

GEORGIA BOARD OF PHARMACY
2 MLK Jr. Drive, SE, 11th Floor, East Tower, Atlanta, GA 30334
September 18, 2024 - Meeting Minutes

Board Members present:

Chuck Page, President
Cecil Cordle, Vice-President
Michael Azzolin
Jim Bracewell
Michael Brinson
Young Chang
Michael Farmer
Dean Stone

Visitors:

Gregory Stennett, Hamilton Medical Center
Sam Smith
Jonathan Marquess, GPHA & AIP
Victoria Ashe, HHCS
Christi Heys, Emory
Stephanie Kirkland, Elder Care
Heather Hughes, Publix
Diane Sanders, Kaiser Permanente
Jordan Khail, UGA
Gary Long, Botanical Sciences

Board Staff present:

James Joiner, Executive Director
Dennis Troughton, Director, GDNA
Michael Karnbach, Deputy Director, GDNA
Tommy Roe, Special Agent GDNA
Alec Mathis, Special Agent GDNA
Justin Cotton, Assistant Attorney General
Itovia Evans, Deputy Director of Licensing
Angela Johnson, Board Administrative Secretary

Dawn Saoine
Tyler McNish, Zipline
Alex Busker
Becca Hallum, GHA
Nicholas McConnell, UGA
Emily Doppel, McKesson
Brandon Brooks, Publix
Helen Sloat, Nelson Mullins
Jon Holn, GDA

Open Session

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

President Page greeted the members of the public who were present.

Approval of Minutes

Mr. Brinson made a motion to approve the Public and Executive Session minutes from the August 21, 2024, meeting. Mr. Stone seconded, and the Board voted unanimously in favor of the motion.

Report of Licenses Issued

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

Petitions for Rule Waiver or Variance

McRae Drug Company, LLC withdrew their Petition.

Correspondences

Correspondence from Philip E.M. Crooker, Esq. with Pistevo Law:

President Page asked if anyone was present on behalf of Pistevo Law. It was established that a representative was not present. The Board discussed the correspondence from Mr. Crooker.

Mr. Crooker's letter advised that Pistevo Law Firm represents compounding pharmacies that they believe have been wrongfully targeted with Board complaints by the Coalition for Responsible

Compounding (“CRFC”) and an individual named “Anthony Connors,” Anthony J. Connors, J.D. and/or another similar alias.

This correspondence serves as notice to the Board that Mr. Crooker and his law firm view the complaints from CFRC as “boilerplate” and feel that the credibility of their complaints are unfounded, and that they feel that it is appropriate that the board should dismiss any complaint received from Anthony Connors or the other alias and CFRC and request that the Board promptly close any open investigations. Mr. Crooker also provided information regarding several civil defamation suits against Mr. Connors and CRFC and believe that it has been established by public record that these complaints lack credibility, and that Mr. Connors has a history of targeting competitors to defame them with false information.

While the Board appreciates the letter from Mr. Crooker, regardless of its thoughts on that particular organization, the Board has a responsibility when a complaint comes through to the board to investigate that and turn the complaint over to GDNA for proper investigation and bring that back to the board if further action is necessary.

Director Joiner advised that the Board does not have the authority to create a policy of blanket dismissal based upon the identity of a complainant and that it would be a dereliction of the board's duty to investigate. Director Troughton agreed with Director Joiner.

President Page directed Board staff to respond to the correspondent as discussed.

Correspondence from Roxanne Hilton

President Page asked if Ms. Hilton was present. It was established that she was not present.

In her correspondence Ms. Hilton asked the Board for clarification on the Board’s requirements for written medication information and interpretation of “written” as to Rule 480-48-.02(e), more specifically centered around provision of information via electronic means aligning with current USP recommendations, etc.

The Board discussed this correspondence seeking clarification of Rule 480-480-.02(e) and determined that electronic communication is written communication, and this rule is consistent with USP.

President Page directed Board staff to respond to the correspondent as discussed.

Correspondence from Mr. Gregory Stinnett - Drone Deliveries

The Board discussed this correspondence seeking guidance on behalf of Hamilton Medical Center regarding utilizing Zipline drone aircraft for delivery of prescription medications to regional patients by 2026.

