# **GEORGIA BOARD OF PHARMACY**

Board Meeting 2 Peachtree Street, NW, 5<sup>th</sup> Floor Atlanta, GA 30303 September 18, 2019 9:00 a.m.

The following Board members were present:

Bill Prather, President

Vicki Arnold

Carrie Ashbee

Michael Brinson

Mike Faulk

Hal Henderson

Dean Stone

**Staff present:** 

Tanja Battle, Executive Director

Eric Lacefield, Deputy Executive Director

Dennis Troughton, Director, GDNA

Michael Karnbach, Deputy Director, GDNA

Russ Moore, Special Agent, GDNA

Kirsten Daughdril, Senior Assistant Attorney General

Max Changus, Assistant Attorney General Macy McCarty, Attorney General's Office

Kimberly Emm, Attorney

Brandi Howell, Business Support Analyst I

**Visitors:** 

TJ Kaplan, JLM

Beth Jarrett, Walmart

Stephen Snow, BSL

Lea Winkles, Mercer University

Mike Chavez, Publix

Greg Reybold, GPhA

John Rocchio, CVS

Negin Moon, Paragon Healthcare

Averi Washington

Diane Sanders, Kaiser Permanente

Amanda Roberson, Eldercare

John Smith, Shepherd Center

Helen Sloat, Kaiser Permanente/Hemophilia of GA

Bobby Zsan, CTCA

Shea Ross-Smith, KP

**Brian Ponder** 

Yu Jin Kang, CAPS

Simy Casasola, Walgreens

Blake Sears, Innovation Compounding

Shauna Markes-Wilson, Walgreens

Becca Hallum, GHA

Steven Corder

Lana Manatrizio

# **Open Session**

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

## **Approval of Minutes**

Vicki Arnold made a motion to approve the Public and Executive Session minutes from the August 7, 2019 meeting and the August 30, 2019 Emergency Conference Call minutes. Michael Brinson 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 issued. Hal Henderson seconded and the Board voted unanimously in favor of the motion.

#### **Petitions for Rule Waiver or Variance**

Mike Faulk made a motion to deny the rule waiver petition from Stokes Healthcare, Inc., PHWH003909 and PHMA000516. Michael Brinson seconded and the Board voted unanimously in favor of the motion.

Carrie Ashbee made a motion to deny the rule waiver petition from Bobby J. Ison, RPH029403. Vicki Arnold seconded and the Board voted unanimously in favor of the motion.

Mike Faulk made a motion to approve the rule waiver petition from Emanuel Medical Center, PHRE010761. Michael Brinson seconded and the Board voted unanimously in favor of the motion.

Michael Brinson made a motion to approve the rule waiver petition from InTouch Pharmacy, LLC, PHRE010748. Dean Stone seconded and the Board voted unanimously in favor of the motion.

#### **Correspondence from ACPE**

The Board considered this correspondence from ACPE inviting a board representative to participate in ACPE's scheduled site visit to South University. The correspondence requests a response by Friday, September 20<sup>th</sup>. The Board directed staff to respond to ACPE by asking if the deadline for a response could be extended as Mr. Brinson expressed interested in attending, but was not sure if he was able to attend on the dates mentioned at this time.

# **Correspondence from George Tzanetakos**

The Board considered this correspondence asking if the Board holds any position or offers any guidance on the matter of pharmacists offering nutritional recommendations to patients during the course of patient counseling. In response, the Board directed staff to respond to Mr. Tzanetakos by suggesting he review O.C.G.A. § 26-4-4 Definition of "practice of pharmacy." The Board states as long as the guidance is related to patient counseling on the taking of drugs, it would be appropriate under O.C.G.A. § 26-4-4.

#### **Correspondence from Omar Hassad**

The Board considered this correspondence regarding pharmacy to pharmacy drug sale for patient-specific need. In his inquiry, Mr. Hassad states FDA guidelines allow pharmacies to transfer up to 5% of their annual sales to another pharmacy without a wholesale license and asks does the Georgia Board of Pharmacy allow such transactions (no narcotics). Additionally, Mr. Hassad asks if a marketplace involved as the "middle man" to facilitate the transaction without ever touching the drug or store has to be authorized by the Board. In response, the Board directed staff to respond by stating a wholesale distributor permit would be required.

#### Correspondence from Mika Pollack

The Board considered this correspondence regarding consumer notification on safety labeling changes. In response, the Board stated that it does not have a system in place to notify customers of new safety labeling changes as the FDA provides that information via the link provided in Ms. Pollack's correspondence.

## **Correspondence from Christopher Vaughan**

The Board considered this correspondence regarding USP <800> implementation for compounders in Georgia. In response to Mr. Vaughan's inquiry, the Board directed staff to respond by stating that Georgia Law and Board Rule require prescription drug compounding to be in compliance with USP-NF standards. The law, O.C.G.A. § 26-4-86(a), is set by the Georgia Legislature and unlike a rule, it cannot be waived or excepted by the Board. Pharmacists, practitioners, and pharmacies licensed or registered in this state will continue to be required by law to be compliant with USP-NF standards. Even though USP 800 is not specifically mentioned in the law or Board Rules, it is a part of the USP-NF standards for compounding and falls under this law. As changes or additions to the USP-NF standards become official per USP, those will be the standards that prescription drug compounders will be required to comply with per Georgia Law and Pharmacy Board Rules. Lastly, Mr. Vaughan can refer to O.C.G.A. § 26-4-86 and Chapter 480-11 Pharmaceutical Compounding for more information.

