

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 36th Floor
Atlanta, GA 30303
April 13, 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 @ 9:41 a.m.*)
Laird Miller
Bill Prather
Bob Warnock

Staff present:

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

Visitors:

Chrs Entrekin-Falk
Derek Entrekin-Falk
Jennifer Hennessy, Enclara
John Loxterman, Enclara
Kristen Smith, Enclara
Helen Sloat, Kaiser Permanente; Hemophilia of GA
Leigh Carpenter, Hemophilia of GA
Jamie Diagostin, Eldercare Pharmacy
John Sisto, ESI
Sonya Nelson, Walmart
Travis Clark, CAPS Pharmacy
Chris Bossi, IN Range Systems, Inc.
Scott Lindsay, CAPS
Bhavesh Patel, Carepoint Pharmacy
Mike King, Publix
Young Chang, Walgreens
Brian Robinson, Walgreens
Greg Reysold, GPhA
Julie Ann Waterfield
Mickey Benson, Premier Kids Care Pharmacy

President Faulk established that a quorum was present and called the meeting to order at 9:02 a.m.

Bill Prather made a motion and Jim Bracewell 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

President Miller declared the meeting back in Open Session to proceed with a report from Director Allen.

Open Session

Georgia Drugs and Narcotics Agency – Rick Allen

Director Allen gave an update on the PDMP program. He reported that they are changing vendors for the program. He stated that this will be the only program that will allow sharing with other states. He added that they will probably switch over to the new program this summer.

Director Allen reported that HB783 passed.

Director Allen reported that he attended the National Drug Abuse Conference last week. He stated that there are new drugs on the horizon. Specifically, synthetic opioids and synthetic fentanyl. He stated that the Board will more than likely need to do emergency rules on these.

Bill Prather made a motion and Jim Bracewell 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

No report.

Cognizant's Report – Chris Jones

- GDNA Case # T-31741
- GDNA Case # T-31752
- GDNA Case # B-31618
- GDNA Case # A31767
- GDNA Case # B-31686
- GDNA Case # B-31691
- GDNA Case # B-31719
- GDNA Case # A31778

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- M.S.
- G.L.
- M.P.
- L.E.R.
- K.S.

Ms. Wray discussed the following cases:

- T.C.D.
- C.V.S.C.
- S.T.C.
- J.Y.C.
- F.S.

Appearances

- C.H.F.
- E.P.I.

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 Christopher E. Bossi, IN Range Systems, Inc: Mr. Bossi thanked the Board for the opportunity to speak to its members. He stated that the purpose of the meeting was to make the Board aware of a device dosing emergency kit and wanted to ensure that there is no objection by the Board to the company selling it in the State of Georgia. He presented a model device of the E-Kit and demonstrated how it functioned. Following his presentation, President Faulk thanked Mr. Bossi for his time.

Appearance by Bhavesh Patel, Carepoint Rx: Mr. Patel was present at the meeting to further discuss correspondence that was presented to the Board at its meeting in March 2016. Mr. Patel stated that the purpose of the correspondence was to ask if the facility can process remotely in Illinois and proceeded to present his proposal to the Board. After further discussion, Ms. Wray stated that Rule 480-36-.02 says the remote retail pharmacy has to be located in this state and that the Board cannot permit or endorse this under current rules. President Faulk advised Mr. Patel that he could submit a rule waiver petition to the Board for consideration.

Approval of Minutes

Bob Warnock made a motion to approve the Public and Executive Session minutes for the March 9, 2016 meeting as amended. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Ratifications

Chris Jones 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 Variance - Rockdale Medical Center, PHH005341

Chris Jones made a motion to grant the rule variance petition provided if their business model changes, they will be required to comply with the requirements set for in the rule. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Tammy McKnight Griffin, RPH020335

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

Petition for Rule Waiver - QOL Medical, LLC

Bob Warnock 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 - Robert J. Conaway, Jr., RPH012847

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

Petition for Rule Waiver - Duchesnay USA, Inc., dba Analog Pharma

Bob Warnock 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 - Select Specialty Hospital – Savannah

Bill Prather made a motion to grant the rule variance petition provided if their business model changes, they will be required to comply with the requirements set for in the rule. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Waiver - Julie Anne Waterfield, PHI-016143

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

Petition for Rule Variance - Genesis Treatment Center, PHOP000062

Laird Miller made a motion to grant the rule variance petition provided that, if their business model changes, they will be required to comply with the requirements set for in the rule. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Petition for Rule Variance - East Georgia Pain Clinic

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

Petition for Rule Waiver - R-Pharm US, LLC

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

Petition for Rule Variance - Select Specialty Hospital – Augusta

Laird Miller made a motion to grant the rule variance petition provided that, if their business model changes, they will be required to comply with the requirements set for in the rule. Chris Jones seconded and the Board voted unanimously in favor of the motion.