President Page asked if Mr. Stinnett was present. Mr. Stinnett was acknowledged, and President Page thanked him for being present to answer questions that the Board has about the drone delivery process.

President Page asked Mr. Stinnett to explain the process of how the medications are loaded into the drone. Mr. Stinnett explained that the drones are housed and there's a docking station that would drop the packaging, called the mother drone and the baby drone. It drops the baby drone into the pharmacy for the pharmacy to add packages for the baby drone.

President Page asked how many medications the drone can hold and would the deliveries be multiple stops. Mr. Stinnett advised that the deliveries are one patient per trip and that question of how many medications per patient depends on the medication's size and that the drone can hold up to eight (8) lbs.

Mr. Farmer asked if controlled substances would be delivered via drone. Mr. Stinnett advised that that no controlled substances would be delivered via drone at this time, but it would be something to look into for the future.

Mr. Azzolin asked what the range was for the drone and primary goals for usage. Mr. Stinnett advised that range is currently 20 miles one way, and the goal is primarily patient convenience. Mr. Azzolin also inquired to how the drone is controlled, how counseling is handled and Mr. Chang asked how the deliveries would be validated.

Ms. Busker advised that the drone is automated and that pharmacists would be available for remote counseling. She explained that as the drone ascends back up to the mother aircraft, it takes a photograph as proof of delivery and that photograph is timestamped with the time and date of the delivery similar to Amazon deliveries.

President Page asked how the temperatures requirements of the medications being delivered would be handled. Ms. Busker explained that it would work like the specialty pharmacies that ship via USPS, FedEx or UPS currently and that the same standards and type of packaging would be used but that the drone deliveries would be more precise as the patient can advise that they are available for the delivery.

President Page commented that if the Board approves the controls as it is currently written that it could be started at any time and asked Director Troughton if he saw any issues with the implementation.

Director Troughton mentioned that as long as the deliveries are compliant with Rule 480-48-.03 Delivery by Pharmacy:

“Any pharmacy may provide for delivery by pharmacy upon the request of the patient or the patient's designee. The Board will hold the pharmacy responsible for any problems in the service of delivery by pharmacy. In order for a delivery to be considered delivery by pharmacy, the delivery must be on a continuous route from the pharmacy to the patient or the patient's designee. All medications shall be maintained within the temperature ranges recommended by the manufacturer until the delivery has been completed. All deliveries of controlled substances must be signed for upon delivery by the patient or patient's designee.”

and that the deliveries were properly recorded that unless someone asks for investigation it shouldn't be an issue.

Ms. Busker advised that the Amazon Pharmacy Texas pilot program is currently under way and that they are currently in a waiting period with the Texas Board of Pharmacy until this pilot program is complete.

Mr. Brinson asked if the drones would be making deliveries in apartment building, duplexes and condo. Mr. Stinnett responded that yes and that the patient would choose where the delivery would be made on the property. Mr. Brinson expressed concern that if the package is delivered wherever the patient is claiming to be that it would just be sitting there for anyone to retrieve.

Ms. Busker responded that the tracking information would be provided to the patient and that since the delivery window would be about ten minutes that the patient should be at the designated spot for the delivery to occur.

Mr. Cotton asked what the procedure is to retrieve any packages that were for whatever reason not delivered appropriately. Ms. Busker responded that it would be like if UPS lost a load on the side of the road, they would deploy a maintenance team, and that package would be retrieved. She also explained that they have dedicated maintenance personnel in every region that are trained to operate the drones because it's a requirement by the FAA and that they are able to maintain the aircraft and respond to emergency situations.

Director Troughton raised the issue of abandonment, weather, location tracking and how secure the package would be and requested that as more information becomes available on the Amazon trial and the Texas deliveries that Zipline and/ or Mr. Stinnett provide more information on how the trial deliveries are being handled so the Board could adopt rules and procedures.

Mr. Stone agreed with Director Troughton that the Board needs to review more information and believes it would be beneficial for a follow-up visit to go over how the Amazon and Texas programs were implemented.

Vice President Cordle agreed and mentioned that delivery by mail/drone would be a good topic for the Spring rules meeting and might need to be revised. He asked that Zipline/ Hamilton Medical Center provide the Board with an update on their progress by April so the topic could be discussed at the Board's May work session.

