

GEORGIA BOARD OF PHARMACY
Board Meeting
University of Georgia College of Pharmacy
250 W Green St
Athens, GA 30602
June 6, 2018
9:00 a.m.

The following Board members were present:

Chris Jones, President
Bill Prather, Vice-President
Vicki Arnold
Jim Bracewell
Mike Faulk
Lisa Harris
Laird Miller
Bob Warnock

Staff present:

Tanja Battle, Executive Director
Dennis Troughton, Director, GDNA
Ronnie Higgins, Deputy Director, GDNA
Max Changus, Assistant Attorney General
Brandi Howell, Business Support Analyst I

Visitors:

Jennifer Bellis, Bendin, Sumrall & Ladner
Mary L. Malchak
Jaclyn Scott, Eldercare Pharmacy
Lindsay Burckhalter, Publix
Simy Casasola, Walgreens
Adam Schrepp, Walgreens
Jeenu Philip Walgreens
Leigh Carpenter, Hemophilia of Georgia
Nichelle Sims, Hemophilia of Georgia
Keri Conley, GHA
Andrew Brown, GHA
Travis J. Clark, CAPS Atlanta
Yu Jin Kang, CAPS Atlanta
Gene Volfson, Walmart
Lindsey Lawing, Student-Eldercare
Jeff Cox
Glenn Parkman, Glenn's Corner Pharmacy
Alecia Lackley
Lou Semrad III, Jefferson Hospital

Open Session

President Jones established that a quorum was present and called the meeting to order at 9:05 a.m.

Approval of Minutes

Bob Warnock made a motion to approve the Public Session minutes from the May 16, 2018 meeting. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Bob Warnock made a motion to approve the Executive Session minutes from the May 16, 2018 meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to approve the Public Session minutes from the May 17, 2018 meeting. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Bill Prather made a motion to approve the Executive Session minutes from the May 17, 2018 meeting. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

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

Petitions for Rule Variance or Waiver

Mike Faulk made a motion to deny the rule waiver petition from Fortis K9 Services, LLC. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Bob Warnock made a motion to approve the rule waiver petition from Verastem Oncology. Vicki Arnold seconded and the Board voted unanimously in favor of the motion. In the same motion, the Board voted to amend the Petition for Rule Variance or Waiver form to include a line on page two of the document for "Printed Name".

Correspondence from Timothy Koch

The Board considered this correspondence asking if the pharmacist can change the dispensed quantity of a medication, using professional judgement, in consultation with the patient, without speaking directly with the practitioner. Bill Prather made a motion to direct staff to respond by stating that there is nothing in the law or rules that would prohibit such and that the Board strongly emphasizes the importance of the pharmacist clearly communicating any changes to the patient. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Andrea Dietze

The Board considered this correspondence asking if there are any steps in place designated by the pharmacy to couriers in regards to protecting prescriptions and should these Uber, Door Dash and other delivery services not be certified and hold that responsibility in accordance with the laws of pharmacy. Bob Warnock made a motion to refer Ms. Dietze to Board Rule 480-48-.03 Delivery by Pharmacy. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence from Leigh Carpenter, Hemophilia of Georgia

The Board considered this correspondence requesting to distribute hemophilia medication outside of the United States. Ms. Carpenter was present and the meeting and spoke to the Board regarding her request. She stated that Hemophilia of Georgia has been asked by the World Federation of Hemophilia, USA, to act as a shipper of donated hemophilia factor products to underdeveloped countries as part of a humanitarian aid project. She stated that Hemophilia of Georgia has obtained an FDA Export Certificate. Jim Bracewell made a motion to approve the request. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Dennis Troughton

In case Board members were to receive calls about the inspection of opioid treatment facilities, Director Troughton reported that GDNA will only conduct inspections of such facilities once the license, through the DCH's Healthcare Facility Regulation Division has been issued.

Director Troughton stated that GDNA hopes to hire another agent in the next fiscal year.

Director Troughton reported that GDNA has conducted 1,915 investigations and received 343 complaints for the fiscal year.

Attorney General’s Report – Max Changus

No report.

