

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
November 19, 2014
9:00 a.m.

The following Board members were present:

Al McConnell, Chairperson
Laird Miller, Vice-Chairperson
Jim Bracewell
Mike Faulk
Chris Jones (*departed @ 4:13 p.m.*)
Tony Moye (*departed @ 4:00 p.m.*)
Bill Prather
Bob Warnock

Staff present:

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

Visitors:

Wayne Sullivan
Roger Morris
Michael Blaire
Chris Madigan
Frank Barker
Melvin Smith, CVS
TJ Kaplan, DaVita
Jimmy England, Walgreens
Melissa Price, Eldercare Pharmacy
Leslie May, Eldercare Pharmacy
Scott Biddulph, Target
Elizabeth Newcomb
Lindsay Burckhalter, Publix
Jennifer Layton, Publix
William Maguire, Omnicell
Daniel Sanchez, Omnicell
Christi Thromberg, Clinical Solutions
Jennifer Bellis, BSL
Robert Stannard, BSL
Scott Piper, Georgia Veterinary Med. Association
John Sisto, ESI
Stephen Snow, BSL
Scott Brunner, GPhA
Andy Freeman, GPhA
Kallarin Mackey, GHA
Lynda Chapman
Donald E. Kriest, GPhA
Renee McPhee, GPhA
Lanetta Mathis, GA Department of Public Health
LaKieva Williams, GA Department of Public Health
Coy Privette, Roadrunner Pharmacy

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

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

Executive Session

Georgia Drugs and Narcotics Agency – Dennis Troughton

- Non-resident pharmacies
- Transfer of drugs

Appearances

- W.T.S.
- M.R.B.
- C.M.

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

Open Session

Appearances

Appearance by William C. Macguire and Daniel Sanchez, Omnicell: Mr. Macguire thanked the Board for allowing him and Mr. Sanchez to meet with them. Mr. Macguire provided a handout to the Board and gave a brief presentation on Remote Automated Medication System (RAMS) in the post-acute care setting. Mr. Macguire mentioned that the intent is to allow the pharmacy technicians to restock the RAMS instead of a pharmacist.

Following the presentation, Ms. Wray commented that under Georgia law, “Remote automated medication system” means an automated mechanical system that is located in a skilled nursing facility or hospice licensed as such pursuant to Chapter 7 of Title 31 that does not have an on-site pharmacy and in which medication may be dispensed in a manner that may be specific to a patient. She stated that what they are presenting is more like a crash box or emergency kit. Ms. Wray also pointed out that, under Georgia law, the pharmacist shall be present and personally supervising the activities of the pharmacy technician at all times.

Mr. Miller commented that the Board decided to err on the side of caution when putting the rule pertaining to RAMS into effect. He expressed his concern with allowing a technician to do the restocking. He stated that the law would need to be changed before the Board could even consider this.

Appearance by LaKieva Williams, Volunteer Program Director, Georgia Department of Public Health: Ms. Williams spoke to the Board regarding Georgia Responds, an emergency preparedness and response program. Ms. Williams explained that out of the 9/11 Commission a credentialing system was set up and Georgia started a state registry of volunteers. She stated that individuals can sign up and affiliate themselves with an organization prior to an emergency. In the event of an emergency, registered individuals will be contacted when they are needed. Mr. Prather responded by stating that the Board appreciated Ms. Williams coming and explaining the program and that the Board is very supportive of this. Mr. Jones suggested putting a link for Georgia Responds on the Board’s website.

Public Hearing

Chairperson McConnell called the public hearing to order at 12:20 p.m.

Rule 480-34-.06 Hydrocodone Combination Products

No comments or written responses were received.

Bill Prather made a motion to adopt Rule 480-34-.06 Hydrocodone Combination Products. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Rule 480-11-.02 Compounded Drug Preparations

Public comments were received from Coy Privette, Regional Manager for Roadrunner Pharmacy. Mr. Privette stated that he is speaking for the veterinary profession and wholeheartedly supports what the Board is requiring; however, there are some areas of concern for Roadrunner Pharmacy. He requested the Board consider the veterinary needs for compounding and how they differ from human compounding when making some of these changes. Mr. Prather responded by stating that he feels the Georgia Board of Veterinary Medicine should express its concerns to the Board as to what changes should be made to this rule.