## **Correspondence from Lori Huff**

The Board considered this correspondence requesting an advisory opinion regarding pharmacy license regulations. In response, the Board directed staff to respond by stating that it does not typically provide advisory opinions regarding whether or not licensure is required as it is up to the entity, often in consultation with its attorney, to determine such based on its practice. Additionally, refer Ms. Huff to the official laws and rules on the Board's website to make a determination.

## **Correspondence from Zachary Ernst**

The Board considered this correspondence regarding pharmacy and pharmacist licensure in Georgia. In response, the Board directed staff to respond by stating that it does not typically provide legal advice or opinions regarding whether or not licensure is required as it is up to the entity, often in consultation with its attorney, to determine such based on its practice. Additionally, refer Mr. Ernst to the official laws and rules on the Board's website to make a determination.

# **Correspondence from Steve Simmerman, The Compliance Team**

The Board considered this correspondence requesting information regarding the Board's specific vetting process for accreditation organizations to evaluate The Compliance Team's Specialty Pharmacy accreditation program for approval by the Board. In response, the Board directed staff to respond by stating that, in line with Board Policy #11 and pursuant to its authority in O.C.G.A. § 26-4-28(a)(21) and as further described in Board Rule 480-12-.01, the Board may approve accreditation or certification programs for specialty pharmacy practice. Upon formal submission of a request for approval for an accreditation or certification program, with accompanying supporting documentation, the Board will consider the application. If consideration of the application would be aided by a physical presentation, the Board may request that the applicant make such a presentation at a regularly scheduled Board meeting.

#### **Correspondence from David Chantal**

The Board considered this correspondence requesting clarification regarding Rule 480-13-.04 Absence of Pharmacist. In response, the Board directed staff to respond by stating that the Board is precluded from offering legal advice, opinions, or interpretations of the Georgia Laws and Rules and Mr. Chantal may wish to seek legal counsel for opinions and interpretations of the laws and rules. The official laws and rules can be found on the Board's website.

### **Correspondence from Dennis Simmons**

The Board considered this correspondence requesting clarification of Rules 480-35-.02 Pharmacist Certification, 480-35-.04 Requirements for a Protocol, and 480-35-.05 Recordkeeping. In response, the Board directed staff to respond by stating that in response to Mr. Simmons' question regarding "protocol or agreement", those terms are interchangeable for purposes of the rule. In regards to the remainder of his questions, the Board states he must comply with the rules or he may petition the Board for a rule variance.

## **Correspondence from Ned Milenkovich**

The Board considered this correspondence regarding USP GC <797> Nonsterile Compounding and Flavoring. In response, the Board directed staff to respond by stating that if a pharmacy is flavoring a prescription drug it would be considered compounding per USP and the pharmacy should comply with Board Rules and Georgia Law that require compliance with USP-NF standards.

# **Correspondence from David de Vries**

The Board considered this correspondence requesting clarification concerning licensure requirements for organizations providing clinical advice and counseling telephonically to Georgia residents. In response, the Board suggested Mr. de Vries review Chapter 480-31 Patient Counseling for more information and stated that it is precluded from offering legal advice, opinions, or interpretations of the Georgia Laws and Rules. Additionally, Mr. de Vries may wish to seek legal counsel for opinions and interpretations of the laws and rules. The official law and rules can be found on the Board's website.

# Correspondence from Richard Burrell, Augusta University

The Board considered this correspondence regarding USP <800> compliance. Director Troughton discussed Mr. Burrell's letter regarding two new pharmacy relocation projects under active construction. Director Troughton stated that it seems to him that Mr. Burrell is stating that they may not be in compliance with USP <800> until the projects are complete, which is supposed to be March 2020. Director Troughton stated that GDNA will continue to conduct its inspections the same way they have always done. He stated that during an inspection, GDNA will point out what the facility is not in compliance with. The facility is then asked to provide GDNA with an action plan. He stated that GDNA will review the action plan and keep record so if it is not addressed promptly the Board can then decide what to do. Mr. Brinson stated that the Board will need to give some leeway in situations like this for these types of facilities. Director Troughton responded by stating that the inspections will not be done any differently from how they are done now. He stated that if the facility is not in compliance, GDNA will request an action plan and the facility must either comply and correct those deficiencies or they will not.

