Quantities dispensed;
- (b) Date of dispensing;
- (c) ~~Serial~~ Prescription number (or equivalent if an institution);
- (d) The identification of the pharmacist responsible for dispensing;
- (e) Documentation of satisfaction of state requirements for drug product selection;
- (f) Records of refills to date to include date(s) of refills, and identification of pharmacist(s) dispensing refills.

(2) Effective May 1, 2019, all pharmacies licensed by the Board must conduct a physical inventory of all controlled substances on hand, and such physical inventory shall be taken biennially on May 1st of the odd-numbered year.

(a) The record of the inventory may be stored electronically or on paper, but the record shall be made available for inspection within two (2) business days of a request made by the Board, its authorized representative, or an agent of the Georgia Drugs and Narcotics Agency (GDNA).

(b) The inventory must conform to all DEA inventory requirements and must be signed and dated by the pharmacist conducting the inventory. The date on which the inventory was made becomes the new biennial inventory date for that licensee and the controlled substances must be inventoried biennially thereafter.

(c) All records of biennial inventories must be maintained for a minimum of two (2) years from the date that the biennial inventory is completed.

(3) Effective May 1, 2019, all pharmacies licensed by the Board must maintain a perpetual inventory of all controlled substances received, stored, distributed and dispensed by the pharmacy.

(a) If there is a discrepancy in the perpetual inventory of controlled substances, a pharmacist must perform a personal reconciliation within seven (7) days to verify the accuracy of the inventory.

(b) If this is considered a significant discrepancy, the discrepancy shall be reported to GDNA using the DEA Form 106. A “significant discrepancy” shall mean an amount consistent with what is considered to be a significant loss as explained in the Pharmacist’s Manual of the U.S. Drug Enforcement Administration (DEA).

(c) Only a pharmacist can reconcile or correct a perpetual inventory.

(d) A reconciliation log must be created which contains the printed name, license number, and signature of both the pharmacist doing the reconciliation or correction along with the pharmacist verifying the reconciliation or correction. Each entry on the log must be dated and accompanied by an explanation for the reconciliation or correction.

(e) All perpetual inventories and reconciliation logs must be maintained for a minimum of two (2) years and be available for inspection within two (2) business days of a request made by the Board, its authorized representative, or an agent of the Georgia Drugs and Narcotics Agency (GDNA).

The Board discussed Chapter 480-7B Durable Medical Equipment. President Jones thanked Ms. Foreman for all of the hard work she has done with drafting this rule. He requested each member review and if anyone has any additional comments to please email those to Ms. Battle.

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, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Attorney General’s Report – Janet Wray

The Board received legal advice from Ms. Wray regarding Rule 480-37-.02 Licensure.

Executive Director’s Report - Tanja Battle

- NAPLEX denials

Applications

- C.A.K.
- C.A.
- P.L.S.
- L.N.
- B.A.A.B.

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

Correspondences/Requests

- A.H.C.
- C.
- N.L.P.
- C.V.S.S.
- A.O.
- B.S.P.S.I.
- F.S.S.P.
- E.P.
- C.V.S.C.
- B.R.
- R.U.P.
- S.E.H.
- I.R.
- M.V.
- A.G.

- H.T.L.
- P.D.U.
- P.N.V.
- R.M.R.
- J.W.T.
- J.B.O.
- T.I.N.
- T.T.H.L.
- A.H.C.

Miscellaneous

- Change of ownership applications

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

Open Session

Bill Prather made a motion to adopt the following policy regarding a change in ownership or change in location application:

If a change of ownership or change in location is submitted during the period in which the same facilities are in renewal (push-period), the status shall go into Active-Renewal Pending status until the application is complete. In these instances, where a change of ownership or change in location application fee is submitted, it will not be necessary for the entity to pay the renewal fee.

Laird Miller seconded and the Board voted unanimously in favor of the motion.