Public comments were received from Robert Stannard. Mr. Stannard stated he would like to address 480-11-.02(2)(a), which states that only a pharmacy licensed or registered by the Board may distribute compounded preparations to practitioners licensed in this state for administration to their patients in the course of their professional practice, either personally or by an authorized person under their direct and immediate supervision. He stated that there have been many questions raised by pharmacies about the interpretation of this. Ms. Wray responded that if a pharmacy distributes more than five percent of its total compounded preparations to practitioners for office use, it would need to be a 503b facility. If they are filling patient specific prescriptions, they can compound and ship out of state if they are compliant in that state. If they are doing office stock, they would be a 503b facility under federal law.

Written comments were received from the following:

Roadrunner Pharmacy

Todd A. Hughes

Dr. Gerald Skees, Family Pet Hospital

Jim Bracewell made a motion to adopt Rule 480-11-.02 Compounded Drug Preparations. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Rule 480-11-.08 Records and Reports.

No comments or written responses were received.

Laird Miller made a motion to adopt Rule 480-11-.08 Records and Reports. Chris Jones seconded and the Board voted unanimously in favor of the motion.

The hearing adjourned at 12:58 p.m.

Open Session

Approval of Minutes

Bill Prather made a motion to approve the Public Session minutes for the October 22, 2014 meeting. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Jim Bracewell made a motion to approve the Executive Session minutes for the October 22, 2014 meeting. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Ratifications

Laird Miller 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 Waiver – McIntosh Trail, Community Service Board d/b/a Pine Woods BHCC

Mike Faulk 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 Variance – Summit Cancer Care

Chris Jones made a motion to grant the rule variance petition pending proof of a favorable inspection by GDNA. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from John C. Saran, McGuire Woods, LLP

The Board considered this correspondence regarding the transfer of excess prescription drugs from one dialysis facility to another. The Board recommended tabling this matter pending receipt of additional information from Mr. Saran.

Correspondence from Patrick Ross, Pharmacy Director, QuadMed

The Board considered this correspondence regarding coverage via pager after hours. The Board recommended tabling this matter pending receipt of additional information from Mr. Ross.

Correspondence from Annika M. Mitchell

The Board considered this correspondence from Ms. Mitchell requesting to terminate her consent order. Laird Miller made a motion to approve the request. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Lynda Chapman

The Board considered this correspondence regarding Rule 480-10-.09 Prescription Drug Orders and the interpretation of “*reduce the same to writing*”. Ms. Chapman inquired as to whether or not this would include a secure tablet, ipad, laptop or PC touch screen. Laird Miller made a motion to direct staff to respond to Ms. Chapman by stating that the technology she mentioned would not qualify under the current rule. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence regarding Pauline M. Badicki, RPH020993

The Board considered this correspondence regarding two proposed pharmacists that Ms. Badicki could practice under the direct supervision of. The Board recommended tabling this matter until additional information is received from GDNA.

Correspondence regarding Alec W. Chan, RPH015567

The Board considered this correspondence regarding a request for the Board to enter an Order on his behalf showing his completion of discipline and termination of the Order. Bill Prather made a motion to direct staff to respond to Mr. Chan by stating that he has completed the terms of the Order and is in good standing. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jan Harris, Sharps, Inc.

The Board considered this correspondence regarding the DEA disposal rule. The Board recommended tabling this matter pending additional information from GDNA.

Correspondence from R. Scott Brunner, GPhA

The Board viewed this correspondence for informational purposes only.

Correspondence from Jennifer Schneider regarding Huvepharma, Inc.

The Board considered this correspondence requesting a Letter of Exemption. The Board recommended tabling this matter pending inspection by GDNA.

