

GEORGIA BOARD OF PHARMACY
Board Meeting
University of Georgia College of Pharmacy
250 W Green Street
Athens, GA 30602
June 15, 2016
9:00 a.m.

The following Board members were present:

Mike Faulk, President
Chris Jones, Vice-President
Vicki Arnold
Jim Bracewell
Lisa Harris (*arrived @ 9:04 a.m.*)
Laird Miller
Bill Prather
Bob Warnock

Staff present:

Tanja Battle, Executive Director
Eric Lacefield, Deputy Executive Director
Rick Allen, Director, GDNA
Dennis Troughton, Deputy Director, GDNA
Michael Poblet, Special Agent, GDNA
Janet Wray, Senior Assistant Attorney General
Anil Foreman, Legal Officer
Brandi Howell, Business Operations Specialist

Visitors:

Kimberly Tackett
Diane Diver
Jack Mills
John Rocchio, CVS
David St. Angelo, CVS
Tommaso Carella, CVS
Jeff Mesarus, CVS
Jennifer Tyler, EGRMC
Bruce Jeffries, DPH
Lindy McFarlin, ElderCare
Shauna Markes-Wilson, Walgreens
Greg Reysold, GPhA
Nora Nanteza-Mukasa, Walgreens
Kim Hazelwood, DPH
Stan Jones, Kaiser
Nichelle Sims, Hemophilia of Georgia
Kimberly Ramseur, MAG
Richard Gardiner, MAG
Sonya Nelson, Walmart
Leighanne Jacobson, Publix
Nattlie Rogers, Houston Healthcare
Melinda Hartley, Houston Healthcare

President Faulk established that a quorum was present and called the meeting to order at 9:00 a.m.

Bill Prather 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, Bill Prather and Bob Warnock.

Executive Session

Appearance

- K.L.T.

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- C.D.P.
- L.P.
- D.W.
- E.P.
- C.J.B.
- C.C.R.

Ms. Wray discussed the following cases:

- R.C.P.
- W.P.C.
- M.V.I.
- C.E.

Appearances

- J.H.M.
- G.C.V.S.P.

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

Open Session

President Faulk welcomed the visitors.

Appearance

Appearance by Kimberley Hazelwood, Georgia Department of Public Health and Bruce Jefferies, Deputy Director of Health Protection, Georgia Department of Public Health: Ms. Hazelwood thanked the Board for the opportunity to speak to its members. Mr. Jefferies explained that the Association of State and Territorial Health Officials (ASTHO) asked Georgia to participate in a pilot program to develop a Memorandum of Understanding (MOU) between the Department of Health and chain pharmacies as part of preparing for a pandemic influenza. He provided the Board with information regarding the MOU. He explained that it was decided Georgia's approach should be to join with the non-chain and independent pharmacies. He stated that the Board's assistance is requested for input and guidance to ensure the success of this pilot program in Georgia. He explained that they would like help from the Board or GPhA in choosing the best pharmacies with which to partner. Ms. Wray commented that as the MOU is developed, the Board could review it. As far as the selection of pharmacies, it was suggested to go through GPhA to see who it would recommend, but also share that list with the Board to ensure that the pharmacies were in good standing. Mr. Jefferies stated that he did speak with Greg Reybold, GPhA, and they are going to meet at a future date to see if this is something the association can assist with. Ms. Wray reiterated that when they narrow down the list of proposals to be sure to share the final selection with the Board. Mr. Jefferies and Ms. Hazelwood thanked the Board for its time.

President Faulk briefly stepped out and handed the meeting over to Vice-President Jones.

Public Hearing

Vice-President Jones called the public hearing to order at 12:49 p.m.

Rule 480-2-.03 Experience Requirements

No public comments were received. Written responses were received from Christin H. Watson, Stacy Tumbleston, Jr., Jeff Lurey, GPhA, and Brett Brownstein.

Rule 480-3.03 Continuing Pharmacy Education

No comments or written responses were received. Ms. Battle stated that this rule, along with Rule 480-2-.03 will be considered for adoption at the Board's conference call scheduled for June 22, 2016.

Rule 480-34-.10 Synthetic Opiates

No comments or written responses were received.

Bill Prather made a motion to adopt Rule 480-34-.10 Synthetic Opiates. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Rule 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes

No public comments were received. A written response was received from Stephen Georgeson.

