

GEORGIA BOARD OF PHARMACY
Board Meeting
University of Georgia College of Pharmacy
South Pharmacy Building, 250 W. Green Street
Athens, GA 30602
June 17, 2014
9:00 a.m.

The following Board members were present:

Al McConnell, Chairperson
Laird Miller, Vice-Chairperson
Jim Bracewell
Mike Faulk
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:

Jim Bartling
Andrew Brinton
Tim Kyburz
Taina Rivera
Doug Jones
Tim Tyre
Deborah Elder, UGA, College of Pharmacy
Leigh Carpenter, Hemophilia of Georgia
Michelle Putman
Brad Borum, Kaiser Permanente
James Rodgers, Walgreens
R. Scott Lindsay, CAPS
Judd Perce, Wal-Mart
Laura Wiggins, PCOM
Michael Lee, PCOM
Melvin Smith, CVS

Chairperson McConnell established that a quorum was present and called the meeting to order at 8:45 a.m.

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 Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Tony Moye and Bill Prather.

Executive Session

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent order for acceptance:

- A.E.M.

The Board received advice from Ms. Wray regarding pharmacy technicians who are on probation.

Appearances

- A.S.B.
- T.C.K.
- T.L.R.
- D.W.J.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Public Hearing

Chairperson McConnell called the Public Hearing to order at 11:03 a.m.

Rule 480-2-.03 Experience Requirements

No comments or written responses were received.

Bill Prather made a motion to adopt Rule 480-2-.03 Experience Requirements. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Rule 480-11-.02 Compounded Drug Preparations

Public comments from Tim Tyre, Southeast Georgia Health System, were received. Mr. Tyre spoke to the Board regarding the interpretation of Chapter 480-11 Pharmaceutical Compounding. He spoke to the Board regarding the repacking of oral medications from bulk into unit dose packages and the mixing of standard bulk mixtures. He stated that the rationale for maintaining a compounding log for these products included the ability to remove from inventory any unused portion of the batch in the event of a recall and the ability to report specific lot numbers if the product is thought to be sub potent or connected to an adverse event.

He went on to say that he has recently been informed by the Georgia Drug and Narcotics Agency that 480-11 is now being applied to all IV preparations prepared in a hospital pharmacy. In doing so, the requirements for records and reports create the significant burden of maintaining a detailed compounding log. Mr. Tyre stated that he will comply with whatever the Board requires; however, he is asking that the Board consider this matter from a practical prospective as this creates a significant challenge.

Mr. Miller responded to Mr. Tyre by stating that in the event there is a drug that had a contaminant, if there is no record of the lot numbers, there is no way to track who received the drug. Mr. Miller went on to state that it is an encumbrance and takes time, but if it saves a life, is well worth the effort.

Dr. Deborah Elder stated that USP 797 requires the tracking of all lot numbers. She went on to state that the log is a new requirement, but she would like to think that in hospital settings, when you get a drug order, the lot numbers are listed. Mr. Tyre responded that they are not. Dr. Elder stated that, per USP 797, they should be.

Ms. Wray explained to Mr. Elder that this requirement is federal law. She further stated that the Board's rule is mirrored after the law and he is going to have to comply with the requirement. Mr. Tyre responded by stating that there needs to be an appeal at the federal level. Mr. Prather responded by telling Mr. Tyre to write his congressman. Mr. Moye stated that the Board is sympathetic to Mr. Tyre's concerns; however, the matter is out of the Board's hands as it is a federal regulation.

Written comments from Mr. Tyre were received.

Bill Prather made a motion to adopt Rule 480-11-.02 Compounded Drug Preparations. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Rule 480-3-.03 Continuing Pharmacy Education

No comments or written responses were received.

Tony Moye made a motion to adopt Rule 480-3-.03 Continuing Pharmacy Education. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Procedural Rules

No comments or written responses were received.

