

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, N.W. 36th Floor
Atlanta, GA 30303
September 16, 2015
9:00 a.m.

The following Board members were present:

Laird Miller, President
Mike Faulk, Vice-President
Vicki Arnold
Chris Jones
Tony Moye
Bill Prather

Staff present:

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

Visitors:

Young Chang, Walgreens
Brian Robinson, Walgreens
Greg Reysold, GPhA
Shari Williams, Walgreens
Yiwen Zou, Walgreens
Barbara Goodwin, East GA Specialty
Sonya Nelson, Walmart
Monica Jolley, PharmD on Demand
Helen Sloat, Kaiser Permanente/Hemophilia of GA
Jamie Diagostino, Eldercare
Mike King, Publix
Sandra Johnson, HST Pharmacy
Philip Marler, City of Gainesville
Chastity Nix, City of Gainesville
Matthew Nguyen, HST Pharmacy
Sy Tran, HST Pharmacy
Debbie Wolf, HST Pharmacy
Sunny Lalli, MedAvail
Patrick O'Donnell, MedAvail
Debra Middleton-Carr
Patricia Yeatts, MAG
Jaime Collier
James Hinzman
Prince Walker
Timothy Ramsey
Jim Bartling

President Miller established that a quorum was present and called the meeting to order at 9:03 a.m.

Chris Jones made a motion and Mike Faulk seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and §43-1-2(k) to deliberate and to receive information on applications, investigative reports and the Assistant Attorney General's report. Voting in favor of the motion were those present who included Vicki Arnold, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, and Bill Prather.

Executive Session

Appearances

- J.M.C.
- P.O.W.
- T.S.R.

Attorney General's Report – Janet Wray

Ms. Wray discussed the following case:

- J.F.

Ms. Wray presented the following consent orders:

- L.A.
- M.D.C.
- P.D.C.

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

Public Rules Hearing

President Miller called the public hearing to order at 11:17 a.m.

Rule 480-22-.15 Refilling of Ophthalmic Topical Products

No comments or written responses were received.

Rule 480-34-.07 Hallucinogens

No comments or written responses were received.

Rule 480-34-.08 Lidocaine

No comments or written responses were received.

Rule 480-34-.09 Additional Compounds Under Schedule IV

No comments or written responses were received.

Rule 480-49-.02 Non-Compliance With An Order For Child Support

No comments or written responses were received.

Bill Prather made a motion to adopt Rules 480-22-.15 Refilling of Ophthalmic Topical Products, 480-34-.07 Hallucinogens, 480-34-.08 Lidocaine, 480-34-.09 Additional Compounds Under Schedule IV, and 480-49-.02 Non-Compliance With An Order For Child Support. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Ms. Battle stated that she would like the minutes to reflect that the Board considered the economic impact statements for each rule at the time of notice.

The hearing adjourned at 11:20 a.m.

President Miller welcomed the visitors.

Approval of Minutes

Chris Jones made a motion to approve the Public and Executive Session minutes for the August 5, 2015 meeting, the Public and Executive Session minutes for the August 21, 2015 Conference Call, and the minutes for the August 31, 2015 Conference Call. Tony Moyer seconded and the Board voted unanimously in favor of the motion.

Ratifications

Tony Moyer 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 Variance from Cameron Pharmaceuticals, LLC

Tony Moyer made a motion to deny the rule variance petition. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver from Cobb/Douglas Stabilization Unit dba The Behavioral Health Center

Mike Faulk 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 Variance/Waiver from East Georgia Specialty Pharmacy

Barbara Goodwin, East Georgia Specialty Pharmacy, spoke to the Board regarding the request. After discussion by the Board, it requested Ms. Goodwin withdraw her current petition and submit a new petition with additional information that would support her request.

Petition for Rule Waiver from Sentynl Therapeutics, Inc.

Mike Faulk 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 Counseling Solutions of Chatsworth

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 Patti Keith, HPSRx Enterprises, Inc.

The Board considered this correspondence requesting clarification regarding medical device requirements. Chris Jones made a motion to direct staff to respond to Ms. Keith by referring her to the appropriate code sections. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Dena Kessler, BakerHostetler

The Board considered this correspondence regarding questions concerning delivering controlled substances in the State of Georgia. Tony Moyer made a motion to direct staff to respond to Ms. Kessler by inviting her to a future meeting with the Board to further discuss this matter. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jennifer Killingsworth, Hall County Schools

The Board considered this correspondence requesting the Board reconsider the requirement that students must have a registration or license from the Georgia Board of Pharmacy to shadow a

pharmacist. Ms. Wray commented that the Board would need to amend the current rule to allow temporary access to the pharmacy under circumstances such as this. The Board recommended staff research this matter and report back to the Board.

