

GEORGIA BOARD OF PHARMACY
South University College of Pharmacy
709 Mall Blvd
Savannah, GA 31406
January 14, 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

Staff present:

Tanja Battle, Executive Director
Rick Allen, GDNA (*via conference call*)
Janet Wray, Senior Assistant Attorney General
Anil Foreman, Legal Officer
Brandi Howell, Business Operations Specialist

Visitors:

Michael Melroy, Memorial Hospital GSHP
Chalet Conrad
Jim Bartling
Brandon T. Wrights
Jeffery L. Joslin
Jennifer Boykin, SGHS
Jennifer Lewis, SGHS
Amanda Roberson, ElderCare
Stephanie Kirkland, ElderCare
Carrie Mott, Kroger
Clinton Cain, Kroger
Trey Freeman, Kroger
Tim Tyre, SGHS
Joey Sturgeon, Silvergate
Kim Ragan, Fred's Pharmacy
Mac Lofton, Fred's Pharmacy
Sophia Novack, Rite Aid
Mike King, Publix
Diane Sanders, Kaiser Permanente
John Fullard, Maximum Rx Credit
Stephen Georgeson, GACDS
Young Chang, Walgreens
Brian Robinson, Walgreens
John Rocchio, CVS
Greg Reysold, GPhA
Stan Jones, Kaiser Permanente
Lori Hensic, Kaiser Permanente
Michael Crooks, Alliant Quality / GMCF

President Faulk established that a quorum was present and called the meeting to order at 9:20 a.m.

Bill Prather made a motion and Jim Bracewell 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, and Bill Prather.

Executive Session

Appearances

- C.C.
- B.T.W.
- J.L.J.

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

Public Rules Hearing

President Faulk called the public hearing to order at 11:00 a.m.

Rule 480-16-.03 Return of Previously Dispensed Drugs or Devices

No comments or written responses were received.

Rule 480-34-.07 Hallucinogens

No comments or written responses were received.

Rule 480-37-.02 Licensure

Public comments from Michael Nole were received. Mr. Nole asked the Board about temporary licensure for those reciprocating from another state. He did not see where that issue was addressed in this rule. Mr. Miller commented that particular matter must be addressed in the law; and pointed out that this rule addresses RAMS.

No written responses were received.

Chapter 480-50 Drug Disposal and Authorized Collectors

No public comments were received. Written responses were received from Scott Brunner on behalf of Georgia Pharmacy Association (GPhA), Gregg Raduka on behalf of The Council on Alcohol and Drugs, and Bent Gay on behalf of Gayco Healthcare.

Rule 480-34-.04 Synthetic Cannabinoids

No comments or written responses were received.

Rule 480-8-.06 Drug Distribution and Control

No comments or written responses were received.

Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security

No comments or written responses were received.

Rule 480-10-.20 Required Notifications to the Board

Public comments from Lori Hensic, Kaiser Permanente, were received. Ms. Hensic commented that there was some concern about using the word “immediately” as some rules have definition and some do not. She stated that it may be helpful to have that incorporated so that there can be better compliance.

No written responses were received.

Rule 480-13-.06 Drug Distribution and Control

No public comments were received. A written response was received from Steve Georgeson on behalf of the Georgia Association of Chain Drug Stores.

Rule 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician

Public comments were received from Steve Georgeson, Georgia Association of Chain Drug Stores. Mr. Georgeson stated that he presented a letter to the Board at its last meeting regarding pharmacist supervision of pharmacy technicians. He stated those comments will tie in with Mr. Radduka's and GPhA's and will hopefully be considered. President Faulk responded that the comments will be considered.

A written response was received from Steve Georgeson on behalf of the Georgia Association of Chain Drug Stores.

Rule 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances

No comments or written responses were received.

Rule 480-18-.06 Drug Distribution and Control

No comments or written responses were received.