Correspondence from Jennifer Schneider regarding Ozburn-Hessey Logistics LLC d/b/a OHL

The Board considered this correspondence requesting a Letter of Exemption. The Board recommended tabling this matter pending inspection by GDNA.

Correspondence from An B. Vo

The Board considered this correspondence regarding pharmacist consultation. Chris Jones made a motion to direct staff to respond by referring Ms.Vo to the law and rules located on the Board’s website. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Severin T. Ritter, RPH015024

The Board considered this correspondence requesting the Board consider lifting all restrictions placed on his license. Bill Prather made a motion to deny his request. Bob Warnock seconded and the Board voted in favor of the motion, with the exception of Tony Moye who abstained from the vote.

Georgia Drugs and Narcotics Agency – Dennis Troughton

No report.

Attorney General’s Report – Janet Wray

No report.

Executive Director’s Report – Tanja Battle

Ms. Battle reported that the Board office currently has 97 non-resident pharmacy applications that are pending and are in various stages.

Chairperson McConnell asked about the clarifying statements on rules from a previous meeting. Ms. Battle responded that staff can research the minutes and bring back to the Board for discussion at the December meeting.

Ms. Wray mentioned that Rule 480-34-.06 was adopted by the Board during the public hearing. The rule adopted uses a date of February 1, 2015. The federal rule says April 6th. The Board needs to amend the rule to reflect the correct date.

Chris Jones made a motion to post Rule 480-34-.06 Hydrocodone Combination Products. Laird Miller seconded and the Board voted unanimously in favor of the motion.

480-34-.06 Hydrocodone Combination Products.

(1) Effective October 6, 2014, Official Code of Georgia Annotated (O.C.G.A.) §§16-13-27(4)(C), 16-13-27(4)(D) are hereby removed from Schedule III of the Georgia Controlled Substances Act, O.C.G.A. 16-13-25, et. seq. The following language shall be deleted from O.C.G.A. §§16-13-27(4): “(C) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with a fourfold or greater quantity of an isoquinoline alkaloid of opium; (D) Not more than 300 milligrams of dihydrocodeinone (hydrocodone), or any of its salts, per 100 milliliters or not more than 15 milligrams per dosage unit, with one or more active, nonnarcotic ingredients in recognized therapeutic amounts.”

(2) Effective October 6, 2014, all Hydrocodone Combination Products (HCPs) in the State of Georgia are Schedule II controlled substances.

(a) Each registrant possessing HCPs must make an actual count inventory of all HCPs as of October 6, 2014 and maintain it with the registrant's biennial DEA inventory.

(b) All HCPs products must be treated as any other Schedule II controlled substance. There can be no oral prescriptions except in the case of an emergency, and all hard-copy HCP prescriptions must be issued on security paper.

(c) For any HCP prescription written and filled before October 6, 2014 with authorized refills, the prescription can be refilled only for the authorized number of refills prior to ~~February 1~~ April 8, 2015.

(3) This rule is based on the following findings of the Board:

(a) that as Schedule III controlled substances, HCPs have an extremely high potential for abuse;

(b) that scientific evidence and scientific knowledge of the pharmacological effects of HCPs demonstrate that the public is at extreme risk if HCPs are not regulated as Schedule II controlled substances;

(c) that the history and pattern of abuse of HCPs as a Schedule III controlled substance and the scope and significance of that abuse support stricter regulation;

(d) that as a Schedule III controlled substance, there exists an imminent peril to the public health and welfare with regard to the abuse of HCPs;

(e) that HCPs have the same risk to the public health of citizens of the State of Georgia as other Schedule II controlled substances already contained in the Georgia Controlled Substances Act;

(f) that as of October 6, 2014, the U.S. Drug Enforcement Administration has removed all reference to HCPs from Schedule III of 21 CFR 1308.13, which places all HCPs under Schedule II of 21 CFR 1308.12.

A motion was made by Chris Jones, seconded by Laird Miller, and the Board voted that the formulation and adoption of this amendment 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.