President Page asked the Board if there were any further comments or questions and mentioned that he believes that the Board is in favor of the program, but it needed to be looked at further once the data has been collected from the pilot programs.

Director Joiner asked President Page if the Board wanted to give a specific response at this time. President stated that the Board should have a formal response.

Mr. Azzolin advised that the Board's response is that they do not see any problems with drone deliveries as long as the current rule is followed but would like a follow-up on the data collected after the Amazon pilot and Texas programs have been implemented.

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton introduced Mr. Sam Smith who is an AG Honor Fellow to the Board and explained that the Honor's Fellowship Program is a program for entry level attorneys that are committed to public services.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

Director Troughton recognized Special Agent Russ Moore. Special Agent Moore currently covers middle eastern Georgia, 18 counties, and that he has been with GDNA for 10 years.

Director Troughton stated Agent Moore does a great job for GDNA. Mr. Azzolin and Mr. Brinson agreed that Agent Moore does a great job.

Director Troughton reported that GDNA conducted 79 investigations and 750 inspections for the first two months of the fiscal year.

Executive Director's Report – Mr. James Joiner

Continuing Education Report – No report.

Correspondence from Heather Hughes with Publix

Ms. Hughes was present for the meeting. Ms. Hughes is requesting clarification of the Board's May decision to grant their waiver request and is specifically requesting guidance as to whether that waiver only applies to the stores which existed on that date or if it's applicable to all stores opened after that date, but which operate in a substantially the same manner with the regard to additional secondary remote pharmacies.

Director Joiner commented that rule has changed since their May waiver request. Ms. Hughes asked if the change has gone through the rule making process. Director Joiner advised that the rule is currently under review. President Page said he didn't see any problems with the request and asked if the Board had any further comment.

Mr. Azzolin commented that Publix could send an updated list as it becomes available until the rule is formally passed. Director Joiner asked how often an updated list would be needed. Mr. Azzolin responded that until the rule is signed because afterward the need would be relevant. Director Joiner advised that the Board could amend the response.

The Board agreed that an amended response would be appropriate until the rule has been formally changed.

Legal Services – Mr. James Joiner

No report.

Discussion Topics

Vice President Cordle made a motion to approve the proposed 2025 calendar with the changes discussed for the 2025 Board Meeting dates. Mr. Brinson seconded, and the Board voted unanimously in favor of the motion.

The Board approved the following Meeting Dates for 2025

January 15, 2025	July 23, 2025
February 12, 2025	August 13, 2025
March 19, 2025	September 10, 2025
April 9, 2025	October 22, 2025
May 21-22, 2025	November 19-20, 2025
June 18, 2025	December 17, 2025

CBD Regulations SB494

Mr. Stone asked Director Troughton to provide an update from his meeting with Director Tyler Harper with the Department of Agriculture regarding enforcement of SB494 and the new CBD regulations that go into effect October 1, 2025.

Director Troughton advised that he did meet with Director Harper, his chief investigative enforcement officer and another officer who will be in charge of hemp licenses. The Department of Agriculture will begin accepting applications for Hemp licenses in late September. He stressed that any one selling Hemp products would need to obtain a Hemp license including pharmacies. The discussion with Director Harper went over enforcement and number of retail pharmacies, and the number of gas stations, etc. that would be applying for licenses. There will be no pre-inspections,

but all vape shops, gas stations, pharmacies etc. selling Hemp/CBD products would be subject to an inspection by the Department of Agriculture and local law enforcement. Director Troughton suggested that the Board and members of the public could help could spread the word about the necessity of having the license.

Director Troughton advised that the way SB494 is written, if a store is selling Hemp/CBD products, the Department of Agriculture or local enforcement agencies have the authority to come in facility review records and inspect CBD/Hemp products. Director Troughton suggested that any stores selling the Hemp/ CBD products to make sure to obtain a license and keep the product out of the pharmacy to protect patients' information. There is discussion about revising SB494 next year to address issues of patients' privacy. GDNA will aid and cooperate with the Department of Agriculture. GDNA will, in the course of their usual site inspections, aid by educating stores regarding Hemp/CBD regulations and compliance with the law. GDNA and the Department of Agriculture are working toward providing communication with each other to aid in the enforcement.

