

**GEORGIA BOARD OF PHARMACY**  
**2 Peachtree St., N.W., 6<sup>th</sup> Floor**  
**Atlanta, GA 30303**  
**February 15, 2023**  
**9:00 a.m.**

**The following Board members were present:**

Michael Azzolin, President  
Jim Bracewell  
Michael Brinson  
Young Chang  
Cecil Cordle  
Dean Stone

**Staff present:**

Eric Lacefield, Executive Director  
Michael Karnbach, Deputy Director, GDNA  
Alec Mathis, Special Agent, GDNA  
Max Changus, Senior Assistant Attorney General  
Kimberly Emm, Assistant Attorney General  
Clint Joiner, Attorney  
Brandi Howell, Business Support Analyst I

**Visitors:**

Jody Smith, Floyd Medical Center  
Angelique Turner  
Melissa Reybold, GPhA  
Lauren Paul, CVS  
Heather Hughes, Publix  
Christi Heys, Emory  
Stephen Georgeson, GRA  
Kayleigh Strech, Impact Public Affairs  
Becca Hallum, GHA  
Freyanna Magee, WCU Pharmacy Student  
Kaitlyn Moreland, Janus Rx  
Jennifer Duckett, Walgreens  
Jameson Bilsborrow, PharmScript of GA LLC  
Laura Churns, Publix

**Open Session**

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

**Approval of Minutes**

Mr. Brinson made a motion to approve the Public and Executive Session minutes from the January 18, 2023, meeting as amended. Mr. Bracewell seconded, and the Board voted unanimously in favor of the motion.

**Report of Licenses Issued**

Mr. Stone made a motion to ratify the list of licenses issued. Mr. Chang seconded, and the Board voted unanimously in favor of the motion.

**Petitions for Rule Waiver or Variance**

**Rule Variance Petition from PharmScript of GA LLC, PHRE010776:** The Board discussed this request for a variance of Rule 480-10-.17. Specifically, President Azzolin explained the request is seeking permission to bring medications that have been dispensed to patients in long term care facilities, even if they have been repackaged with an appropriate label, and bring those back into the pharmacy to be

reutilized. Deputy Director Karnbach stated there is already a provision to allow for some of that with Medicaid. He explained it has to be in the manufacturer's packaging alone, it has been billed to Medicaid and it has been sent to the long term care facility and bring those medications back into the pharmacy. He continued by stating it his understanding that the petition is asking for all eligible drugs only billed to Medicaid under their packaging and remanufacturing packaging to come back to the pharmacy. President Azzolin commented that the logic to him seems that once the medication has been dispensed to the patient that medication then belongs to that patient.

President Azzolin inquired if there was a representative from Pharmcript of GA LLC at the meeting who wished to speak regarding the petition. A visitor responded by stating that he was counsel from Pharmcript of GA LLC and had nothing further to add beyond what was already in the request.

After further discussion, President Azzolin inquired if the Board wanted to allow a product that has been removed from its original manufacturer's packaging and dispensed outside the purview of the pharmacy to come back into the pharmacy outside of the original packaging and be reused. Mr. Changus responded by stating that it is not just whether or not the Board wants to allow it, but whether there is a hardship for the Board to make an exception in this case as he did not see a hardship demonstrated. Mr. Stone made a motion to deny the petition. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

**Rule Waiver Petition from Atrium Health Floyd Chattanooga Emergency Dept:** The Board discussed this request for a waiver of Rule 480-33-.05(4) regarding the requirement of a laminar flow hood. President Azzolin explained that the waiver states no IV medications will be prepared in this location so there is no need for a laminar flow hood. He said that he and Deputy Director Karnbach discussed that the requirement in this particular section under Chapter 480-33, and to have a laminar flow hood is contingent upon mixing and preparing parenteral medications. He stated that the way the rule is written is if you are not going to mix parenteral medications, then there is no requirement for a laminar flow hood. He continued by stating that upon inspection, as long as no parenteral medications are dispensed, there will not be an issue for not having a hood. He added that there is no need for this waiver as long as no parenteral medications are prepared. Deputy Director Karnbach responded by stating that when GDNA does its inspection, they would not require the facility to have it as long as no parenteral medications were being prepared.