#### Correspondence from Stephen Snow, Bendin, Sumrall & Ladner LLC

The Board considered this correspondence regarding the combining of refills for non-controlled maintenance medications within the full quantity and expiry of the prescription. President Prather discussed the request with Mr. Snow, who was present at the meeting. President Prather stated to Mr. Snow that he did not think there would be a pharmacist anywhere that would be upset if they were told they did not have to call the physician to get clarification about things on a prescription. President Prather asked the Board for its input. Mr. Henderson stated this is for one specific thing, for total refills. He stated if a patient has a script for 30 tabs once a day with twelve refills, that is one year's worth of medications. Mr. Henderson stated, however, that insurance is calling to say they want a 90-day supply. He asked if they can just do a 90-day supply. President Prather stated he read it differently. He stated there are various things the pharmacist has to call the physician about. Mr. Snow stated that in regards to this specific issue there are all sorts of reasons why patients ask to combine refills. He stated that, for instance, if the patient is traveling abroad, etc., and out of an abundance of caution, the pharmacist will call the prescribing physician for clarification. Mr. Snow stated he met with the Georgia Composite Medical Board and they expressed a willingness to provide a formal position statement regarding the issue, but asked that Mr. Snow first speak to the Georgia Board of Pharmacy for its input on whether or not to allow pharmacists to combine refills. Mr. Stone commented that he runs into this issue all the time and always waits on the physician to call him back as that is what he thought the pharmacists had to do. Ms. Emm stated that O.C.G.A. § 26-4-80(f)(1) states, "When filling a prescription or refilling a prescription which may be refilled, the pharmacist shall exercise professional judgment in the matter. No prescription shall be filled or refilled with greater frequency than the approximate interval of time that the dosage regimen ordered by the practitioner would indicate, unless extenuating circumstances are documented which would justify a shorter interval of time before the filling or refilling of the prescription." She stated that the Board office

receives this question a lot and staff has always responded by stating that if the physician wrote the prescription this way, then that is how the pharmacist should fill it, and if the patient wants it another way, then the pharmacist needs to contact the physician. Mr. Stone commented that the insurance companies turn around and say that documentation would be required. Mr. Snow stated that he is not talking about reducing the interval, so it does not necessarily fall under that rule. He stated that the insurance component is a real issue. He further stated that this is a patient access issue. Mr. Brinson stated that he believes this is the Medical Board's prerogative to see that prescribers and medical staff have to be on board. He stated that the Medical Board also needs to be involved to get this changed. Mr. Snow responded by stating that this is why he went to Medical Board and asked for a statement. He stated that they seem willing to provide it, but asked him to go speak with the Board of Pharmacy. Mr. Changus commented by stating that the provision Ms. Emm quoted restricts the pharmacist from doing too much. He stated that he thinks the Medical Board wants to articulate more information as to how this should be interpreted. Mr. Changus stated that he wonders if it is not necessarily the practitioner's need to be more aware of how these insurance things will come out and need to think of that in advance. He expressed concern about what the provision states. Director Troughton commented that there had been discussion at a previous meeting about not being able to change the prescription without physician approval. Mr. Snow responded by stating if one looks at the rule itself it is talking about dosage regimen, not dosage supply. Mr. Faulk commented that if the physician writes the prescription for 30 days, that is how it is interpreted. He stated that if the physician would write it for 90 days, that would be better. Mr. Faulk stated he does not have issues reducing the quantity. He is concerned with expanding the quantities. Mr. Snow responded by stating that is why he is speaking with each Board. Discussion was held regarding the Board not being able to change anything due to what the law states. Mr. Snow stated that if the Medical Board issues a statement, would the Board of Pharmacy defer to them and that statement. After further discussion, Mr. Changus stated that the pharmacists may be on board with this, but they only have so much leeway. He stated that rather than the Board saying the pharmacist can change the prescription as they see fit, maybe the Medical Board needs to put this out as an educational piece saying physicians may want to think about how they are writing prescriptions as the pharmacists' hands are tied. Mr. Changus suggested that this may be something to bring up with the legislature. Mr. Snow asked if the statement is issued by the Medical Board saying it is implied, would that satisfy the law. Director Troughton stated that the law says it cannot be done, so if GDNA is asked about it, they will say you cannot do it. Mr. Changus stated to Mr. Snow that there is concern when it is said that you can interpret what the statement says, as it can lead to enforcement concerns as well. He stated that the law seems kind of definite here as (f)(1) states that no prescription shall be filled or refilled with greater frequency, and in (f)(2) it speaks of ophthalmic products. President Prather asked Mr. Changus to speak to the Medical Board and express the Board's concerns regarding this issue.

### Georgia Drugs and Narcotics Agency - Dennis Troughton

Director Troughton reported that Special Agent Eric Durham will be graduating from the Police Academy on Friday.

Director Troughton reported that GDNA has conducted 510 inspections and completed 87 investigations year-to-date.

Director Troughton reported that there were a number of lapsed facility licenses following this past renewal cycle and GDNA has worked with Ms. Battle's office to address those.

# Attorney General's Report – Max Changus

Mr. Changus stated that the Board voted to post Rule 480-36-.03 Personnel and Supervision and it was sent to his office for legal authority. He stated that after he reviewed it, he did have a concern. He discussed the Board's proposed change to section (4) of the rule which states:

The pharmacist on duty at the primary dispensing pharmacy shall be responsible for assuring the accuracy of the all filled or dispensed prescriptions products including those prepared processed through the use of remote prescription drug order processing. This shall include, but not be limited to, viewing and verifying the hardcopy or electronic prescription. The pharmacist on duty at the primary dispensing pharmacy shall have access to the hardcopy image of the original prescription and shall maintain his/her professional judgment in dispensing the final product.