Bob Warnock made a motion to adopt Rule 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

The hearing was adjourned at 12:55 p.m.

Open Session

Approval of Minutes

Ms. Wray explained there was an issue in prior minutes that dealt with a rule variance from East Georgia Pain Clinic and a rule variance from Statesboro Imaging Center. Jennifer Tyler, East Georgia Regional Medical Center (EGRMC), stated that she understood from the Board's discussion that a separate pharmacy permit would be issued and if that should change, EGRMC would need to come back to the Board. She stated that the variance was so that the hospital could continue to distribute the drugs there. Ms. Wray responded that the minutes need to reflect that the Board agreed to grant the application as a new pharmacy license and in connection with that, will grant the variance concerning the space, staffing and equipment provisions so long as they keep the same drugs there and do not have controlled substances. Additionally, if controlled substances become an issue, then the petition will need to be revisited. Ms. Wray also stated that the Board clarified a wholesale license would not be required of the hospital. Director Allen responded that the rules will have to be changed and it will need to be clarified because right now they will need a wholesale license. Ms. Battle requested that the Board go forward with agenda and the minutes at this time and to discuss the matter later to ensure a proper understanding of the Board's intent.

Ratifications

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

Petition for Rule Waiver - Sarah McClure

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

Petition for Rule Waiver - Linda Faye Cook

Laird Miller made a motion to deny the rule waiver petition. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance/Waiver - Henry C. Ezeasor, PHI-016481

Laird Miller made a motion to grant the variance/waiver petition. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Lakeview Behavioral Health System, PHH007933

The Board recommended tabling this petition until its July meeting to allow for further consideration.

Petitions for Rule Variance and Waiver - Highland Rivers Health Community Service Board

Vicki Arnold made a motion to deny two rule variance petitions and three rule waiver petitions submitted by Highland Rivers Health Community Service Board. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver – Coastal Behavioral Health

The Board recommended tabling the three rule waiver petitions submitted by Coastal Behavioral Health until its July meeting to allow for further consideration.

Petitions for Rule Waiver – Coastal Harbor Treatment Center

The Board recommended tabling the three rule waiver petitions submitted by Coastal Harbor Treatment Center until its July meeting to allow for further consideration.

Correspondence from Dr. Lee A. Resnick, Wellstreet Urgent Care

The Board considered this correspondence seeking the Board’s guidance regarding the use of an automated dispensing unit. The Board directed staff to schedule Dr. Resnick for an appearance to present this information to the Board.

Correspondence from Paul Harder

The Board considered this correspondence regarding cold chain management. The Board directed staff to respond to Mr. Harder by stating that he must submit it where it is less likely to be adulterated and if he feels the need to use temperature strips, he should do so. Additionally, the Board suggests he refer to House Bill 926.

Correspondence from Paige Porter

The Board considered this correspondence regarding texting orders via a secured texting platform. The Board directed staff to respond to Ms. Porter by stating that the Board does not permit texting orders for purposes of a pharmacy.

Correspondence from Julian Polaris

The Board considered this correspondence regarding operational requirements for non-resident pharmacies. The Board directed staff to respond to Mr. Polaris by stating that the Board appreciates his analysis and suggests he review each rule specifically to see if it applies to his client’s situation.

Correspondence from Kim Russo

The Board considered this correspondence requesting approval from the Board for pharmacies to offer its patients MedsOnCue as an alternative to the traditional paper leaflets of drug information. The Board directed staff to respond to Ms. Russo by stating that what has been presented cannot substitute a pharmacist's duty to offer patient counseling under applicable laws and rules including without limitation O.C.G.A. §§26-4-5, 26-4-82(b), 26-4-85 and Ga. Comp. R. & Regs. c. 480-31.

Correspondence from Olivia Bianco

The Board considered this correspondence regarding a snoring device. The Board directed staff to respond to Ms. Bianco by stating that if it can only be dispensed with a prescription, the client must register; however, if it can be sold directly at a cost without a prescription to the consumer, a license would not be required.

Correspondence from Jeffrey Callaway

The Board considered this correspondence requesting clarification regarding Board Rule 480-10-.02. The Board directed staff to respond by stating that if the pharmacist is on lunch within the prescription department, work may continue. However, if the pharmacist leaves the prescription department, the pharmacy must shut down.