Rule 480-27-.03 Records of Dispensing

Public comments from Trey Freeman, Kroger, were received. Mr. Freeman stated that he understands this rule will be tabled and asked if there will be a revision for the public to look at. President Faulk stated yes. Mr. Freeman commented that it states on the rule notice that the Board decided these regulations would not cause any undue cost to any licensee and asked what kind of timetable would the Board looking at in making this effective. Mr. Miller commented that the goal was May 1st, but that can be changed. Mr. Freeman commented on perpetual inventory. Mr. Miller responded that everyone in the room knows that there are problems with drugs being diverted. He stated that the Board does not take this issue lightly and wants to address it the right way. Mr. Freeman commented that the language presented today is very aggressive and hopes that there can be a suitable compromise.

Public comments from Lori Hensic, Kaiser Permanente, were received. Ms. Hensic stated that within Kaiser, they really try to address this issue to minimize occurrences where medications are lost. She stated that Kaiser has done a number of different changes and wants to mention them in the spirit of coming up with a creative solution. President Faulk encouraged Ms. Hensic to put her comments and suggestions in writing and once received, the Board would be happy to take those into consideration.

Written responses were received from Richard Watson, Steve Georgeson on behalf of Georgia Association of Chain Drug Stores, Bent Gay on behalf of Gayco Healthcare, and Jeff Lurey on behalf of Georgia Pharmacy Association (GPhA).

Rule 480-33-.06 Drug Distribution and Control

No comments or written responses were received.

Bill Prather made a motion to adopt Rules 480-16-.03 Return of Previously Dispensed Drugs or Devices, 480-34-.07 Hallucinogens, 480-37-.02 Licensure, Chapter 480-50 Drug Disposal and Authorized Collectors, and 480-34-.04 Synthetic Cannabinoids. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

In the same motion, the Board voted to table Rules 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, Rule 480-13-.06 Drug Distribution and Control, 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Technician, 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances, 480-18-.06 Drug Distribution and Control, and 480-33-.06 Drug Distribution and Control.

Mr. Bracewell spoke to the members of the audience regarding controlled substance loss. He stated that as members of the public send in comments, he wanted to ask that it be included as to who shall be responsible for the theft, who should be carrying the responsibility and the oversight of these dangerous drugs. He feels the pharmacists in the corporate portion could really give the Board some suggestions on this matter.

The hearing was adjourned at 11:53 a.m.

Open Session

President Faulk welcomed the visitors.

Approval of Minutes

Chris Jones made a motion to approve the Public and Executive Session minutes for the December 16, 2015 meeting. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Petition for Rule Waiver – HLS Therapeutics (USA), Inc.

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

Petition for Rule Waiver – Biomune Company dba Ceva Biomune

Chris Jones made a motion to table the petition pending receipt of an amended application. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from MCM Vaccine Co.

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

Correspondence from Alexander Mathews, Animal Health Institute (AHI)

The Board viewed this correspondence for informational purposes only.

Correspondence from Christine Cassetta, Quarles & Brady, LLP

The Board considered this correspondence from Ms. Cassetta. In her letter, she states that she is trying to determine if utilizing a CMR is permissible when performed by pharmacists in the non-resident facility who may or may not be licensed by Georgia. Bill Prather made a motion to direct staff to respond by stating that a Georgia license would be required in order to do such and suggested she refer to O.C.G.A. § 26-4-4 Definition of “practice of pharmacy” for more information.

Correspondence from Ben Harvey, Neovia Logistics

The Board considered this correspondence from Mr. Harvey requesting to verify that there have been no changes relating to medical devices in the past year. Laird Miller made a motion to direct staff to respond to Mr. Harvey by confirming that there have been no changes relating to medical devices in the past year. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Tim Simpson, Seasons Hospice & Palliative Care

The Board considered this correspondence from Mr. Simpson requesting to know if any laws would prohibit nurses from taking receipt of and transferring medications from local pharmacies to a patient's place of residence in Georgia. Additionally, he requests to know if there are any laws regarding pick-up and transport of medications by medical providers in this jurisdiction. Lisa Harris made a motion to direct staff to respond to Mr. Simpson by stating that the Board suggests he consults with his own legal counsel for advice regarding this matter. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Martin Dix, Akerman, LLP