Executive Director’s Report – Tanja Battle

Continuing Education Report: Report presented. Jim Bracewell made a motion to ratify the below continuing education programs approved since the previous meeting. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
05/30/2018	.5	Kaiser Permanente	Migraines: What a Pain! The Next Era of Migraine Prevention	2018-0007

Correspondence from Marjorie Roberts, Newton Homeopathics & American Academy of Clinical Homeopathy: The Board considered this correspondence regarding the Board’s denial of the continuing education application for the program “Basic Homeopathic Principles”. In Ms. Roberts’ letter, she requests suggestions from the Board in order to gain approval for the program. Mr. Prather indicated that he, as cognizant, completed research regarding the scientific value of homeopathy. Mr. Prather suggested Ms. Roberts contact ACPE to see if it would review and approve the course. Mr. Miller stated that he did see the value regarding courses related to homeopathy; however, he did agree on the suggestion to have ACPE review the materials. Bill Prather made a motion to direct staff to respond to Ms. Roberts by suggesting she contact ACPE to review the course, and if ACPE approves it, resubmit the continuing education application to the Board for consideration. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence from Tim Wakeley: The Board considered this correspondence which states that Mr. Wakeley is in the process of writing a business plan to supply a medication dispensing system in homes for the functioning (self-administration) elderly population. Mr. Wakeley requests the Board supply him with the rules and regulations he would need to comply with to be able to offer this service or any related information. Bill Prather made a motion to direct staff to respond to Mr. Wakeley by stating there is nothing specific to his inquiry and suggesting he review the law and rules listed on the Boards website. Lisa Harris seconded the motion and the Board voted unanimously in favor of the motion.

Inquiry Regarding Technician Education: Ms. Battle reported that at the May 16, 2018 meeting, the Board requested staff inquire with NABP regarding this matter. The response from NABP was provided to the Board. President Jones recommended tabling this information until the July meeting to allow additional time to review.

Constituent Inquiry from Senator William Ligon: The Board considered an inquiry regarding issues relating to accessible drugs. Bob Warnock made a motion to direct staff to respond by stating to be aware that prescription fentanyl is not prohibited in Georgia. Regarding the matter of hydromorphone, it is the Board’s understanding that the shortage is due to a manufacturing shortage. Lastly, the Board has no oversight or input regarding costs of drugs. Unfortunately, the Board does not have a remedy to address this issue. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Legal Services – Kimberly Emm

No report.

Miscellaneous

Institutional Pharmacy Rule Draft: Mr. Warnock spoke to the Board regarding the draft presented. He stated that this addresses things for institutional pharmacies that are currently licensed as retail pharmacies. He stated that institutional pharmacies tend to have differing practices at times that do not always fit into the retail pharmacy rules. He gave an example of chart orders. He stated that the purpose of this rule is trying to bridge the gap between institutional and retail pharmacies. He stated this is not to exclude anyone from practicing in retail pharmacy. Mr. Warnock stated that he tried to add language that would either clarify or permit certain practices in institutional pharmacies. Mr. Faulk responded by stating the example related to chart orders makes sense; however, his concern regarding any unintended consequences related to carving out these types of pharmacies and how they may impact cost. President Jones requested Ms. Emm review the draft presented with Mr. Changus and report back to the Board. Mr. Miller stated that he can see this being an issue for insurance companies down the road where they mandate the designation as an institutional pharmacy. Mr. Warnock responded that there are already those regulations addressing such. Mr. Miller expressed his concerns and stated that he agrees with taking the next step, but feels the Board should proceed slowly. President Jones commented that there has been discussion regarding having an institution license and to him it seems easier to do this than change a number of rules. He added that the Board has begun work on this rule and is confident that it will receive a lot of feedback from each member and the public. He further suggested the Board read through the draft and send his/her concerns to Ms. Emm. After further discussion, the Board recommended tabling the matter for further discussion at the July meeting.

Rule 480-34-.13 Triamcinolone Acetonide Nasal Spray: Mike Faulk made a motion to post Rule 480-34-.13 Triamcinolone Acetonide Nasal Spray. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Rule 480-34-.13 Triamcinolone acetonide nasal spray

(1) This rule was adopted to protect the health, safety, and welfare of the public. Triamcinolone acetonide nasal spray 55mcg per spray or less, is hereby deleted from the dangerous drug list as referenced in the Official Code of Georgia Annotated (O.C.G.A.) § 16-13-71(b)(976).

