

GEORGIA BOARD OF PHARMACY
Board Meeting
South University School of Pharmacy
709 Mall Blvd
Savannah, GA 31406
January 15, 2020
9:00 a.m.

The following Board members were present:

Lisa Harris, President
Carrie Ashbee
Michael Azzolin
Michael Brinson
Hal Henderson
Bill Prather
Dean Stone

Staff present:

Tanja Battle, Executive Director
Eric Lacefield, Deputy Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Tommy Roe, Special Agent, GDNA
Max Changus, Assistant Attorney General
Kimberly Emm, Attorney
Brandi Howell, Business Support Analyst I

Visitors:

Maria Lam, Publix
Becca Hallum, GHA
John Rocchio, CVS Health
John Sisto, ESI

Open Session

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

Approval of Minutes

Bill Prather made a motion to approve the Public and Executive Session minutes from the December 11, 2019 meeting. Dean Stone seconded and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

Michael Brinson made a motion to ratify the list of licenses issue. Dean Stone seconded and the Board voted unanimously in favor of the motion.

Petitions for Rule Waiver or Variance

Michael Brinson made a motion to approve the rule waiver petitions from University Hospital McDuffie, PHH007930, Grady General Hospital, PHH006595, Memorial Hospital and Manor Pharmacy, PHRE006099, and Memorial Hospital and Manor, PHH005916. Bill Prather seconded and the Board voted unanimously in favor of the motion.

President Harris welcomed new member, Mr. Azzolin.

Correspondence from Pam Wilkinson, C3 Healthcare Rx

The Board considered this correspondence regarding medication therapy management (MTM) work. Specifically, Ms. Wilkinson's correspondence asks if the pharmacist doing the MTM work needs to be licensed in Georgia, or just licensed in North Carolina where the dispensing pharmacy is. Carrie Ashbee

made a motion to direct staff to respond by stating that the pharmacist doing the MTM work does not have to be licensed. Dean Stone seconded and the Board voted unanimously in favor of the motion.

Correspondence from Eric Hartkopf

The Board considered this correspondence asking whether or not a pharmacy can fill/dispense a schedule II prescription before the “fill on or after date” with verbal approval from the prescriber’s office. Dean Stone made a motion to direct staff to respond to Mr. Hartkopf by referring him to O.C.G.A. § 26-4-80(f)(1) for more information. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jan Howell, Envolve

The Board considered this correspondence asking how the Board treats pharmacists who are serving on behalf of a pharmacy benefits manager (PBM) conducting medication therapy management (MTM). President Harris stated that this correspondence was similar to the first correspondence discussed from Pam Wilkinson. Ms. Emm discussed O.C.G.A. § 26-4-110.1(b). Mr. Changus commented that this provision a little different for PBMs. He stated that it allows the Board to inspect out-of-state. Discussion was held regarding whether it is the pharmacist or the PBM being licensed. Mr. Changus stated that the law seems to contemplate both in the definition. After further discussion was held, Mr. Stone made a motion to refer this correspondence and the correspondence from Pam Wilkinson to the Department of Law for advice. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Trephe Brown

The Board considered this correspondence asking if it is legal to dispense CBD oil 0.3%. President Harris commented that it is assumed Ms. Brown means as a prescription. Director Troughton responded that it is not dispensed over-the-counter, so he assumes she is asking to dispense as a prescription. Mr. Henderson asked if it is certain Ms. Brown meant to state “dispense” or “sell”? Director Troughton responded by stating that while he did not speak previously with her regarding this matter, this question was sent to him. He stated that he will be glad to communicate with Ms. Brown to verify that she is talking about dispensing. He further stated that if it is 0.3% or less, the individual would have to comply with the law. The Board agreed to Director Troughton responding to Ms. Brown.

Correspondence from Hayward E. Mayfield

The Board considered this correspondence regarding Mr. Mayfield being unable to obtain his wife’s prescription on time. Mr. Mayfield’s correspondence goes on to state that he requested the pharmacist issue his wife a single tablet which would be replaced the following morning when he would see her physician and obtain a written prescription. Mr. Mayfield stated that the pharmacist was unable to process his request. Dean Stone made a motion to direct staff to respond to Mr. Mayfield by stating that it is sympathetic to his concerns; however, O.C.G.A. § 26-4-80(j) states that the pharmacist cannot dispense a controlled substance without a prescription. Carrie Ashbee seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jason Elliott, MAP International

The Board considered this correspondence requesting permission to export prescription drugs outside the United States. Hal Henderson made a motion to approve the request with the understanding that they must comply with all state, federal, and other country’s laws that pertain to the shipping of drugs. Michael Azzolin seconded and the Board voted unanimously in favor of the motion.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton welcomed Mr. Azzolin to the Board. He stated that Mr. Azzolin, and any other board members were welcome to visit GDNA to see what they do.