Miscellaneous

Mike Faulk made a motion to approve the 2015 meeting and exam dates as presented. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Discussion was held by the Board regarding an additional practical exam date in 2015. Mr. Miller will contact the University of Georgia to verify graduation dates and ask how many exams they would be comfortable giving and bring this information back to the Board for discussion in December. Ms. Battle will contact PCOM.

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

Applications

- D.W.
- Q.A.
- L.H.
- S.R.
- K.S.Y.
- M.G.
- R.B.
- C.C.
- A.L.M.
- A.P.P.
- N.P.
- K.W.G.
- M.F.D.
- C.A.W.
- K.B.
- A.J.P.
- B.B.S.
- S.M.S.
- P.S.P.
- O.P.I.
- C.P.
- P.
- C.S.L.
- C.P.
- C.P.
- C.P.
- O.P.M.

Cognizant's Report – Laird Miller

- GDNA Case #A-14-41
- GDNA Case #A-14-37
- GDNA Case #A-14-42
- GDNA Case #A-14-38
- GDNA Case #T-31267
- GDNA Case #A-31215
- GDNA Case #A-31228
- GDNA Case #B-31249
- GDNA Case #B31223
- GDNA Case #A31230

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- J.D.A.H.
- B.A.

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

Ms. Wray discussed the following cases:

- A.B.
- M.C.
- A.P.
- R.P.
- B.R.

- S.B.
- K.B.

Correspondences/Requests

- F.K.U.L.
- C.L.W.
- J.A.S.
- J.W.
- M.B.
- T.W.
- T.E.K.
- K.W.
- B.F.H.
- J.L.D.
- R.B.H.S.

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

Open Session

Bob Warnock made a motion for the Board to take the following actions:

Georgia Drugs and Narcotics Agency – Dennis Troughton

- The Board received advice from Ms. Wray regarding non-resident pharmacies.
- The Board received advice from Ms. Wray regarding the transfer of drugs between hospitals and doctor’s offices.

Appearances

- W.T.S. Denied pharmacy technician registration
- M.R.B. Overturn denial pending receipt of additional information
- C.M. Approve with private consent order to be accepted upon receipt of the original

Applications

- | | | |
|--------------------|---------------------|--|
| • Delarion Walls | Pharmacy Technician | Approved registration |
| • Q.A. | Pharmacy Technician | Denied registration |
| • L.H. | Pharmacy Technician | Approved pending receipt of additional information |
| • S.R. | Pharmacy Technician | Denied registration |
| • K.S.Y. | Pharmacy Technician | Overturned denial and approved registration |
| • M.G. | Pharmacy Technician | Denied registration |
| • Racquel Brewster | Pharmacy Technician | Approved registration |
| • C.C. | Pharmacy Technician | Denied registration |
| • A.L.M. | Pharmacy Technician | Approved pending receipt of additional information |
| • Anoop P. Patel | Pharmacist Renewal | Approved |
| • Nitesh Patel | Pharmacist Renewal | Approved |
| • Kevin W. Garrett | Pharmacist Renewal | Approved |

- Matthew F. Duff Pharmacist Renewal Approved
- C.A.W. Pharmacist Applicant Denied application
- Kassahun Beimnet Pharmacist Renewal Approved
- Anish J. Patel Pharmacist Renewal Approved
- Brandon B. Savage Pharmacist Intern Approved application
- Stephen M. Shim Pharmacist Intern Approved application
- Par Sterile Products Wholesaler Pharmacy Approved application
- O.P.I. Wholesaler Pharmacy Send Voluntary C&D
- C.P. Non-Resident Pharmacy Table pending receipt of additional information

- Pharmerica Non-Resident Pharmacy Approved application
- Clinical Solutions Non-Resident Pharmacy Approved application
- C.P. Non-Resident Pharmacy Table pending receipt of additional information