Debra Middleton-Carr commented that she feels a request like this should begin at the school level first. She stated that she feels this is a great responsibility as there are already interns in the pharmacy. She further stated that she does not mind training them, but feels it would be a conflict of interest. President Miller responded that this would allow the student to come in and see what a pharmacist does. He stated that he is certainly sensitive to her concerns; however, if there is a pharmacy that would be willing to do this, the Board would allow it once an amended rule is adopted. He also stated that no pharmacy would be mandated to allow students to shadow pharmacists. Lastly, he stated that if anyone had any concerns, there will be a comment period to allow for such once the rule has been posted.

Correspondence from Edward Rickert on behalf of HST Health Retail Pharmacy and MedAvail Technologies, Inc.

The Board considered this correspondence requesting approval of an automated pharmacy system. President Miller stated that the Board's position is that under the current law this would not be permitted. Sunny Lalli, MedAvail, stated that representatives were present that could clarify the request. President Miller responded by stating that the request involves patients receiving medications out of a machine. Mr. Lalli stated that their request involves a pharmacist on the back end. They are using automated technology. Ms. Wray responded to Mr. Lalli by stating that, regardless of his argument, what the Board looks at from a legal perspective, the act of dispensing to a patient, is the act of dispensing and would require a pharmacy license. She added that only RAMS machines in nursing homes are licensed with the Board per se. She stated that what he is requesting to do is the very same thing. She stated that his options are practitioner dispensing or you set inside a qualified licensed pharmacy and have it prepackaged and handed to a person. The scenario they have set out does not fit within Georgia law and does not qualify as a pharmacy under Georgia law; therefore, it cannot be approved by the Board. Mr. Lalli was advised that if he wanted to amend his proposal, he can do that and submit it for consideration at another meeting. Mr. Lalli thanked the Board for its time and clarity.

Correspondence from Kenneth Wells, Oregon Board of Pharmacy

The Board considered this correspondence from Mr. Wells requesting the Board consider the Patient Safety & Medication Error Prevention for Pharmacists Course. Chairperson Miller recommended tabling this matter and appointed Jim Bracewell and Bob Warnock to research the course further and bring their recommendations back to the Board for consideration at its October meeting.

Correspondence from Lisa M. Woolard, Kaiser Permanente

The Board considered this correspondence regarding Rule 480-3-.03 and who is considered the "administrative authority" and who provides the "authorized signature" as referenced in the rule. Vicki Arnold made a motion to respond to Ms. Woolard by stating that the sponsoring organization designates the administrative authority in its bylaws. Additionally, the authorized signature is generally the person designated by the sponsoring organization. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jenny McGovern regarding Hospitality Rx, LLC

The Board considered this correspondence requesting to know if Hospitality Rx, LLC needs to apply for a non-resident pharmacy license as a PBM. Vicki Arnold made a motion to respond to Ms. McGovern by stating that the Board suggests she refer to O.C.G.A. § 26-4-110.1 for more information. Chris Jones 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 reported that there are 17, 605 active pharmacy licenses. She stated that prior to the expiration date there were 23,000. She added that pharmacy technicians who did not renew are ineligible for reinstatement and will need to reapply in order to be registered.

Ms. Battle discussed whether or not out-of-state facilities could ship nuclear drugs into Georgia. Director Allen responded that the non-resident pharmacy rule does not address nuclear drugs. Chris Jones made a motion to amend the non-resident pharmacy application to include a question that asks if the facility is licensed as a nuclear pharmacy in its home state and if so, does it intend to ship nuclear drugs into Georgia. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Miscellaneous

Chris Jones made a motion to post Rule 480-37-.02 Licensure. Vicki Arnold 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. Renewals are contingent upon the renewal of the pharmacy facility license. 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 an application for reinstatement shall be required. Reinstatement is at the sole discretion of the Board.

~~(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.

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

The Board discussed Chapter 480-50 Drug Disposal by Authorized Collectors. Ms. Wray discussed her memo to the Board regarding the changes that needed to be addressed. The Board suggested staff revise the rule with the changes discussed and bring back to the Board for reconsideration.

The Board discussed Chapter 480-51 Controlled Substances or Dangerous Drug Losses. Mr. Prather stated that due to the discovery of losses of hundreds of thousands of doses of controlled substances, President Miller asked Mr. Prather and Mr. Jones to look into a rule or policy regarding this matter. He stated that agents from Georgia Drug and Narcotics Agency assisted with drafting the rules. Ms. Wray commented on changes that needed to be addressed before the Board can vote to post. President Miller commended Mr. Prather and Mr. Jones on the work they have done with drafting this information and suggested that this matter be tabled until the October meeting to allow additional time for the changes discussed to be made.