Mr. Stone commented that his store has been selling CBD since 2018. He estimates that approximately 45% of independent pharmacies are selling CBD. He advised that he has started the application process for his store and would be sharing information with other independent pharmacies regarding the placement and storage of the product. He added that he appreciates that the GDNA agents are dedicated in educating pharmacies to protect patients. Mr. Stone asked if anyone knew how the applications are being processed since the enforcement to of the law goes into effect October 1, 2024.

President Page recognized Gary Long with Botanical Sciences. Mr. Long stated that October 1, 2024, is the day that has been set for the SB494 to be enforced and instituted. Mr. Long advised that the even though the application has just come out last week that the application process at this point seems relatively easy for people apply.

He added that word has about 80 to 90% of the product, that's being sold in Georgia today will no longer be legal come October 1st. His company sells hemp derived products as well as medical cannabis products, which are complaint with the state regulations, and we part of the group that helped lobby for the change which is going to be instituted. He believes that with the new law many stores will no longer sell the products and had only been doing so because there was no law to regulate production.

Mr. Azzolin added that he saw Representative Houston Gaines on the news this morning speaking about vapes and how a lot of the vapes sold in various shops are actually illegally shipped in from China through the port of Savannah. Mr. Long added that there is a whole industry that are illegally generating certificates of analysis for some products that are coming in the ports. Mr. Long stated that Botanical Sciences surveyed about 50 locations in Georgia, bought product and sent the product to an independent lab for analysis. He advised that every sample that was received and testes was over the legal potency limits and had microbials and heavy metals.

Mr. Brinson commented that he believed the intent of the law was not to allow investigators to come into the pharmacy, come behind the counter and inspect the pharmacy. Director Troughton advised that the intent of the law is to make sure that products are being legally sold. They are looking to verify that the product is labeled correctly, the facility is licensed to sell the product, verify that the certificate of analysis matches the product, and as part of the enforcement of the law that the product could be inspected and analyzed.

Mr. Azzolin stated that it is important to educate pharmacies as to the changes in laws and that he would like to see open meetings live streamed to provide more transparency and allow for more communication options.

Executive Session

Appearances

- G.N.
- L.F.

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton
M.A.P.P. application.

Cognizant's Report – Mr. Cecil Cordle

GDNA Case #A35144	GDNA Case #A35222	GDNA Case #A35308
GDNA Case #A35389	GDNA Case #A35420	GDNA Case #A35386
GDNA Case #A35438	GDNA Case #A35377	GDNA Case #A35401
GDNA Case #B35410	GDNA Case #B34764	GDNA Case #B34772
GDNA Case #B34811	GDNA Case #B35304	GDNA Case #B35218
GDNA Case #B35364	GDNA Case #A35452	

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton discussed the following:

- E.F.P.
- J.M.
- U.S.P.
- A.H & P.A.J.
- M.P.
- C.P.
- S.A.T.
- M.R.B.
- C.P.S. / E.J.H.

Mr. Cotton presented the following consent orders for acceptance:

- S.D.C.
- W.G.
- C.P.

Mr. Cotton presented the following counterproposals:

- N.P.

Executive Director's Report – Mr. James Joiner

- a. Amendment of the Board's application form
- b. ACPE Inspection

Legal Services – Mr. James Joiner

No report.

Applications

- C.F.
- K.F.

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

Correspondences/Requests

- A.H.C.
- A.H.C.M.
- A.P.L.
- E.R.P.L. d/b/a P.P.S.
- W.G.
- I.D.
- M.D.S.D.L.
- P.M.I.
- A.V.I.
- A.M.M.
- C.A.
- H.D.
- K.B.
- L.S.
- M.C.
- P.P.
- R.T.
- R.D.
- S.P.

Open Session

Mr. Stone made a motion for the Board to take the following The Board voted to accept all of their recommendations.