Mr. Changus stated that the last sentence is significant. He stated that the Board is holding that person responsible for the final product. Mr. Changus stated the patient is expecting the prescription that was delivered to be what walked out the door. He stated "Having access" from "shall review" is a change. He added that the pharmacist is required to use judgement but he/she is now excused from looking at the prescription. Mr. Changus stated it is a bit unclear and he wanted to bring this back to the Board for discussion. President Prather responded by stating that he believes the intent is that everyone involved has responsibility, but the ultimate responsibility lies with the two (2) pharmacists involved which would be the one that touches it and the one that dispenses the prescription. Mr. Henderson stated there are two pharmacists sharing responsibility. Mr. Stone added that if he is that second pharmacist, he wants to see the prescription to make sure everything matches. He added that when the duties are divided up, how do you go about pointing the finger? He stated he does not like the idea of blindly giving something that he has not checked. Mr. Changus stated there is a bit of discussion since the Board has this procedure in place, and as far as the Board and regulating, in a civil context if there was a mistake made and someone were to initiate a lawsuit, they would sue everyone involved. He stated in a regulatory sense, what is the Board requiring here? What it appears to be is that the Board is looking to eliminate judgement/responsibility over this process and that warrants discussion. Mr. Henderson responded by stating that the intention is not to let anyone off the hook but is a division of responsibility. He stated the first pharmacist is responsible for entering correctly and the other is responsible for ensuring that the right medication goes in the bottle. After further discussion, President Prather stated to table discussion until the October meeting to allow time for the Board to review this matter.

#### **Executive Director's Report – Tanja Battle**

**Continuing Education Report:** Vicki Arnold made a motion to deny the course titled, "Mental Health First Aid" sponsored by JAD Services Info. Mike Faulk seconded and the Board voted unanimously in favor of the motion.

**Statistics for FY2019:** Ms. Battle reported that the Board oversees a population of approximately 15,049 pharmacists and 19,342 pharmacy technicians. In addition, its total number of licenses, registrations and certifications is 43,308 including but not limited to the following: Clinics, Hospitals, Durable Medical Equipment Suppliers, Retail, Manufacturing, Non-Resident, Researchers, Schools, 3 PLs, Wholesalers, Prisons, Interns, and Nuclear pharmacists and pharmacies. The Board issued a total of 6,827 new licenses and registrations during FY2019. The Board was presented, for consideration and determination, 188 cases from GDNA.

# <u>Legal Services – Kimberly Emm</u>

No report.

#### Miscellaneous

**2020 Meeting & Practical Exam Dates:** Ms. Ashbee made a motion to approve the dates as presented. Mr. Brinson seconded and the Board voted unanimously in favor of the motion.

**Job Description for Director of Georgia Drugs & Narcotics Agency:** Mr. Brinson made a motion to adopt the Job Description for Director of Georgia Drugs & Narcotics Agency with the change noted. Ms. Ashbee seconded and the Board voted unanimously in favor of the motion. The Job Description for

Director of Georgia Drugs & Narcotics Agency is as follows:

Georgia Drugs and Narcotics Agency Job Description: Director

#### Agency Overview

Georgia Drugs and Narcotics Agency (GDNA) was created to ensure and protect the health, safety and welfare of Georgia citizens by enforcing state laws and rules pertaining to manufactured or compounded drugs and to ensure only licensed facilities or persons dispensed or distributed pharmaceuticals. GDNA and its Special Agents investigate violations of the GA Controlled Substances Act and Dangerous Drug Act in reference to diversion of legitimately manufactured pharmaceuticals and how they are distributed, dispensed, or transferred by a firm registered by the State of Georgia. GDNA inspects every facility licensed by the state to handle, possess, distribute or dispense pharmaceuticals. GDNA provides education to law enforcement entities, registrants, and the general public as to the current drugs of abuse while acting as the law enforcement and regulatory division for the Georgia State Board of Pharmacy (Board). GDNA also serves as the information resource for pharmacy and drug questions for registrants, the general public, and law enforcement. GDNA is assigned to the Department of Community Health for administrative purposes only, as defined in Code Section 50-4-3.

### Appointment

The Board shall appoint the Director of the GDNA by a majority vote. The Director shall hold office at the pleasure of the board, and should any vacancy occur in such office for any cause whatsoever, the Board shall appoint a successor at a regular or called meeting. The salary of the Director shall be fixed by the Board. The whole time of the director shall be at the disposal of the Board.

