

GEORGIA BOARD OF PHARMACY
Board Meeting
2 Peachtree Street, NW, 5th Floor
Atlanta, GA 30303
May 16, 2018
9:00 a.m.

The following Board members were present:

Chris Jones, President
Bill Prather, Vice-President
Vicki Arnold
Jim Bracewell
Mike Faulk (*arrived @ 10:44 a.m.*)
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:

Jim Bartling
Andrew Brinton
Heather Durie
Devin Kreel, CSG
Anne Compton-Brown
Stacy Burke, Publix
Rena Estep, Walgreens
Diane Sanders, Kaiser Permanente
Helen Sloat, Kaiser Permanente/Hemophilia of GA
John Rocchio, CVS Health
Stephen Georgeson, GRA Pharmacy Council
Amanda Roberson, Elder Care Pharmacy
Beth Jarrett, Walmart
Snehal Doshi, WellStar
Susan Jackson, WellStar Kennestone
TJ Kaplan, JLM
Heather Prichard, Med Allergy, LLC
John Sundstrom, DVM, Veterinary Board
Heather Lindell, UGA
Scott Piper, GA Veterinary Medical Association
Thomas Beusse, Georgia Retailers
Mary Leslie Malchak
Shea Ross-Smith, Kaiser Permanente
Keri Conley, GA Hospital Association
Lea Bonner, Mercer University
Ryan Koenig, JFC
Stephen Snow, BSL
Leigh Carpenter, Hemophilia of Georgia

President Jones established that a quorum was present and called the meeting to order at 9:25 a.m.

Jim Bracewell 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. Voting in favor of the motion were those present who included Vicki Arnold, Jim Bracewell, Lisa Harris, Chris Jones, Laird Miller, Bill Prather and Bob Warnock.

Executive Session

Appearance

- A.S.B.

Open Session

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

Appearance

- A.S.B. Pharmacist Examination Approved to sit for the exam

Laird Miller seconded and the Board voted unanimously in favor of the motion.

Appearance

Appearance by Mr. Robert Brennan, Parker Hudson Rainer & Dobbs, Ms. Susan Jackson and Mr. Snehal Doshi, WellStar Kennestone. Mr. Brennan stated that the purpose of the appearance was based on his letter to the Board dated March 2, 2018 regarding the relocation of the Kennestone Emergency Department. The correspondence requested clarification as to whether Kennestone could continue servicing its emergency department patients under its current hospital pharmacy license once the emergency department is moved into a new building located on the Kennestone main campus. He provided the Board with handouts and a picture of the enclosed sky bridge that connects the main hospital to the proposed hospital emergency department. Mr. Brennan stated that he knows this has been a prior concern of the Board's in regards to a facility being on campus or not. Ms. Jackson explained that hospital personnel and patients will have access to the enclosed sky bridge. Family members may use the sky bridge but only while escorted by hospital personnel. The general public will not have access. President Jones asked Director Troughton for his input. Director Troughton responded that this would be consistent with other places the Board has ruled on previously. He added that as long as GDNA would still be able to access Pyxis and records, it would not change anything. Mr. Miller commented that the Board may need to see something in writing saying that the sky bridge would not be used for anything other than hospital personnel and transporting patients. Ms. Jackson responded by stating that only personnel with a secured badge have access. After further discussion, Laird Miller made a motion to direct staff to respond to Mr. Brennan by stating that a separate pharmacy license will not need to be obtained for this purpose. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Mr. Brennan stated the other issue that they would like to speak to the Board about concerns a proposal to begin bedside delivery of medications to uninsured and underinsured patients being discharged from WellStar Douglas Hospital. Patients who elect this option would have their medications delivered to them on the day of their discharge from the hospital by the retail pharmacy located at WellStar Cobb Hospital. A summary of the program was provided to the Board. Concerns from the Board were raised regarding patient counseling. After questions and concerns were raised by the Board, Mr. Changus stated that what is being proposed sounds like central fill. He stated O.C.G.A. § 26-4-60(11)(c) reads, "A pharmacist or pharmacy to dispense a prescription and deliver it to another pharmacist or pharmacy to make available for a patient to receive the prescription and patient counseling according to Code Section 26-4-85. The State Board of Pharmacy shall adopt any rules and regulations necessary to implement this subparagraph". Mr. Miller commented that the Board is finalizing rules regarding Central Fill and until those rules are adopted, this matter should be tabled.