The Board considered this correspondence from Mr. Dix. In his email, he asks whether Georgia will require a non-resident drug wholesaler permit for intracompany transfers in light of the Drug Quality and Security Act's preemption of state law. Vicki Arnold made a motion to direct staff to respond by stating that in his email dated August 24, 2015 to Ms. Lori Breault, Director Rick Allen, GDNA, stated Georgia law requires that a pharmacy in this state must receive prescription drugs from a wholesale distributor licensed by the Board. Additionally, to receive drugs from a distributor not licensed by the Board is considered a felony violation of our law by the receiving pharmacy. Please be advised that the Board confirms this position. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency Open Session – Rick Allen

No report.

Attorney General's Report Open Session –Janet Wray

No report.

Executive Director's Report Open Session – Tanja Battle

Ms. Battle stated that the deadline to submit a voting delegate for the NABP meeting is January 31, 2016. The Board voted to table this matter until the end of the afternoon to allow time for additional consideration.

Miscellaneous

The Board discussed potential amendments to Rule 480-13-.05 Physical Requirements. Amended and Rule 480-10-.16 Security System Approval. The Board recommended tabling these two rules to allow for additional time to make the changes discussed.

Bill Prather made a motion to post Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Rule 480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel.

(a) In dispensing drugs, no individual other than a licensed pharmacist, intern or extern working under direct supervision of a licensed pharmacist shall perform or conduct those duties or functions which require professional judgment. It shall be the responsibility of the supervising pharmacist to ensure that no other employee of the pharmacy, excluding pharmacy interns or externs, performs or conducts those duties or functions which require professional judgment.

(b) For all prescription drug orders, it shall be the responsibility of the Pharmacist on duty at a facility to ensure that only a pharmacist or a pharmacy intern and/or extern under the direct supervision of a registered pharmacist provides professional consultation and counseling with patients or other licensed health care professionals and that only a pharmacist or a pharmacy intern or an extern under the direct supervision of a registered pharmacist accepts telephoned oral prescription drug orders or provides or receives information in any manner relative to prescriptions or prescription drugs.

(c) Registered pharmacy technicians and other pharmacy personnel, i.e. clerks, cashiers, observers, etc., in the prescription department shall be easily identifiable by use of a name badge or other similar means which prominently displays their name and the job function in which the personnel are engaging at that time. Any pharmacy personnel or other person present in the pharmacy department must be under the direct supervision of a licensed pharmacist.

(d) In the dispensing of all prescription drug orders:

(1) The pharmacist shall be responsible for all activities of any registered pharmacy technician in the preparation of the drug for delivery to the patient.

(2) The pharmacist shall be present and personally supervising the activities of any registered pharmacy technician at all times.

(3) When electronic systems are employed within the pharmacy, registered pharmacy technicians may enter information into the system and prepare labels; provided, however, that it shall be the responsibility of the pharmacist to verify the accuracy of the information entered and the label produced in conjunction with the prescription drug order.

(4) When a prescription drug order is presented for filling or refilling, it shall be the responsibility of the pharmacist to review all appropriate information and make the determination as to whether to fill the prescription drug order, and

(5) Any other function deemed by the Board to require professional judgment.

(e) The pharmacist to registered pharmacy technician ratio shall not exceed one pharmacist providing direct supervision of three registered pharmacy technicians. One of the three technicians must:

(1) Have successfully passed a certification program approved by the Board of Pharmacy;

(2) Have successfully passed an employer's training and assessment program which has been approved by the Board of Pharmacy; or

(3) Have been certified by the Pharmacy technician Certification Board.

(f) In addition to the utilization of three (3) registered pharmacy technicians, if one is certified, a pharmacist may be assisted by and directly supervise at the same time one (1) pharmacy intern, as well as one (1) pharmacy extern, and one (1) pharmacy observer.

(g) The board may consider and approve an application to increase the ratio in a pharmacy located in a licensed hospital. Such application must be made in writing and may be submitted to the Board by the pharmacist in charge of a specific hospital pharmacy in this state.

