

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree St, N.W. 5th Floor
Atlanta, GA 30303
July 6, 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
Bob Warnock

Staff present:

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

Visitors:

Shawn Veres
Jim Bartling
Deanne Redman
Shaquan Liverpool
Francis Casey
Cameron Brown, Wal-Mart
Rick Harrell, Kroger
Karen Waters, GHA
Stan Jones, Kaiser
Jamie Diagnostino, Eldercare
Jessi Eastenwood, Eldercare
Lisa Sparks, Riverwoods Behavioral Health System
Anthony Ganter, Coastal Behavioral Health/Coastal Harbor Treatment Center
Brad Schraut, InstyMeds
Greg Reybold, GPhA
Matthew Burnette, GPhA
Michael Harding
Mike King, Publix
Young Chang, Walgreens
Brian Robinson, Walgreens
Richard Gardner, MAG
Beth Patrick, Lakeview Behavioral (APC)
Burt Wrenn, CVS
Dr. Lee Resnick, WellStreet Urgent Care
Kimberly Ramseur, MAG
Carrie Moss

President Faulk established that a quorum was present and called the meeting to order at 9:04 a.m.

Laird Miller made a motion and Bill Prather 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

Georgia Drugs and Narcotics Agency – Rick Allen

- PDMP Audit

Appearance

- S.R.V.

Attorney General’s Report – Janet Wray

Ms. Wray presented the following consent orders:

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

Ms. Wray discussed the following cases:

- B.D.S.V. and B.H.
- M.W.

Appearances

- D.K.R.
- S.S.L.

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

Open Session

President Faulk welcomed the visitors.

Appearances

Appearance by Dr. Lee A. Resnick, WellStreet Urgent Care, and Brad Schraut, InstyMeds: Dr. Resnick thanked the Board for the opportunity to speak to its members. Handouts were provided to each of the board members regarding the InstyMeds system. Dr. Resnick stated that the purpose of the meeting was to present the InstyMeds system to the Board to see if there were any questions or concerns about the system.

Mr. Schraut introduced himself to the Board. He stated InstyMeds was founded sixteen (16) years ago. He stated the concept resulted from the following: how do we increase compliance and how do we partner with the pharmacy community regarding in office dispensing? Mr. Schraut continued by explaining the features of the system and how it worked. Following his presentation and discussion by the Board, Ms. Wray made suggestions such as keeping the machine in a secured location in the back of the office as opposed to the waiting room; and have the physician do the reconstituting. She suggested Dr. Resnick and Mr. Schraut review the RAMS law and follow up with materials for the Board to review.

Appearance by Lisa A. Sparks, Riverwoods Behavioral Health System, PHH007784: Ms. Sparks gave the Board information regarding her background and explained that the rule petition previously submitted by Riverwoods Behavioral Health System had been denied. She explained the purpose for the waiver to the Board members. Ms. Wray explained that the petition was denied because she had requested a waiver from the incorrect rule. Ms. Wray further explained that Ms. Sparks may submit a new petition to the Board with the correct rule number and the Board will reconsider the request.

Approval of Minutes

Chris Jones made a motion to approve the Public Session minutes for the June 15, 2016 meeting. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Bob Warnock made a motion to approve the Executive Session minutes for the June 15, 2016 meeting. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Laird Miller made a motion to approve the Public Session minutes for the June 22, 2016 Conference Call. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the Executive Session minutes for the June 22, 2016 Conference Call. 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. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Lakeview Behavioral Health System, PHH007933

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

Petitions for Rule Waiver – Coastal Behavioral Health

Bill Prather made a motion to grant the three (3) rule waiver petitions submitted by Coastal Behavioral Health provided that, if their business model changes, they will be required to comply with the requirements set forth in the rule. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver – Coastal Harbor Treatment Center

Laird Miller made a motion to grant the three (3) rule waiver petitions submitted by Coastal Harbor Treatment Center provided that, if their business model changes, they will be required to comply with the requirements set forth in the rule. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – W Central GA Regional Hospital, PHH005082

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

Petition for Rule Waiver – Puma Biotechnology, Inc.