Mr. Jody Smith, Director of Atrium Pharmacy, spoke to the Board regarding the request. He stated that they are building out a free standing emergency department in Chattooga County about 45 miles away from the nearest hospital. He stated they will have six bays built out and will function as an emergency department. For clarification, he added that there will be parenteral medications in use; however, the distinction is there will be nothing for non-immediate use. He stated the patients will come in with an urgent need. He explained that the facility is not going to anticipate and mix ahead of time. Mr. Smith continued by stating that USP <797> states you can do that within an hour and the provisions that are coming out will allow for a lag phase and give them four hours. Mr. Smith explained that the facility will have an inspection when the site is built for that space and they would like to have the waiver in place because it will be a hardship. He added that space is limited and would like to reserve all space in the pharmacy for drug storage. Mr. Smith stated that with the new requirements for USP <797> all of that would have to go on even though they are not doing anything but using immediate use products.

President Azzolin asked that based on Mr. Smith's comments of providing immediate use parenteral medications, some of which may involve a syringe being put into a bag to add medications for that immediate use, but will be administered in less than an hour and in less than four hours once the revisions are made, would that constitute the need for a laminar flow hood as long as they meet that requirement? Deputy Director Karnbach responded it would not. President Azzolin commented that he would like the minutes to reflect the Board's dialogue and document that the Board supports the request without the need

for a waiver. Mr. Stone made a motion to deny the petition. Mr. Brinson seconded, the Board voted unanimously in favor of the motion.

**Rule Waiver Petition from Publix Super Markets, Inc.:** The Board discussed this request for waiver of Rule 480-10A-.05(4)(a) which requires that “Central Fill” be written on the face of any hard copy prescription processed by a Central Fill Pharmacy. President Azzolin stated the waiver explains what the hardship is. He inquired if there were any comments from the board members. Mr. Stone commented that will all the technology that is available now, unless GDNA states otherwise, and it is clearly marked on the electronic record that it is central fill he is okay with that. Deputy Director Karnbach stated that if the Board were to approve the request, GDNA would request the Board include a statement in the response stating that the records must be retrievable during the inspection on site.

Mr. Changus commented that he believes this may be a matter that should require the Board adjusting the rule rather than giving ongoing exceptions based on objections to the rule itself. He added that it seems like it is something the facility does not want to do. He stated that the Board has seen this type of request in the past from another pharmacy looking for a waiver for all its stores. Mr. Changus continued by stating that he does not see any unique hardship that faces them that will not be faced by anyone else. President Azzolin agreed that the rule does need to be addressed and requested it be added to the April meeting for discussion. He stated that he disagrees it does not impose a hardship. He stated that if a pharmacist sends a prescription to a central fill location and does not know if that location will be able to fill it, then the pharmacist has to retain the prescription and later check to be sure it will be filled at the central fill location. The Rule promotes opportunity for error, in that the pharmacist has to make sure not to forget to come back to the prescription to check. This puts the pharmacist in a precarious situation. Deputy Director Karnbach stated that there may not be a hardcopy. He continued by stating that if the prescription is received electronically, most pharmacies do not print those. He added that the electronic image is sort of the hard copy. He stated that he does not know if they are able to comply with the rule sometimes.

Mr. Changus stated that the statute that allows for the waiver of rules states that sometimes the applicability of the rule imposes a substantial hardship on a particular licensee. He further stated that in this case, whether or not the rule needs to be changed, allowing this ongoing waiver for a whole host of entities when you are not allowing that for other entities is a concern. President Azzolin commented that if the Board was not willing to address the rule as soon as possible, in light of how it is currently written and there is not much practical application of central fill rules then he would agree that the Board should not provide rule waivers. However, he stated that if it is the Board’s intent to review the rule in April, he suggests the Board grant the waiver now. Mr. Stone agreed and stated that as technology has changed the prescription is not printed unless it came as a hardcopy. He added that the pharmacist makes the documentation on the prescriptions themselves. He stated that he would be in favor of granting the waiver, but feels the Board does need to address the rule.