President Jones stated that the Board wants to ensure that they are being compliant with what is out there right now, but until the rules have been adopted the Board will be unable to give them a firm answer.

Approval of Minutes

Jim Bracewell made a motion to approve the Public Session minutes from the April 18, 2018 meeting. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Lisa Harris made a motion to approve the Executive Session minutes from the April 18, 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

The Board discussed the rule waiver petition submitted by Complete Care Pharmacy, PHNR000382. A representative of Complete Care Pharmacy was present. The representative explained that the company will undergo a change of ownership. Under Illinois law, which is their home state, they must obtain a new resident pharmacy license; however, Illinois is currently backlogged with processing applications. She explained the application was submitted expeditiously so when they go to closing they can continue to serve as an out of state pharmacy, but the application has not been processed by Illinois of yet. She stated that the buyer and seller have executed a power of attorney. President Jones asked if the Board needs to do anything if the seller has power of attorney. Mr. Changus responded that in Illinois they are proceeding with moving the application forward and she has submitted the application here in a timely fashion. He stated he does not see this as an issue. Mr. Changus added that the rule petition should be withdrawn. President Jones advised the representative to send notice in writing to withdraw the rule petition and to also notify the Board office once the application in Illinois has been approved.

Vicki Arnold made a motion to grant the rule waiver petition from Unison Behavioral Health, PHRE005641, and suggested the facility have hand sanitizer available where medications are dispensed. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Jim Bracewell made a motion to grant the rule waiver petition from Vyair Medical, Inc. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Vicki Arnold made a motion to grant the rule waiver petition from Vyair Medical, Inc. Lisa Harris seconded and the Board voted unanimously in favor of the motion.

Correspondence from Jonathan Sistare

The Board considered this correspondence regarding DME licensure. Bob Warnock made a motion to direct staff to respond by requesting additional information. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Correspondence from Julie Surdy

The Board considered this correspondence regarding Rule 480-10-.09 Oral Prescription Drug Orders. Ms. Sturdy's correspondence asks if the rule requires oral prescriptions be handwritten, or is typewritten or electronic acceptable. Additionally, are pharmacies allowed to enter the oral prescription directly into the computer system. Laird Miller made a motion to direct Ms. Emm 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."* Bill Prather seconded and the Board voted

unanimously in favor of the motion. In the same motion, the Board directed staff to respond to Ms. Sturdy by stating there are no issues with the practice you describe in your inquiry.

Correspondence from Nick Meza, Quarles & Brady, LLP

The Board considered this correspondence regarding physician ownership of pharmacies in Georgia and referrals to such entities if integrated into the practice and what is the Board's position regarding Rule 480-5-.03(b). Jim Bracewell made a motion to direct staff to respond by stating regarding the issue of Board Rule 480-5-.03(b), the Board would certainly need to review the specific circumstances of any arrangement that came to its attention that implicates this provision. However, the Board would certainly keep in mind the statutes comprising the Patient Self-Referral Act and the directives provided by the General Assembly in this area before concluding that there was any violation of the Board's Patient Self-Referral prohibition. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Heather Prichard, MedAllergy, LLC

The Board considered this correspondence asking if the company needs to apply for a wholesaler permit. Ms. Prichard, who was present at the meeting, gave a description of what the company does. She explained that MedAllergy provides a software portal through which medical providers can order compounded prescriptions of allergen extracts from pharmacies with whom they partner. After further discussion, Laird Miller made a motion to direct staff to respond to Ms. Prichard by stating that the facility would need a wholesale license. Additionally, request Ms. Prichard submit a powerpoint presentation of the software discussed for the Board to review. Jim Bracewell seconded and the Board voted unanimously in favor of the motion.

Correspondence from Bob Warnock

The Board considered this correspondence requesting clarification of Rule 480-22-.04(5)(a). Specifically, Mr. Warnock, who was present at the meeting, asked if the Board allows a pharmacy to accept a faxed copy of a controlled drug prescription from a nursing facility which received the original order as a faxed copy from the original prescriber if all of the requirements in section (5)(a) of Rule 480-22-.04 are followed regarding the transmitted order? Mike Faulk made a motion to direct staff to respond by stating that it would take a legislative change for this to be permitted. Laird Miller seconded and the Board voted unanimously in favor of the motion.