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

Petition for Rule Waiver - Truong Thach Ho Lam

Laird Miller 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 – Emmanuel Dingsangha

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

Petition for Rule Variance – Kathryn A. Broze

Laird Miller made a motion to deny the rule variance petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance – New Horizons Behavioral Health, PHRE005059

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

Correspondence from Greg Reybold, GPhA

The Board considered this follow up correspondence from Mr. Reybold regarding the issue of retail pharmacists' supervisory responsibilities of technicians. The Board recommended creating a subcommittee to further discuss this issue. Mr. Prather and Mr. Jones will serve on the committee and will be in touch with Mr. Reybold to get additional input on this matter.

Correspondence from David Eichenblatt, Smart Door & Delivery, LLC

The Board considered this correspondence concerning a request for clarification regarding the patient signature requirement for medication shipments. The Board directed staff to schedule Mr. Eichenblatt for an appearance to present this information to the Board.

Correspondence from Michele Moore, Containment Technologies Group, Inc.

The Board viewed this correspondence for informational purposes only.

Correspondence from Amaru Sanchez, Morgan, Lewis & Bockius LLP

The Board considered this correspondence requesting clarification regarding wholesale distribution regulations in Georgia. The Board directed staff to respond to Mr. Sanchez by referring him to O.C.G.A. §16-13-32 and §26-4-5 for additional information.

Correspondence from Justin Haskamp

The Board considered this correspondence regarding whether or not Georgia has any length requirements for prescription renewals for both OTC and RxOnly devices (non-drugs, such as catheters). The Board directed staff to respond by stating that the Board does not have authority over this matter. Additionally, how long the prescription would last for the payor would be up to his/her individual policy.

Correspondence from Jonathan Briley, Pfizer Americas Logistics Compliance

The Board recommended tabling this correspondence until its August meeting to allow time for additional review.

Correspondence from Ryan A. Forrey, Emory University Hospital Midtown

The Board considered this correspondence regarding licensing for a new infusion pharmacy. The Board directed staff to respond to Mr. Forrey by stating the facility does need a separate license. Additionally, the facility cannot be a satellite location without a separate license under the hospital license. Lastly, the facility cannot license all of the infusion pharmacies under one license.

Georgia Drugs and Narcotics Agency – Rick Allen

No report.

Attorney General's Report – Janet Wray

No report.

Executive Director's Report – Tanja Battle

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

Ms. Battle discussed correspondence received from a physician concerning a particular prescription that previously cost \$10 and is now more than \$30. He further had concerns about this how this correlates to membership cards. Ms. Battle stated that she responded to the physician that the Board does not have authority over pricing, but would relay his concerns to the Board. The Board directed staff to respond to the individual by stating it appreciates his/her concern regarding this matter, but as previously relayed by Ms. Battle, the Board does not have authority over pricing.

Discussion Topics

Private Consent Orders versus Public Consent Orders: Mr. Warnock stated that it is sometimes difficult for him to understand how the Board would recommend a private consent order versus a public consent order. He questions if all consent orders should be public. He stated there are times where he understands why an order would need to be private; however, he would just like to know if there is a certain criteria the Board goes by. President Faulk responded by stating that the Board does take the offense into consideration. Mr. Bracewell asked how the Board decides what is discussed in executive session versus open session. Ms. Wray responded by stating that executive and public session contents are established as a matter of law. She stated that the code provisions on the confidentiality of investigations are O.C.G.A. §§26-4-28.1(b)(1), 43-1-2(k)(1). She continued by stating that O.C.G.A. §§43-1-19(h)(4) says the board is authorized to meet with an applicant in executive session. She stated that various boards have a pattern of meeting with individuals for various reasons in executive session. She explained if a person has a medical condition and he/she sought treatment for it, he/she is covered by the Americans with Disabilities Act (ADA). She stated most of the individuals the Board meets with have an impairment issue and are covered by the ADA. She stated it would be the same if the individual had a stroke or neurological issue. She went on to state that the Board can come outside of executive for particular circumstances such as an individual falsifying prescriptions, that could be public because the Board is disciplining the individual for his/her criminal conduct. If someone surrendered his/her license due to disciplinary reasons and is applying for reinstatement of licensure, then that is an application and is considered executive.