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

(a) that triamcinolone acetonide nasal spray 55mcg per spray or less does not have a high potential for abuse;

(b) that the Board has considered the scientific evidence of its pharmacological effects; the state of current scientific knowledge regarding the drug; the history and current pattern of abuse; the scope, duration, and significance of abuse; the potential of the drug to produce psychic or physiological dependence liability; and

(c) that the drug, when in nasal spray form of 55mcg per spray or less has been approved for non-prescription status by the Federal Food and Drug Administration.

Rule 480-34-.14 Sodium Chloride Injection for Catheter Flush: Mike Faulk made a motion to post Rule 480-34-.14 Sodium Chloride Injection for Catheter Flush. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Rule 480-34-.14 Sodium chloride injection for catheter flush

(1) This rule was adopted to protect the health, safety, and welfare of the public. Sodium chloride injection in quantities of 10cc or less, when used as a catheter flush solution to act by physically occupying space within a catheter and exerting pressure on the patient's circulating blood, is hereby deleted from the dangerous drug list as referenced in Official Code of Georgia Annotated (O.C.G.A.) § 16-13-71(b)(867).

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

(a) that sodium chloride injection in quantities of 10cc or less does not have a high potential for abuse;

(b) that the Board has considered the scientific evidence of its pharmacological effects, the state of current scientific knowledge regarding the drug, the history and current pattern of abuse, the scope, duration, and significance of abuse, the potential of the drug to produce psychic or physiological dependence liability; and

(c) that the Federal Food and Drug Administration concluded that sodium chloride injection (saline injection or flush), when used as a catheter flush solution and acting in this manner, this solution meets the definition of a device in that it affects the structure or function of the body, and does not achieve its primary intended purposes through chemical or metabolic action.

Rule 480-10-.09 Oral Prescription Drug Orders: Ms. Emm stated that based on the minutes from the May 16, 2018 meeting, the Board discussed correspondence received regarding Rule 480-10-.09. She stated that the Board directed her to amend the rule to add language stating, *“If the prescription is reduced to writing via electronic means, such record must be readily retrievable and produced to the Board or a GDNA Agent upon request.”* Discussion was held by the Board. President Jones asked if it is ok for someone to handwrite the prescription or type it up. Director Troughton responded by stating that an electronic reflection of the reduction is acceptable if it has all the information. He added that GDNA likes to see the handwritten prescriptions, too. Mr. Warnock commented that while he is not familiar with the system the other members use, he stated there is a system where everyone has his/her own login. He stated one can go back and see who entered the prescription. If this scenario happened over the phone, the initials would be of the pharmacist receiving the call. Director Troughton added that written prescriptions are great as any evidence and actions are helpful for them. Ms. Arnold commented that in a hospital setting, the Joint Commission requires the pharmacist to reduce it to paper and repeat it back just to reduce the number of errors. President Jones asked if this needs to be changed in the rule. After further discussion, the Board recommended not pursuing any amendments to the rule at this time.

Rule 480-13-.01 Definitions: Ms. Emm stated that due to changes in the law, which will be effective July 1st, the Board will need to make changes to its rule. President Jones requested Ms. Arnold work with Ms. Emm on the necessary changes to present back to the Board.

Rule 480-13-.04 Absence of Pharmacist: Ms. Emm stated that due to changes in the law, the Board will need to make changes to this rule.

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

In the same motion, the Board also 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 § 50-13-4(a)(3)(A), (B), (C) and (D). The formulation and adoption of these rule amendments will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Notice of Proposed Rulemaking from the Department of Public Health: In regards to the notice from the Department of Public Health regarding revisions to Chapter 511-7-2, Bill Prather made a motion to respond by suggesting they add the word “extern” to 511-7-2.04(2)(b). Laird Miller seconded and the Board voted unanimously in favor of the motion.

Miscellaneous

Correspondence from Todd Pledger: The Board considered this correspondence requesting clarification of Rule 480-7B Durable Medical Equipment Suppliers and exemptions. Lisa Harris made a motion to

direct Board staff to respond by referring Mr. Pledger to section (6) of Rule 480-7B-.02. Mike Faulk seconded and the Board voted in favor of the motion.