Correspondence from Rachael Andersen-Watts

The Board considered this correspondence regarding remote drug processing regulations. The Board directed staff to invite Ms. Andersen-Watts in for an appearance with the Board to further discuss the matter.

Correspondence from Margaret J. Geneau

The Board considered this correspondence requesting clarification on licensure requirements for freight forwarder. Lisa Harris made a motion to direct staff to respond to Ms. Geneau by referring her to House Bill 926.

Correspondence from Tracy Dabrowiak

The Board considered this correspondence requesting clarification on prescription transfer of controlled substances. In her correspondence, Ms. Dabrowiak mentions that Rule 480-22-11(3) states original and transferred prescriptions for controlled substances must be maintained for a period of 30 months, but 480-28-.08(c) states the required time period to maintain such records is two years. Additionally, Ms. Dabrowiak requested clarification on the required age of a pharmacy technician as Rule 480-15-.02 states the age is 17 years old; however, the FAQ on the Board's website states the required age is 18. Discussion was held by the Board regarding the time period listed in Rules 480-22-11(3) and 480-27-.08(c) and stated both rules need to be consistent and reflect two years. Ms. Foreman stated she would prepare a proposed amendment to the rule and bring it back to the Board for consideration at a later date.

The Board directed staff to respond to Ms. Dabrowiak that the required time period to maintain records for original and transferred prescriptions is two years. Additionally, the required age of an applicant for a pharmacy technician registration is 17 years old.

Correspondence from IWLA

The Board considered this correspondence from IWLA that was tabled from the Board's March 2016 meeting. The Board directed staff to respond by referring IWLA to House Bill 926.

Correspondence from Donna Tyburczy, State Licensing Servicing, Inc.

The Board considered this correspondence requesting a letter of exemption for Ozburn-Hessey Logistics, LLC d/b/a OHL. The Board directed staff to respond to Ms. Tyburczy by stating that it does not require companies that only ship non-prescription OTC drugs to be licensed in this state.

Correspondence from William White

The Board considered this correspondence from Mr. White. The Board directed staff to respond to Mr. White by referring him to House Bill 926.

Correspondence from Stuart T. Williams

The Board viewed this correspondence for informational purposes only.

Correspondence from Jena Burns, Efficiency Plus Medical Billing

The Board considered this correspondence regarding Durable Medical Equipment providers in the State of Georgia. The Board directed staff to respond to Ms. Burns by stating that the Board only regulates the distribution of prescriptive devices; otherwise, a license is not required at this time.

Correspondence from L.R. Dillon

The Board considered this correspondence requesting to know if the Board has specific plans for addressing the recently released USP Chapter 800 on hazardous drugs. The Board directed staff to respond by stating the Board would require all licensees to comply with the professional standards in the industry.

Correspondence from Martiyha Simmons, Cantrell Drug Company

The Board considered this correspondence regarding licensure of outsourcing facilities. The Board directed staff to respond to Ms. Simmons by referring her to House Bill 926.

Attorney General's Report – Janet Wray

Ms. Wray reported that Attorney General Samuel Olens has sent a press release stating that he is supporting a change in the federal rules that would require opioid treatment centers to submit data regarding the prescriptions they dispense to the State's Prescription Drug Monitoring Program (PDMP). Bill Prather made a motion to direct staff to send a letter of support of this position from the Board. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Executive Director's Report – Tanja Battle

Correspondence from James Taylor, Governor's Office of Planning and Budget: The Board viewed this correspondence for informational purposes only.

Continuing Education Report (programs approved January 2016 to present): Report presented.

Correspondence from Michele Noble: The Board considered this correspondence regarding whether a Georgia pharmacy license is required for the shipment of diabetic testing materials into Georgia by a non-

resident pharmacy. The Board directed staff to respond by stating if it is dispensed by a pharmacy, pursuant to a prescription, then the pharmacy needs to be licensed.

Correspondence from Kimberley Hazelwood, Georgia Department of Public Health: The Board considered this correspondence requesting the Board's assistance regarding a pilot program for pandemic influenza. The Board directed staff to invite Ms. Hazelwood in for an appearance with the Board to further discuss the matter.