Correspondence from Bradley Cook, Brown & Fortunato

The Board considered this correspondence regarding what types of transactions constitute changes of ownership. President Jones directed Mr. Prather to review Rule 480-6-.01 Pharmacy Licenses for updating. Laird Miller made a motion to direct staff to respond to Mr. Cook by stating that the Board is working to revise the rules regarding this matter. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Correspondence from Christine Cassetta, Quarles & Brady

The Board considered this correspondence regarding the National Suppliers Clearinghouse List. Jim Bracewell made a motion to direct staff to respond by stating the Board has previously been in correspondence with them and is not inclined to respond further. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

Correspondence from Juan Morado, Jr.

The Board considered this correspondence regarding whether therapeutic interchange is allowed in Georgia. The Board recommended tabling this correspondence to allow time for additional review by Mr. Changus.

Georgia Drugs and Narcotics Agency – Dennis Troughton

Director Troughton reported that GDNA has conducted 1,783 investigations and received 322 complaints for the fiscal year.

Director Troughton reported that he participated in a panel discussion concerning the opioid crisis. He stated it was very informative. He commented that he was representing GDNA, who works for the Board, not the Board itself. He added that Mr. Bracewell was also in attendance.

Director Troughton stated that Deputy Higgins received the NABP John Atkinson Service Award for National Compliance Officer of the Year. He stated that Deputy Higgins is invaluable to the agency.

Director Troughton reported that the legislature approved an increase in GDNA’s budget for agents’ salaries. He stated that he and the agents appreciate everyone’s support. He added that GDNA would be able to hire another agent sometime in the near future.

Attorney General’s Report – Max Changus

Mr. Changus reported that he appeared on an opioid panel for the Georgia Academy of Healthcare Attorneys. He stated he was there as a representative of the Attorney General’s office and not a representative of the Board. He commented that it was a well-attended conference.

Mr. Changus reported on correspondence from Sue Spohn, Gemco Medical, that was referred to his office for review at the April 2018 meeting. The correspondence was in reference to whether they need DME license. Mr. Changus suggested referring Ms. Spohn to O.C.G.A. § 26-4-51 for more information.

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. Bob Warnock seconded and the Board voted unanimously in favor of the motion.

Date of Program	Hours	Sponsoring Group	Program Title	CE Code
05/10/2018	.5	Kaiser Permanente	Mythical Methadone	2018-0005
05/03/2018	.5	Kaiser Permanente/Urvi Choksi	Infusion/Ambulatory Clinic/Oncology CPS at Kaiser Permanente	2018-0006

Mr. Prather commented that he has reviewed two or three requests for homeopathic continuing education and has denied them. He stated he will continue to do so unless the Board states otherwise.

Initial License/Score Transfer: Ms. Battle stated that she received correspondence from a potential applicant interested in reciprocity. Georgia law requires reciprocity applicants to use their first issued license by NAPLEX examination or score transfer to use as a basis for transfer. Ms. Battle stated that the email from NABP to the individual states NABP and every other state considers two states to be the individual’s primary license by exam. Georgia’s law states the initial license has to be in good standing in order to reciprocate. Tennessee was the first license issued in this case, so that license must be used; however, the individual would be required to reinstate the Tennessee license or apply by exam and retake the NAPLEX. Ms. Harris asked if the Board should look at this issue if it is the only state with this specific restriction. Mr. Warnock asked if there was any explanation as to why the individual would not switch to the other one and apply? Ms. Battle responded because she would need to reinstate it. She stated the individual would have to take the NAPLEX again in Tennessee and she is trying to avoid that. Mr. Miller asked if one could not take the exam in multiple states and have two licenses issued independently.

Ms. Battle responded that one could, but one will be issued before the other and Georgia law says “initial” and not “dual”. The Board agreed that the license that was issued first would need to be active.