Chris Jones made a motion to adopt the following chapters:

Chapter 480-38, General Information

480-38-.01 Scope and Application of These Rules

480-38-.02 Docket

480-38-.03 Office Hours

480-38-.04 Communications

480-38-.05 Date of Filing

480-38-.06 Computation of Time

480-38-.07 Extension of Times

480-38-.08 Signatures

480-38-.09 Ex-parte Communication

480-38-.10 Petition for Promulgation, Amendments, or Repeal of Rules

Chapter 480-39, Pleadings

480-39-.01 Initial Pleading

480-39-.02 Answer

480-39-.03 Replies

480-39-.04 Amendments

Chapter 480-40, Motions and Pre-Hearing Procedures

480-40-.01 Motions: Written and Oral

480-40-.02 More Definite Statement

480-40-.03 General Procedures

480-40-.04 Witness Lists and Respondent Statements

480-40-.05 Pre-Hearing Discovery

Chapter 480-41, Service

480-41-.01 By the Board

480-41-.02 Service on All Parties

480-41-.03 To Party's Attorney

480-41-.04 Filing of Pleading

Chapter 480-42, Intervention

480-42-.01 Intervention

Chapter 480-43, Evidence; Subpoenas

480-43-.01 Evidence on Hearings

480-43-.02 Evidence on Motions

480-43-.03 Objections and Exceptions

480-43-.04 Subpoenas

Chapter 480-44, Taking of Testimony by Deposition or Interrogatory

- 480-44-.01 Taking of Testimony by Deposition
- 480-44-.02 Conduct of the Deposition
- 480-44-.03 Taking of Testimony by Interrogatory
- 480-44-.04 Taking of Testimony by Telephone

Chapter 480-45, Hearings

- 480-45-.01 Notice of Hearing
- 480-45-.02 Conduct of the Hearing

Chapter 480-46, Consolidation

- 480-46-.01 Consolidation

Chapter 480-47, Briefs and Post-Hearing Procedure

- 480-47-.01 Briefs
- 480-47-.02 Filing of Documents Subsequent to Hearing
- 480-47-.03 Motion to Reopen Hearing
- 480-47-.04 Review of Initial Decision
- 480-47-.05 Rehearing
- 480-47-.06 Appeals of Final Decisions

Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

The hearing was adjourned at 11:35 a.m.

Open Session

Appearance

Appearance by Deborah L. Elder, UGA College of Pharmacy: Dr. Elder provided a syllabus for the Board's review and stated that the school is in the process of revamping its curriculum. She asked the Board to review her submission and let her know if the school is doing enough or too much. Mr. Moyer responded by stating that one of the biggest issues is the students cannot multiply without a calculator or phone and the Board does not allow this when taking the exam. He went on to state that the pharmacy schools need to stop allowing the students to utilize a calculator as they are simplistic conversions that need no calculator. Mr. Miller responded by stating that he feels it is about time that the Board consider lifting that restriction as this is a time where most people do have a calculator and maybe the Board needs to evolve as technology changes. He went on to state that it is a skill that makes a pharmacist more valuable. Mr. Prather stated that the Board has discussed this issue many times over the years and stated that it cannot furnish those items to the students to use. He stated that the Board has always felt there may be an opportunity for the students to access more information on the phone or electronic device. Dr. Elder noted the Board's concern about the students' abilities as it relates to calculations.

Mr. Miller stated that compounding is not going away. This was in response to hearing that students are under the impression that the Board is doing away with the practical examination. He further stated that, in regards to the desire to test with the practical exam, the Board is committed to that exam as it gives the Board a measure of a person's ability to work under pressure. Dr. Elder stated that if the Board has any comments or anything that needs to be added or address in her syllabus, to please contact her.

Approval of Minutes

Bill Prather made a motion to approve the Public and Executive Session minutes for the May 14, 2014 meeting, the Public Session minutes for the May 27, 2014 Conference Call, and the Public and Executive Session minutes for the June 9, 2014 Conference Call. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Ratifications

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

Petition for Rule Variance Petition – Coastal Hospital Pharmacy 2

Mike Faulk made a motion to grant the rule variance petition. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Amirio J. Armour

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 – Debbie H. Michel

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 – Rockwell Medical, Inc.

Jim Bracewell made a motion to deny the rule waiver petition. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver – Vensun Pharmaceuticals, Inc.