Vicki Arnold made a motion and Mike Faulk 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

Appearances

- J.F.C.
- A.L.L.

No voted were taken in Executive Session. President Jones declared the meeting back in Open Session.

Open Session

Appearance

Lou Semrad III, CEO of Jefferson Hospital: Mr. Semrad provided a handout of information and spoke to the Board regarding Jefferson Hospital. He stated that, as most of the members are pharmacists, he is sure they are aware of the overall costs of pharmaceuticals. He stated that while in a small hospital, the volume is low, but they have to buy in bulk. He added that the average cost to the pharmacy for a particular drug that they only use three to four times per year may cost over \$5000. Mr. Semrad went on to discuss Jefferson Hospital’s proposal to repackage selected, non-scheduled pharmaceuticals for resale to hospital pharmacies with an emphasis on rural hospitals. One of the benefits of which would decrease pharmacy inventory expenses. Mr. Semrad stated the facility would be unable to do this under its existing license. He added that he has researched and has been unable to find this service available to a pharmacy in this scope. After further discussion with the Board, the Board recommended Mr. Semrad contact the FDA to find out how he should proceed.

Mr. Semrad inquired about licensure for over-the-counter products. Deputy Troughton responded that licensure is not required as long as the drug is not on the dangerous drug list.

Bill Prather made a motion and Lisa Harris 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

Applications

- W.M.R.
- K.E.D.
- B.A.E.
- K.T.N.

Appearance

- M.L.M.

Georgia Drugs and Narcotics Agency – Dennis Troughton

- L.S.
- GDNA Case #A-32511

Cognizant’s Report – Bill Prather

- GDNA Case #A-32424
- GDNA Case #B-32451
- GDNA Case #A-32499
- GDNA Case #A-32537
- GDNA Case # T-32474
- GDNA Case # T-32544
- GDNA Case # B-32432
- GDNA Case # B-32493
- GDNA Case # B-32495
- GDNA Case # A-32427
- GDNA Case # B-32524
- GDNA Case # A-32500
- GDNA Case # B-32540
- GDNA Case # A-32536
- GDNA Case # A-32538
- GDNA Case # B-32530
- GDNA Case # B-32489
- GDNA Case # A-32522
- GDNA Case # A-32461
- GDNA Case # A-32552
- GDNA Case #A-32549

Attorney General’s Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- E.F.P.
- S.T.G.
- C.P.

Mr. Changus discussed the following cases:

- A.H.G.I.
- P.P.S./J.C.
- M.C.

Executive Director’s Report – Tanja Battle

No report.

Legal Services – Kimberly Emm

- P.R.

Applications

- T.A.F.
- J.A.R.
- R.N.B.
- H.L.C.
- J.R.
- S.K.H.
- C.W.J.
- C.W.J.
- H.N.
- S.M.V.
- H.A.J.

Correspondences/Requests

- S.P.
- A.R.W.P.
- A.H.
- E.P.
- L.S.C.P.
- R.P.
- O.P.S.I.
- U.S.C.I.
- A.D.V.I.
- A.D.V.I.
- G.A.T.
- B.M.Z.
- T.H.
- L.A.B.
- M.B.B.
- C.V.S.C.

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

Open Session

Mike Faulk made a motion for the Board to take the following actions:

Appearances

- | | | |
|----------|-------------------------------------|------------------|
| • J.F.C. | Request to lift supervised practice | Approved request |
| • A.L.L. | Denied Pharmacy Technician | Denial Upheld |

Applications

- | | | |
|----------|------------------------|--|
| • W.M.R. | Pharmacist Reciprocity | Approved to sit for the exam/once individual has passed the exam, schedule to meet with the Board. |
| • K.E.D. | Pharmacist Exam | Approved to sit for the exam |
| • B.A.E. | Pharmacist Exam | Approved to sit for the exam |
| • K.T.N. | Pharmacist Exam | Approved to sit for the exam |

Appearance

- M.L.M. Request to discuss pending reinstatement Table pending receipt of additional information

Georgia Drugs and Narcotics Agency – Dennis Troughton

- L.S. Third Party Distributor Denied application
- GDNA Case #A-32511 Table pending receipt of additional information