Request for Advisory Opinion from Steve Minor: The Board considered this correspondence requesting an advisory opinion regarding the ability of a licensed hospital pharmacy to serve multiple locations. The Board directed staff to invite Mr. Minor in for an appearance with the Board to further discuss the matter.

Miscellaneous

The Board discussed potential amendments to Rule 480-2-.03 Experience Requirements. The Board recommended tabling this item until the May meeting to allow for additional time to make the changes discussed.

The Board discussed revisions to Chapter 480-51 Interchangeable Biological Products. The Board recommended tabling this item until the May meeting to allow for additional time to make the changes discussed.

Lisa Harris made a motion to post Rule 480-22-.11 Transfer Between Pharmacies of Controlled Substance Prescription Drug Order Information for Refill Purposes as amended. Bob Warnock 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.

(1) The transfer of original prescription drug order information for a C-III, IV, or V substance for the purpose of refill dispensing is permissible between pharmacies one time only.

(a) However, pharmacies electronically sharing a real-time, online computerized database may transfer the prescription drug order information as many times as there are authorized refills, up to the maximum of five (5) times, if it is within six (6) months from the date of issuance.

(2) A transfer is considered a communication between two licensed pharmacists and/or pharmacy interns/externs. Transfers are subject to the following requirements:

(a) The transferring pharmacist or pharmacy intern/extern shall record the following information in either real time or at the first opportunity after the transfer:

1. The word "VOID" must be written on the face of the original, hard copy, invalidated prescription drug order;

2. The following must be written on the back of the original, invalidated prescription drug order: the name, address, telephone number, and DEA number of the pharmacy to which it is transferred, and the name of the pharmacist receiving the prescription information; and

3. The date of the transfer and the name of the pharmacist transferring the information must be recorded on the back of the prescription drug order.

(b) The pharmacist or pharmacy intern/extern receiving the transferred prescription drug order information shall reduce it to writing and record the following information:

1. The word "TRANSFER" shall be written on the face of the transferred prescription drug order hard-copy;

2. All information required to be recorded on a prescription drug order pursuant to this chapter, which shall include:

(i) Date the prescription drug order was originally issued by the prescribing practitioner;

- (ii) The number of refills authorized on the original prescription drug order.
 - (c) Date the prescription drug order was originally dispensed by the transferring pharmacy;
 - (d) Number of valid refills remaining, and date(s) and pharmacy location(s) where any previous refills were dispensed;
 - (e) The pharmacy's name, address, telephone number, DEA number, and prescription serial number from which the prescription information was transferred; and
 - (f) The name of the pharmacist who transferred the prescription drug order.
- (3) The original and transferred prescription(s) must be maintained for a period of ~~30 months~~ two years from the date of the last refill.
- (4) Pharmacies electronically transferring a prescription drug order for the purpose of refills must maintain the same information and record keeping requirements as do pharmacies with manual, non-electronic record keeping systems.

A motion was made by Bill Prather, seconded by Chris Jones, and the Board voted that the formulation and adoption of this rule does not impose excessive regulatory cost on any licensee and any cost to comply with the proposed rule cannot be reduced by a less expensive alternative that fully accomplishes the objectives of the relevant code sections.

In the same motion, the Board voted that it is not legal or feasible to meet the objectives of the relevant code sections to adopt or implement differing actions for businesses as listed at O.C.G.A. § 50-13-9 16 5 9 4(a)(3)(A), (B), (C) and (D). The formulation and adoption of this rule will impact every licensee in the same manner and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

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 Vicki Arnold, Jim Bracewell, Mike Faulk, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Executive Director's Report – Tanja Battle

- GDNA Case #B-30916C

Applications

- S.S.L.
- T.L.C.
- D.K.R.
- K.M.D.
- R.G.W.
- N.G.
- C.W.
- G.C.
- W.R.
- R.G.S.
- F.G.S.
- B.Z.A.
- A.U.
- B.M.Z.

- K.N.S.
- L.G.
- R.W.M.
- T.G.
- S.B.
- D.M.T.
- E.P.

Correspondences

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

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

Open Session

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

Georgia Drugs and Narcotics Agency – Rick Allen

No report.