Director Troughton reported that GDNA has conducted 1400 inspections and received 210 complaints for FY2020.

Director Troughton discussed the prescription pick-up locker that was presented to the Board in November and discussed again at its December meeting. He stated that Ms. Nishi sent some information to GDNA. He further stated that Ms. Nishi had said there are five states that allow these kiosks. Director Troughton stated that their concept is to make that locker system a wall. He stated that the Board asked GDNA to look into several items. The first being: Are you allowing access to a pharmacy? He stated the patient accesses a code through his/her phone to get the medications. Director Troughton commented that, by law, the drugs are not allowed to be stored outside the pharmacy.

Director Troughton stated the other issue pertains to patient counseling. He commented that the offer of counseling is made on the screen and according to Ms. Nishi, the company says the patient can touch a button and contact the pharmacist with any questions. Director Troughton stated the Board needs to consider if they provide a pharmacist after hours and if the patient contacting a pharmacist that is not physically there, only via remote counseling, would be sufficient? Mr. Henderson asked how does the counseling work with mail order? Director Troughton responded by stating that is covered in the rule. Ms. Emm added that the Board also needs to consider the security side of it. She stated if this product were to be put in an independent pharmacy, the entire building has to lock down when the pharmacy closes. She added that how a pharmacy has to be secured is addressed in the law. After further discussion, Bill Prather made a motion to refer this matter to the Department of Law for legal analysis. Michael Brinson seconded and the Board voted unanimously in favor of the motion.

Attorney General's Report – Max Changus

Mr. Changus introduced himself to Mr. Azzolin and explained his role with the Board. He suggested Mr. Azzolin review Title 26-4 and 16-13 and Board of Pharmacy Rules and Regulations.

Executive Director's Report – Tanja Battle

Ms. Battle welcomed Mr. Azzolin to the Board. She explained to Mr. Azzolin that now that he has been sworn in, he could expect inquiries regarding board matters such as applications and investigations, both of which are confidential. Ms. Battle indicated that she has shared her contact information and he may use it to refer any inquiries.

Ms. Battle reported that she emailed the board members information regarding the financial disclosure form that is due by the end of the month. She informed Mr. Azzolin that he does not have to complete it; however, all other board members need to complete it as quickly as possible because it is due at the end of the month. She stated that this is a requirement through the Ethics Commission.

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

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
01/25/2020	1	UGA Gamma Phi chapter of Kappa Psi	Hepatitis C and You	2019-0016

ACPE Invitation for Site Evaluation: Ms. Battle reported that the site evaluation is in March. She stated that if anyone is interested in going to please let her know.

PDMP Advisory Committee: Ms. Battle reported the upcoming meeting is on 01/29/2020 from 10:00 a.m. to 12:00 p.m. She stated that a new board member will need to be appointed to the committee. President Harris stated her intention is to appoint Mr. Faulk and he can check his availability for such.

Medical Cannabis Commission Meeting: Ms. Battle reported that she, along with Mr. Lacefield and Ms. Emm, attended the first meeting of the Georgia Access to Medical Cannabis Commission on December 18th. Mr. Prather, who is on the Commission, stated the next meeting is scheduled for January 25th. Mr. Prather stated that at the first meeting, they mainly listened to patients. He stated that he always thought it was not a good thing to have drugs not approved being dispensed; however, he stated that, if you listen to the patients that are using this, it would be somewhat of a travesty to not allow them access to it. Mr. Prather stated that the Board of Pharmacy will be involved in this and one of those will be licensing. Ms. Emm added that the Board will only be responsible for licensing the pharmacies that want to dispense. Mr. Prather stated that he personally feels pharmacies are ideally set up to do this type of thing as far as infrastructure to deal with what is narcotics. He stated that as far as how dispensaries will work, he is very concerned about that. Mr. Prather stated that he contacted all four pharmacy schools in Georgia and none of them teach a course on marijuana. He stated that they are all planning to add courses regarding such. He further stated that the Commission will have to establish an entire new industry in Georgia beginning with who plants the seeds, who harvests it, who grows it, etc. Mr. Prather stated that to him, it is essential for the people who really need this product. He further stated he will keep the Board updated and informed.