Cognizant’s Report – Bill Prather

- GDNA Case #A-32424 Misfill Policy #3 for two misfills/ Board will revisit GDNA Cases #B-32451 and A-32499 if facility does not close
- GDNA Case #B-32451 Close with no action
- GDNA Case #A-32499 Close with no action
- GDNA Case #A-32537 Accept Voluntary Surrender
- GDNA Case # T-32474 Revoke Technician Registration
- GDNA Case # T-32544 Revoke Technician Registration
- GDNA Case # B-32432 Close with a letter of concern
- GDNA Case # B-32493 Close with a letter of concern in reference to #A-32532
- GDNA Case # B-32495 Misfill Policy #1
- GDNA Case # A-32427 Schedule Investigative Interview
- GDNA Case # B-32524 Close with no action
- GDNA Case # A-32500 Refer to the Department of Law
- GDNA Case # B-32540 Misfill Policy #1
- GDNA Case # A-32536 Schedule Investigative Interview
- GDNA Case # A-32538 Refer to the Department of Law
- GDNA Case # B-32530 Close with no action
- GDNA Case # B-32489 Close with no action
- GDNA Case # A-32522 Approved to sit for the exam/once individual has passed the exam, schedule to meet with the Board.
- GDNA Case # A-32461 Refer to the Department of Law
- GDNA Case # A-32552 Refer to the Department of Law
- GDNA Case #A-32549 Revoke Technician Registration

Attorney General’s Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

- Express Food and Pharmacy Public Consent Order accepted
- S.T.G. Public Consent Order to be accepted and signed with express permission upon receipt of the original
- Concord Pharmacy Public Consent Order accepted

Mr. Changus discussed the following cases:

- A.H.G.I. Close with no action
- P.P.S./J.C. Update provided
- M.C. Update provided

Executive Director’s Report – Tanja Battle

No report.

Legal Services – Kimberly Emm

- P.R. Correspondence Board directed staff to respond by stating a valid license is needed.

Applications

- T.A.F. Pharmacy Technician Table pending receipt of additional information
- J.A.R. Pharmacy Technician Table pending receipt of additional information
- R.N.B. Pharmacy Technician Table pending receipt of additional information
- H.L.C. Pharmacy Technician Table pending receipt of additional information
- J.R. Pharmacy Technician Schedule to meet with the Board
- S.K.H. Pharmacy Technician Denied application
- C.W.J. Pharmacist Examination Approved to sit for the exam
- C.W.J. Pharmacist Intern Denied application
- H.N. Temporary Pharmacist Denied application
- S.M.V. Pharmacist Reinstatement Table pending receipt of additional information
- H.A.J. Pharmacist Reciprocity Approved to sit for the exam

Correspondences/Requests

- S.P. Notice of Discipline No action
- A.R.W.P. Notice of Discipline No action
- A.H. Notice of Discipline No action
- E.P. Notice of Discipline No action
- L.S.C.P. Notice of Discipline No action
- R.P. Notice of Discipline Refer to the Department of Law
- O.P.S.I. Notice of Discipline No action
- U.S.C.I. Notice of Discipline No action
- A.D.V.I. Explanation re FDA inspection No action
- A.D.V.I. Explanation re FDA inspection No action
- G.A.T. Appearance request Approved request
- B.M.Z. Request to lift PIC restriction Approved request
- T.H. Request to take MPJE a 5th time Approved request
- L.A.B. Request to take MPJE a 4th time Approved request
- M.B.B. Request to terminate probation Approved request
- C.V.S.C. Request to terminate probation Approved request

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

Miscellaneous

Ms. Battle commented that the practical examination at the University of Georgia is always a huge undertaking due to the high number of candidates. She stated that there are 423 candidates scheduled for such. Ms. Battle spoke of the many components required to administer the examination and publicly acknowledged staff along with Deputy Lacefield, who is responsible for ensuring a successful administration. The Board expressed its appreciation for the hard work of the staff.

There being no further business to discuss, the meeting was adjourned at 4:01 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, July 18, 2018 at 9:00 a.m. at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5th Floor, Atlanta, GA 30303.

Minutes recorded by Brandi Howell, Business Support Analyst I
Minutes edited by Tanja D. Battle, Executive Director