(h) No completed prescription drug order shall be given to the patient requesting same unless the contents and the label thereof shall have been verified by a registered pharmacist.

(i) The Board of Pharmacy may revoke or suspend the registration of a pharmacy technician for any of the grounds set forth in O.C.G.A. Sections 43-1-19 or 26-40-60. The revocation or suspension of the registration of a pharmacy technician is not a contested case under the Georgia Administrative Procedures Act, O. C.G.A. T. 50, Ch.13, and the technician is not entitled to a hearing, but the technician may be entitled to an appearance before the Board.

The Board discussed Rule 480-15-.06 Other Pharmacy Personnel and recommended section (8) reflect "no more than 40 hours". Bill Prather made a motion to post Rule 480-15-.06 Other Pharmacy Personnel. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Rule 480-15-.06 Other Pharmacy Personnel.

(1) Effective March 1, 2016, a pharmacy may permit pharmacy observers to shadow licensed pharmacists for the limited and exclusive purpose of education about the practice of pharmacy.

(2) Requirements. In order to be pharmacy observer, an individual must:

(a) Be at least seventeen (17) years old;

(b) Be currently enrolled in high school or in general education diploma preparation courses; and

(c) Not have been convicted of a felony and/or any offense that was related to drugs and have an attestation by the principal of his/her school or parent or guardian stating that the observer has neither been convicted of a felony or any offense that was related to drugs.

(3) Limitation of Duties. A pharmacy observer shall not perform any duties that require licensure as a pharmacist or pharmacy intern or registration as a pharmacy technician under the Georgia Pharmacy Practice Act (O.C.G.A. Title 26, Chapter 4) or the Rules of the Georgia Board of Pharmacy. It shall be the responsibility of the supervising pharmacist and the pharmacist-in-charge to ensure that no pharmacy observer performs or conducts those duties or functions that require licensure or registration under Georgia law or rules.

(4) Restriction of Access. A pharmacy observer shall not be present in the pharmacy for more than eight (8) hours per day and in no circumstance for more than forty (40) hours.

(5) Requirement of Direct Supervision. The supervising pharmacist shall be present and personally supervise the pharmacy observer at all times that the observer is in the pharmacy. The pharmacist to pharmacy observer ratio shall not exceed one pharmacist providing direct supervision of one pharmacy observer.

(6) Identification of Pharmacy Observers. The pharmacist-in-charge shall be responsible for ensuring that any pharmacy observer in the prescription department is easily identifiable by the use of a name badge or other similar means which prominently displays the observer's name and job title. The pharmacist-in-charge is responsible for ensuring that such a person wears or displays such identification at all times when the person is present in the prescription department.

(7) Professional Conduct. A pharmacy observer shall be subject to any confidentiality restrictions under state and/or federal law or regulation to which other pharmacy employees are subject. The pharmacist-in-charge shall conduct all training required to ensure that the pharmacy observer understands and complies with his/her obligations of confidentiality under state and federal law or regulation.

A motion was made by Chris Jones, seconded by Laird Miller, 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.

Chris Jones 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, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, and Bill Prather.

Georgia Drugs and Narcotics Agency – Rick Allen

- E.P.
- C.P.
- Discussed report of most dispensed drugs in Georgia from 2014-2015.

Cognizant's Report – Chris Jones

- GDNA Case # A-15-33
- GDNA Case # T-31603
- GDNA Case # T-31690
- GDNA Case # T-31680
- GDNA Case # T-31667
- GDNA Case # T-31618
- GDNA Case # T-31679
- GDNA Case # T-31668
- GDNA Case # A-31626
- GDNA Case # A-31567
- GDNA Case # A-31670
- GDNA Case # A-31568
- GDNA Case # A-31665

Executive Director's Report – Tanja Battle

- S.H.P.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

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

Applications

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

- F.L.I.
- M.P.