Ms. Wray stated that as the Board discusses consent orders, the Board has discretion for public and private reprimands. She stated that the Board has looked at this on a case by case basis, but there has generally been a pattern. If this is the first violation for the individual and there are no criminal charges, the Board may consider the first violation to be a private reprimand. If there is a second violation, then the Board may consider it to be a public reprimand. She explained that if there is harm to the public, if there has been a criminal conviction, the Board has always done a public reprimand. Additionally, if the individual is a repeat offender, the Board will issue a public reprimand. She explained that there is an option for the Board that is required by matter of law and that is a letter of concern. She stated some boards will not close a case with a letter of concern unless the individual gets retraining through continuing education. She stated that some boards will close the case with a letter of concern. Mr. Bracewell responded that his point is regarding the Cognizant Report as the cognizant member of the Board just reports a case number to the Board and nothing further is disclosed. Ms. Wray responded by stating the report is given in executive session as a matter of law. Mr. Bracewell stated if there is a violation and the order is private, the public never knows the problems the Board of Pharmacy deals with. He further stated if a member of the public looked at the Board's website, he/she would think there have never been any public violations. Mr. Miller added that if there is harm done, the Board does issue a

public reprimand and he feels that is fair. He continued by stating that he feels the Board does a good job of handling these matters. He stated that if the issue concerns a misfill, the Board requires training. Mr. Miller stated that Board needs to be very careful about harming an individual's career over a mistake. Ms. Wray stated the confidentiality provision is not to just protect the licensee, it is also to protect the complainant. Mr. Bracewell responded that he was not talking about any impairment issues. He stated he was talking about violations of pharmacy laws, technician ratios, etc... Mr. Miller asked if the Board can report statistically on those items. Ms. Wray responded yes. The Board can do statistics, but that will be a burden on board staff. She explained that the Board does not have staff to code it in the system to just pull information up. She went on to say that there are a number of people who complain about misfills, who would not want his/her information public and have to come in to testify regarding such. President Faulk stated that he was in agreement with Mr. Miller and feels that what the Board has been doing is working pretty well.

Genetic Testing by a Pharmacist: Ms. Wray discussed O.C.G.A. § 26-4-4, § 43-34-26.1 and §43-34-24. She stated that the Board needs to be aware that this type of genetic testing is a money maker for a company. The company charges anywhere from \$800-\$1000 for this kind of testing. Physicians who have gotten into this type of testing have had multiple complaints because of the non-covered cost of this type of testing. She further stated there is no authority in the law that would allow genetic testing by a pharmacist. Mr. Warnock asked if there anything in the law that would prevent a family member from swabbing a person's mouth. Ms. Wray responded no. This type of testing would probably need a doctor's order. She stated that if you start encouraging pharmacists to do this type of testing, this board can take action against you for failure to comply with the minimal standards as it is not clear within the practice of pharmacy. Mr. Miller commented that he just had a friend that got his report back and asked if it is excluded from the operation of a pharmacy. He stated that he can look at someone's arm and tell them they need Neosporin and asked is that practice of medicine. Ms. Wray responded yes. After further discussion, Ms. Wray stated she was only responding to this particular proposal. She stated if the pharmacist has a prescription for it, it would be like an individual coming in for a shot. If there is a prescription that is submitted to the pharmacy, the Board is standing on good ground.

Repackaging Medications: Ms. Wray stated that this subject stems from an individual asking the Board to reconsider its rule on repackaging. She stated that if the Board wants to revise the rule, she suggests it appoint a small committee to work on the matter. President Faulk stated that the Board will just take this as information only at this juncture.

Pharmacy's Legal Name Being Distorted by Inclusion of Wholesaler's Network Name: President Faulk stated a wholesaler is using "Community Health" as its logo, as an example. If a facility decided to put "Prather's Community Health" on its sign, though that is not its legal name. Ms. Wray stated that it would be helpful for the Board to provide information on its website stating that signs should accurately reflect the name as registered with the Board so it is not misleading to the public. Mr. Bracewell asked if the facility could do a dba. Ms. Wray responded by stating that she thinks the Board has talked about not having a dba provision on the application. Ms. Wray stated this subject came up as a case referred to the Board and the Board stated it wanted to further discuss. Mr. Prather asked what the issue was. Director Allen responded that it does not match the permit. Mr. Miller stated that the Board has to be clear for the agents, and if the Board does not have a problem with it, then the agents should not. Ms. Wray responded by stating the label has to be correct on the drugs as that is required per rule. She further stated the labeling on the drugs being dispensed is not an issue. Mr. Miller commented that the rule says the label has to be the same, but does not mention the sign. He suggested the Board putting something into policy regarding this matter.