Discussion Topics

Pharmacy Technician Education/Certification: President Jones stated that right now the Board requires them to just be registered. There has been some discussion on a national level of requiring a bachelor’s degree of pharmacy technicians. He asked the Board for its opinion on this matter. Mr. Prather responded by stating from a historical perspective, the only reason the Board required registration of technicians was due to the number of incidences of theft. At the time, the Board considered education requirements but was concerned that it might impeded the passing of legislation. The Board agreed that it was most important to have technicians registered. Mr. Bracewell commented by stating with expanded roles of technicians and ratios, the Board should consider a minimum level of training to have a skilled person to assist the pharmacist. President Jones stated that if the Board pursued this avenue, it would not want to implement the requirement of certification immediately; instead, the Board could consider giving everyone two years to meet the requirement. Mr. Prather suggested starting the process slowly and giving a timeframe of saying when one had to be certified. Mr. Miller commented by stating that one can go online and take a test and be certified. He stated there are individuals who spend a year and a half in vocational school to become certified. He stated that he found that those who went to school have a better concept of what a drug does. However, while he does feel the technicians need to be certified, he sees there being a problem with almost having to grant those individuals who have PTCB certification more than two years to complete additional training. He added that the Board then puts itself in the situation of having to evaluate the coursework. He stated that PTCB, to him, is more of a testing organization than an educational organization. He stated the Board requires applicants for a pharmacist license to go to school before a test is taken. He asked what the Board would require for technicians. He stated maybe it is the PTCB test, but he feels the Board would want them to have the education prior to such. Mr. Bracewell stated that PTCB was looking for a proposal to require education, but that did not happen. President Jones responded by stating that he thinks some of the colleges of pharmacy are looking to put that under their umbrella. Mr. Bracewell suggested incentivizing people. He stated that by having a certified person in the mix may be the way to increase the ratio. Mr. Miller expressed his concern over the cost of college. Ms. Harris stated she felt this would already be in place with vocational schools. Mr. Miller commented that vocational schools are also expensive. President Jones responded by stating that he does not know if the Board would want to go down the education path. He was looking at this as the Board has a responsibility to protect the public. He stated technicians are all the same now, but if they are going to take care of patients, does the Board need to make sure they are certified. Mr. Miller responded by stating that if it just involves passing a test, he does not think that is accomplishing anything. He stated that all of his technicians are certified, but as far as their effectiveness in the pharmacy and taking care of patients, they were not any more effective. He stated that maybe going forward the Board require certification, but he does not want to punish those who are already registered. Mr. Warnock stated that Mr. Bracewell and Mr. Miller made good points. He suggested the Board let the educating organizations know what needs to be included in programs in order for them to be recognized by the Board. After further discussion, President Jones suggested contacting NABP.

Who should be registered to enter the Pharmacy Department: President Jones commented that there are many individuals that enter the pharmacy department such as IT personnel working on the computers, individuals servicing water purifiers, electricians, etc. Ms. Harris responded by stating those individuals cannot be registered, but the pharmacist is still responsible for those people. President Jones stated the he agrees it is the responsibility of the pharmacist to be aware of who is in the pharmacy and why. Mr. Jones mentioned specifically the role of the pharmacy cashier. Ms. Harris commented that the pharmacy cashier should be registered, but should not be counted in the technician ratio. Mr. Miller concurred by stating that who is counted in the ratio is an issue. He asked how GDNA looks at it. Director Troughton responded by stating that when GDNA does a routine inspection, the agents observe first. He stated the agents ask if

there is a list of technicians. He stated his understanding from previous conversations is that if someone is in the prescription department working the register and the only thing they do is grab the script from Will Call, they are not counted that in ratio. He stated the only time the Board would see a complaint regarding a ratio violation is when the individual is working on patient profile and counting pills. He stated if the agents are inspecting and see someone is working on the air purification system, sweeping, inventory, they are not counted. Mr. Bracewell stated that when an individual goes into the pharmacy prescription department, they are under the authority of the pharmacist and suggested there should be a log where someone signs in and is also checked by the pharmacist. Ms. Harris responded by stating that she thinks a lot of the chains do that and that is a good idea. Director Troughton stated that would certainly add clarity for GDNA and suggested adding that to the rule. President Jones asked Director Troughton about a scenario in the pickup area, where a customer hands a prescription to the cashier. He asked if the cashier can scan the prescription into the computer. Director Troughton responded by stating if the agents see them do that, it would be considered part of a technician duty.