Appearances:

G.N.B.	Reinstatement	Approved
L.F.	Reinstatement	Denied

Georgia Drugs and Narcotics Agency – Mr. Dennis Troughton

GDNA Case M.A.P.P. Update provided

Cognizant's Report – Mr. Cecil Cordle

GDNA Case #A35144	O.M.H	Refer to the Department of Law
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GDNA Case #A35222	V.S.I.	Refer to the Department of Law
GDNA Case #A35308	W.M.S.	Null and void the permit.
GDNA Case #A35389	A.P.	Refer to the Department of Law
GDNA Case #A35420	M.M.A.I.	Null and void the permit.
GDNA Case #A35386	J.W.P. / J.A.W.	Refer to the Department of Law
GDNA Case #A35438	TD.I. / T.I.P.	Letter of Concern
GDNA Case #A35377	U.S.I.P.	Refer to the Department of Law
GDNA Case #A35401	U.S.I.P.	Refer to the Department of Law
GDNA Case #B35410	W.G. / T.D.	Misfill guidance #2A, letter of concern / Misfill guidance #3 & refer to the Department of Law
GDNA Case #B34764	P.S.	Close no action
GDNA Case #B34772	V.M.S.	Close no action
GDNA Case #B34811	A.P.	Close no action
GDNA Case #B35304	W.P.	Close no action
GDNA Case #B35218	M.P. & U. / R.A.W.E. / J.W.S.	Close no action
GDNA Case #B35364	L.W.P.	Close no action
GDNA Case #A35452	E.M.L.	Refer to the Department of Law

Attorney General's Report – Mr. Justin Cotton

Mr. Cotton discussed the following:

- E.F.P. AG's office will proceed with Consent Order
- J.M. AG's office will proceed with Consent Order
- U.S.P. AG's office will proceed with Cease & Desist Order
- A.H & P.A.J. AG's office will proceed with Consent Order
- M.P. AG's office will proceed with Consent Order
- C.P. AG's office will proceed with Consent Order
- S.A.T. AG's office will proceed with Consent Order
- M.R.B. AG's office will proceed with Consent Order
- C.P.S. / E.J.H. AG's office will proceed with Consent Order

Mr. Cotton presented the following consent orders for acceptance:

- S.D.C. Accept Private Consent Oder
- W.G. Accept Private Consent Oder
- C.P. Accept Public Consent Oder

Mr. Cotton presented the following counterproposals:

- N.P. AG's office will proceed with new proposal

Applications

C.F.	Pharmacy Technician	Issue Registration
K.F.	Pharmacy Technician	Issue Registration
Q.M.L.	Pharmacy Technician	Issue Registration
K.T.	Pharmacy Technician	Issue Registration
M.B.	Pharmacy Technician	Issue Registration
T.W.	Pharmacy Technician	Issue Registration
B.S.	Pharmacist	Approved Application
J.B.	Pharmacy Intern	Approved Application
V.P.	Pharmacy Intern	Approved Application
A.B.	RPH Certification DTM	Approved Application
J.D.	RPH Certification DTM	Approved Application
K.P.	RPH Certification DTM	Approved Application
B.M.L.	DME Supplier	Pending Inspection
B.G.D.C.	DME Supplier	Denied Application
R.M.L.	DME Supplier	Denied Application
G.H.I	Non-Resident Pharmacy	Approved Application

Correspondences/Requests

A.H.C.	Notice of Discipline	Take as Information
A.H.C.	Notice of Discipline	Take as Information
A.P.L.	Notice of Discipline	Take as Information
E.R.P.L.	Notice of Discipline	Take as Information
W.G.	Notice of Discipline	Take as Information
I.D.	Notice of Discipline	Take as Information
M.D.S.D.L.	Notice of Discipline	Take as Information
P.M.I.	Notice of Discipline	Take as Information
A.V.I.	Notice of Discipline	Take as Information
A.M.M.	Reciprocity	Approved
C.A.	Request for 4 th NAPLEX attempt	Approved
H.D.	Request for 5 th MPJE attempt	Approved
K.B.	Request to extend Application	Approved
L.S.	Request for 8 th NAPLEX attempt	Denied
M.C.	Request to extend Intern License	Approved
P.P.	Request to extension of time to take NAPLEX & MPJE Exams	Approved
R.T.	Request for 4 th NAPLEX attempt	Approved
R.D.	Request to extend Intern License	Approved
S.P.	Request to extend Intern License	Approved

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 2:23 p.m.

The next scheduled meeting of the Georgia Board of Pharmacy will be held on Wednesday, October 16, 2024, at 9:00 a.m. at 2 MLK Jr., Drive, SE, 11th Floor, East Tower, Atlanta, GA 30334.

Minutes recorded by Angela Johnson, Board Administrative Secretary

Edited by J. Clinton Joiner, II, Executive Director