Transfer of Prescriptions (requested by a patient): President Faulk stated that the pharmacist does not have to transfer a prescription. He stated the pharmacy is not under any obligation to do this, but it may

put the patient at risk. Mr. Miller asked President Faulk if he felt the Board should be able to require it if the patient requests it. President Faulk responded by stating if the patient is going to leave the pharmacy, he/she will leave. The pharmacy is under no obligation to transfer the prescription and if the patient wants to go to a different store, he/she should be allowed to do so.

Temporary Absence of the Pharmacist: The Board directed this subject be referred to the pharmacy technician subcommittee.

Rules tabled from January Public Hearing: Ms. Wray discussed changes that need to be made to Rule 480-8-.06 Drug Distribution and Control, Rule 480-10-.01 Controlled Substances and Dangerous Drugs: Inspection, Retention of Records and Security, Rule 480-10-.20 Required Notifications to the Board, Rule 480-13-.06 Drug Distribution and Control, Rule 480-15-.05 Duties or Functions Prohibited from Being Performed by a Registered Pharmacy Technician, Rule 480-16-.06 Theft, Loss, or Unaccounted for Controlled Substances, Rule 480-18-.06 Drug Distribution and Control, Rule 480-27-.03 Records of Dispensing, and Rule 480-33-.06 Drug Distribution and Control before they can be considered for a vote to post.

Policy Book: Director Allen requested the Board consider a policy on granting a rule waiver for space requirements. He stated that it is very time consuming to send GDNA agents out to inspect. Discussion was held by the Board regarding space requirements. Ms. Wray commented that the rule states the facility can file a rule waiver petition, be inspected and GDNA can determine yes or no. She stated the Board is currently dealing with this and decided to have the inspection occur prior to the Board receiving the report and the petition. After further discussion on whether or not to require specific parameters regarding the space requirement, the Board recommended continuing with its current process.

Director Allen requested the Board review all of its current policies and revise as needed. He requested the Board consider a policy regarding retired licenses versus inactive. Ms. Wray stated that there is not a provision for a retired license. President Faulk appointed Mr. Faulk and Ms. Arnold to review the policy manual and bring any suggestions for revisions back to the Board for consideration.

Rule Change to Require "Sentinel Events": Ms. Wray stated the Board needs to have "sentinel event" amended into the hospital pharmacy rule. She suggested a board member review and define pharmacy related sentinel event. Mr. Bracewell asked what is considered a "sentinel event". Ms. Arnold replied that it is any event harming a patient. She stated that the Board may want to reconsider calling it a "sentinel event". President Faulk appointed Ms. Arnold was to review this matter and report back to the Board.

3PL's, Virtual Manufacturers and Outsourcing Facilities: President Faulk stated that 3PL's, Virtual Manufacturers and Outsourcing Facilities were addressed during the legislative session. Director Allen stated that a new license type and a new rule will need to be required for each. President Faulk appointed Ms. Harris, Mr. Miller and Director Allen to review this matter.

Lisa Harris made a motion for the Board to take the following actions:

Georgia Drugs and Narcotics Agency – Rick Allen

- PDMP Audit: Approved request for release of information.

Appearance

- S.R.V. Request to discuss reinstatement Request approved

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- M.C.W. Private consent order accepted
- T.S. Private consent order accepted
- A.R.M.I. Private consent order accepted
- S.J.P.I. Private consent order accepted
- B.L. Private consent order to be accepted and signed with express permission upon receipt of the original
- K.T. Private consent order to be accepted and signed with express permission upon receipt of the original

Ms. Wray discussed the following cases:

- B.D.S.V. and B.H. Table pending receipt of additional information
- M.W. Request for reduced fine approved

Appearances

- D.K.R. Denied Pharmacy Technician Overturn denial and approve registration
- S.S.L. Denied Pharmacy Technician Overturn denial and refer to the Attorney General's office

Chris Jones seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 4:21 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Thursday, July 7, 2016 at 8:00 a.m. at 254 Washington Street, SW, Ground Floor, Atlanta, GA 30334.

Minutes recorded by Brandi Howell, Business Operations Specialist
Minutes edited by Tanja D. Battle, Executive Director