Pharmacist Work Conditions: President Jones stated that about once a month, the Board receives correspondence from pharmacists complaining about work conditions. He stated that he has always been under the impression that this is not within the Board's jurisdiction and asked for confirmation that there is not anything the Board can do. Mr. Prather responded by stating the Board previously redefined direct supervision. Mr. Miller commented that the employer would have to decide what is tolerable or not. Ms. Harris stated that the Board is here to protect the public and that pharmacy today is so much different than 20 years ago. She further expressed concern regarding the volume of prescriptions a pharmacist is expected to fill with little to no time to talk to patients. President Jones asked if the Board was allowing for technology to be utilized adequately. Mr. Miller suggested there may be a need for a legislative change to address work conditions. He suggested a study to accumulate data regarding such. Mr. Warnock discussed taking action regarding patient counseling and failure to provide such. He further suggested that enforcing such would cause employers to change ratios and hire more pharmacists thereby resulting in improved service to patients. Director Troughton responded by stating that patient counseling is an item that is looked for on inspections and the agents make a note if the pharmacist is not counseling. He stated that the Board will receive 30 more complaints a month if that is an item that it wants to start seeing where GDNA takes public disciplinary action. Mr. Prather commented that with the majority of misfills this year, there was no patient counseling involved. He stated that many misfills can be caught if there is proper counseling. Discussed ensued about whether or not every instance of missed counseling should be brought to the Board as a case. Director Troughton stated that when an agent goes over inspection results with the pharmacist, the agent goes over every single item and talks to the pharmacist about it and writes it up. He added that the agents are instructed to explain deficiencies and make a note of them. He stated if the Board decides to get the cases now regarding if there was no patient counseling, GDNA already writes them up. He stated that if GDNA feels like it was egregious or a repeat offender, then the Board would see that already.

Long Term Care Licensure: President Jones stated that a few months ago, Mr. Warnock worked on long term care licensure. He stated after today's discussion, he wonders if the Board needs to revisit the issue. He feels long term care does not really fit under retail and does not fit under hospital. Mr. Prather stated that he thinks long term care would be a good place to try and streamline some things. Mr. Warnock stated he had previously been working with Greg Reybold at GPhA to make sure they did not have any issues. Mr. Warnock stated that GPhA did not come back with any suggestions other than saying if you had a retail license you were excluded. Mr. Warnock stated that it was the request of the Board to run this by GPhA; however, Mr. Reybold is no longer with GPhA. Mr. Warnock asked if the Board would like for him to run it by GPhA again. President Jones directed Mr. Warnock to revisit this matter with GPhA for input.

Prescription Content/Advertising: Mr. Bracewell stated he previously brought this matter up because advertising put on by doctors had been mentioned a few times. He stated perhaps maybe the companies that were doing it may be cost effective. He stated the Board has received complaints about it and he did not know where the Board could go with this. He asked if this would be a matter for the Georgia Composite Medical Board. President Jones agreed and suggested addressing this with the Medical Board. Ms. Harris commented that they really do not know what the sure script looks like by the time it gets to the pharmacist. Mr. Bracewell stated if this could be referred to the Medical Board, it could at least show some proactivity on the Board's part. Mr. Bracewell will send a draft letter to Ms. Battle to send to the Georgia Composite Medical Board.

Central Fill: Laird Miller made a motion to post Chapter 480-10A Central Filling Regulations. Bill Prather seconded and the Board voted unanimously in favor of the motion.

Chapter 480-10A. Central Filling Regulations

Rule 480-10A-.01 Central Filling of Prescriptions

(1) Definitions

(a) "Board" shall mean the Georgia Board of Pharmacy

(b) "Dispensing Pharmacy" shall mean the licensed retail pharmacy outsourcing the prescription filling services.

(c) "Central Fill Pharmacy" shall mean a pharmacy which is permitted by the state in which it is located to prepare prescription orders for dispensing pursuant to a valid prescription transmitted to it by a licensed retail pharmacy and to return the labeled and filled prescriptions to the retail pharmacy for delivery to the ultimate user.

(2) All pharmacies providing central prescription filling processing services to retail pharmacies in Georgia must be appropriately licensed in Georgia.

(3) A central fill pharmacy shall be deemed "authorized" to fill prescriptions on behalf of a dispensing pharmacy only if the dispensing pharmacy and central fill pharmacy have a contractual relationship providing for such activities or share a common owner.

(a) The contract or agreement shall outline the services to be provided and the responsibilities and accountabilities of each pharmacy in compliance with federal and states laws and regulations.

(b) Except when there is common ownership, the central fill pharmacy shall only deliver prescriptions to the dispensing pharmacy for delivery to the patient.