Jim Bracewell made a motion to grant the rule waiver petition. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Melissa Hollis

The Board considered this correspondence regarding whether or not pharmacists in Georgia are allowed to administer medications. Laird Miller made a motion to direct staff to respond to Ms. Hollis by stating that it is Georgia law does allow it and refer her to O.C.G.A. Sections 26-4-4, 26-4-5, which define the practice of pharmacy and O.C.G.A. Section 26-4-80 regarding the requirement of a pharmacist license to practice pharmacy. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jennifer Schneider, State License Servicing, Inc.

The Board considered this correspondence regarding license verifications for facilities. Tony Moye made a motion to direct staff to respond to Ms. Schneider by stating that verifications of licensure for all licenses held are required to move forward on applications, per the instructions given to her previously by GDNA. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Gillian Russell, King & Spalding, LLP

The Board considered this correspondence regarding licensing and registration requirements for manufacturers, wholesale distributors and retailers of over-the-counter (OTC) drugs. Mike Faulk made a motion to direct staff to respond to Ms. Russell by stating that it appears under O.C.G.A. § 26-4-113 and 26-4-5 that the Board licenses manufacturers and wholesalers who distribute “drugs” into this state regardless of whether they are OTC. Furthermore, O.C.G.A. § 16-13-20.3(b.1)(3) says it is illegal to buy ephedrine, pseudoephedrine, etc. from a wholesaler or manufacturer not licensed by the Board. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Tenicia Johnson

The Board considered this correspondence regarding whether or not student organization meetings held outside of school hours or attending a community service event for their organization would count as intern hours. Tony Moyer made a motion to deny the request. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen reported that two new agents will start on July 1st.

Executive Director’s Report – Tanja Battle

No report.

Miscellaneous

Mr. Jones stated that, while at the National Association of Boards of Pharmacy (NABP) conference in Phoenix, Carmen Catizone asked if it was possible for him to come meet with the Board. After further discussion, the Board recommended meeting with him in an informal setting. Chairperson McConnell stated that he will contact Mr. Catizone about meeting in August.

Laird Miller made a motion to join MALTAGON and allow the Board to pay that out of retained revenue. Bill Prather seconded and the Board voted unanimously in favor of the motion.

The Board discussed direct supervision. Mr. Prather stated that the law and rules says that pharmacy technicians must be under direct supervision. He has had some inquiries as to what the Board considers “direct supervision”. Mr. Prather feels that the Board needs to further define this for pharmacists and the GDNA agents. Mr. Miller suggested that the Board table this matter to allow for the Board to think of suggestions and discuss further at the meeting in August. Mr. Prather requested Mr. Allen check with surrounding states to see how each state defines direct supervision.

Bill Prather 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 Al McConnell, Laird Miller, Jim Bracewell, Mike Faulk, Chris Jones, Tony Moyer and Bill Prather.

Executive Session

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen discussed the following:

- P.N.E. and P.P.

Cognizant’s Report – Laird Miller

- GDNA Case #A-14-18
- GDNA Case #A-14-16
- GDNA Case #T-31120
- GDNA Case #T-31099
- GDNA Case #A-14-19
- GDNA Case #A14-20
- GDNA Case #B-31113
- GDNA Case #A-31063

Executive Director's Report – Tanja Battle

- M.E.

Applications

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

Correspondences/Requests

- M.C.P.C.
- D.F.L. and W.J.C.
- C.H.
- P.C.
- R.M.W.
- M.G.
- P.Y.
- X.P.I.

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Open Session

Bill Prather made a motion to approve all recommendations based on deliberations in Executive Session as follows:

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent order for acceptance:

- A.E.M. Public Consent Order to be accepted and signed with express permission upon

receipt.

The Board received advice from Ms. Wray regarding pharmacy technicians who are on probation. The Board recommended adding the following statement to the Board's website and to the pharmacy technician application:

The Georgia Board of Pharmacy does not approve registrations for individuals who are currently on criminal probation for offenses including but not limited to: theft, fraud, forgery, providing a false name, any crime of moral turpitude, or any crime related to substance abuse. In limited circumstances, the Georgia Board of Pharmacy may approve registrations for individuals who are on criminal probation for minor traffic offenses. Driving under the influence of drugs or alcohol is not considered a "minor traffic offense."