President Azzolin inquired if there was a representative from Publix at the meeting. Heather Hughes and Laura Churns were present. Mr. Cordle asked the representatives if the records would be retrievable during the inspection on site. Ms. Hughes responded by stating they would be retrievable both electronically and by having a physical copy.

Mr. Cordle made a motion to grant the waiver with the understanding that the records must be immediately retrievable onsite. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

#### **Low THC Committee Report – Mr. Cecil Cordle**

Mr. Cordle reported that the Committee has held two meetings thus far. He added that the purpose of what the Committee is trying to accomplish is establish rules for the licensure for dispensing low THC products through pharmacies and trying to balance the concerns about keeping the playing field as level as possible

in relation to the dispensaries who will also be providing this product to the public. He explained that the Committee has drafted rules for the subsequent low THC license. Mr. Cordle stated that the draft will be provided to the Board to review.

Mr. Cordle stated that, in summary, if a pharmacist wants to dispense low THC, he/she will be required to have an active retail license and they will apply for a subsequent license to dispense the product. He further stated that the product would be housed in the pharmacy and would be treated similar to other prescription medications that are being dispensed from the pharmacy with rules and regulations that are spelled out from the Committee as far as storage, tracking, etc. Mr. Cordle stated that the intent is to provide the rules worked on by the Committee to the Board for review and the Board can further discuss at next month's meeting.

Mr. Joiner informed the Board that the draft reflecting the changes discussed at Committee's meeting earlier that morning were available on Sharepoint for review by the Board.

President Azzolin inquired as to what would happen when a patient is admitted to a hospital and what does the hospital pharmacist and hospital physician do in that situation. He stated that if a patient walks into the hospital and has medications, including low THC that has not been prescribed by a physician, but has been dispensed by a pharmacy and the patient says he/she has to have the low THC to control seizures, how will the physician and pharmacist handle that. He continued by stating that most physicians will not order it because they are not authorized. He added that the pharmacist will say they cannot repackage it and give to the patient. President Azzolin stated that most hospitals will not allow the patient to have their own meds unless it has been redispensed by the hospital. He stated that in order to protect the patient and promote their welfare, he would suggest the Committee find a way to address that particular scenario.

Mr. Stone stated he is not a hospital pharmacist and understands things are handled differently. He inquired as to how hospitals handle herbal supplements used by the patient. President Azzolin responded by stating that in his experience, those herbal medications are not continued in the hospital. He added that if it is not an over the counter or dangerous drug, it is discontinued upon admission of the patient to the hospital while the patient is in the hospital.

Deputy Director Karnbach stated that many hospitals do not have retail pharmacy permits and if all non-over-the-counter and non-prescription drugs are discontinued upon admission to the hospital, would that hospital pharmacy even be allowed to apply for that permit. He added that he believes this is something that the Board will realistically see in the situation where a patient goes to the hospital. Mr. Stone responded by stating that the way he looks at it is if the pharmacy will not dispense it, the patient will not always get it from a pharmacy. He added that the patient can get low THC products from a dispensary. He inquired as to how that would be handled. He stated that it does not mean the Board needs to address that when the whole problem is not going to be solved immediately. Mr. Stone stated there will be dispensaries out there whether a pharmacy is doing it or not. Deputy Director Karnbach commented that he does not know if that has any bearing on the patient in the hospital. He stated that whether the patient received low THC products from a dispensary or from a pharmacy, when the patient goes into the hospital, the hospital pharmacy will not be able to dispense low THC products to the patient. He further stated that the hospital will not be able to service that patient with low THC products.

President Azzolin commented that there are so many scenarios that will not be able to be addressed as a result of this relative to patient care. He stated that if this therapy has pharmacologic benefits to help the patient clinically, but it is not FDA approved and not handled the way traditional drugs are, you will have detrimental patient issues in those scenarios. He further stated that he is not aware of how effective this treatment is and if it is effective, but in the event it is effective and does prevent seizures abruptly stopping

it in a hospital setting may precipitate seizures or other issues. He added that he could see where this could be a liability issue.