- C.P. Non-Resident Pharmacy Table pending receipt of additional information

- C.P. Non-Resident Pharmacy Table pending receipt of additional information

- 1800 Pet Meds Non-Resident Pharmacy Approved application

Cognizant's Report – Laird Miller

- GDNA Case #A-14-41 Accept Private Interim Consent Order
- GDNA Case #A-14-37 Accept Private Interim Consent Order
- GDNA Case #A-14-42 Accept Private Interim Consent Order
- GDNA Case #A-14-38 Accept Interim Consent Order for Assessment
- GDNA Case #T-31267 Refer to the Attorney General's office for discipline and refer the investigative file to the Georgia Board of Nursing

- GDNA Case #A-31215 Refer to the Attorney General's office for discipline
- GDNA Case #A-31228 Close with letter of concern
- GDNA Case #B-31249 Close with no action
- GDNA Case #B31223 Close with no action
- GDNA Case #A31230 Refer to the Attorney General's office for discipline

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- J.D.A.H. Private consent order accepted
- B.A. Private consent order accepted
- S.J.B. Private consent order accepted
- L.B. Private consent order accepted
- C.H.S.R. Private consent order accepted
- D.D. Private consent order accepted
- E.H. Private consent order accepted
- E.U.H. Private consent order accepted
- F.R.H. Private consent order accepted
- F.M.C. Private consent order accepted
- G.P. Private consent order accepted
- H.M.C. Private consent order accepted
- W.H. Private consent order accepted

- W.K.K. Private impairment order accepted
- E.M. Private consent order accepted
- M.P. Private consent order accepted
- H.R. Private consent order accepted
- John Romeo Public consent order accepted
- S.J.H. Private consent order accepted
- S.I.P. Private consent order accepted
- A.S. Private consent order accepted
- T.S. Private consent order accepted
- T.M.C. Private consent order accepted
- V.S. Private consent order accepted
- W.M.H. Private consent order accepted
- W.C.H. Private consent order accepted
- W.D.H. Private consent order accepted
- W.K. Private consent order accepted
- W.P.H. Private consent order accepted
- W.G.M.C. Private consent order accepted
- B.B. Private consent order to be accepted and signed with express permission upon receipt of the original
- C.M.C. Private consent order to be accepted and signed with express permission upon receipt of the original
- C.C./R.D.S. Private consent order to be accepted and signed with express permission upon receipt of the original
- C.R. Private consent order to be accepted and signed with express permission upon receipt of the original
- C.V.S. Private consent order to be accepted and signed with express permission upon receipt of the original
- C.V.S. Private consent order to be accepted and signed with express permission upon receipt of the original
- J.D. Private consent order to be accepted and signed with express permission upon receipt of the original
- J.P. Private consent order to be accepted and signed with express permission upon receipt of the original
- I.E. Inactive status application to be accepted upon receipt of the original
- M.F. Private consent order to be accepted and signed with express permission upon receipt of the original
- S.F.H. Private consent order to be accepted and signed with express permission upon receipt of the original
- W.T. Private consent order to be accepted and signed with express permission upon receipt of the original

Ms. Wray discussed the following cases:

- A.B. Reject private consent order and close with letter of concern returning fine monies
- M.C. Close with letter of concern
- A.P. Close with letter of concern
- R.P. Close with letter of concern
- B.R. Close with letter of concern
- S.B. Close with no action

- K.B. Close with no action

Correspondences/Requests

- F.K.U.L. Notice of Discipline No action taken
- C.L.W. Intern Extension Request Request approved
- J.A.S. Request to lift consent order Request approved
- J.W. Correspondence Directed GDNA to handle
- M.B. Request to discontinue weekly therapy meetings Request approved
- T.W. Request to waive registration fee Request approved
- T.E.K. Correspondence No action taken
- K.W. Correspondence Directed staff to void license
- B.F.H. Correspondence Tabled pending receipt of additional information
- J.L.D. Request to obtain PIC status Request approved
- R.B.H.S. Remote Order Entry Denied

Laird Miller seconded and the Board voted in favor of the motion, with the exception of Chris Jones, who abstained from the vote regarding K.W.G.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, December 17, 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 5:05 p.m.

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