# **Authority and Responsibility**

- Supervises, and/or instructs the work assignments of GDNA subordinate staff and the oversight of and enforcement of federal and state laws and regulations for all pharmacies, drug wholesalers, drug researchers, health care practitioners, and others that possess prescription drugs throughout the state of Georgia
- Enforces all applicable federal and state laws and regulations related to any registrants and other individuals handling and responsible for accounting of all prescription drugs received, possessed, dispensed, or distributed in or out of the state of Georgia
- Conducts investigative interviews, issues investigative subpoenas and review/compiles monthly Investigative reports by deputy director or director
- Responsible for reviewing registrant policies and procedures and providing drug abuse and impairment education for health care registrants as needed or directed by the Board
- Prepares for and attends monthly Board meetings
- Participates in the development, review, revision, interpretation, and/or implementation of policies, procedures, standards, and guidelines with the Board
- Assists the Board during each annual legislative session by compiling and submitting a list of substances to add to or reschedule substances enumerated in the schedule
- Compiles and submits to the General Assembly during each annual legislative session a list of known dangerous drugs and any other drugs or devices which the Board has determined may be dangerous or detrimental to the public health and safety and should require a prescription
- Engages with state and federal lawmakers, judicial members and government affairs representatives from the pharmaceutical industry
- Understands, interprets and reports developments and outcomes of state and federal regulations, policies, and legislative action to the Board

- Maintains responsiveness to outside counsel and constituents related to matters and inquiries regarding the application of regulations
- Responsible for GDNA's annual budget proposal and ongoing review and approval of all expenditures made by the Agency
- Interviews, hires, directs, counsels, trains, evaluates the performance of, and when necessary, disciplines and discharges GDNA employees
- Manages quarterly meeting of GDNA agents and evaluates training progress of each agent
- Completes required courses in law enforcement continuing education, firearms training and pharmacy continuing education
- Creates and maintains badges and other forms of identification for GDNA employees and members of the Board
- Participates in the planning, coordination, development and implementation of long-range goals and objectives with the Board
- Assists the Board during practical examinations on a quarterly basis
- Participates in the development of the annual MPJ exam
- Attends meetings with DEA, FDA-OCI, GBI and other law enforcement agencies as needed or directed by the Board
- Attends annual meetings such as GPHA, GSHP, NABP and make presentations when asked
- Performs such other duties as may be directed by the Board

#### Removal

The Director may be removed by the Board upon an affirmative majority vote at a regular or called meeting.

# **Salary**

Director salary is determined by the board as defined in O.C.G.A. § 26-4-29

#### Minimum Oualifications

The Director shall be and shall remain an employee of the State of Georgia, be a graduate from an accredited school or college of pharmacy, hold a current pharmacist license issued by the Georgia State Board of Pharmacy, have at least five years of professional active experience as a full-time GDNA Agent 1 or 2 and Georgia P.O.S.T. Certification.

### *History of the Agency*

The GDNA was created by the General Assembly in 1908 as the Office of the Chief Drug Inspector. In 1939, the General Assembly passed legislation which allowed the Board to appoint the Chief Drug Inspector (CDI), and all of the CDI complaints to be reported to the Board. In 1964, the law was again changed to give the CDI and his assistant inspector the authority and power that Sheriffs possess to make arrests. In 1968, the Board changed its rules to require all inspectors to be pharmacists. In 1976, the Office became known as the Georgia Drugs and Narcotics Agency, and the CDI became the Director.

Policy Discussion on Diversion: President Prather stated the Board has discussed this matter at length. He stated there is a tremendous amount of diversion from hospitals and pharmacies due to technician theft. He stated that a small bit of is due to pharmacy theft. President Prather stated that he previously asked each board member to come up with three to four suggestions regarding how the Board could help stop diversion. Mr. Faulk responded by stating that it appears to him that the Board has meetings to determine what controlled substances exit a pharmacy. He stated that wholesalers know what controlled substances are entering the pharmacy. He stated that if the Board could determine what is going into the pharmacy and what is exiting the pharmacy and have some means of interfacing, a discrepancy could be flagged. He

stated the program could detect shortages without utilizing manpower. Mr. Faulk stated, for example, if a pharmacy had 20,000 tablets of oxycontin going in the pharmacy and only sold 10,000, but they kept ordering more and more. He stated that what is happening is they are entering the pharmacy more and more, but not exiting. He added that once that discrepancy has reached a certain level, it should be able to be detected. Mr. Changus stated that with Mr. Faulk's suggestions, the Board would be requiring a system to monitor this information. Mr. Faulk agreed and stated that this would require funds from the legislature. He stated that wholesalers know what they are selling to the store and the PDMP registry shows what exits. He stated that if you start having large discrepancies, that would pull up a flag. Mr. Changus responded by stating that he does not see any legal concern, it just boils down to the practicality. Ms. Arnold stated that hospitals would not feed into PDMP. Mr. Changus commented that where that data is going is the concern. Mr. Faulk stated that if people are serious about stopping diversion, and he thinks legislators are, then maybe they could come up with the funds for such. Mr. Changus stated that if the Board is requesting something that is not required in the statute, this would require a legislative change. Mr. Faulk asked Mr. Changus if he foresees this being an issue with the Attorney General's office. Mr. Changus responded by stating that the concept of it does not bother him, but he would need to see the specifics. President Prather commented that Mr. Faulk's suggestion is a good idea; however, the Board needs to think of things it can do immediately. He stated that he is not saying that is a bad idea, but that would take some time.