Legal Services – Kimberly Emm

Rule 480-31-.01 Patient Counseling: Ms. Emm stated that at the Board's last meeting, she was asked to add that personal offers to counsel may be made verbally or in written format to section (c) of the rule. She stated that the proposed amendment is available on Sharepoint for the Board to review.

O.C.G.A. § 26-4-119 Pharmacy Anti-Steering and Transparency Act: Ms. Emm stated that originally, when this was posed to the Board of Pharmacy, it was not expected to create a huge impact; however, as of January 1st, the Board office has been receiving numerous calls. She stated that staff is directing complainants to complete the electronic form on the website. She further stated that subsection (f) is what the Board needs to address. Subsection (f) reads, *"If a pharmacy licensed or holding a nonresident pharmacy permit in this state has an affiliate, it shall annually file with the board a disclosure statement identifying all such affiliates."* Ms. Emm stated that it does not pose a deadline. She added that the board office is receiving questions asking when is the annual disclosure date. Mr. Prather asked what is being disclosed. Mr. Azzolin responded by stating whether or not they have an affiliate. He continued by stating that it is directing the PBM to say if they are a pharmacy and if they own a PBM, that information has to be disclosed. Mr. Azzolin suggested June 30th as the deadline as that date would fall in line with pharmacy renewals. Ms. Emm responded by stating that the Board would need to add this into Chapter 480-10 and Rule 480-6-.02. Mr. Prather suggested postponing the matter until the Board sees what passes in legislature. Mr. Azzolin stated that this is simply notification of an affiliate and the Board could amend the rule, if needed. Ms. Emm commented that if the Board proceeds with making this change, staff would have information to provide to callers who are inquiring about such. Discussion was held by Mr. Changus, stating that the Board would need to look at this closely to determine how to proceed.

At this time, the Board went back to discussing Rule 480-31-.01 Patient Counseling. Michael Azzolin made a motion to post Rule 480-31-.01 Patient Counseling. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Rule 480-31-.01 Patient Counseling

Purpose: The purpose of the regulations issued in this part is to comply with the requirements of the Omnibus Budget Reconciliation Act of 1990 and to enhance the public health and welfare by providing

that pharmacists shall offer consultation to patients regarding their medications and various conditions which could affect or be affected by the use of those medications.

(a) Patient Records.

1. A patient record system shall be maintained by all pharmacies for patients for whom Prescription Drug Orders are dispensed. For purposes of the regulations under this part, "Prescription Drug Order" is defined to mean the lawful order of a Practitioner for a Drug or Device for a specific patient. The patient record system shall provide for the immediate retrieval of information necessary for the Dispensing Pharmacist to identify previously dispensed drugs at the time a prescription drug order is presented for dispensing. The Pharmacist or his designee shall make a reasonable effort to obtain, record, and maintain the following information:

- (i) full name of the patient for whom the Drug is intended.
- (ii) address and telephone number of the patient;
- (iii) date of birth; and
- (iv) patients gender.

2. The Pharmacist shall make a reasonable effort to obtain from the patient or the patient's agent and shall record any known allergies, drug reactions, idiosyncrasies, and chronic conditions or disease states of the patient and the identity of any other Drugs, including over-the-counter Drugs, or devices currently being used by the patient which may relate to Prospective Drug Review unless the patient or the patient's agent refuses such information. The Pharmacist shall make a reasonable effort to obtain, record, and maintain the following information:

- (i) A list of all Prescription Drug Orders obtained by the patient at the Pharmacy where the Prescription Drug Order is being filled within the preceding two years, showing prescription number, name and strength of the Drug, the quantity and date dispensed, the name of the Practitioner; and
- (ii) comments from the Pharmacist relevant to the individual's drug therapy, including any other information peculiar to the specific patient or Drug.

3. A patient record shall be maintained for a period of not less than two years from the date of the last entry in the profile record. This record may be a hard copy or a computerized form.

(b) Prospective Drug Review.

1. A pharmacist shall review the patient record and each Prescription presented for Dispensing for purposes of promoting therapeutic appropriateness by identifying:

- (i) over-utilization or under-utilization;
- (ii) therapeutic duplications;
- (iii) drug-disease contraindications;
- (iv) Drug-Drug interactions;
- (v) incorrect Drug dosage or duration of Drug treatment;
- (vi) Drug-allergy interactions;
- (vii) clinical abuse/misuse.

2. Upon recognizing any of the above, the Pharmacist shall take appropriate steps to avoid or resolve the problem which shall, if necessary, include consultation with the Practitioner.

(c) Patient Counseling.