Appearances

- A.S.B. Approved with private consent order
- T.C.K. Overturn denial and table pending receipt of additional information
- T.L.R. Overturn denial and approve for registration
- D.W.J. Approved with private consent order

Georgia Drugs and Narcotics Agency – Rick Allen

Mr. Allen discussed the following:

- P.N.E. and P.P. Refer to the Attorney General's office for discipline

Cognizant's Report – Laird Miller

- GDNA Case #A-14-18 Accept Voluntary Surrender
- GDNA Case #A-14-16 Accept Private Interim Consent Order
- GDNA Case #T-31120 Accept Voluntary Surrender
- GDNA Case #T-31099 Revoke technician registration
- GDNA Case #A-14-19 Accept Private Interim Consent Order
- GDNA Case #A14-20 Private Interim Consent Order to be accepted and signed with express permission upon receipt
- GDNA Case #B-31113 Refer to the Attorney General's office for discipline
- GDNA Case #A-31063 Schedule Investigative Interview

Executive Director's Report – Tanja Battle

- M.E. Proceed with reciprocity application

Applications

- | | | |
|----------------------|---------------------|---|
| • D.L.F. | Pharmacy Technician | Denied registration |
| • Alainah J. Dowding | Pharmacy Technician | Approved for registration |
| • Jordan A. Hicks | Pharmacy Technician | Approved for registration |
| • S.A.L. | Pharmacy Technician | Table pending receipt of additional information |
| • S.T.S. | Pharmacy Technician | Denied registration |
| • L.D.M. | Pharmacy Technician | Denied registration |
| • M.J.M. | Pharmacy Technician | Denied registration |
| • T.S.S. | Pharmacy Technician | Denied registration |
| • S.R.A. | Pharmacy Technician | Denied registration |
| • Leandria D. McIver | Pharmacy Technician | Approved for registration |

- H.J. Pharmacy Technician Approve pending receipt of additional information
- S.S.G. Pharmacy Technician Denied registration
- Olga A. Pashnyak Pharmacy Technician Approved for registration
- Anoop P. Patel Pharmacist Applicant Approved application
- Joshua B. Becher Pharmacist Applicant Approved application
- Warner H. Wolf Pharmacist Applicant Approved application
- Sowra Ibrahim Hamid Pharmacist Applicant Approved application
- Melody C. Castro Pharmacist Reciprocity Approved application
- Jack McGuire Pharmacist Reciprocity Approved application
- Adrienne Allen Pharmacist Reciprocity Approved application
- Conner J. Mansfield Pharmacist Intern Hours approved
- C.H.I. Wholesaler Pharmacy Refer to the Attorney General's office for discipline
- D.V.M.S.I. Wholesaler Pharmacy Refer to the Attorney General's office for discipline
- T.C. Wholesaler Pharmacy Refer to the Attorney General's office for discipline

Correspondences/Requests

- M.C.P.C. Remote Order Entry Approved
- D.F.L. and W.J.C. Correspondence For informational purposes only
- C.H. Correspondence Send response affirming the facility can ship into Georgia
- P.C. Request for termination of probation Request approved
- R.M.W. Request to terminate consent order Schedule for an appearance with the Board
- M.G. Correspondence Accept Voluntary Surrender
- P.Y. Correspondence Directed staff to send a response referring to the appropriate code section
- X.P.I. Notice of discipline No action taken

No votes were taken in Executive Session. Chairperson McConnell declared the meeting back in Open Session.

Laird Miller seconded and the Board voted in favor of the motion, with the exception of Tony Moye, who abstained from the vote regarding W.H.W., and Chris Jones, who abstained from the vote regarding GDNA Case #A-31063.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, July 16, 2014, at 9:00 a.m. at Department of Community Health's office located at 2 Peachtree Street, N.W., 36th Floor, Atlanta, GA 30303.

The Board meeting adjourned at 2:53 p.m.

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