President Prather discussed perpetual inventory. Mr. Henderson stated in regards to a perpetual inventory, CIIs, high volume IIIs, IVs and Vs should be counted. He stated he does not think phenobarbital needs to be counted. Director Troughton stated that if the Board is going to call for an inventory, specifically benzodiazepines and CIIs, physicians are required to look at the PDMP registry before prescribing. He stated that those are the most abused and diverted drugs. Mr. Brinson stated that he agrees with a perpetual inventory. He stated that in the hospital, they count every seven (7) days, but asked when a retail pharmacy would count these. Mr. Brinson stated that it is easy to say that they need the count and inventory, but the Board needs to think about how long it takes to actually complete these inventories as he believes this will cause a problem. He stated that he thinks people need to be held accountable, such as managers and PICs. Mr. Brinson stated that he knows the Board cannot bring the offending party in before the full Board, but could not find anything saying the Board cannot bring in the PIC and ask pertinent questions. Mr. Changus responded by stating that those questions are always asked from his understanding by GDNA. Mr. Brinson responded by stating that he is speaking more specifically about bringing the PIC of the chain drug store in to meet with the Board and if the Board does not get the answers it likes, to bring in someone higher up. President Prather stated that he does not disagree at all; however, the Board separates investigative interviews from appearances to maintain impartiality of the Board. Mr. Changus stated that his understanding is when there is a typical diversion case where there is a pharmacy technician that has been diverting, when that is discovered, GDNA moves in and the pharmacy technician's registration is either surrendered or revoked; however, someone is still responsible. Ms. Ashbee commented that she thought in the PIC's job description it states that the PIC is responsible to ensure that the pharmacy complied with the laws and rules; however, the Board needs to be able to identify something the PIC or owner did wrong to establish statutory grounds for any disciplinary action. Mr. Changus stated that the PIC can be found to be in violation of the law and rules by the pharmacy, but the Board has to be able to identify what he/she did wrong in order to take discipline. He further stated that if the Board cannot point to any violation that the owner or PIC did, it is difficult to discipline that individual. Mr. Brinson stated that the Board would like to bring the individual in to speak to them and maybe not to discipline them. Mr. Changus responded by stating that to the extent this is incorporated into the investigation and the Board wants to make a point, it can do that. President Prather asked if the Board should be more specific in its rules about PICs or hospital personnel as to what exactly they are responsible for. For example, say the PIC is responsible for seeing to it that the CII drugs are inventoried. President Prather stated that PICs in a chain store environment are in a bad situation. He stated that he wished the Board could have some way to hold corporate responsible if they do not see to it if their drugs are not secured. Mr. Changus responded by stating that in order to change the rules, the Board would need specifics.

Specifically, a PIC needs to do "x". President Prather suggested the Board get more specific on in its rules in terms of controls. He stated in the case of a pharmacy technician diverting, the only thing the Board can do is revoke his/her registration or the individual can surrender it. He stated that if there are technicians that are not being supervised properly, being able to order and check in narcotics, given the keys to the pharmacy, that falls on the responsibility of the PIC or even corporate. President Prather stated the Board needs to be more specific in its rules as to what the Board expects from PICs and from Corporate. After further discussion, President Prather directed Director Troughton to work with Ms. Emm and Mr. Changus before the Board's next meeting to come up with suggestions on how the Board can be more specific in the rules and how the Board can hold the PIC or a corporate entity responsible.

**Technician Education:** President Prather stated that he previously asked Mr. Brinson to chair a committee to look into technician education. Mr. Brinson read the following:

Pharmacy Technician Continuing Training Report

The purpose of continuing education for Pharmacy Technicians is to maintain and enhance the competency of Pharmacists Technicians registered in Georgia. The continuing education requirement for Technicians will assist Pharmacists in the protection of the health, safety and welfare of the people of the State of Georgia.

The Georgia State Board of Pharmacy has the statutory responsibility and authority to require continuing education as a prerequisite for registration renewal for Pharmacy Technicians.

Forty-five states and Washington, DC have regulations that specify registration, licensure, and/or certification requirements for pharmacy technicians, even though the language and format of these regulations may vary from state to state. Of the 45 states and DC that regulate technicians, 24 states and DC include the Certification by the Pharmacy Technician Certification Board (PTCB) in their regulations. A State Board of Pharmacy approved educational program is required in 13 other states, which do not require the PTCB. Technicians are required to be registered in 18 states with no continuing education requirements, as does Georgia.

Of 12 southern states, all require the registration of pharmacy technicians, 3 states require PTCB certification, 4 states require a Board approved technician program, 7 states require continuing education from 3 hours per year to 10 hours per year and 5 states have no educational or certification requirements. After reviewing the data and talking with pharmacists thru out the State, I present these options to the Board:

# Option 1)

Require all Pharmacy Technicians to obtain 10 hours of Continuing Education credits prior to the next renewal on 6/30/2021. Thereafter, as a requirement for the biennial renewal of his/her license, a Pharmacy Technician must complete not less than twenty (20) hours of approved continuing education, either A.C.P.E., P.T.C.B. or other education as approved by the Georgia Board of Pharmacy, prior to each renewal.

#### Option 2)

Same as Option 1, except require all Pharmacy Technicians be Certified by the biennial renewal on 6/30/25.