Georgia Drugs and Narcotics Agency – Rick Allen

Director Allen reported that the DEA issued a warning to police and public regarding synthetic opioids.

Director Allen also reported on new DEA procedures that will be effective starting October 1, 2016. The new procedures are:

- DEA will start conducting inspections based on pharmacy applicants
- DEA will not schedule an inspection until it receives a copy of an approved GDNA inspection based on the application
- A GDNA inspection marked 'pending' will cause DEA to delay their inspection to wait on an approved status by GDNA
- Types of application changes that will trigger a DEA inspection
 - o New Applications
 - o Change of Ownership applications (when a total change, not for those changes within a current existing ownership)
 - o Change of Address application – unless everything stays the same but at a different location
 - o Change of Name application – unless everything stays the same except the name
- DEA registration numbers
 - o A new DEA number for any change in ownership address, or name – unless everything stays the same or ownership stays within the existing structure (see above)
 - o DEA grants a 90 day grace period using DEA 222 forms to allow existing pharmacies with changes to continue using their old DEA forms
- DEA will inspect new Pharmacies, Physicians, Dentists, Veterinarians – virtually any person or location applying for a DEA registration or changing a DEA registration
- DEA is changing the Office Based Opioid Treatment (OBOT) rules to allow physicians to treat 200 patients instead of the current 100 (DEA does audit physicians to make sure they comply with these requirements)

Attorney General's Report – Janet Wray

No report.

Approval of Minutes

Bob Warnock made a motion to approve the Public and Executive Session minutes for the May 11, 2016 meeting. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Executive Director's Report – Tanja Battle

Continuing Education Report: Ms. Battle reported that no additional programs have been approved for this time period.

Fee for Temporary Pharmacist License: Ms. Battle reported that a temporary pharmacist license will be able to be issued beginning July 1, 2016 for those going into a residency. She asked the Board if it would like to impose a fee for the temporary license. Laird Miller made a motion to set the fee for temporary pharmacist licensure to \$50. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

President Faulk rejoined the meeting at 1:43 p.m.

Ms. Battle discussed correspondence received from Phelim Rowe, Healthcare Conference Network, regarding an invitation to participate at the annual Healthcare Supply Chain Visibility and Compliance summit in Dallas on October 6th and 7th. The Board directed staff to respectfully decline and send its regrets.

Ms. Battle pointed out that the GPhA conference is going on this week which has left the Board with a few examiners that cannot assist with the examination. She stated that our office will put the 2017 dates on the calendar so that there will be no conflicts with the practical examination next year.

Ms. Battle discussed the rule variance petition voted on by the Board at its March meeting. She stated that the Board voted to deny the petition for the East Georgia Pain Clinic at its April meeting. The issue is with the petition submitted from Statesboro Imaging Center. Ms. Wray stated that the response to the letter will need to be specific as to what the petition requested. She continued to state that the letter needed to be revised to reflect that the Board revisited the rule petition in an effort to clarify its previous communication regarding this matter. Additionally, in reviewing the letter previously sent, the Board wants to clarify that the Statesboro Imaging Center must obtain a clinic pharmacy license. The application has been received and is pending a final inspection. She further stated that the variance granted by the Board concerned only the minimum equipment, space required, and the appropriate staffing and to be advised that the previous letter and the revised letter provides that if there are changes to the practices outlined in the variance request, then the facility will be required to comply with the requirements set forth in the rule. The Board confirmed this as its intent.

Miscellaneous

The Board discussed proposed policy regarding continuing education. Mr. Bracewell stated that he appreciated the policy and recommended changing the word "committee" as it implies "more than one." He stated he does not feel the Board can delegate authority for one person to review and asked if voting on the policy can be postponed until the meeting in July or proceed if the Board prefers to make the changes now. Mr. Miller responded that he does not have any objection to discussing it further now. He stated that he was under the impression the Board voted to delegate reviewing continuing education to the committee at its meeting in March. He stated the committee would review it and the recommendations would be reported back to the Board. Mr. Bracewell responded that he does not think the Board has the authority to delegate approval to someone. President Faulk responded by asking why the Board cannot