Correspondences/Requests

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

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

Open Session

Lisa Harris made a motion to nominate Bill Prather as the voting delegate on behalf of the Board at the upcoming NABP national meeting with Laird Miller being the alternate. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

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

Appearances

C.C.	Request to discuss reinstatement	Request approved
B.T.W.	Denied Pharmacy Technician	Overturn denial and approve for registration
J.L.J.	Request to discuss reinstatement	Request approved

Georgia Drugs and Narcotics Agency – Rick Allen

E.P.	Non-Resident Pharmacy	Denied application
C.P.	Non-Resident Pharmacy	No action taken

Discussed report of most dispensed drugs in Georgia from 2014-2015.

Cognizant’s Report – Chris Jones

GDNA Case # A-15-33	Accept Private Interim Consent Order
GDNA Case # T-31603	Accept Voluntary Surrender
GDNA Case # T-31690	Revoke technician registration

GDNA Case # T-31680	Revoke technician registration
GDNA Case # T-31667	Accept Voluntary Surrender
GDNA Case # T-31618	Revoke technician registration
GDNA Case # T-31679	Revoke technician registration
GDNA Case # T-31668	Accept Voluntary Surrender
GDNA Case # A-31626	Schedule for Investigative Interview
GDNA Case # A-31567	Refer to the Attorney General's office for discipline
GDNA Case # A-31670	Close case with letter of concern
GDNA Case # A-31568	Refer to the Attorney General's office for discipline
GDNA Case # A-31665	Refer to the Attorney General's office for discipline

Executive Director's Report – Tanja Battle

S.H.P.	Request for reinstatement	Request denied
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Attorney General's Report – Janet Wray

Ms. Wray discussed the following cases:

E.U.H.M.	No action taken
J.F.	No action taken
F.S.	No action taken
N.G.T.C.	No action taken

Applications

C.N.R.	Pharmacy Technician	Overturn denial and approve for registration
Christina L. Huether	Pharmacy Technician	Approved for registration
C.S.F.	Pharmacy Technician	Denied registration
K.M.W.	Pharmacy Technician	Denied registration
M.L.A.	Pharmacy Technician	Denied registration
Tiara S. Vinson	Pharmacy Technician	Approved for registration
Alina A. Dzyuba	Pharmacy Technician	Approved renewal
A.T.S.	Pharmacist Reciprocity	Approved to sit for the exam
B.R.P.	Pharmacist Reciprocity	Approved to sit for the exam
M.D.C.	Pharmacist Examination	Approved to sit for the exam
M.L.M.	Pharmacist Examination	Approved to sit for the exam
G.B.P.	Pharmacist Reciprocity	Approved to sit for the exam
L.K.A.A.	Pharmacist Reinstatement	Table pending receipt of additional information
S.B.	Pharmacist Reinstatement	Table pending receipt of additional information
J.F.O.	Pharmacist Interns	Approved application
F.L.I.	Wholesaler Pharmacy	Refer to the Attorney General's office for discipline
M.P.	Non-Resident Pharmacy	Approved application

Correspondences/Requests

L.D.I.P.	Notice of discipline	No action taken
C.H.D.O.I.	Notice of discipline	No action taken
C.H.D.F.I.	Notice of discipline	No action taken
S.R.G.	Request to lift probation	Request approved

A.H.G.I.	Notice of discipline	No action taken
A.O.	Request regarding PIC for two locations	Request denied
A.	Notice of discipline	No action taken
M.R.P.	Notice of discipline	No action taken
W.M.S.I.	Notice of discipline	No action taken
L.J.H.	Request for CE approval	Table for consideration at February 2016 meeting
L.J.M.	Request for extension	Extension approved until end of classes
D.S.N.	Request regarding intern hrs	Request denied
E.S.M.	Denied Pharmacy Technician	Request denied
J.W.T.	Appearance request	Request approved
R.M.S.	Appearance request	Request approved
K.M.D.	Correspondence	For informational purposes only
N.L.C.	Correspondence	For informational purposes only
W.M.G.I.	Records request	Request approved
A.S.W.	Correspondence regarding ownership	Directed staff to respond that the company needs to be in the executor's name

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

There being no further business to discuss, the meeting was adjourned at 4:49 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, February 17, 2016 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 P. Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director