The Board discussed proposed 2016 meeting dates. Chairperson Miller stated there was one conflict with the proposed date for July 2016 and suggested tabling this matter until the October meeting.

Chairperson Miller discussed the possibility of conducting another practical examination in March 2016. Ms. Arnold asked about out-of-state residents as there are currently sixty-five (65) students who cannot get into the June examination. Chairperson Miller responded that residency programs are growing rapidly and will become an issue. He would like to address this matter sooner rather than later. He stated the Board will have another early August examination next year and hopefully that will help. He stated that, in talking with Ms. Arnold, the Board needs to see what it can do to come up with some type of license that would get them into the pharmacy. Mr. Jones asked if the Board can allow a temporary license. Ms. Wray responded that O.C.G.A. § 26-4-43 is the temporary license provision, but it expires at the end of the month during which the first week is when the meeting is conducted. She stated if issued on July 14th, the license will last until the end of August. It cannot be reissued or renewed. Ms. Arnold commented that most students start July 1st so that is a gray area. Ms. Wray stated that if the Board expanded the temporary license and say “shall expire no later than two months following issuance”, that would require a change in the statute. After further discussion, the Board suggested checking with Mercer University on available dates for the practical to be held at that location in March 2016.

Bill Prather made a motion and Vicki Arnold seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h)(2) and §43-1-2(k) to deliberate and to receive information on applications, investigative reports and the Assistant Attorney General’s report. Voting in favor of the motion were those present who included Vicki Arnold, Mike Faulk, Chris Jones, Laird Miller, Tony Moye, and Bill Prather.

Executive Session

Attorney General’s Report – Janet Wray

Ms. Wray discussed the following case:

- R.E.J.

Ms. Wray presented the following consent order:

- A.R.E.

Georgia Drugs and Narcotics Agency – Rick Allen

- M.P.
- P.B.P.

- T.M.S.
- R.B.
- Requested and received legal advice regarding non-resident pharmacies.
- P.M.S.

Applications

- K.L.G.
- M.L.C.
- D.S.J.
- L.C.B.
- A.S.H.
- B.K.L.
- N.B.K.
- D.C.D.
- Z.F.D.
- A.C.C.
- E.L.J.

Cognizant's Report – Mike Faulk

- D.O.O.
- GDNA Case #A15-20
- GDNA Case #T-31543
- GDNA Case #A15-24
- GDNA Case #A15-17
- GDNA Case #T-31556
- GDNA Case #B-31444
- GDNA Case #B-31476
- GDNA Case #B15-25
- GDNA Case #B-31326
- GDNA Case #A-31456
- GDNA Case #B-31451
- GDNA Case #B-31433
- GDNA Case #B-31461
- GDNA Case #A-31462
- GDNA Case #B-31454
- GDNA Case #B-31477
- GDNA Case #B-31576
- GDNA Case #B-31588
- GDNA Case #B-31592

Executive Director's Report Open Session – Tanja Battle

- W.C.

Applications

- A.G.
- C.R.A.
- R.U.K.
- J.M.K.

- E.K.
- A.J.S.
- D.H.K.
- L.S.L.
- T.A.
- C.L.M.
- B.A.P.
- K.N.G.
- M.P.

Correspondences

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

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

Open Session

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

Appearances

J.M.C.	Pharmacist Renewal	Refer to the Attorney General's Office
P.O.W.	Denied Pharmacy Technician	Overturn denial and approve pending receipt of additional information
T.S.R.	Request to reinstate license	Request denied

Attorney General's Report - Janet Wray

Ms. Wray discussed the following case:

J.F.	Pharmacist	Close case with letter of concern
------	------------	-----------------------------------

Ms. Wray presented the following consent orders:

Latricia Andrews	Public consent order accepted
M.D.C.	Private consent order accepted
P.D.C.	Public consent order to be accepted and signed with express permission upon receipt of the original

Ms. Wray discussed the following case:

R.E.J.	Refer case back to the Attorney General's office
--------	--

Ms. Wray presented the following consent order:

A.R.E.	Private consent order accepted
--------	--------------------------------

Georgia Drugs and Narcotics Agency - Rick Allen

M.P.	Non-Resident Pharmacy	Denied application
P.B.P.	Non-Resident Pharmacy	Denied application
T.M.S.	Non-Resident Pharmacy	Denied application
R.B.	Non-Resident Pharmacy	Denied application
Requested and received legal advice regarding non-resident pharmacies.		
P.M.S.	Wholesaler Pharmacy	Table pending receipt of additional information