allow the cognizant member to decide. Ms. Battle added that staff routinely approves applications administratively as the Board has delegated administrative authority to staff to issue registrations and licenses. President Faulk stated that the cognizant member of the Board is responsible for continuing education review and approval. He further stated that each member has been through a lot of continuing education and should have reasonable intelligence to see if it is acceptable to the Board. Ms. Harris added that if the cognizant member has an issue with what has been submitted, then it can be brought before the Board. Mr. Prather asked why there needs to be a policy. He stated that the way the Board has always dealt with it has been by delegating it to a cognizant member of the Board, who is a licensed pharmacist in this state. Mr. Prather stated that the Board has been using this process for many years even using a committee of one. Mr. Bracewell responded by stating that it would be okay if there was more than one person on the committee. He added that he has been a member of the Board for a couple of years and did not know this was the process. He stated that he really questions the authority to give one person that decision. Mr. Miller stated that he did not feel the Board wanted to go through each program. Mr. Bracewell responded by stating that he was in agreement with Mr. Miller except for not bringing it to the Board for final approval. President Faulk stated that all points are valid; however, going forward the Board will continue with the process it has been doing which includes cognizant review of continuing education courses and a monthly report to the Board regarding such. Ms. Battle stated that if Mr. Jones has any questions about any of the programs submitted, bringing it before the Board is clearly an option.

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

Executive Session

Correspondence

- H.M.C.

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

Open Session

Miscellaneous

Mr. Prather discussed having a two day meeting each month due to the size of the agenda each month. President Faulk stated that the Board will proceed with its two day meeting in July and will decide at its August meeting if a two day meeting is needed for September as the Board will be conducting the practical exam in August.

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

Georgia Drugs and Narcotics Agency – Rick Allen

- Discussed pharmacy floor plans for new Kroger's
- C.P.C.
- W.V.P.
- P.P.
- P.P.
- E.
- R.P.R.

Cognizant's Report – Chris Jones

- GDNA Case #A-31767A
- GDNA Case #B15-25
- GDNA Case #A-31767C
- GDNA Case # A-31801
- GDNA Case # T-31848
- GDNA Case # B-16-05

Applications

- A.A.I.
- C.L.B.
- P.R.C.

Correspondence

- M.T.T.

Cognizant's Report – Chris Jones

- GDNA Case # A-16-06
- GDNA Case # A-13-52
- GDNA Case # A-16-07-01

Applications

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

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

Correspondences

- C.M.L.
- W.K.K.
- W.V.P.
- A.P.
- C.P.F.
- E.P.I.
- E.S.
- F.S.S.P.
- O.M.
- P.C.
- R.R.V.P.
- W.S.P.
- W.S.P.
- W.S.P.
- C.H.

Miscellaneous

- Certifying intern hours

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

Open Session

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

Appearance

- K.L.T. Request to discuss reinstatement Request approved

Attorney General’s Report – Janet Wray

Ms. Wray presented the following consent orders:

- C.D.P. Private consent order accepted
- L.P. Private consent order accepted

- D.W. Private consent order accepted
- Enclara Pharmacia Public consent order accepted
- C.J.B. Private consent order accepted
- C.C.R. Private consent order accepted

Ms. Wray discussed the following cases:

- R.C.P. Refer to the Attorney General's office
- W.P.C. Rescind referral and close case
- M.V.I. Allow facility to withdraw its application with the understanding that no shipments of prescription drugs will continue into GA. Based on this information, the Board will not pursue any fines or other disciplinary action.
- C.E. Letter of corrections received

Appearances

- J.H.M. Request to discuss reinstatement Request denied
- G.C.V.S.P. Presentation of security system Approved

Correspondence

- H.M.C. Table pending receipt of additional information

Georgia Drugs and Narcotics Agency – Rick Allen

- Discussed pharmacy floor plans for new Kroger's: Table until July meeting to allow for additional consideration
- C.P.C. Request for fee waiver Request approved
- W.V.P. Non-Resident Pharmacy Denied application
- P.P. Non-Resident Pharmacy Denied application
- P.P. Manufacturing Pharmacy Denied application
- E. Non-Resident Pharmacy Denied application
- R.P.R. Non-Resident Pharmacy Denied application