Mr. Stone agreed with President Azzolin. He stated that the Board cannot do anything about how the law is written, but he feels pharmacists are poised in a certain way where they can help benefit patients and this is a new thing pharmacists need to educate themselves on.

Ms. Emm stated that when reviewing the draft rules, the Board may want to review O.C.G.A. § 51-1-29.6(b), which states, “A health care institution shall not be subject to any civil liability, penalty, licensing sanction, or other detrimental action and a health care provider shall not be subject to any civil liability, penalty, denial of a right or privilege, disciplinary action by a professional licensing board, or other detrimental action for allowing an individual or caregiver to possess, administer, or use low THC oil on the premises of a health care institution or offices of a health care provider, provided that the possession of such substance is in accordance with the laws of this state.”

President Azzolin commented that was great from a liability perspective, but does not fix the patient issue. He continued by stating that language states that the pharmacist can easily refuse it and not get in trouble. Ms. Emm responded by stating that it says the facility and the pharmacist are not under any detrimental action for allowing an individual or caregiver to possess, administer, or use low THC oil on the premises.

Mr. Brinson commented that goes back to what he previously stated about allowing a patient to use their own medication. He discussed methadone, for example. It cannot be changed unless it is detrimental to the patient.

There being no further discussion, Mr. Cordle requested the members review the draft rules and be prepared to discuss further at next month’s meeting.

**Georgia Drugs and Narcotics Agency – Mr. Michael Karnbach**

Deputy Director Karnbach reported that GDNA conducted 1559 inspections and received 330 complaints for FY2023.

**Attorney General’s Report – Mr. Max Changus**

Mr. Changus discussed Senate Bill 157. He explained this bill will change the analysis of when someone applies that has a conviction of some sort. He added that it is looking to continue Governor Deal’s impetus to allow individuals back into the profession. He stated that the bill would affect all boards and suggested the members review it for further information.

**Executive Director’s Report – Mr. Eric Lacefield**

**Continuing Education Report:** Mr. Stone made a motion to ratify the below continuing education programs approved since the previous meeting. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

<b>Date of Program</b>	<b>Hours</b>	<b>Sponsoring Group</b>	<b>Program Title</b>	<b>CE Code</b>
02/01/2023	.5	Atrium Health – Navicent	Adult Antibiotic Desensitization and Graded Challenge Protocol	2023-0001
03/30, 04/20, 05/11, 06/15, 07/07	5	Northside Hospital (NSH)	NSH BMT Fundamentals Course	2023-0002

**Pharmacy Member Appointment:** Mr. Lacefield announced the appointment of Mr. Michael Farmer to the Board. He added that Mr. Farmer will be attending the March meeting. Mr. Lacefield thanked Mr. Bill Prather for his dedication to the Board of Pharmacy and the citizens of Georgia during his tenure on the Board.

**Legal Services – Clint Joiner**

Mr. Joiner reported that a list of approved rules and effective dates for each have been posted to Sharepoint. Those rules are:

<b>Rule</b>	<b>Effective Date</b>
480-9-.03 Conditions	February 28, 2023
480-13-.06 Drug Distribution Control	February 28, 2023
480-15-.02 Registration of Pharmacy Technicians	February 20, 2023
480-15-.03 Use of Registered Pharmacy Technicians and Other Pharmacy Personnel	February 28, 2023
480-22-.07 Requirements of Schedule III, IV and V (C-III, IV, V) Controlled Substance Prescription Drug Orders	February 28, 2023
480-28-.10 Loss or Theft of Controlled Substances	February 20, 2023
480-31-.01 Patient Counseling	February 28, 2023
480-34-.15 Epidiolex	February 28, 2023

**Rules Discussion**

**Rule 480-10-.16 Security System Approval:** The Board discussed subsection (7) of the rule relative to lockboxes when there is a corporation or entity that operates multiple pharmacies and the pharmacist in charge shall develop a method, approved by the Board, of allowing authorized access to that area. Deputy Director Karnbach explained that the Board had concerns about a pharmacy and the process they wanted to use concerning the lockbox. He added that the Board had questions about what systems could or could not be used. He continued by stating that technology has changed a good bit since the rule was written and believes that the Board was considering making changes to the rule.