Applications

Kristen L. Gamble	Pharmacy Technician	Approved registration
Megan L. Carter	Pharmacy Technician	Approved registration
D.S.J.	Pharmacy Technician	Denied registration
L.C.B.	Pharmacy Technician	Approve pending receipt of additional information
Alexandra S. Hughes	Pharmacy Technician	Approved registration
Benjamin K. Lineberger	Pharmacy Technician	Approved registration
N.B.K.	Pharmacy Technician	Denied registration
Dana C. Drummer	Pharmacy Technician	Approved renewal
Zachariah F. Dorminey	Pharmacy Technician	Approved renewal
Amber C. Crawford	Pharmacy Technician	Approved renewal
Ethan L. Jones	Pharmacy Technician	Approved registration

Cognizant's Report - Mike Faulk

D.O.O.	Refer to the Attorney General's office
GDNA Case #A15-20	Accept Private Interim Consent Order
GDNA Case #T-31543	Revoke technician registration
GDNA Case #A15-24	Accept Private Interim Consent Order
GDNA Case #A-15-17	Accept Private Interim Consent Order
GDNA Case #T-31556	Accept Voluntary Surrender
GDNA Case #B-31444	Close case with letter of concern
GDNA Case #B-31476	Close case with no action
GDNA Case #B15-25	Refer to the Attorney General's office
GDNA Case #B-31326	Close case with no action
GDNA Case #A-31456	Refer to the Attorney General's office
GDNA Case #B-31451	Close case with no action
GDNA Case #B-31433	Close case with no action

GDNA Case #B-31461	Close case with letter of concern
GDNA Case #A-31462	Close case with no action
GDNA Case #B-31454	Close case with no action
GDNA Case #B-31477	Board misfill policy #2
GDNA Case #B-31576	Refer to the Attorney General's office
GDNA Case #B-31588	Refer to the Attorney General's office
GDNA Case #B-31592	Refer to the Attorney General's office

Executive Director's Report Open Session – Tanja Battle

W.C.	Request for approval of misfill course	Request approved
------	--	------------------

Applications

A.G.	Pharmacist Reinstatement	Approved with letter of concern
C.R.A.	Pharmacist Reinstatement	Approved with letter of concern
R.U.K.	Pharmacist Reinstatement	Board misfill policy #3A
J.M.K.	Pharmacist Reciprocity	Approved to sit for the exam
E.K.	Pharmacist Reciprocity	Approved to sit for the exam
Andrew J. Schaefer	Pharmacist Intern	Approved application
D.H.K.	Pharmacist Intern	Approved pending receipt of additional information
L.S.L.	Pharmacist Intern	Table pending receipt of additional information
Tosin Adelokun	Pharmacist Intern	Approved application
Crystal L. Massey	Pharmacist Intern	Approved application
Bradley A. Proctor	Pharmacist Intern	Approved application
Kristin N. Gillis	Pharmacist Intern	Approved application
M.P.	Manufacturing Pharmacy	Table pending receipt of additional information

Correspondences

H.L.C.	Appearance Request	Request approved
A.L.M.	Request to terminate consent order	Request approved
T.R.H.	Remote Order Entry	Denied
J.F.C.	Appearance Request	Request approved
C.J.B.	Request to return to pharmacy	Request denied
P.C.	Notice of discipline	No action taken
R.M.B.	Correspondence	Offer private interim suspension
K.S.A.	Correspondence	Directed staff to respond by stating that the individual may take any course he/she wants in order to refresh knowledge on compounding
M.M.S.U.	Refund request	Request denied
W.P.	Request for approval of lockbox method	Request approved
G.E.T.	Appearance Request	Request approved
C.C.R.	Appearance Request	Request denied
C.M.S.P.	Notice of discipline	No action taken
P.C.	Notice of discipline	No action taken
C.A.V.	Notice of discipline	No action taken

D.R.B.	Request for ext of intern license	Request denied
L.J.M.	Request for ext of intern license	Request denied
M.N.	Request to attempt NAPLEX a fourth time	Request denied
S.L.H.	Request to renew intern license	Request approved
R.T.R.	Fee waiver request	Request approved
K.A.S.	Appearance Request	Request approved

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

There being no further business to discuss, the meeting was adjourned at 3:57 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, October 14, 2015 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi P. Howell, Business Operations Specialist

Minutes edited by Tanja D. Battle, Executive Director