Cognizant’s Report – Chris Jones

- GDNA Case # T-31741 Revoke technician registration until signed interim consent order received
- GDNA Case # T-31752 Revoke technician registration

- GDNA Case # B-31618 Refer to the Attorney General's office
- GDNA Case # A31767 Table the application and conduct investigative interview
- GDNA Case # B-31686 Refer to the Attorney General's office
- GDNA Case # B-31691 Close case with no action
- GDNA Case # B-31719 Close case with no action
- GDNA Case # A31778 Refer to the Attorney General's office / approve 2nd location for permit

Attorney General's Report – Janet Wray

Ms. Wray presented the following consent orders:

- Mark Sharer Public consent order accepted
- G.L. Private consent order accepted
- Metter Pharmacy Public consent order accepted
- L.E.R. Private consent order accepted
- K.S. Private consent order accepted

Ms. Wray discussed the following cases:

- T.C.D. Close case with no action
- C.V.S.C. Close second referral
- S.T.C. Private consent order to be accepted and signed with express permission upon receipt of the original
- J.Y.C. No action taken
- F.S. No action taken

Appearances

- C.H.F. Request to discuss reinstatement The Board directed staff to notify applicants of requirements.
- E.P.I. Denied Non-Resident Pharmacy Overturn denial for non-resident pharmacy application / Refer PBM to Attorney General's office for discipline

Executive Director's Report – Tanja Battle

- GDNA Case #B-30916C Close case with no action

Applications

- S.S.L. Pharmacy Technician Denied registration
- T.L.C. Pharmacy Technician Denied registration
- D.K.R. Pharmacy Technician Denied registration
- K.M.D. Pharmacy Technician Denied registration
- Ramon G. Wilmot Pharmacy Technician Approve for registration
- N.G. Pharmacy Technician Denied registration
- Colton White Pharmacy Technician Approve for registration
- G.C. Pharmacy Technician Denied registration
- W.R. Pharmacy Technician Denied registration
- Ryan G. Smith Pharmacist Intern Approved application
- Francis G. Sykes Pharmacist Intern Approved application
- B.Z.A. Pharmacist Intern Table pending receipt of additional information
- A.U. Pharmacist Reinstatement Approve application for reinstatement, but deny request for refund
- B.M.Z. Pharmacist Reinstatement Denied application
- K.N.S. Pharmacist Reciprocity Approved to sit for the exam
- L.G. Pharmacist Reciprocity Approved to sit for the exam
- R.W.M. Pharmacist Reciprocity Approved to sit for the exam
- T.G. Pharmacist Examination Denied application

- S.B. Pharmacist Reinstatement Table pending receipt of additional information
- D.M.T. Pharmacist Reinstatement Table pending receipt of additional information
- E.P. Retail Pharmacy Table pending receipt of additional information

Correspondences

- K.S.M.I. Notice of discipline No action taken
- C.M.P.S. Notice of discipline No action taken
- P.C. Notice of discipline No action taken
- Z.P.I. Notice of discipline No action taken
- C.P.F. Notice of discipline No action taken
- B.I.S. Notice of discipline No action taken
- W.K.F.P. Request to terminate probation Request approved
- L.T.C. Request to terminate probation Request approved
- R.S. Request to meet via conf call Request denied
- E.G.R.M.C.S. Remote order entry Table pending receipt of additional information
- C.L. Request for expedited review Request denied
of application
- C.P. Notice of discipline No action taken
- M. Notice of discipline No action taken
- C.H. Notice of discipline No action taken
- T.E.D. Request to lift PIC restriction Request denied
- T.S.H. Remote order entry Table pending receipt of additional information
- S.R.V. Appearance request Request approved
- C.P. Correspondence For informational purposes only
- A.I. Request for reduction of Request denied
reinstatement fee
- B.R. Notice of discipline No action taken
- N.J. Request to retake NAPLEX Request denied
- J.F.C. Correspondence For informational purposes only
- W.L.R. Request to be reconsidered as Request denied
Pharmacy technician
- K.R.S. Request to lift PIC restriction Request denied
- T.P.S.I. Notice of discipline No action taken
- D.G. Request to lift no ownership Request approved
of pharmacy restriction
- E.P. Correspondence Table pending receipt of additional information.
Once information has been received, refer to the
Attorney General's office

Lisa Harris seconded and the Board voted unanimously in favor of the motion.

In the same motion, the Board directed staff to respond to Christopher E. Bossi, IN Range Systems, Inc. by stating that while the Board does not endorse or approve specific products, the product does not appear to be in violation of the law and rules of the Board. Additionally, the company needs to notify Georgia Drugs and Narcotics Agency as to when the product will become operational.

There being no further business to discuss, the meeting was adjourned at 3:43 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, May 11, 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