1. Upon receipt of a Prescription Drug Order and following a review of the patient's record, the dispensing Pharmacist shall personally offer to discuss matters which will enhance or optimize drug therapy with each patient or caregiver of such patient. The personal offer to counsel may be made verbally or in written format; a written offer must provide a telephone number and business hours during which the dispensing pharmacist can be reached. Such discussion shall be in person, whenever practicable, or by telephone and shall include appropriate elements of patient counseling, based on the professional judgment of the pharmacist. Such elements may include but are not limited to the following:

- (i) the name and description of the Drug;
- (ii) the dosage form, dose, route of Administration, and duration of drug therapy;
- (iii) intended use of the Drug and expected action;

- (iv) special directions and precautions for preparation, Administration, and use by the patient;
 - (v) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;
 - (vi) techniques for self-monitoring drug therapy;
 - (vii) proper storage;
 - (viii) prescription refill information;
 - (ix) action to be taken in the event of a missed dose; and
 - (x) Pharmacist comments relevant to the individual's Drug therapy, including any other information peculiar to the specific patient or Drug.
2. Additional forms of patient information shall be used to supplement Patient Counseling when appropriate.
3. Patient Counseling, as described above and defined in the Act, shall not be required for:
- (i) in-patients of a hospital or institution where other licensed health care professionals are authorized to administer the drug(s).
 - (ii) inmates of correctional institutions where pharmacy services are provided by the Georgia Department of Corrections or by county or municipal political subdivisions either directly or by a subcontractor of the above; or
 - (iii) patients receiving drugs from the Georgia Department of Human Resources Division of Public Health; provided however, that pharmacists who provide medications to patients in accordance with Section 43-34-26.1 of the Official Code of Georgia Annotated shall include in all dispensing procedures a written process whereby the patient or the caregiver of such patient is provided with the information contained in Chapter 480-31 of the Rules of the Georgia State Board of Pharmacy.
 - (iv) refills of prescription drug orders for which, in the professional judgment of the Pharmacist, appropriate counseling has taken place or has been declined. The need for counseling on refills resides in the professional judgment of the dispensing Pharmacist.
4. A Pharmacist shall not be required to counsel a patient or caregiver when the patient or caregiver refuses such consultation.
5. These rules will become effective January 1, 1993.
- (d) Nothing in these rules shall be interpreted so as to prohibit the pharmacist from being remunerated for said professional services.

A motion was made by Dean Stone, seconded by Bill Prather, and the Board voted that the formulation and adoption of this rule amendment does not impose excessive regulatory cost on any licensee and any cost to comply with the rule amendment 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 this rule amendment will impact every licensee in the same manner, and each licensee is independently licensed, owned and operated and dominant in the field of pharmacy.

Michael Brinson made a motion and Dean Stone 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 Carrie Ashbee, Michael Azzolin, Michael Brinson, Lisa Harris, Hal Henderson, Bill Prather and Dean Stone.

Georgia Drugs and Narcotics Agency – Dennis Troughton

- C.M.H.
- W.C.R.M.C.

Cognizant’s Report – Dennis Troughton

- GDNA Case # T33153
- GDNA Case # T33160
- GDNA Case # A32954
- GDNA Case # B33015
- GDNA Case # A33035
- GDNA Case # B33055
- GDNA Case # A33089
- GDNA Case # B33093
- GDNA Case # B33094
- GDNA Case # B33097
- GDNA Case # A33100
- GDNA Case # B33111
- GDNA Case # B33114
- GDNA Case # A33123
- GDNA Case # B33129
- GDNA Case # B33130
- GDNA Case # A33134
- GDNA Case # A33136
- GDNA Case # T33167
- GDNA Case # A33137
- GDNA Case # A33141
- GDNA Case # A33172

Attorney General’s Report – Max Changus

The Board received legal advice regarding O.C.G.A. § 26-4-48 and O.C.G.A. § 50-18-70.

Mr. Changus discussed board member recusal from applications/investigative matters.

Mr. Changus discussed the following individuals:

- H.B.C.
- D.A.R.

Mr. Changus presented the following consent orders for acceptance:

- C.V.S.
- P.P.
- W.

Executive Director’s Report – Tanja Battle

- P.W.G.P.

Legal Services – Kimberly Emm

- S.P.C.

Applications

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

Correspondences/Requests

- Y.R.P.
- H.F.P.A.S.
- A.
- F.S.S.P.
- C.D.
- H.S.T.
- G.R.
- A.P.
- C.
- K.C.P.
- W.
- W.
- W.
- E.A.S.
- C.N.S.