Cognizant's Report – Chris Jones

- GDNA Case #A-31767A Withdraw application for change in ownership and refer to the Attorney General's office
- GDNA Case #B15-25 Table pending receipt of additional information
- GDNA Case #A-31767C Close case with letter of concern
- GDNA Case # A-31801 Letter of concern to PIC / Refer facility to the Attorney General's office
- GDNA Case # T-31848 Accept Voluntary Surrender
- GDNA Case # B-16-05 Refer to the Attorney General's office

Applications

- A.A.I. Pharmacist Examination Approved to sit for the exam
- C.L.B. Pharmacist Examination Approved to sit for the exam
- P.R.C. Pharmacist Examination Approved to sit for the exam

Correspondence

- M.T.T. Pharmacist Examination Approved to sit for the exam

Cognizant's Report – Chris Jones

- GDNA Case # A-16-06 Refer to the Attorney General's office
- GDNA Case # A-13-52 Schedule for Investigative Interview
- GDNA Case # A-16-07-01 Schedule for Investigative Interview

Applications

- Rick Lasica Pharmacist Intern Approved application
- Sapna J. Charania Pharmacist Intern Approved renewal
- Shaghaigh Shahriari Pharmacist Intern Approved renewal
- S.Y.K. Pharmacist Intern Denied application
- B.Z.A. Pharmacist Intern Table pending receipt of additional information

- W.A.R. Pharmacy Technician Overturn denial and approve for registration

- Shannon J. Marshall Pharmacy Technician Approve for registration
- Yokie V. Green Pharmacy Technician Approve for registration
- Theresa C. Odums Pharmacy Technician Approve for registration
- C.L.N. Pharmacy Technician Denied registration
- E.R.B. Pharmacy Technician Approve pending receipt of additional information

- Nicole L. Shivers Pharmacy Technician Approve for registration
- R.B.B. Pharmacy Technician Denied registration
- C.Q.C. Pharmacy Technician Denied registration
- Abby D. Templeton Pharmacy Technician Approve for registration
- C.L.S. Pharmacy Technician Denied registration
- A.E.S. Pharmacy Technician Table pending receipt of additional information

- D.M.T. Pharmacist Reinstatement Denied application
- K.L.B. Pharmacist Reciprocity Approved to sit for the exam
- D.L.B. Pharmacist Examination Approved to sit for the exam
- R.E.D. Pharmacist Examination Denied application
- D.R.L. Nuclear Pharmacist Reinstatement Approved application and request for waiver of the reinstatement fee

- D.R.L. Pharmacist Reinstatement Approved application and request for waiver of the reinstatement fee

- W.C.G. Pharmacist Reinstatement Denied application
- C.L.L. Wholesaler Pharmacy Refer to the Attorney General's office
- M.P.C. Wholesaler Pharmacy Refer to the Attorney General's office
- S.I. Wholesaler Pharmacy Refer to the Attorney General's office
- S.J.P. Wholesaler Pharmacy Refer to the Attorney General's office
- S.C.A. Wholesaler Pharmacy Refer to the Attorney General's office
- T.A.D.S.C. Wholesaler Pharmacy Approved with letter of concern
- K.K. Manufacturing Pharmacy Approved

Correspondences

- C.M.L. Correspondence Board directed staff to place additional license on inactive status
- W.K.K. Request for appearance Request approved
- W.V.P. Notice of discipline No action taken

• A.P.	Notice of discipline	No action taken
• C.P.F.	Notice of discipline	No action taken
• E.P.I.	Notice of discipline	No action taken
• E.S.	Notice of discipline	No action taken
• F.S.S.P.	Notice of discipline	No action taken
• O.M.	Notice of discipline	No action taken
• P.C.	Notice of discipline	No action taken
• R.R.V.P.	Notice of discipline	No action taken
• W.S.P.	Notice of discipline	No action taken
• W.S.P.	Notice of discipline	No action taken
• W.S.P.	Notice of discipline	No action taken
• C.H.	Request regarding intern hours	Board directed staff to certify all hours

Miscellaneous

- Certifying intern hours: Board directed staff to certify all school hours if requested

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

Ms. Battle discussed correspondence received from Lyndsey McDonald regarding the ExCPT from National Healthcareer Association. The Board directed staff to invite Ms. McDonald in for an appearance with the Board.

Bob Warnock made a motion to table the rule variance petition request submitted by New Horizons Behavioral Health. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 5:38 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, July 6, 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 Howell, Business Operations Specialist
 Minutes edited by Tanja D. Battle, Executive Director