(4) A licensed retail pharmacy that desires to provide and/or use central prescription filling services must submit its policies and procedures to the Georgia Board of Pharmacy for approval.

(a) The policies and procedures must include:

1. A clear description of the activities in the prescription filling process to be performed by each pharmacy;

2. An outline of the responsibilities of each pharmacy;

3. An outline of the accountabilities of each pharmacy;

4. A list of the names, addresses, telephone numbers, and all license/registration numbers for the pharmacies participating in the central fill prescription filling;

5. Guidelines for:

(i) Protection of the confidentiality and integrity of patient information;

(ii) Maintenance of appropriate records to identify the names, initials, or identification codes and specific activities of each pharmacist who performed any processing;

(iii) Compliance with all federal and state laws, regulations, and rules;

(iv) Operation of a continuous quality improvement program for pharmacy services designed to objectively and systematically monitor and evaluate the quality and appropriateness of patient care, pursue opportunities to improve patient care, and resolved and identify problems; and

(v) Annual review of the written policies and procedures and documentation of such review.

- (5) Central prescription filling of controlled substances requires compliance with all Drug Enforcement Administration (“DEA”) regulations permitting a central fill pharmacy to fill prescriptions for controlled substances on behalf of a dispensing pharmacy.
- (6) The dispensing and central fill pharmacies must share common electronic files or have appropriate technology to allow secure access to sufficient information necessary or required to dispense or process the prescription.
- (7) The dispensing pharmacy must designate staff members to be responsible for signing for the receipt of prescriptions delivered from the central fill pharmacy. Such receipts must be maintained as a part of the prescription record.
- (8) A dispensing pharmacy using central prescription filling services is responsible for maintaining records of the processing of all prescriptions entered into their information system including prescriptions filled at a central fill pharmacy.
- (a) The pharmacist at the dispensing pharmacy must comply with the minimum required information for the patient record system and all requirements of a prescription drugs order as outlined in the Georgia law and Board rules prior to sending a prescription to the central fill pharmacy.
- (b) The information system must have the ability to audit the activities of the individuals at the central fill pharmacy filling the pharmacy’s prescriptions.
- (9) A pharmacy that utilizes central prescription filling services must, prior to outsourcing the prescription, notify patients that prescription filing may be outsourced to another pharmacy.
- (a) The patient shall have the choice to not have the prescription outsourced.
- (10) The prescription label of a central fill prescription must show the name and address of both the dispensing pharmacy and the central fill pharmacy, except when there is common ownership.

A motion was made by Mike Faulk, seconded by Lisa Harris, and the Board voted that the formulation and adoption of this proposed 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 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 proposed 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.

CBD Oil: President Jones stated the Board had a discussion on this subject at last month’s meeting. He stated right now CBD oil is legal to possess. He added that the Governor just signed a bill regarding disease states. He stated the problem the Board is running into is a lot of pharmacies are selling the CBD oil. Mr. Prather added that pharmacies are selling it and it is being sold on the street corner. Discussion was held regarding CBD oil with THC up to 5% can be legally possessed. Anything outside the scope of that with THC cannot be possessed legally. Discussion ensued.

Dr. Heather Lindell, UGA, spoke to the Board regarding CBD oil. She stated that after discussion with researchers and extraction personnel, it was found that there was no way to get all of the THC out of it. She stated GW Pharmaceuticals has a product with the FDA going thru phase III that is close to having approval. They will have CBD oil that is an approved drug product. She stated that is what the FDA has as a written description on. She stated CBD is not a botanical. She further commented that there was no enforcement. Director Troughton clarified by stating he did not say GDNA was not enforcing laws. President Jones responded by stating that their concern is regarding whether or not it is legal for a pharmacist to sell CBD oil. Mr. Changus responded by stating that he has had dialogue with Mr. Troughton. The issue is whether or not it is legal to sell a product if it has any THC. He stated that low THC oil is legal to possess if you have permit in Georgia. President Jones commented that the Board

cannot grant approval regarding this matter. Director Troughton responded by stating those individuals interested in possessing such products would need to obtain their own legal advice as to whether or not they could sell it. Mr. Snow asked what the plan is from an enforcement standpoint. Director Troughton responded by stating that it is a criminal violation. If it says THC on the bottle, GDNA will seize it and will contact the local prosecutor to take the necessary steps. Mr. Snow asked if it is considered illegal to have any THC in GA. Mr. Changus replied that it is illegal to sell and referred Mr. Snow to O.C.G.A. §16-12-191(c). President Jones asked what the Board should advise regarding any inquiries about THC. Mr. Changus responded by stating that the best legal advice was given by Director Troughton and that is to suggest they obtain their own legal advice. The sale aspect is a felony for a pharmacist or pharmacy if it contains THC.