In regards to Rule 480-27-.03 Records of Dispensing, a motion was made by Jim Bracewell, seconded by Mike Faulk, 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 proposed 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.

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

Cognizant’s Report – Bob Warnock

- GDNA Case # A-17-06 Accept Private Interim Consent Order
- GDNA Case # T-32151 Revoke Technician Registration
- GDNA Case # T-32155 Accept Voluntary Surrender
- GDNA Case # T-32002 Accept Voluntary Surrender
- GDNA Case # T-32165 Accept Voluntary Surrender
- GDNA Case # B-32046 Close with a letter of concern
- GDNA Case # B-32064 Close with no action
- GDNA Case # A-32152 Misfill Policy #2

- GDNA Case # B-32132 Misfill Policy #1
- GDNA Case # B-32024 Close with no action
- GDNA Case # B-32138 Misfill Policy #1 for the pharmacist/Misfill Policy #3 for the pharmacy

Appearances

- L.M.W. Denied Pharmacist Reciprocity Uphold denial
- L.K. Request to discuss reinstatement Refer to the Department of Law

Applications

- Alecia P. Minton Pharmacy Technician Approved for registration
- Aspen T. Smith Pharmacy Technician Approved for registration
- Angela D. Wilkins Pharmacy Technician Approved for registration
- Ashlee R. Palmer Pharmacy Technician Approved for registration
- E.C.F. Pharmacy Technician Table pending receipt of additional information
- C.H.S. Pharmacy Technician Approved for renewal

Attorney General’s Report - Janet Wray

Ms. Wray presented the following consent orders:

- M.P. Private Consent Order accepted
- A.W.B. Private Consent Order accepted
- D.S.G. Private Consent Order accepted
- H.W. Private Consent Order accepted
- G.M. Private Consent Order accepted
- Sheila E. Welton Public Consent Order accepted
- M.P. Private Consent Order accepted

Mr. Changus discussed the following case:

- P.P.S. Update provided

Mr. Changus discussed the following individuals:

- C.C.A. The Board directed staff to send the letter drafted by the Department of Law to the complainant.

Appearance

- J.D.P. Request to discuss reinstatement Denied request

Georgia Drugs and Narcotics Agency - Rick Allen

Director Allen presented a report regarding CSU inspections.

Attorney General’s Report – Janet Wray

The Board received legal advice from Ms. Wray regarding Rule 480-37-.02, Licensure.

Executive Director’s Report - Tanja Battle

NAPLEX denials: In response to the requests to the Board to attempt the NAPLEX after three (3) failures, the Board directed staff to send a response stating, *“Because you have not demonstrated the minimum level of competency to practice in the State of Georgia, the Board voted to deny your request. You do have the option to become licensed in another state and apply for licensure by reciprocity in Georgia.”*

Applications

- | | | |
|-------------------------|--------------------------|--|
| • Chelsea A. Keedy | Pharmacist Intern | Approved application |
| • Christine Agudosi | Pharmacist Intern | Approved application |
| • Pierra L. Smith | Pharmacist Intern | Approved application |
| • L.N. | Pharmacist Intern | Table pending receipt of additional information |
| • Bernard A.A. Britton | Temporary Pharmacist | Approved to sit for the examination |
| • H.S. | Pharmacist Examination | Denied application |
| • A.K.E. | Pharmacist Reinstatement | Table pending receipt of additional information |
| • John L. Vanderpool | Pharmacist Renewal | Approved renewal |
| • Thora A. Brown | Pharmacist Renewal | Approved renewal |
| • Deborah L. Schaff | Pharmacist Renewal | Approved renewal |
| • Exactus Pharm Sol | Non-Resident Pharmacy | Approved renewal |
| • Lee Silsby Com Phar | Non-Resident Pharmacy | Approved renewal |
| • MedQuest Pharmacy | Non-Resident Pharmacy | Approved renewal |
| • Wellpartner, Inc. | Non-Resident Pharmacy | Approved renewal |
| • Wickliffe Vet Pharm | Non-Resident Pharmacy | Approved renewal |
| • Irmat Pharmacy | Non-Resident Pharmacy | Approved application |
| • A.Z.P. | Wholesaler Pharmacy | Refer to the Department of Law |
| • Capital Wholesale | Wholesaler Pharmacy | Approved renewal |
| • C.H. | Wholesaler Pharmacy | Approved renewal with a letter of concern |
| • Lundbeck, LLC | Wholesaler Pharmacy | Approved renewal |
| • Total Pharmacy Sup | Wholesaler Pharmacy | Approved renewal |
| • McKesson Spec Care | Wholesaler Pharmacy | Approved renewal |
| • McKesson Spec Dis | Wholesaler Pharmacy | Approved renewal |
| • Prodigy Health Sys | Wholesaler Pharmacy | Approved renewal |
| • Capital Returns, Inc. | Reverse Distributor | Approved renewal |
| • R.A.I.P. | Retail Pharmacy | Board directed staff to send response regarding information presented to the Board at its May meeting. |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |
| • Costco Pharmacy | Retail Pharmacy | Approved renewal |