The Board discussed adding this matter to the Board’s April meeting for discussion. Mr. Stone commented that request has to be submitted to the Board and approved by the Board. He added that the Board has discussed what will not work as it depends on what type of box. He stated that he felt if the Board starts getting too specific the Board would be changing rule regularly as technology changes.

President Azzolin stated that when the rule discusses a single pharmacy it does not address in the security section anything about a lockbox. He added that “lockbox” is not defined anywhere in the rule nor is “security”. He continued by stating that allowing a retail pharmacy, that is a single pharmacy, to put a lockbox outside is not an issue because it is not addressed. In regards to multiple pharmacies, President Azzolin stated that section (7) mentions securing a key or access code but does not reference security access code or other means in subsection (a) of the rule. He asked if a single pharmacy or multiple pharmacies that are using those key access codes are required to obtain approval when it is specified the lockbox has to obtain board approval. President Azzolin stated it needs to be clarified. Mr. Chang commented that he feels the Board should further discuss the matter in April as it could be a simple lockbox, or multiple layers. He added that it is at the discretion of the Board to decide. There being no further discussion, Mr. Stone made a motion to table discussion on this rule until the Board’s April meeting. Mr. Cordle seconded and the Board voted unanimously in favor of the motion.

Mr. Brinson made a motion and Mr. Stone seconded, and the Board voted to enter into **Executive Session** in accordance with O.C.G.A. § 43-1-19(h) and § 43-1-2(h) 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 Michael Azzolin, Jim Bracewell, Michael Brinson, Young Chang, Cecil Cordle, and Dean Stone.

## **Executive Session**

### **Appearance**

- J.R.

### **Georgia Drugs and Narcotics Agency – Mr. Michael Karnbach**

No report.

### **Cognizant's Report – Mr. Michael Brinson**

- GDNA Case # B34610
- GDNA Case # A34611
- GDNA Case # B34514
- GDNA Case # B34470
- GDNA Case # A34435
- GDNA Case # A34492
- GDNA Case # T34365
- GDNA Case # B34619
- GDNA Case # B34581
- GDNA Case # B34580
- GDNA Case # B34370
- GDNA Case # B34512
- GDNA Case # B34523
- GDNA Case # B34591
- GDNA Case # B34582
- GDNA Case # B34597
- GDNA Case # B34525
- GDNA Case # T34614

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

Mr. Changus presented the following consent orders for acceptance:

- R.T.O.
- B.N.S.
- C.V.S.P.
- E.P.H.
- E.H.R.H.C.
- J.J.P.I.
- E.P.I.C.
- C.D.I.

### **Executive Director's Report – Mr. Eric Lacefield**

No report.

### **Legal Services – Mr. Clint Joiner**

No report.

### **Applications**

- C.N.P.
- A.L.J.
- S.S.A.
- P.J.G.
- C.M.H.
- L.L.B.
- A.M.C.
- A.M.P.
- J.L.S.
- J.M.D.
- A.L.C.
- A.T.T.
- C.M.W.
- J.M.N.
- R.H.S.

### **Appearances**

- N.S.M.
- P.M.

### **Correspondences/Requests**

- I.R.
- P.P.A.P.
- P.S.
- C.
- M.W.R.
- M.W.R.
- M.W.R.
- C.R.
- K.P.A.I.
- M.P.S.C.
- W.
- W.P.N.
- H.V.
- T.H.C.P.
- J.W.S.
- C.M.C.
- J.P.
- N.D.S.
- R.R.

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

### **Open Session**

Mr. Stone made a motion for the Board to take the following actions:



**Appearance**

- J.R. Request regarding security system Approved request

**Georgia Drugs and Narcotics Agency – Mr. Michael Karnbach**

No report.