### Option 3)

Same educational requirements as Option 1 for all Technicians, however any new Technician registered by the Board after 6/30/2021 the Board would require those Technicians to become certified within 2 years of being registered as a Pharmacy Technician.

Audits will have to be completed on any of these options, thus the Board of Pharmacy must determine if the Staff of the Board has the necessary personnel available to complete this educational requirement. If it is determined that staffing is an issue, then I recommend delaying the implementing of any of these options until the Board Meeting in July 2020.

President Prather asked each board member to review the information submitted by Mr. Brinson and if he/she had any suggestions, to provide those at the Board's October meeting.

Vicki Arnold made a motion and Michael Brinson 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, Carrie Ashbee, Michael Brinson, Mike Faulk, Hal Henderson, William Prather and Dean Stone.

#### **Executive Session**

#### **Appearance**

• S.P.C.

### Georgia Drugs and Narcotics Agency - Dennis Troughton

- U.S.E.
- E.F.P.
- A.E.P.
- A.E.P.

### Cognizant's Report - Michael Karnbach, Deputy Director, GDNA

- GDNA Case # A32994
- GDNA Case # A33018
- GDNA Case # T33013
- GDNA Case # A32818
- GDNA Case # B32840
- GDNA Case # A32861
- GDNA Case # A32908
- GDNA Case # B32925
- GDNA Case # B32941
- GDNA Case # B32942
- GDNA Case # B32943
- GDNA Case # B32944
- GDNA Case # A32946
- GDNA Case # A32947
- GDNA Case # A32948
- GDNA Case # B32960
- GDNA Case # B32961
- GDNA Case # B32962

- GDNA Case # B32964
- GDNA Case # B32969
- GDNA Case # B32978
- GDNA Case # B32995
- GDNA Case # T33000
- GDNA Case # B32980
- GDNA Case # A33031
- GDNA Case # A32702
- GDNA Case # B32831
- GDNA Case # A32844
- GDNA Case # B32828

# **Attorney General's Report – Max Changus**

Mr. Changus presented the following consent orders for acceptance:

- S.S.B.
- M.F.D.P.C.
- P.C.I.

Mr. Changus discussed the following cases:

- L.F.A.
- G.R.J.

# **Executive Director's Report – Tanja Battle**

- R.M.P.
- M.S.
- K.D.L.

### **Legal Services – Kimberly Emm**

- C.Z.P./Z.Z.P.L.
- P.R.P.

# **Applications**

- L.M.T.
- S.L.B.
- A.M.S.
- L.L.W.
- S.N.P.
- S.L.C.
- B.S.C.
- N.Y.B.
- D.E.B.
- S.A.H.
- K.A.M.
- I.M.W.
- S.Z.G.
- S.N.E.
- B.C.T.
- K.M.S.
- S.A.A.

- M.N.B.
- N.D.
- B.P.C.
- M.M.U.
- K.A.H.
- A.P.J.
- J.J.M.
- S.M.
- T.F.P.W.S.
- E.P.I.

# **Correspondences/Requests**

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

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

# **Open Session**

Michael Brinson made a motion for the Board to take the following actions:

Appearance

• S.P.C. Request to return to practice Denied request

Georgia Drugs and Narcotics Agency - Dennis Troughton

• U.S.E. Reverse Distributor Pharmacy Table pending receipt of

additional information

• E.F.P. Retail Pharmacy Update provided

• A.E.P. Non-Resident Pharmacy Refer to the Department of Law

• A.E.P. Manufacturing Pharmacy Refer to the Department of Law

# Cognizant's Report - Michael Karnbach, Deputy Director, GDNA

• GDNA Case # A32994 Accept Voluntary Surrender

• GDNA Case # A33018 Accept Private Interim Consent Order

GDNA Case # T33013 Accept Voluntary Surrender

GDNA Case # A32818
Schedule Investigative Interview

• GDNA Case # B32840 Close with no action

• GDNA Case # A32861 Refer to the Department of Law

• GDNA Case # A32908 Suspend or revoke if there is no closure or surrender

• GDNA Case # B32925 Close with no action

• GDNA Case # B32941 Refer to the Department of Law

• GDNA Case # B32942 Close with no action

• GDNA Case # B32943 Close with a letter of concern

• GDNA Case # B32944 Close with no action

• GDNA Case # A32946 Close with no action

• GDNA Case # A32947 Close with no action

• GDNA Case # A32948 Close with no action

• GDNA Case # B32960 Close with no action

• GDNA Case # B32961 Close with no action

• GDNA Case # B32962 Close with no action

• GDNA Case # B32964 Close with no action

GDNA Case # B32969 Misfill Policy #1

• GDNA Case # B32978 Misfill Policy #1

• GDNA Case # B32995 Close with no action

• GDNA Case # T33000 Revoke Technician Registration

• GDNA Case # B32980 Schedule Investigative Interview

• GDNA Case # A33031 Refer to the Department of Law

• GDNA Case # A32702 Refer to the Department of Law

• GDNA Case # B32831 Misfill Policy #1 for RPh1/Private Letter of Concern to RPh2/Send

correspondence to Corporate

• GDNA Case # A32844 Deny request to resume sterile compounding

• GDNA Case # B32828 Close with a letter of concern

# Attorney General's Report – Max Changus

Mr. Changus presented the following consent orders for acceptance:

Sandipkumar S. Bhagat
Public Consent Order accepted

• Medi-Fare Drug Public Consent Order accepted

Pharmaceutical Compounding

Park Compounding Inc. Accept Voluntary Surrender

Mr. Changus discussed the following cases:

L.F.A. Close with no action • G.R.J. Close with no action

## **Executive Director's Report – Tanja Battle**

• R.M.P. Correspondence re Policy 3A Approved request to obtain

direct supervision hours in NV

and LA

M.S. Request regarding practical exam Denied request

Karen D. Lewis Accept Public Consent Order

#### <u>Legal Services – Kimberly Emm</u>

• C.Z.P./ Open records request Denied request

C.Z.P.L.

• P.R.P. Open records request Denied request; however, if a

> request from the original owner of the records is received, the

Board will approve.

# Applications

$\mathbf{n}$	<u>Jucations</u>				
•	Lashawn M. Thompson	Pharmacy Technician	Approved for renewal		
•	Shaquieva L. Bostick	Pharmacy Technician	Approved for renewal		
•	Ashley M. Sheppard	Pharmacy Technician	Approved for renewal		
•	Ladaysha L. Walker	Pharmacy Technician	Approved for renewal		
•	S.N.P.	Pharmacy Technician	Table pending receipt of additional information		
•	S.L.C.	Pharmacy Technician	Table pending receipt of additional information		
•	BrenAnna S. Coney	Pharmacy Technician	Approved for renewal		
_	NVD	Phormocy Tochnician	Danied application		

N.Y.B. Pharmacy Technician Denied application Danita E. Baker Pharmacy Technician Approved application Shakyma A. Hess Pharmacy Technician Approved application Pharmacy Technician Approved application Kiara A. Mustafa Imari M. Wright Pharmacy Technician Approved application Pharmacy Technician Approved application Steven Z. Grant Sequoia N. Ellerton Pharmacy Technician Approved application Brandon C. Thao Pharmacy Technician Approved application K.M.S. Pharmacy Technician Denied application Approved application Sandra A. Abram Pharmacy Technician Marleana N. Banton Pharmacy Technician Approved for renewal

Pharmacy Technician Approved for renewal Noell Davila Nuclear Pharmacist Approved application Brian P. Croft

Megan M. Unger **Nuclear Pharmacist** Approved application Schedule to meet with the K.A.H. Pharmacist Exam

Board

A.P.J. Pharmacist Intern Approved for extension until 07/2021

J.J.M. Pharmacist Intern Approved pending receipt of additional information

•	E.P.I.	Manufacturing Pharmacy	Table pending receipt of additional information
Corr	espondences/Requests		
•	B.P.	Notice of discipline	No action
•	H.W.	Notice of discipline	No action
•	K.C.P.	Notice of discipline	No action
•	M.D.I.	Notice of discipline	No action
•	M.D.I.	Notice of discipline	No action
•	M.D.I.	Notice of discipline	No action
•	M.D.I.	Notice of discipline	No action
•	M.L.	Notice of discipline	No action
•	E.P.	Notice of discipline	No action
•	M.V.	Notice of discipline	No action
•	P.H.I.	Notice of discipline	No action
•	H.F.P.A.S.	Notice of discipline	No action
•	W.P.N.	Notice of discipline	No action
•	W.P.N.	Notice of Discipline	No action
•	S.M.	Appearance request	Approved request
•	L.D.R.	Appearance request	Approved request
•	C.N.C.	Correspondence	Table pending receipt of
			additional information
•	D.D.S.	Correspondence	The Board viewed this
			correspondence for
			informational purposes only
•	K.D.T.	Request to lift PIC restriction	Approved request
•	S.C.B.	Request to lift PIC restriction	Approved request
•	T.N.	Request regarding reciprocity	Denied request
•	M.S.	Request regarding reciprocity	Denied request
•	L.L.	Request for 4 <sup>th</sup> attempt at MPJE	Approved request
•	C.D.S.	Correspondence re relocating a	The Board viewed this
		compounding room	correspondence for
			informational purposes only
•	P.P.	Request to install drive-thru	Approved request
•	N.G.M.C.	Remote order entry	Approved
•	C.N.S.	Appearance request	Approved request
•	K.N.R.	Request for 4 <sup>th</sup> attempt at MPJE	Approved request
•	J.C.M.	Correspondence	The Board viewed this
			correspondence for
			informational purposes only

Wholesaler Pharmacy

Non-Resident Pharmacy

Solo Mia

T.F.P.W.S.

Approved application

Refer to the Department of Law

Hal Henderson seconded and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 5:17 p.m.

The next meeting of the Georgia Board of Pharmacy is scheduled for Wednesday, October 16, 2019 at 9:00 a.m., at the Department of Community Health's office located at 2 Peachtree Street, N.W., 5<sup>th</sup> Floor, Atlanta, GA 30303.

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