Correspondences/Requests

- | | | |
|------------|----------------------|---|
| • A.H.C. | Notice of discipline | No action |
| • C. | Notice of discipline | No action |
| • N.L.P. | Notice of discipline | Table pending receipt of additional information |
| • C.V.S.S. | Notice of discipline | No action |

• A.O.	Notice of discipline	No action
• B.S.P.S.I.	Notice of discipline	No action
• F.S.S.P.	Notice of discipline	No action
• E.P.	Notice of discipline	No action
• C.V.S.C.	Notice of discipline	No action
• B.R.	Notice of discipline	Table pending receipt of additional information
• R.U.P.	Notice of discipline	Letter of concern
• S.E.H.	Notice of discipline	No action
• I.R.	Notice of discipline	No action
• M.V.	Notice of discipline	No action
• A.G.	Remote Order Entry	Approved
• H.T.L.	Req to take NAPLEX a 6 th attempt	Denied request
• P.D.U.	Req to take NAPLEX a 4 th attempt	Denied request
• P.N.V.	Req to take NAPLEX a 4 th attempt	Denied request
• R.M.R.	Correspondence	Board directed staff to forward information provided to the GBI
• J.W.T.	Request for appearance	Request approved
• J.B.O.	NAPLEX score transfer	Board directed staff to respond by stating the individual may apply by reciprocity
• T.I.N.	Request to take MPJE a 6 th Attempt and request to extend application	Denied request
• T.T.H.L.	Request for extension	Approved three month extension
• A.H.C.	Req to take NAPLEX a 4 th attempt	Denied request

Miscellaneous

- Change of ownership applications

Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Cindy Shepherd, MatchRx: Ms. Battle stated that Ms. Shepherd is requesting a meeting with the Board in June. The Board suggested she submit additional information regarding how the facility adheres to track and trace first and then, once reviewed by the Board, it will consider her request for an appearance.

Ms. Battle reported that she has been meeting with the Department of Public Health (DPH) about the delegate issue and sharing that information with DPH. Ms. Battle explained this would increase the licensee/registrant population significantly and that there currently were approximately 65,000 licensees/registrants between the Board of Pharmacy and the Board of Dentistry. They are working on making the registration process as simple as possible and are gearing towards an online application system. The secure and verifiable document, however, will need to be collected. Mr. Miller asked what the effective date will be date to register all these delegates. Ms. Wray responded that the law goes in effect July 1. Ms. Battle stated that she is working with DPH to facilitate a smooth transition and implementation.

There being no further business to discuss, the meeting was adjourned at 2:03 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, June 7, 2017 at 9:00 a.m. at the University of Georgia, College of Pharmacy, 250 W Green St, Athens, GA 30602.

Minutes recorded by Brandi Howell, Business Support Analyst I

Minutes edited by Tanja D. Battle, Executive Director