Inconsistency in Rule 480-27-.05 and Rule 480-22-.04 regarding the requirement to sign schedule II prescriptions: Mr. Faulk asked why the Board prohibits schedule II's from being printed out. President Jones responded that he prints his out. He asked if it is an electronic prescription, does it need to be printed out? Mr. Faulk responded by stating probably reason to sign hard copy is to void them and to give them a trail of who is filling the prescription. He added that it looks too simple just to print out and sign. President Jones asked Director Troughton if GDNA had any issues with this. Director Troughton responded by stating yes because the rule states it does not have to be printed. He stated the agents would still look at it. He stated the Board decided to no longer require it being printed. Director Troughton stated at some point in time there will no longer be paper anyway. Mr. Faulk asked if printing them out would make GDNA's job easier. President Jones replied by stating it has been like this for 2-3 years. He asked Director Troughton if there have been any issues from not being able to track something. Director Troughton responded that typically they are able to find the electronic prescription they are looking for and cannot say that GDNA has had any issues of not having a hard copy printed. Mr. Faulk responded by stating that if there are no issues, then he is fine with that. Mr. Miller stated that there are two conflicting rules. Mr. Faulk stated that the Board does not need to correct because one of the rules pertains to electronic prescriptions.

Compounding Rule: Scott Piper, Georgia Veterinary Medical Association, Dr. John Sundstrom, Georgia Board of Veterinary Medicine, and Dr. Heather Lindell, UGA. Dr. Sundstrom spoke to the Board regarding concerns of wanting to send home compounded medications with their patients as currently the law prohibits such. Mr. Piper stated GVMA thought Rule 480-11-.02(f) could be amended to address this matter; however, they know the path would be a legislative fix. He stated that they are before the Board to ask for its support and involvement in addressing this issue. Mr. Changus asked Mr. Piper if he knew how to move forward with legislature. Mr. Piper responded that GVMA does have language they have looked at, but he did not bring it today. Mr. Changus stated that the Board of Pharmacy does not have any objections with what was being requested. He stated that the Board's hands were tied because of the way the law is written. Mr. Changus suggested Mr. Piper submit language to the Board. President Jones discussed the current opioid crisis. He asked Dr. Sundstrom how the veterinarians are currently operating. Dr. Sundstrom responded that they rely on 503A pharmacies, which may take several days to compound the drug. President Jones asked if there was anyone locally that could be partnered with. Dr. Sundstrom stated he was not aware. Discussion ensued on this needing a legislative fix. President Jones commented that, in the current environment we are in, he is concerned about controlled drugs. However, if the profession has a need, he does not know that the Board would object. you see a need there, does not know if the Board would stand in your way. President Jones suggested GVMA reach out to the Georgia Pharmacy Association to determine if they would be willing to work with some of the veterinarians as he believes there is an alternative. Mr. Miller asked if they had ever thought about reasonable limits about what could be on hand in the veterinarian's office. He stated the Board's concern is who has access to the medication. He commented that the Board would really like to work with the veterinarians and feels there is opportunity for cooperation, but there have to be some parameters set. He requested they submit a copy of the formulary. He stated that drug lists can be amended. Dr. Sundstrom responded that he understands

the Board's concerns and they are their concerns as well. Mr. Piper stated that he will get back to the Board with some proposed language. Mr. Miller suggested he contact Jeff Lurey to obtain a list of compounding pharmacies that prepare patient specific medications. Mr. Warnock commented that the Board has not heard any real discussion on storage. One piece he suggested is to add that the Board clearly does not want the drugs sitting on a counter accessible to everyone. President Jones thanked Mr. Piper, Dr. Sundstrom and Dr. Lindell for their time.

There being no further business to discuss, the meeting was adjourned at 3:21 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Thursday, May 17, 2018 at 8:00 a.m. at 254 Washington Street, Suite G2000, Atlanta, GA 30334.

Minutes recorded by Brandi Howell, Business Support Analyst I

Minutes edited by Tanja D. Battle, Executive Director