No votes were taken in Executive Session. President Harris 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 – Dennis Troughton

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| <ul style="list-style-type: none"> • C.M.H. • W.C.R.M.C. | <ul style="list-style-type: none"> Retail Pharmacy Retail Pharmacy | <ul style="list-style-type: none"> Denied application Denied application |
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Cognizant’s Report – Dennis Troughton

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| <ul style="list-style-type: none"> • GDNA Case # T33153 • GDNA Case # T33160 • GDNA Case # A32954 • GDNA Case # B33015 • GDNA Case # A33035 • GDNA Case # B33055 • GDNA Case # A33089 • GDNA Case # B33093 | <ul style="list-style-type: none"> Accept Voluntary Surrender Accept Voluntary Surrender Refer to the Department of Law Close with a letter of concern Investigative Interview Misfill Policy #1 Refer to the Department of Law Close with no action |
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- GDNA Case # B33094 Close with a letter of concern
- GDNA Case # B33097 Close with no action
- GDNA Case # A33100 Refer to the Department of Law
- GDNA Case # B33111 Close with no action
- GDNA Case # B33114 Close with no action
- GDNA Case # A33123 Refer to the Department of Law
- GDNA Case # B33129 Issue Cease & Desist letter and refer to the Georgia Board of Cosmetology and Barbers
- GDNA Case # B33130 Investigative Interview
- GDNA Case # A33134 Refer to the Department of Law
- GDNA Case # A33136 Refer to the Department of Law
- GDNA Case # T33167 Revoke Technician Registration
- GDNA Case # A33137 Close with a letter of concern
- GDNA Case # A33141 Refer to the Department of Law
- GDNA Case # A33172 Refer to the Department of Law/Table pending additional information on pharmacy #2

Attorney General’s Report – Max Changus

The Board received legal advice regarding O.C.G.A. § 26-4-48 and O.C.G.A. § 50-18-70.

Mr. Changus discussed board member recusal from applications/investigative matters.

Mr. Changus discussed the following individuals:

- H.B.C. Pharmacist Reinstatement Close case and approve application
- D.A.R. Pharmacist Reinstatement Amend referral to the Department of Law

Mr. Changus presented the following consent orders for acceptance:

- CVS #5692 Public Consent Order accepted
- Pineview Pharmacy Public Consent Order accepted
- Walgreens #10479 Public Consent Order accepted

Executive Director’s Report – Tanja Battle

- P.W.G.P. Durable Medical Equipment Supplier Overturn denial and approve application

Legal Services – Kimberly Emm

- S.P.C. Correspondence Board directed staff to respond to individual that it will reconsider him for reinstatement once the criminal matter has been resolved.

Applications

- K.E.Z. Pharmacy Technician Denied application
- Britney D. Jennings Pharmacy Technician Approved for registration
- Samuel R. Parks Pharmacy Technician Approved for registration
- A.L.J. Pharmacy Technician Denied application

- Ayshley Y. Bautista Pharmacy Technician Approved for registration
- D.N. Pharmacist Reciprocity Approved to sit for the exam
- K.E.T. Pharmacist Reinstatement Table pending receipt of additional information
- M.A.J. Pharmacist Certification of DTM Table pending receipt of additional information
- C.A.K. Pharmacist Certification of DTM Table pending receipt of additional information
- G.C.S. Pharmacist Certification of DTM Table pending receipt of additional information
- C.E.V.A.F. Durable Medical Equipment Supplier Denied application

Correspondences/Requests

- Y.R.P. Notice of Discipline No action
- H.F.P.A.S. Notice of Discipline No action
- A. Notice of Discipline No action
- F.S.S.P. Notice of Discipline No action
- C.D. Notice of Discipline No action
- H.S.T. Notice of Discipline No action
- G.R. Notice of Discipline No action
- A.P. Notice of Discipline No action
- C. Notice of Discipline No action
- K.C.P. Notice of Discipline No action
- W. Request for approval of security system Denied request
- W. Request for approval of security system Denied request
- W. Request for approval of security system Denied request
- E.A.S. Request to lift PIC restriction Approved request
- C.N.S. Correspondence Refer to the Department of Law

Hal Henderson seconded and the Board voted in favor of the motion, with the exception of Michael Azzolin, who recused himself from the vote regarding C.M.A. and W.C.R., and Michael Brinson, who recused himself from the vote regarding GDNA Case # B33015.

There being no further business to discuss, the meeting was adjourned at 4:02 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, February 12, 2020 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, NW, 6th Floor, Atlanta, GA 30303.

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