**Cognizant’s Report – Mr. Michael Brinson**

- GDNA Case # B34610 Flag the pharmacist’s license in the event the individual attempts to renew or reinstate.
- GDNA Case # A34611 Refer to the Department of Law
- GDNA Case # B34514 Refer to the Department of Law
- GDNA Case # B34470 Close case and refer to the Georgia Composite Medical Board
- GDNA Case # A34435 Refer to the Department of Law
- GDNA Case # A34492 Refer to the Department of Law
- GDNA Case # T34365 Revoke Technician Registration
- GDNA Case # B34619 Close with no action
- GDNA Case # B34581 Close with no action
- GDNA Case # B34580 Close with no action
- GDNA Case # B34370 Close with no action
- GDNA Case # B34512 Close with no action
- GDNA Case # B34523 Close with no action
- GDNA Case # B34591 Close with no action
- GDNA Case # B34582 Close with no action
- GDNA Case # B34597 Close with no action
- GDNA Case # B34525 Close with no action
- GDNA Case # T34614 Accept Voluntary Surrender

**Attorney General’s Report – Mr. Max Changus**

Mr. Changus presented the following orders for acceptance:

- R.T.O. Voluntary Surrender accepted
- B.N.S. Revised Private Consent Order accepted
- C.V.S.P. Private Consent Order accepted
- E.P.H. Private Consent Order accepted
- E.H.R.H.C. Private Consent Order accepted
- J.J.P.I. Private Consent Order accepted
- E.P.I.C. Private Consent Order accepted
- C.D.I. Private Consent Order accepted

**Executive Director’s Report – Mr. Eric Lacefield**

No report.

**Legal Services – Mr. Clint Joiner**

No report.

**Applications**

- C.N.P. Pharmacy Technician Approved for registration
- A.L.J. Pharmacy Technician Approved for registration
- S.S.A. Pharmacy Technician Approved for registration
- P.J.G. Pharmacist Intern Approved application

• C.M.H.	Pharmacist Renewal	Approved for renewal
• L.L.B.	Pharmacist Renewal	Approved for renewal
• A.M.C.	Pharmacist Renewal	Approved for renewal
• A.M.P.	Pharmacist Renewal	Approved for renewal
• J.L.S.	Pharmacist Renewal	Approved for renewal
• J.M.D.	Pharmacist Renewal	Approved for renewal
• A.L.C.	Pharmacist Reciprocity	Approved application
• A.T.T.	Nuclear Pharmacist	Approved application
• C.M.W.	Pharmacist Certification of DTM	Approved application
• J.M.N.	Pharmacist Certification of DTM	Approved application
• R.H.S.	Pharmacist Certification of DTM	Table pending receipt of additional information

**Appearances**

• N.S.M.	Request to reinstate pharmacist license	Refer to the Department of Law
• P.M.	Request regarding revocation	Denied request

**Correspondences/Requests**

• I.R.	Notice of Discipline	No action
• P.P.A.P.	Notice of Discipline	No action
• P.S.	Notice of Discipline	No action
• C.	Notice of Discipline	No action
• M.W.R.	Notice of Discipline	No action
• M.W.R.	Notice of Discipline	No action
• M.W.R.	Notice of Discipline	No action
• C.R.	Notice of Discipline	No action
• K.P.A.I.	Notice of Discipline	No action
• M.P.S.C.	Notice of Discipline	No action
• W.	Notice of Discipline	No action
• W.P.N.	Notice of Discipline	No action
• H.V.	Notice of Discipline	No action
• T.H.C.P.	Notice of Discipline	No action
• J.W.S.	Request to Terminate Probation	Approved as of 03/12/2023
• C.M.C.	Correspondence	The Board viewed this correspondence for informational purposes only.
• J.P.	Request for 4 <sup>th</sup> attempt to retake NAPLEX	Approved request
• N.D.S.	Request for 5 <sup>th</sup> attempt to retake NAPLEX	Approved request
• R.R.	Correspondence	The Board viewed this correspondence for informational purposes only.

Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

There being no further business to discuss, the meeting was adjourned at 12:26 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, March 8, 2023, at 9:00 a.m., at Mercer University College of Pharmacy, 3001 Mercer University Drive, Atlanta, GA 30341.

Minutes recorded by Brandi Howell, Business Support Analyst I

